

## Fresh Produce, Food Safety Regulation and Compliance Issues

### Introduction:

The fresh produce industry is facing a number of pressures, including increasing production costs, limited human resources, increasing packaging supply costs, and now regulatory compliance as it governs food safety. Product tracking “farm to fork” is no longer an option it is mandatory and your company’s ability to comply is the question.

The recent news of E-coli, tainted spinach and the condemnation of the entire spinach crop in the United States, by the FDA clearly demonstrates the food safety concerns. The FDA is demanding rapid delivery of data requested on food products, such as supplier/grower data, including lot no., production date and time, what brands were the product packaged as and what customers were the product shipped to, etc: Rapid is defined as four (4) hours.

The CDC reports millions of illnesses are caused by food contamination every year in the United States\*. In addition to the public cost, the impact of a recall/condemnation such as the spinach condemnation will have devastating effects within the industry, the long-term damage to brands and companies has been done.

### Food Safety—Regulations Issue:

#### U.S. Bioterrorism Act

The U.S. Bioterrorism Act of 2002 is playing a major role in food safety in the US\*\*. With the FDA having authority over 85 percent of the U.S. food supply, the Bioterrorism Act has more impact on the nations’ food supply industry than all other regulations combined. While some exemptions do exist, the law is intended to be broadly applied to all companies that manufacture, process, pack, hold, transport, distribute, or receive food products. It is estimated that the U.S. Bioterrorism Act covers more than 475,000 U.S. and foreign facilities. Under this act, there are several regulations which govern not only fresh produce companies but all food producers...

There are two areas of the act that have significant impact on operations:

#### • Establishment and maintenance of records

Companies must establish and maintain a record of the source and destination of ingredients and products; this is called the *one up and one down* rule. When the FDA requests information, companies have four hours to respond to FDA inquiries.

#### • Tracking and Tracing

The capability to track (*farm to fork*) and trace (*fork to farm*) product details, per product and/or per lot is critical and is the core of the regulations. Organizing data and retrieving it as required, using the *one up and one down* rule or tracking farm-to-fork includes collecting the appropriate information and displaying the data on-demand. For food manufacturers and distributors, recording shipping information that includes product lot numbers provides the final link for *one up and one down* tracking.

The components tracked must include more than just the final product or ingredients, considering the tracking procedure begins at receipt of materials, date and time of receipt must be recorded including the product name, shipping data, and supplier lot number and product quantity prior to product storage.

Manufacturers must record products consumed and link products consumed to the end product lot. This includes ingredients (such as onions, spice, and bell peppers), packaging material (such as bottles and plastic wrap) and equipment that contacts the ingredients in the creation of the intermediate or final products must be recorded.

Operating personnel who are involved in the manufacturing or distribution process should also be recorded, including personnel that receive the material at the packing facility, those who weigh and stage product, personnel that run the process and packaging lines. The key people are those who receive the material and run the process, they have the greatest impact on the safety and security of the product.

### Food Safety—Cost of Compliance:

Without a doubt, regulatory compliance costs money, including investments in hardware and software systems and devices. More important, it includes the ongoing cost of human resources and the possible loss of productivity due to training and/or acquiring personnel due to regulatory requirements.

However, non-compliance can be even more costly, considering fines of \$100,000.00 per day and possible shutdown of your business, the question is, how much risk is a company willing to take? Non-compliance can lead loss of business opportunities, and even the end of the company. For most companies these risks are too great, and compliance is seen as mandatory.

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### Compliance Small and Mid-Sized Companies

Although the FDA and/or other regulatory authorities have the power to request information, the regulations are not specific on what information can be requested, nonetheless, authorities expect requested information to be provided quickly.

Notwithstanding, a few differences in compliance deadlines, food safety compliance regulations apply to all companies without regard to size,\*\* small companies have the same requirements as large companies but of course with fewer resources.

Regulations demand the collection, organization, and retrieval of information, for even the simplest food company, making a manual recording approach to compliance nearly impossible. For these companies, dependence on computer system is mandatory for successful compliance efforts. The core of every compliance effort is the company's enterprise resource planning (ERP) system. Computer systems are the only way to collect the information required and return the data on-demand within minutes. Only computers can do the job of organizing data and producing the information required in a timely and organized fashion, for example, meeting the four-hour requirement established in the U.S. Bioterrorism Act.

Large companies can afford complex and expensive compliance solutions, while small and mid-sized companies need compliance options that are both affordable and effective. When considering compliance solutions, manufacturers and/or distributors should evaluate suppliers based on the practicality of the solution: Will it work in your environment, and can your company afford the initial investment and any ongoing costs?

\* See [www.cdc.gov/ncidod/eid/volno3\\_supp/tauxe.htm](http://www.cdc.gov/ncidod/eid/volno3_supp/tauxe.htm)

\*\* See [www.fda.gov/oc/bioterrorism/bioact.html](http://www.fda.gov/oc/bioterrorism/bioact.html)

\*\*\*U.S. Bioterrorism Act states Companies with 500 or more employees must comply by Dec 6, 2005; companies with 11-499 employees must comply by June 6, 2006 and companies with 10 or fewer employees must comply by Dec. 6 2006.