

**Statement by
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**U.S. Food and Drug Administration Public Meeting on
Product Tracing Systems for Fresh Produce**

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Hello, my name is Robert Guenther, senior vice president of public policy for United Fresh Produce Association (United Fresh). United Fresh is an international trade association representing the fresh fruit and vegetable industry in managing critical public policy issues; shaping legislative and regulatory action; providing scientific and technical leadership in food safety, quality assurance, nutrition and health; and developing educational programs and business opportunities for members to better meet consumer needs for increased consumption of fresh produce. Founded in 1904, United Fresh represents the interests of member companies from small family businesses to the largest international corporations throughout the global fresh produce supply chain, including growers, shippers, fresh-cut processors, wholesalers, distributors, retailers, foodservice operators, industry suppliers and allied associations.

What I will focus on in today's discussion is how traceability works today, and the strengths and weaknesses of the current product tracing systems in the produce industry. I also want to thank FDA for giving us the opportunity to present our views on the current traceability outlook in the produce industry.

Let me begin with a basic principle that I believe is shared throughout the produce industry – This industry is committed to being able to effectively and efficiently track the source of our products from retail stores and restaurants back to their original farm source.

It is well known, that the Bioterrorism Act requires mandatory record-keeping 'one-step-up' and 'one-step back' of all foods, with the ability for each person in the supply chain to provide such records within 24 hours. The industry is committed to full compliance with these requirements, and urges FDA to rigorously enforce this law. We know of no instances where FDA has taken any regulatory action to cite a produce company or its customers for failure to provide

adequate records as required by the Act. Rather, we hear generalized concerns about the inadequacy of records, without specific examples. The produce industry stands ready to work with the Agency to ensure full and total compliance with these requirements.

Through the Bioterrorism Act the industry is also required by FDA regulation to maintain records that demonstrate the source – transporter and non-transporter – of all raw materials used in the production of foods ultimately offered for consumption. These records must include the material description, the supplier lot number, quantity and date received. The same law requires the industry to maintain records that demonstrate the recipient – transporter and non-transporter – of all outgoing products, including the material description, lot number, quantity and date shipped. The existing regulation exempts farms and restaurants, but the first commercial recipient of produce from the farm is required to maintain these traceability records, as are companies distributing produce to restaurants and other consumer points-of-purchase. As an industry, we support this regulation.

Packaged produce with brand names and lot numbers, such as bagged salads and branded cut fruit, are the most visible examples of fresh produce traceability. Lot codes may be proprietary company codes or serve double duty as “use by” or “sell by” dates, but all retail-available, branded, packaged produce is expected to have lot coding information clearly printed on the package, traceable back to specific lot information. That lot information is expected to include the source and lot numbers of the product’s ingredients, just like other formulated and commercially- available food products. We are unaware of any instances in which public health investigators, having a package in hand, have been unable to quickly and efficiently reach the company that packaged the product and obtain information about the product’s component ingredients. In a blended product, like a salad, it is likely that investigators will not know which ingredient is of special interest, and so would need to obtain source and lot code information for all ingredients; but that need for multiple commodity traceback is often unavoidable in an investigation and not unique to produce.

Repacking operations have been noted by FDA to be a special problem for produce traceability; however we do not believe that to be the case today. Repackers may receive fruit or vegetables, like apples or tomatoes, from several growers or packinghouses. Each incoming produce lot, because it is harvested at the same time, is likely to contain items of different sizes, colors, shapes and stages of ripeness. Repackers’ customers, on the other hand, want the produce to be the same size, color, shape, et cetera. This reduces waste, and storage by

the customer, and is more cost efficient and actually safer for consumers than for retail or foodservice operations to receive and process single-lot product themselves. Repackers uncase incoming produce, sort, commingle and re-case the produce to meet customers' orders. However, this is not unlike the blended product example I just referenced, with different suppliers of a common ingredient instead of different ingredients. Repackers are still expected to provide the outgoing cases with lot code information that is internally traceable to the produce lots used in that case. In the industry-developed *2nd edition Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain*, recommendations to repacking facilities specify that "if incoming lots are mixed/commingled, then documentation shall be maintained to identify all included sources."

So, whether we are discussing packaged or whole commodity produce, the industry has procedures in place that provide traceability information from the farm to consumers' points-of-purchase.

We expect that FDA finds diversity in traceability sophistication and compliance among produce facilities, just like it does in other practices across the food industry. Some companies have exquisite traceability programs, providing consumers with Internet-accessible information about a product's grower and lot-specific analyses. Less sophisticated traceability programs may still utilize paper-based receiving and shipping records. Depending on the size of the facility, the complexity and volume of its distributions, such a program may be adequate for the facility and compliant with the regulation.

However, we do recognize that there are potential issues and opportunities for improvement in current produce traceability practices.

Common Language and Standards

As noted by PMA, produce companies today often use proprietary codes and labeling practices that fit well with their internal traceability and inventory control practices, but which are different from the codes and practices used by their suppliers and their customers. As a result, codes must be "translated" as they move from one point in the supply chain to the next. In the event of a traceback, investigators must move along the supply chain in a linear and sequential fashion, relying on each point in the supply chain to accurately translate the customer's codes into the suppliers'. Late last year, our Association along with Produce Marketing Association and Canadian Produce Marketing Association co-launched the Produce Traceability Initiative.

The goal of this Initiative is to agree to one language and set of standards to be used to label cases of fresh produce. With uniformity in external traceability practices, translations between customer and supplier codes become unnecessary and multiple points in the supply chain can be made aware, at the same time, whether or not and when they “touched” a particular product and lot number.

Inclusion of Industry in Traceback Investigations

Even when the Produce Traceability Initiative has been fully implemented, investigators will still need to understand the internal traceability and recordkeeping practices in place at each company visited. These practices will vary greatly from facility to facility in order to meet the needs of the company’s culture and other practices. We have heard that investigators sometimes struggle to understand these practices, abandoning or sidestepping the company’s official program, relying on other supply chain records to determine the sources of materials of interest and copying and searching through reams of paper to understand from where and when materials were obtained. This approach could result in missed or misunderstood trace records and therefore delay the traceback. Such delays do not help the investigation nor the companies involved, let alone public health. To speed the investigation, we encourage FDA to find ways to work with the facility’s personnel to understand their internal traceability program, or at least work with industry to understand and overcome obstacles to this approach.

Imports

We believe that imported produce be held to the same requirements as domestically sourced produce. Food safety has no state or international boundaries when it comes to protecting consumers. Therefore any application related to traceability must be consistent and applicable.

“Cash and carry” Operations

While the vast majority of the produce supply chain operates as I have already described, there are still situations where produce is transacted on a “cash and carry” basis, such as at farm markets and discount retail markets, where records assuring traceability may not be kept. These are typically operations close to the consumer points-of-purchase end of the supply chain. These types of operations tend to be local, a minor part of the overall produce supply chain and not representative of current industry practices. However, we also believe that these operations should be required to maintain records demonstrating the source of the ingredients they use. As noted earlier, the recordkeeping required at such operations need not be sophisticated – purchase records may suffice – but they should be adequate to assure

traceability to their point of purchase. Again referring to the industry-developed 2nd edition Tomato Food Safety Guidelines, recommendations for retail and foodservice operations specify that “direct-to-consumer retail and foodservice operations shall maintain purchase records that will facilitate traceability. Each facility’s ability to comply with [this requirement] shall be verified at least annually. A record of this verification shall be kept on file [and] all records recommended in this section shall be maintained for at least six months and be readily available.” This requirement we believe can be translated across the produce supply chain as it will be for tomatoes.

Relabeled Cartons

We also recognize that a common practice among whole produce handlers is to reuse produce cartons. This practice has provided significant cost savings to handlers and, ultimately, to consumers. However, this practice must be controlled by the handler to ensure, first, that direct food contact cartons do not pose a contamination risk to the produce they contain and, second, that labels on the carton are accurate to their contents. Again referring to the 2nd edition Tomato Food Safety Guidelines, the recommendation to packing operations specifies “Used boxes may only be used as primary containers for mixed/commingled lots if they are clean, sanitary and the original identification information on the box is still accurate to the original source of all of the tomatoes in the box.”

Invisible Ingredients

Finally, we encourage the Agency to remember that traceability can only be performed if product of interest has been specifically and accurately identified. Tracebacks cannot be used as a substitute for case control and other epidemiological studies, just as epidemiological conclusions that are not supported by traceback investigations should not be assumed to be accurate. Using this summer’s *Salmonella* Saintpaul outbreak as an example, while a “fresh salsa” may seem to an adequate food description in an epidemiological study, the primary ingredient may not be the product of interest. Such products can have many ingredients, some of which may be invisible or unrecognizable to the average consumer. Ingredients may be unrecognizable even to investigators. For example, while long-shelf life salsa products typically contain heat processed ingredients to reduce their spoilage potential, it is possible to have unprocessed peppers, diced and invisible to the consumer. It is important for investigators to test their assumptions about products, and a close working relationship with industry during an investigation, as noted earlier, can help to avoid epidemiological misdirections.

In summary, the produce industry today, as a whole, has practices that comply with FDA's recordkeeping regulations to provide traceability "one step back and one step forward" in the supply chain. If FDA is aware of facilities required to follow this regulation, and are not, we support FDA taking action consistent with the regulation. If there are gaps in the current regulation inhibiting FDA's ability to perform tracebacks during an investigation, we encourage FDA to clearly identify the root cause of those issues and fix those, rather than reinvent a system that is already working. And finally, while the Produce Traceability Initiative will enhance the supply chain's traceability practices, it is not a "cure all" or silver bullet. Many details remain to be worked out, and the industry is in the best position to help determine those details, to ensure they achieve their objectives within the cultures of the various facilities and in a manner that is efficient and cost effective, providing security and the best value to consumers.

Thank you for your attention and the opportunity to present these views.