March 3, 2010

To: Food and Drug Administration, HHS

From: Dr. Bob Whitaker, Chief Science & Technology Officer
Produce Marketing Association

Re: Docket No. FDA-2009-N-0523, Product Tracing Systems for Food

Produce Marketing Association (PMA) is pleased to submit these comments to the Food and Drug Administration regarding the agency’s request for comments on Product Tracing Systems for Food.

PMA is the largest global not-for-profit trade association representing companies that market fresh fruits and vegetables. We represent 3,000 companies from grower-shippers and supermarket retailers, to foodservice operators and importers. Within the United States, PMA members handle more than 90 percent of fresh produce sold to consumers.

Prevention of foodborne illness is a top priority for the fresh produce industry and the FDA. On the rare occasions when a foodborne illness outbreak occurs, our collective priority is to stop the spread of the outbreak, often by removing the food linked to the outbreak from the supply chain. Effective food tracing systems are essential to that undertaking.

We applaud the agency for its efforts to further enhance food safety through effective tracing systems. We offer the following comments specifically in response to questions pertinent to the fresh produce (fresh fruits and vegetables) industry. Although the request for comments applies to all foods, we restrict our comments to applications to the fresh produce industry.

PMA supports effective and efficient tracing systems, and we encourage our members to include such systems in their food safety and business operations. Most companies in the industry can already trace their products internally, within their own companies, one step forward and one step back – but internal traceability is no longer enough to meet today’s food safety challenges. Our industry must be able to track product as it moves through the supply chain – that’s external, chain-wide traceability. PMA supports and helps to administer the Produce Traceability Initiative (www.producetraceability.org) and its concepts of supply-chain-wide, electronic traceability that uses companies’ internal recordkeeping systems in conjunction with global standard technologies that enable external traceability between trading partners. These internal and external traceability systems combine for whole-chain traceability.

When addressing potential protocols for traceability, consider the following:
- Case-level, rather than item-level, traceability is appropriate because the case is the unit of commerce that is recognized and "touched" at each link in the chain.
- Existing standards and systems may provide practical, real-world solutions.
- Solutions should be globally applicable. The fresh produce industry is a global industry that relies on product movement around the world. Systems must work for product entering the United States from other countries and must work for U.S. producers who export their products. It is highly inefficient for companies to maintain multiple traceability systems. Globally recognized, market-proven product identification standards are essential to the success of global traceability.
- Traceability should apply to all companies, regardless of size, method of production, location, or commodity type. There cannot be any holes in the safety net. That said, solutions must be scalable and workable for companies of all sizes, and the industry's varied production methods, locations and commodity types.

We offer the following answers to FDA's questions outlined in the docket.

1. Lot Code or Number (or Other Identifier of the Food)

   Question 1a. Should a lot or code number (or other identifier of the food) be assigned to food? If so, at what stage or stages in the supply chain should it be assigned or modified? For example, should a lot or code number (or other identifier of the food) be assigned for all finished food products, whether sold in packaged or unpackaged form? Should a lot or code number (or other identifier of the food) be assigned whenever food is manipulated (such as when fresh produce is commingled, packed, or repacked)?

   Lot numbers/codes should be established and maintained at the case level throughout the supply chain, including during any transformation (such as repacking/commingling) of the product. Lot numbers may be assigned differently based on the type of company and/or the product being packed. Lot numbers should be assigned by the entity that packs the product.

   In practice, a lot number is generally assigned by each grower to a specific piece of land or planting block based on their planting schedule. This lot number is then linked to a harvest schedule and appears on receiving documents when product harvested from that lot is moved from the farm to the cooler, packinghouse or shipping point. A shipper or processor may or may not assign a new number to this lot when they receive it. If they do assign a new "lot" number, then it is invariably linked to the grower lot; i.e. the original lot information is preserved because that is how the shipper/processor pays the grower. Anytime a new lot number is assigned, it must be linked to the lot numbers of the product used to create the new pack configuration and lot number.

   Question 1b. What data or information would be useful to include in a lot or code number (or other identifier of the food)?

   Typically the creation of a lot, including the information it captures, is left to the discretion of the lot creator or handler. It has been noted by some that the date of packing is helpful in narrowing the scope of implicated product in the event of a recall. Other information such as the location of the point of harvest, the field crew which harvested the product and the inputs to the production of the product should be accessible via the lot number. In general, information captured in the lot should not be prescribed by any one entity. It can be as granular as desired, and the more granular the better in the event of a "lot" being investigated.
Question 1c. What (if any) procedures should be used to establish a lot or code number (or other identifier of the food)? Should any such procedures address the size of a lot or the time frame for production of a lot (e.g., 21 CFR 113.60(c) provides that codes may be changed on the basis of one of the following: Intervals of 4 to 5 hours; personnel shift changes; or batches, as long as the containers that constitute the batch do not extend over a period of more than one personnel shift)?

In practice, a "lot" is a designation for a volume of product that is harvested from a designated piece of ground. As indicated above, lot numbers are assigned by the grower based on a planting schedule and correlate to a piece of ground planted for a specific harvest time and using the same agricultural inputs. In the processing area (for salads), industry may use the word "batch" instead of "lot" if a product is blended. That is, when making spring mix, a company might use seven to nine types of leaves, and when that is blended, it is called a batch. A batch sheet may be used to track what lots of raw products were used to make that batch. While "batch" is a term of processing, companies still refer to putting a "lot code" on the bag. There is great deal of inconsistency in the terminology. In repacking operations companies mix lots and sort raw products by size and quality (color) so they can fill specific orders. These would have order numbers. An order number can certainly be tied to the original grower lot numbers if a log is maintained.

b. Location of a lot code or number (or other identifier of the food).

Question 1d. Should the location of a lot or code number (or other identifier of the food) depend on the type of food, other factors, or both?

There are no universal guidelines for lot placement on consumer packages and it would be difficult to prescribe given the complexity of packaging materials, container types, size of label etc. Additionally, it is crucial to remember that the logistics of lot placement on loose/bulk food is often impossible or extremely costly and, if prescribed, could lead to increased packaging of foods which will add unnecessarily to environmental concerns and costs. Because it is important to maintain lot information at the case level, it is essential to have the code on the case. The case is the unit that moves through commerce and can be tracked by each link in the distribution chain. The marketplace should and will determine where lot numbers will be placed. Customers want lot numbers and code dates positioned so that they are easily visible to those that have to "pick" the product at distribution centers.

Question 1e. Should a lot or code number (or other identifier of the food) be located:

On the label (or container or package) of a packaged food?

Yes, this is common today. The sophistication of the label varies widely; e.g. packaged salads most often have jet printers incorporated into the packing machines so that lot codes/dates can easily be printed on each bag or clamshell and a sticker or jet print of the same code placed on the carton. Consumers recognize what the lot code is and, in fact, use this code when calling producers with quality issues, asking for recipes, etc. Smaller producers or those that field-pack products often use a small sticker that is printed with the lot information. These can be as simple as half inch stickers printed off a sticker gun as one would see in a retail store or laser jet printed stickers prepared by the harvest supervisor. As long as there is a surface (bag, clamshell or carton), a lot code can be affixed to a product.

On the shipping container of packaged food, unpackaged food, or both?
Yes, a lot code should appear on the shipping container – in produce that would be at the case/container level. In fact it is a common practice in the industry to do so.

**In internal records (such as receiving records, batch production records, inventory records, and distribution lists)?**

Maintaining records that link product to the lot is crucial to ensure full chain traceability. Internal records have to have lot codes on them to link receipt of products to shipments internally. Each step in the handling of the product needs to be linked and the lot code (and a date) is that link. Not everyone currently does this electronically, but at a minimum they are required to do it via paper records as required by federal law.

**In external records accompanying commercial transactions (such as a bill of lading, airway bill, invoice, manifest, shipping record, or packing list)?**

Other types of information codes (which could take many formats) often are used on external records so that receivers can match them to cartons/pallets received and they can be entered into the receiver's documentation. It is important that all official records be accurate with the ability to cross-reference all official transactional records relevant to the shipment. These records could include bills of lading, sales records, shipping or receiving records.

**Question 1f. What ways might the lot or code number (or other identifier of the food) be linked to internal and external records associated with the food?**

Common industry practice is to use the lot code on some internal and external records. In general, whole-chain traceability will be ensured if a unique identifier, such as a Global Trade Item Number (GTIN), and a lot code are used at the case level in produce, and each company in the chain that handles that case maintains records of those codes that are linked to that company's internal records.

2. **Information Elements Not Already Required in 21 CFR Part 1, Subpart J**

**Question 2a. Should a shipment identifier be considered an information element of an enhanced product tracing system? If so, are there any business practices (e.g. the way shipments are currently identified) that would be impacted?**

A shipment identifier is a key element for product tracing. It is important that each company has internal procedures for identifying and retrieving all supporting transactional records relevant to a specific shipment. There is an enormous diversity in how companies maintain their internal traceability records. All companies should have policies and procedures describing the records that demonstrate disposition of all produce lots received, shipped or otherwise disposed of. Government investigators can then verify the accuracy of records by cross-referencing those records that may have the same or supporting information.

3. **Information Elements on the Package of a Packaged Food and/or on the Shipping Case**

**Question 3a. Should product tracing information not currently required to be on the package of a packaged food or on a shipping case be present on the package or shipping case?**

Yes, this should be a requirement to implement full chain traceability.
**Question 3b. If so, what additional product tracing information should be present on the package or shipping case?**

The only way to achieve full supply chain traceability is to recognize that we must use a globally recognized standard to ensure our coding formats are harmonized and compatible with others. The GS1-based system meets these criteria. GTINs are globally recognized and many companies already have them for their products. Using a standardized system such as GS1’s, with GTINs and lot numbers on produce cases, provides for identification of both the produce and the producer, allowing each distribution chain link that handles the product to track its handling/movement. One of the objectives of any traceback activity is to determine the source of the problem, which could occur anywhere in the distribution chain, so that one can then investigate the cause and determine whether other related products might also present a public health risk.

These case-level codes certainly should link to the internal records of any company that handles the case. In practice, it is common for additional information to be contained in product codes, which may vary based on the company, its business practices, and the requirements of its supply chain partners. So these additional items may be available in times of traceback, but cannot be standardized because they vary based on business needs.

**Question 3c. If so, at what stage or stages in the supply chain should such information be included?**

It is important to start at the source or at the creation/ transformation of the product.

**Question 3d. If so, should such information be present for all food, or only some food?**

All fresh fruits and vegetables should carry this information at the case level.

**4. Information Elements.Transmitted Beyond ˜One Up/One Down”**

**Question 4a. Should some information about fresh produce (such as information identifying the name and physical location of any farm, packer or repacker that provided, processed, or packed fresh produce) be sent forward farther in the supply chain than ˜one down’? If so, how far in the supply chain should such information go? For example, should such information be transmitted as far as the retail establishment that sells the fresh produce to consumers, or as far as the last person in the supply chain before the retail establishment?**

If all links in the supply chain maintain one-up, one-down information, full chain traceability is achieved. Within that one-up, one-down system of external traceability, each individual company that “touched” the product can access its own internal records related to the product to provide even more information on the product.

**Question 4b. Should some information about packaged food (such as information identifying the manufacturer of a processed food) be sent forward farther in the supply chain than ˜one down’? If so, how far in the supply chain should such information go? For example, should such information be transmitted as far as the retail establishment that sells the food to consumers, or as far as the last person in the supply chain before the retail establishment?**

No. If all links in the supply chain maintain one-up, one-down information, full chain traceability is achieved. As long as the traceability system connects all the links in the supply chain, then more detailed information about what might have happened at each link can be accessed through internal
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5. Standardized Information Elements

Question 5a. What (if any) information elements in an enhanced product tracing system should be standardized? Are there specific information elements (such as a shipment identifier and a lot or code number (or other identifier of the food)) that are particularly amenable to standardization? Would such standardization be specific to a specific industry sector or type of food (e.g., fresh produce, frozen seafood, milk, baked goods, breakfast cereal) or could it apply across industry sectors or types of food?

Information required may need to vary based on the type of food, but in the case of fresh produce, industry leaders have determined that a standardized approach to case coding can be effective.

Using a GS1 standards-based GTIN that identifies the producer and the product should be the underlying or enabling platform. Additional data fields can be used to provide grower, lot, harvest company, harvest date, production line, location, shift and pack date. The GS1 platform permits inclusion of this information in the code and various pieces of the code can be provided as they are appropriate to a specific operation or product.

Question 5b. What standards already exist and how useful are they for product tracing?

Currently two references exist that support the global produce industry. The first is the GS1 Global Traceability Standard, which forms the basis for the produce-specific Traceability for Fresh Fruits & Vegetables Implementation Guide. Both of these references took into consideration both Codex Alimentarius and ISO traceability efforts (which are more about principles of traceability than specific guidance for implementation). Additionally both references represent considerable time and effort invested by traceability experts from around the globe who developed them or provided professional input. In the case of the produce-specific guide, these experts also have specific produce traceability expertise. Because the GS1 system of standards forms the basis for business supply chain efforts around the globe, these firmly entrenched standards that support the traceability-specific standards are the logical basis for standardization of traceability.

Question 5c. If standards can and should be used for certain information elements in an enhanced product tracing system, should FDA develop the standards?

No, as noted above, these standards already exist and were developed by industry for industry to ensure whole-chain traceability. Using existing standards will shorten the implementation curve for FDA and be more cost-effective for industry. The expertise for this task resides in the industry where the knowledge of the supply chain exists and can be married to existing, internationally recognized standards. The combination of these two elements will ultimately produce a robust traceability system.

Question 5d. Would current or newly developed standards for the content and format of electronic systems have practical utility for persons who continue to use paper-based records? For example, could human-readable data that supports standardized electronic data be useful to persons who continue to use paper-based records?
To ensure traceability implementation, it is crucial that information compiled and captured via electronic systems be compatible with human readable information. For example, a bar code requires a scanner to read it. The bar code should be accompanied by human-readable numbers that point to the same information.

B. Records

1. Record of the Lot or Control Number (or Other Identifier of the Food)

Question 6a. Would it be useful for persons, in addition to those who manufacture, process or pack food, to establish and maintain a record of a lot or code number (or other identifier of the food)? If so, for which persons (e.g., distributors, retailers) would it be useful?

No, the lot number, along with other traceability information including information about the immediate previous source and subsequent recipient of the product is sufficient as long as the source and recipient have records that identify transporters. New lot numbers should only be created if the product is transformed in some way – through processing, a new pack configuration, or commingling.

Question 6b. If it would be useful for some persons, in addition to those who manufacture, process, or pack food, to establish and maintain a record of a lot or code number (or other identifier of the food), would it be equally useful irrespective of the type of food (e.g., packaged food or fresh produce)?

No, see answer to 6a.

2. Records to Facilitate Linkage

Question 7a. Would it be useful for nontransporters who manufacture, process, or pack food to establish and retain any additional records to facilitate linkage? In particular, would it be useful for persons who manufacture, process, or pack food to establish and maintain a “linking record” that would link a specific lot of an incoming ingredient to all released food containing that specific lot of ingredient?

Linking traceability data is the key to full chain traceability. However there is no need to create a “linking record” if all the data required is captured, stored and shared as required. All companies must have policies and procedures describing the records that demonstrate disposition of all produce lots received, repacked, shipped or otherwise disposed of.

Question 7b. If so, should some or all of these records be created at the time of receipt or release of food or be existing records, or should some or all of these records be new records created upon the request of FDA (e.g., during an outbreak investigation or traceforward operation)?

It is not necessary to create additional records because companies should already have this information in their internal records, already linked to the external codes that are transmitted to trading partners. If a traceback should be needed, the company would be responsible for providing those records to FDA. It would be a difficult task to create a standard format for “linking” records as each commodity is different and each traceback activity is unique. It might be helpful for FDA to issue guidance on the types of information the agency might need in performing a traceback so that suppliers can use it to further enhance their own internal systems and data storage programs.

Question 7c. If so, would it be useful for FDA to specify the format of the record? For example, should FDA provide a model form that could be used to provide the information in such a record? Or would it be more useful for FDA only to specify the information elements of such a record?
Because food systems differ in many ways, even in the fresh produce industry, it would be more useful for FDA to specify the information elements and allow businesses to determine the best ways to gather, store, and distribute the information.

**Question 7d. If so, should all such records be in electronic form?**

It is not practical to assume that all participants in the produce industry have the capacity to provide electronic data at this time. But ultimately, that should be the goal.

### 3. Records That Are Both Electronic and Human-Readable

**Question 8. Should some or all product tracing records be established and maintained in electronic form? If so, should information established and maintained in electronic form also be human-readable?**

Yes. Encoded information, such as bar codes, should also be expressed in a human-readable format, such as a series of numbers beneath the bar code. Those numbers can be put into a computer system without needed a scanner for the bar code. This is important for those times when a scanner is not available or practical.

### 4. Mechanisms to Make Product Tracing Information Available to FDA

**Question 9a. What can be done to speed the process whereby persons who have product information relevant to a traceback investigation provide the information to FDA? For example, should some information be sent to FDA, rather than have FDA travel to a facility that has the information?**

Certainly electronic information can be transmitted to FDA. Additionally, paper-based records can be scanned, appended, and sent to FDA (as per practices currently in place for the Reportable Food Registry). FDA can employ video conferences or web-based communication with companies to permit immediate communication and dispatch inspectors only after the preliminary data sets are evaluated and FDA determines additional information is needed.

**Question 9b. If information would be sent to FDA, how should it be transmitted? For example, could the information be transmitted by e-mail, fax, or courier service (e.g., by overnight delivery)? Or should there be an electronic portal (such as the portal FDA developed for the Reportable Food Registry)?**

Automating data exchange to the greatest extent possible will speed investigations by quicker delivery and quicker assimilation. FDA and industry experts – including their information technology experts – should work together to determine efficient, practical data exchange. We would encourage FDA to look at the Reportable Food Registry as a model for a communications system for helping data exchange during a traceback.

### C. Role of Risk in Developing an Enhanced Product Tracing System

**Question 10. Should any or all enhancements to current product tracing systems apply regardless of risk, or should such enhancements be based on risk? If based on risk, what criteria should be used to determine risk? If not based on risk, should such enhancements be developed or phased in based on risk?**

There should be a consistent and level playing field for traceability. There is no guarantee that products currently deemed of greater risk will be the products implicated in the next foodborne illness outbreak. Even a commodity identified as low risk is still at risk as it moves through the
supply chain and changes hands. In addition, companies may produce a variety of products, each with a different risk profile. Companies should not be expected to maintain different tracing systems for different products.

D. Costs, Benefits, and Feasibility of Implementing an Enhanced Product Tracing System

Question 11a. What are the costs, benefits and feasibility of implementing an enhanced product tracing system for each of the persons in the supply chain for various segments of the food industry?

The costs for any company, including distributors and retailers, will be related to the extent of change needed to current systems. This may involve technology costs (hardware, software), business practice costs (revamping business processes), and labor costs (having personnel to implement and maintain the process). Though there are many business types in the fresh produce industry (including growers, wholesalers, retailers, and foodservice operators), most of the traceability issues surround information technology needs – hardware, software and labor. These do not necessarily vary by business type or size.

The benefits to enhanced traceability are significant. Faster tracebacks (and, if needed, traceforwards) will more quickly protect public health by identifying the problem product and removing it from the marketplace. That also protects industry by freeing up all products not identified as the problem so they can move through the marketplace. When outbreaks are linked to broad categories of product (e.g. all bulk spinach or all round red tomatoes), all companies who market those products suffer financial and reputational losses. Swift identification of a particular lot from a particular company is essential.

Question 11b. To what extent would an enhanced product tracing system affect current business practices? What would be the cost of any such changes in current business practices for each link in the supply chain?

This will vary from business to business. Improved traceability could have important impacts on business practices as traceability gives more visibility to product flow in production, inventory practices, product aging, pick efficiencies, load efficiencies and receiving costs. The impact and cost of these changes will vary from business to business depending on the extent of change.

Question 11c. What determines the costs for food distributors and retailers to maintain records of lot code information for manufactured products, and farm-related information for fresh produce?

The costs for any company, including distributors and retailers, will be related to the extent of change needed to current systems. This may involve technology costs (hardware, software), business practice costs (revamping business processes), and labor costs (having personnel to implement and maintain the process). Though there are many business types in the fresh produce industry (including growers, wholesalers, retailers, and foodservice operators), most of the traceability issues surround information technology needs – hardware, software and labor. These do not necessarily vary by business type.

Question 11d. What determines the costs for small food retailers to maintain records consistent with the BT regulations, as well as lot code information for manufactured and processed food products, and farm-related information for fresh produce?
The costs for any company will be related to the extent of change needed to their current systems. These do not necessarily vary by business size. For example, a smaller company that is more technologically sophisticated than a larger company may have fewer costs.

*Question 11e. What determines the costs for food service establishments to maintain records consistent with the BT regulations, as well as lot code information for manufactured or processed food products and farm-related information for fresh produce?*

The costs for any company will be related to the extent of change needed to their current systems.

*Question 11f. What determines the size of a lot of manufactured or processed food products and how do lot sizes vary by food category and size of the manufacturer?*

The size of a lot is determined by the owner of the product. A grower may define a lot as all product from a particular field. Or a salad processor may define a lot as the production of salads from a particular processing line during a defined shift. A tomato repacker may define a lot by product repacked on a particular line during a defined time shift. Each business must be able to define a lot according to its needs.

*Question 11g. What determines the costs for maintaining "linking" records for manufacturers?*

The cost depends on their current internal systems and how they link that internal information to the standard codes used for external links between trading partners.

**E. Outreach**

*Question 12a. What, if any, additional outreach from FDA would better enable manufacturers, processors, and packers to comply with the requirements to maintain records of the lot or code number (or other identifier) to the extent this information exists?*

As with any compliance issue, ongoing outreach and enforcement from FDA are needed.

*Question 12b. What, if any, additional outreach from FDA would better enable all persons subject to 21 CFR part 1, subpart J to better comply with its requirements?*

Additional clarity and brevity in documents and all communications would be helpful. It might also help to have access to FDA officials who understand the markets and who can be available for public presentations at industry gatherings.

We thank the agency for its attention to this important matter. We look forward to working with you in any way that will help advance fresh produce safety. Please call on us at any time.