meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 16, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–22437 Filed 9–23–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0513]

Product Tracing Systems for Fresh Produce; Public Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comment.

SUMMARY: The Food and Drug Administration (FDA) is announcing two public meetings regarding product tracing systems for fresh produce. The purpose of the meetings is to stimulate and focus a discussion about mechanisms to enhance product tracing systems for fresh produce and to improve FDA's ability to use the information in such systems to identify the source of contamination associated with fresh produce-related outbreaks of foodborne illness. This discussion will help FDA determine what short and long term steps we should take to enhance the current tracing system.

DATES: See ''How to Participate in the Meetings'' in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: See ''How to Participate in the Meetings'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: *For registration, requests to make an oral presentation, and submission of written material for the presentation*: Deborah Harris, EDJ Associates, Inc., 11300 Rockville Pike, suite 1001, Rockville, MD 20852, 240–221–4326, FAX: 301–945–4295, e-mail: *dharris@edjassociates.com*.

For general questions about the meeting, to request onsite parking for the October 16 meeting, or for special accommodations due to a disability: Juanita Yates, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–009), 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1731, e-mail: *Juanita.Yates@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. How to Participate in the Meetings

Stakeholders will have an opportunity to provide oral comments. Due to limited space and time, we encourage all persons who wish to attend one or both of the meetings, including those requesting an opportunity to make an oral presentation at one or both of the meetings, to register in advance. Depending on the number of oral presentations, we may need to limit the time of each oral presentation (e.g., 5 minutes each). If time permits FDA may grant requests for an opportunity to make a presentation from individuals or organizations that did not register in advance.

Table 1 of this document provides information on participation in the meetings and on submitting comments.

TABLE 1.

	Date	Address	Electronic Address	Other Information
First Public Meeting	October 16, 2008, from 9 a.m. to 5 p.m.	Harvey W. Wiley Federal Building, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740-3835 (Metro stop: College Park on the Green Line)		
Advance registration	October 8, 2008	We encourage you to use electronic registration if possible.[1]	*http://www.cfsan.fda.gov/register.html*	Registration information, information on requests to make an oral presentation, and written material associated with an oral presentation may be posted without change to *http://www.regulations.gov*, including any personal information provided.
Make a request for oral presentation	October 1, 2008			
Provide a brief description of the oral presentation and any written material for the presentation	October 8, 2008			
Request special accommodations due to a disability	October 8, 2008	See **FOR FURTHER INFORMATION CONTACT**		
Request onsite parking	October 10, 2008	See **FOR FURTHER INFORMATION CONTACT**		

TABLE 1.—Continued

	Date	Address	Electronic Address	Other Information
Second Public Meeting	November 13, 2008, from 9 a.m. to 5 p.m.	Ronald V. Dellums Federal Building, Edward Roybal Auditorium, 1301 Clay St., 3d floor, Oakland, CA 94612		
Advance registration	October 30, 2008	We encourage you to use electronic registration if possible.[1]	*http://www.cfsan.fda.gov/register.html*	Registration information, information on requests to make an oral presentation, and written material associated with an oral presentation may be posted without change to *http://www.regulations.gov*, including any personal information provided.
Make a request for oral presentation	October 23, 2008			
Provide a brief description of the oral presentation and any written material for the presentation	October 30, 2008			
Request special accommodations due to a disability	October 30, 2008	See **FOR FURTHER INFORMATION CONTACT**		
Submit comments	January 22, 2009	Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane rm. 1061, Rockville, MD 20852	*http://www.regulations.gov*	All comments should be identified with the docket number found in brackets in the heading of this document. For additional information on submitting comments, see section IV of this document.

[1] You may also register by mail, fax, e-mail, or phone by providing registration information (including name, title, firm name, address, telephone number, fax number, and e-mail address), requests to make an oral presentation, and written material for the presentation to the contact person for registration (see **FOR FURTHER INFORMATION CONTACT**).

II. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

III. Background

A. Introduction

Food can become contaminated at many different steps in the farm-to-table continuum—on the farm; in packing, processing, or distribution facilities; during storage or transit; at retail establishments; in restaurants; and in the home. In recent years, FDA has done a great deal to prevent both deliberate and unintentional contamination of food at each of these steps. FDA has worked with other Federal, State, local, tribal, and foreign counterpart food safety agencies, as well as with law enforcement agencies, intelligence-gathering agencies, industry, and academia, to significantly strengthen the Nation's food safety and food defense systems across the entire distribution chain. This cooperative work has resulted in a greater awareness of potential vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and the ability to respond more quickly to outbreaks of foodborne illness. (An ''outbreak'' is the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.) However, changes in consumer preferences, changes in industry practices, and the rising volume of imports continue to pose significant challenges for the agency, particularly with respect to fresh produce. Outbreaks involving various types of fresh fruit and vegetables have led to thousands of confirmed illnesses in recent years (72 FR 8750, February 27, 2007, and Ref. 1), and many more unconfirmed or unreported illnesses.

When an outbreak of foodborne illness occurs, quick action is critical to prevent additional illness. The Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services, and State, local, and/or tribal health departments conduct epidemiologic investigations to identify the possible food(s) involved in an outbreak. After CDC and/or the State/local/tribal entity notify FDA that a specific food is implicated, FDA reviews and evaluates the epidemiologic data and assesses other potential causes for the outbreak (e.g., food worker illness, environmental contamination). Based on FDA's review and evaluation, an investigation to trace back the implicated food may be initiated to identify the source of the food and, potentially, of the contamination. Working with industry and with other domestic and, in some cases foreign, government agencies, FDA inspects or investigates points throughout the supply chain to determine where the contamination is likely to have occurred. Tracing food through a supply

chain may require us to find and examine products, packaging, and documentation (such as bills of lading, invoices, and other records maintained by the firm).

The ability to quickly identify the source of a contaminated product, and the path the product traveled between production and consumption, is critical to responding effectively to ongoing outbreaks of foodborne illness. Timely and accurate information gained from an investigation of the source of produce implicated in an outbreak of foodborne illness (traceback investigation) may:

- Help limit the public health impact of a foodborne illness outbreak, for example, by more quickly removing the contaminated produce from the market;
- Enable public health authorities and the food industry to provide targeted and accurate information about affected food to consumers and, as a result, restore or enhance consumer confidence in produce safety; and
- Help limit the source of the problem to a particular region or locality so that firms or regions that are not connected to the contaminated food are not adversely affected by a foodborne illness outbreak or the investigation of an outbreak.

In addition, the identification of sources of contaminated products may prevent future outbreaks by helping FDA and the food industry to identify and eliminate conditions that may have resulted in the food becoming contaminated and by helping them to understand better how the food became contaminated, so that the lessons learned can be used to prevent contamination in the future.

When an outbreak occurs, it also is critical that we be able to act quickly to take steps to prevent further illness. FDA may attempt to document the distribution of all implicated lots of food (traceforward operation) once the source of an outbreak is known to ensure that all contaminated food in commerce is removed from the market. Traceback investigations and traceforward operations are components of a ''product tracing'' system. As defined by the Codex Alimentarius Commission (Codex),[1] traceability/product tracing is the ability to follow the movement of a food through specified stage(s) of production, processing, and distribution (Ref. 2).

Traceback investigations involving fresh produce are among the most challenging investigations we face because the food is perishable and may no longer be available for testing by the time we conduct our investigation. In addition, fresh produce is often sold loose, without any packaging that would provide information about its source. Further, cases in which the produce was shipped, which may have provided such information, may also have been discarded by the time a traceback investigation is initiated. Industry practices, such as repacking produce from multiple sources, using different names for the same fresh produce as it travels throughout the supply chain, and not assigning specific identifiers to the produce, can complicate our traceback investigations even further.

We have had some recent successes in quickly identifying the source of an outbreak, but in some situations efforts to identify the source of the outbreak have proven difficult or impossible. We have learned that we need to be able to respond to the increased size and complexity of the fresh produce supply chain with a traceback capacity that is likewise more sophisticated, effective, and efficient and that reflects and responds to changing production and distribution patterns.

We are holding the public meetings to stimulate and focus a discussion about mechanisms to enhance product tracing systems for fresh produce and to improve FDA's ability to use the information in such systems to identify the source of contamination associated with fresh produce-related outbreaks of foodborne illness.

B. Information Elements Available in Current Product Tracing Systems

A product tracing system consists of information elements provided by parties in the supply chain. In general, this information is available in the form of records that parties in the supply chain establish and maintain apart from the produce. Some of this information may also be present on packaged food or on shipping cases of food items such as loose produce; some information applied to loose produce (e.g., on a sticker) may also provide information related to product tracing.

In the context of a foodborne illness outbreak, the information available through a product tracing system should enable an interested party (such as a party in the supply chain or a public health agency conducting a traceback investigation) to identify, at any specific stage of the supply chain, where the fresh produce came from, where the fresh produce was or is (e.g., in situations where a party in the supply chain has the fresh produce in its possession), where the fresh produce went, and who transported the fresh produce. This is commonly known as a ''one up/one down'' or ''one step back/one step forward'' system. In general, records that are part of such a system fall into one of two categories: Paper-based, human-readable records; or technology-based records with automated data capture (e.g., via bar codes or radiofrequency identification (RFID)), which may or may not also be human-readable.

To facilitate product tracing, FDA's regulations, at 21 CFR part 1, subpart J, ''Establishment, Maintenance, and Availability of Records,'' impose ''one up/one down'' recordkeeping requirements on certain persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. The regulations identify the information that must be established and maintained, how long it must be maintained, and how quickly it must be available to FDA. This information includes where the food product came from and where it went. A detailed discussion of those requirements is beyond the scope of this document, which does not address compliance with the recordkeeping regulations.[2]

Other product information, relevant to some traceback investigations, is available on the product label of packaged foods. For example, section 403(e)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(e)) provides that a food in package form is misbranded unless it bears a label containing the name and place of business of the manufacturer, packer, or distributor. As another example, section 403(i)(1) of the act provides that a food is misbranded unless its label bears the common or usual name of the food, if there is one. Our regulations implementing these provisions are in part 101 (21 CFR part 101). However, under our labeling regulations, the term ''package'' does not include shipping containers or wrappings used solely for the transportation of such commodities in bulk or in quantity to manufacturers, packers, processors, or wholesale or retail distributors (see 21 CFR 1.20(a)).

[1] The Codex Alimentarius Commission was formed in 1963 by the Food and Agriculture Organization and the World Health Organization of the United Nations to develop food standards, guidelines, and related texts such as codes of practice, and is recognized under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures as the international standards organization for food safety.

[2] For more information on the recordkeeping regulations, see ''What You Need to Know About Establishment and Maintenance of Records'' (Ref. 3) and ''Questions and Answers Regarding Establishment and Maintenance of Records'' (Ref. 4).

C. Structural and Geographic Characteristics of the Fresh Produce Industry Relevant to Product Tracing Systems

The fresh produce industry is particularly diverse, both structurally and geographically (Ref. 6). Structurally, the industry varies not only by commodity, region, and season, but also by distributor and retailer. For example, as discussed later in this section, parties in the supply chain may use one or more suppliers for the same type of fresh produce depending on factors including growing season, demand, and the variability of different harvests in different locations.

Geographically, more than 55 billion pounds of fresh produce are grown within the United States annually, and more than 26 billion pounds of fresh produce are imported into the United States every year from 58 countries (Ref. 7). These 81 billion pounds of produce often travel hundreds or thousands of miles on the way to consumers (usually in shipments of 10,000 pounds or much less), and change hands several times between different points in the complex supply chain (Ref. 7). The nature and complexity of the global produce market raise special challenges for public health agencies, and even those within the industry, to be able to trace the path of a particular product throughout the supply chain.

D. Challenges Associated with Traceback Investigations of Fresh Produce

The supply chain for a given type of fresh produce may be very complex. For example, several growers might supply their produce to a packer or distributor, and there may be multiple distributors who receive the product before its sale to or use by the ultimate consumer. Growers may send their produce to several packers or distributors, and suppliers may obtain produce from several packers or distributors as well as directly from growers. Parties in the supply chain may be within the United States or abroad; thus, produce might be imported into or exported from any point in the supply chain one or more times. Other parties in a food supply chain may include processors of fresh produce, who may chill it, cut it into smaller pieces, or combine pieces of fresh produce with other foods to make another food product (such as using lettuce to make a salad). Contamination can occur at almost any point in the fresh produce supply chain.

In some fresh produce supply chains, produce from multiple sources may be combined or commingled during packing or processing operations. This practice can complicate or even frustrate efforts to trace fresh produce throughout the supply chain. For example, a packing firm may buy a particular type of vegetable from multiple farms, and then sort the vegetables by size, color, quality, or some other attribute before packing into containers. As another example, a large truck may collect loose produce from multiple farms and then deliver the collected loose produce to a single processor or distributor. Even if we could trace a contaminated product back to the processor or distributor, or, in the second example, back to the packing firm, the commingling of loose produce before it reaches the processor or distributor or at the packing firm makes it difficult or impossible to distinguish which farm is the source of the contaminated produce. The complexity increases if the truck delivers the loose produce to more than one processor or distributor.

An additional challenge associated with a traceback investigation for fresh produce is that the produce may not always retain the same description as it moves through the supply chain. For example, one party in the supply chain may describe its fresh produce as ''red round tomatoes,'' while the next party in the supply chain may describe the same fresh produce as ''cooker tomatoes.'' Different descriptions for the same produce can make it very difficult or impossible to determine whether two records refer to the same or different products or shipments.

Another challenge associated with a traceback investigation for fresh produce is that there may be no identifier on the produce, its package, or its case, and in associated records. Moreover, there currently is no industry-wide or sector-wide standardization of the information captured in the documentation. This lack of standardization makes it difficult and time-consuming to cross-reference information currently available in product tracing systems.

E. How Has Product Tracing Information Available in Records and on Product Packages/Containers Helped Us During Traceback Investigations?

In the following paragraphs, we describe how we used product tracing information to conduct two recent traceback investigations—one involving a nonperishable packaged food, and one involving a perishable packaged food. The information available to us included information available in records established and maintained by parties in the supply chain and information available on packages or containers of the packaged food.

- In February 2007, CDC notified FDA of a multi-State outbreak of *Salmonella* Tennessee infections associated with the consumption of peanut butter. Peanut butter is a nonperishable packaged food, sold in jars. Consumers who became ill had open jars of peanut butter available for testing. Investigators were able to test samples of peanut butter taken from the jars and confirm the presence of *Salmonella* Tennessee in the peanut butter. Investigators were able to identify the manufacturer through information required to be on the label of the jars (§ 101.5(a)) and through a product code the manufacturer had voluntarily placed on the jars. This information made it possible for FDA to visit the manufacturing facility the day after we learned of the outbreak from CDC. Investigators were able to use the product code to look in the manufacturing facility for unopened jars of peanut butter manufactured at the same time as the jars available from consumers. Investigators took samples of peanut butter from these unopened jars and confirmed the presence of *Salmonella* Tennessee in those samples. Investigators uncovered conditions at the manufacturer's facility that were likely to have caused the contamination and obtained a positive environmental sample so there was no need to further trace the peanuts back to the farm. Our traceback investigation was facilitated because the implicated food was a nonperishable, packaged food that was available to investigators and contained information about the source of the implicated food on the product container.
- In September 2006, CDC informed FDA of a multi-State outbreak of illnesses associated with the consumption of fresh spinach contaminated with *E. coli* O157:H7. Fresh spinach is a perishable food that may not remain in consumers' homes after consumers become ill and CDC finds an association between the illness and the food. However, in this situation the spinach was sold in a package. The traceback investigation was facilitated because several consumers who became ill still had packages of fresh spinach in their refrigerators. As with the peanut butter, investigators were able to identify the processor through information required to be on the label of the packaged spinach (§ 101.5(a)) and through a product code the processor had voluntarily placed on the package. By looking at the processor's records, the investigators were able to identify the implicated farms associated with the

identified production lot of bagged spinach. This traceback investigation was more complex than the investigation for the peanut butter, because it required traceback beyond the processor to the farms. However, as with the peanut butter, the traceback investigation was greatly facilitated by the information on the label of the packaged food and on the package itself.

F. Industry Product Tracing Systems That Are in Use or Under Development in the United States

1. Commodity-Specific Efforts

Various recordkeeping and other practices designed to enhance product tracing systems are already carried out by industry within the food supply chain. For instance, to better monitor food safety practices of growers, the California cantaloupe industry has incorporated product tracing requirements that involve maintaining information such as packing date, field, and packing crew as part of their State marketing order (Ref. 9).

Similarly, the California Tomato Farmers cooperative has instituted documentation requirements in its membership agreement with growers to facilitate one up/one down tracking and product tracing. The documentation of packed tomatoes must include information about the source (i.e., grower, production location, lot identification, personnel/crew involved in the harvest of the product) and about the customer receiving the product. A system to track and trace tomatoes back to supply source and forward to customers must be developed and tested annually (Ref. 10).

Stakeholders have developed commodity-specific food safety guidelines for the entire supply chain for three commodities: Melons (Ref. 11), tomatoes (Ref. 8), and lettuce and leafy greens (Ref. 12).

2. Buyer-Led Initiatives

Large food retailers, such as supermarket chains, have become more active in ensuring the safety of the food products they purchase. One example of this is the increasing use of independent third-party food safety audits of grower and shipper operations to verify compliance with good agricultural and manufacturing practices. These practices generally include requirements that the grower or shipper maintain records that facilitate the tracing of product produced, handled, or processed in order to pass an audit.

For example, in February 2008, Wal-Mart, Inc., became the first U.S. grocery chain to require suppliers of its private label and other food products to have their factories certified against one of the internationally-recognized Global Food Safety Initiative (GFSI) standards (Ref. 13). The GFSI standard for traceability requires the supplier to develop and maintain appropriate procedures and systems to ensure (1) identification of any out-sourced product, ingredient, or service; (2) complete records of batches of in-process or final product and packaging throughout the production process; and (3) record of purchaser and delivery destination for all product supplied (Ref. 14).

3. Produce Traceability Initiative (PTI)

In October 2007, the Produce Marketing Association (PMA), the United Fresh Produce Association (UFPA), and the Canadian Produce Marketing Association (CPMA) initiated the joint PTI (Ref. 15). The PTI now includes more than 50 companies, including distributors, grower-shippers, and retailers. A principal objective of the PTI is to drive adoption of consistent ''traceability best practices'' throughout the produce supply chain from ''field to fork.'' In pursuing the goal of broad adoption of tracking and product tracing standards and practices, the PTI has established a timeline for a series of milestones for recording, tracking, and product tracing data on produce shipments. These milestones include establishing company prefixes; establishing an identification number for location; assigning global trade item numbers (GTINs) to produce cases; showing GTINs, lot numbers, and packing/harvesting dates on each case; encoding this information in bar codes; and reading and storing the information at each point in the supply chain. The PTI also calls for tracking and product tracing standards to be adopted at the case level initially, followed by standards for item-level coding (Refs. 5 and 16).

G. International Product Tracing Systems

Some countries have mandatory product tracing systems in place in various forms, although these systems are more prevalent with respect to animal identification than for food in general. The European Union (EU), in addition to having a mandatory product tracing system for animals, also requires a product tracing system for all food and feed businesses. Specifically, the EU requires all food and feed to be traceable ''one step forward and one step back'' in EU member states. Food and feed business operators must be able to document where a particular food or feed product came from and where it is going next. Specifically, they must be able to document the names and addresses of suppliers and customers, as well as the nature of the product and date of delivery. They are also encouraged to keep information on the volume and quantity of a product; the batch number, if one exists; and a more detailed description of the product, such as whether it is fresh or processed. Food and feed business operators must also have systems and procedures that allow them to provide this information to the competent authorities on demand. In addition to these general requirements, sector-specific requirements apply to certain categories of food products (fruit and vegetables, beef, fish, honey, olive oil) (Refs. 17 through 20). In 2007, the EU began a 4-year study to develop, test, and evaluate two full pilot product tracing systems—one for the tomato food chain and the other for the feed/dairy chain (Ref. 21).

In 2006, Codex established principles for tracing food through production and distribution processes (Ref. 2). The Codex principles are intended to assist government authorities in utilizing product tracing as a tool within their food inspection and certification system.

Certain private international standard setting organizations have also developed principles and other guidelines on product tracing systems for use by industry. For example, in 2007 the International Standards Organization (ISO) issued ISO 22005:2007, which provides general principles and basic requirements for designing and implementing a product tracing system along a food processor's supply chain.[3] Another example is the GS1 Global Traceability Standard (Ref. 22), which is being used by the PMA, CPMA, UFPA, and other associations involved in the PTI.

H. Actions Suggested by Stakeholders

Some consumer advocacy groups have asked us to develop and implement emergency regulations that would require source tracing for produce (farm-to-table); written food safety plans for farmers, processors, and packinghouses; and tighter controls on repacking (Ref. 23). Some industry trade associations have asked FDA and CDC to convene a meeting with industry representatives and work together to minimize the human and economic impact of an outbreak (Ref. 24). These

[3] ISO 22005:2007. ''Traceability in the feed and food chain—General principles and basic requirements for system design and implementation.'' July 2007. Available for purchase at *http://webstore.ansi.org*.

trade associations urged FDA and CDC to work in partnership with industry to find solutions to speed up and streamline outbreak identification and response. These trade associations also recommended that a working group be established to look at crisis management systems and that teams of industry experts be established to help in traceback investigations.

I. Issues and Questions for Discussion

As previously noted, we need to increase the speed and accuracy of traceback investigations to help limit the public health impact of a foodborne illness outbreak; to limit to a particular region, locality, farm(s), or processor(s) the source of the problem (where the source is in fact limited), so that an entire industry is not unnecessarily affected; to enable public health authorities and the food industry to provide targeted and accurate information about affected food to consumers; to institute steps to correct the source of contamination; and, as a result, to restore or enhance consumer confidence in produce safety.

We intend the public meetings to stimulate and focus a discussion about mechanisms to enhance product tracing systems for fresh produce and to improve FDA's ability to use the information in such systems to identify the source of contamination associated with fresh produce-related outbreaks of foodborne illness. This discussion will help FDA determine what short and long term steps, such as issuing regulations, we should take to enhance the current tracing system. Aspects of these measures could require new legal authority. We welcome public comments and/or data on the following issues related to product tracing systems for fresh produce:

1. Should a ''fresh produce identifier'' be assigned to fresh produce? If so, at what stage or stages in the supply chain should such an identifier be assigned or modified? What data or information would be useful to include in such an identifier? Should the identifier be placed on the fresh produce, the package, the shipping container, and/or the invoice or bill of lading? Should the location of the identifier depend on the type of produce or on other factors?

Our investigations of the 2006 outbreak associated with packaged fresh spinach and the 2007 outbreak associated with peanut butter were greatly facilitated by a product ''code'' that the party who packaged the implicated product had assigned to the packaged product. We seek comment on whether a ''fresh produce identifier'' should be assigned to fresh produce, and, if so, at what stage or stages in the supply chain and with what information elements.

2. What other data or information would be useful on the invoice or bill of lading, fresh produce, package, or shipping case? At what stage or stages in the supply chain should such data or information be included?

The product ''codes'' assigned to the packaged fresh spinach associated with the 2006 outbreak and to the peanut butter associated with the 2007 outbreak were present on the packaged products. We seek comment on whether any other data or information (in addition to or instead of the fresh produce identifier discussed in question 1) should be on or attached to the invoice, bill of lading, fresh produce, its package (when feasible), or the shipping case.

3. Should an enhanced product tracing system extend to all fresh produce? If not, what criteria should be used to determine coverage?

There are a number of factors that may increase or decrease the risk for contamination of produce. Such factors may include crop characteristics (e.g., proximity of the edible portion of the crop to the soil, or rough surface, such as cantaloupe); production practices or conditions (e.g., water quality for field and packing operations); method of irrigation; likelihood of animal intrusion; and worker health and hygiene. Should these or other factors (e.g., history of outbreaks) be considered in prioritizing the development and application of an enhanced product tracing system?

4. Should fresh produce be commingled? If commingling is unavoidable, what practices should an enhanced product tracing system include to ensure that fresh produce can be traced effectively and efficiently?

Some industry food safety guidelines advise against commingling (Ref. 8). Should parties in the supply chain for some or all commodities consider refining or designing their product tracing systems so that they can identify the source of individual pieces of fresh produce if they combine or commingle produce from multiple sources and link this information to the one-up/one-down records they establish and maintain? If such identification is not feasible, should parties in the supply chain for some or all commodities consider no longer combining or commingling produce? We seek comment on any measures already in place to address product tracing of commingled fresh produce and the extent to which such measures have been demonstrated to be successful in ensuring product tracing, particularly during traceback investigations.

5. What should be the scope of an enhanced product tracing system for fresh produce?

As stated previously, the supply chain for fresh produce is often complex. We seek comment concerning how an enhanced product tracing system for fresh produce should apply to various parties in the supply chain, including producers, packers, distributors, and retailers. More specifically, we seek comment on whether some or all aspects of an enhanced product tracing system for fresh produce should apply to some or all farms. For example, if a fresh produce identifier includes information about the date of harvest, the farm is the party who would have that information. It may be more practical for the farm to identify the date of harvest on the invoice when it ships the fresh produce than for the first party in the supply chain to subsequently contact the farm to determine the date of harvest.

We also seek comment on whether some or all aspects of an enhanced product tracing system for fresh produce should apply to some or all restaurants or retailers. For example, if a ''fresh produce identifier'' is assigned to produce a restaurant receives, we seek comment on whether the restaurant could establish and maintain records of that identifier or could retain the invoice or bill of lading if the information is contained on those documents.

We also seek comment on whether some or all aspects of an enhanced product tracing system for fresh produce should extend to consumers. Product tracing systems currently used by the fresh produce industry typically do not reach the consumer level. However, some segments of the supply chain can and do record some individual consumer information, and may be able to use this information to alert specific consumers about product recalls or for other purposes. For example, a retailer who has a ''frequent customer'' or ''bonus card'' program may record each cardholder's purchases. The retailer's consumer purchasing information also would be very helpful in those situations where the fresh produce that is possibly linked to a foodborne illness outbreak is eaten and the consumers have disposed of any identifiers on the fresh produce before a traceback investigation begins. Could such systems be adapted or modified to provide assistance with traceback investigations? Would there be any issues or concerns associated with such systems?

6. Should the data or information in an enhanced product tracing system be human-readable, technology-based, or both? If technology-based, what technology should be used?

''Human-readable'' information should enable all parties in the supply chain, regardless of the technology used, to read this information. By ''human-readable,'' we mean information consisting of numbers and/or letters capable of being read by the human eye. Technology-based systems could make it faster and easier to accurately record information such as a fresh produce identifier. For example, a person making a paper record of a human-readable identifier expressed in numbers or letters may mistakenly transpose or omit numbers or letters, thus creating erroneous entries in the records. In contrast, the potential for such mistakes is greatly reduced if the identifier is recorded using an automatic system such as a bar code or RFID. In addition, technology-based systems could greatly speed a traceback investigation. However, some parties may not have access to electronic technologies. We seek comment on whether data or information in an enhanced product tracing system should be human-readable, technology-based, or both. If technology-based, what technology should be used?

7. What (if any) data or information in an enhanced product tracing system should be standardized?

The lack of standardization in the information in current product tracing systems can frustrate traceback investigations. We seek comment on whether the various segments of the fresh produce industry should develop standards for the content and format of records, particularly of electronic records that could help make electronic record systems interoperable. We seek comment on the existence and utility of existing standards relevant to some or all of the information elements that would be in an enhanced product tracing system, such as in a fresh produce identifier. We also seek comment on whether such standards should be developed and on whether current or newly developed standards should be identified in any guidance or regulations issued by FDA. We also seek comment on whether and how current or newly developed standards for the content and format of electronic systems could have practical utility for parties who continue to use paper-based technology. For example, could human-readable data that support standardized technology-based data be useful to parties who continue to use paper-based technology?

8. What are the costs, benefits, and feasibility of implementing an enhanced product tracing system?

Further enhancing the product tracing system for fresh produce could aid us in shortening the duration of outbreaks and limiting the number of people who become ill. It could also give us more information to use in preventing future outbreaks. However, these benefits will not come equally from all types of fresh produce. Enhancing the product tracing system beyond current practices and requirements for certain types of fresh produce might not significantly enhance public health if the fresh produce has not been associated with foodborne illness or any known risk factors. An enhanced fresh product tracing system for fresh produce may also impose burdens on entities in the supply chain. We seek comment on the costs, benefits, and feasibility of implementing an enhanced product tracing system for each of the parties in the supply chain.

We recognize that enhancing product tracing of fresh produce may not be just a matter of keeping more or different records or adding more information to product or packaging, but also of changing business practices. We request comment on the extent to which an enhanced product tracing system for fresh produce will affect comingling and repacking of produce and the cost of any such changes in the supply chain.

9. Would enhancing FDA's role in developing and implementing effective product tracing systems for fresh produce, through increased regulation, guidance, or additional legal authorities, improve the effectiveness of traceback investigations and traceforward operations? What mandatory and voluntary measures would be most effective in achieving the goal of enhancing product tracing systems for fresh produce and improving FDA's ability to use the information in such systems to identify the source of contamination associated with fresh produce-related outbreaks of foodborne illness? How would these measures help FDA work better with industry and other stakeholders during traceback investigations and traceforward operations?

IV. Comments

Interested persons may submit to the Division of Dockets Management (see table 1 of this document) written or electronic comments for consideration at or after the meeting in addition to, or in place of, a request for an opportunity to make an oral presentation. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

V. References

We have placed the following references on display in the Division of Dockets Management (see table 1 of this document). You may see them between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to Web sites after this document publishes in the **Federal Register**.)

1. U.S. Food and Drug Administration, 1996–2007 Produce Outbreaks (unpublished compilation).

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3. U.S. Food and Drug Administration. 2004. ''What You Need to Know About Establishment and Maintenance of Records.'' Available at *http://www.cfsan.fda.gov/~acrobat/fsbtrec.pdf*.

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5. Produce Marketing Association and Canadian Produce Marketing Association. 2006. Fresh Produce Traceability. A Guide To Implementation. Available at *http://www.pma.com/cig/tech/traceability.cfm*. Accessed and printed on June 18, 2008.

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7. U.S. Department of Agriculture, Agricultural Marketing Service. Issued February 2006. Fresh Fruit and Vegetable Shipments By Commodities, States, and Months. FVAS–4 Calendar Year 2005. Available at *http://www.ams.usda.gov*. Accessed and printed on July 22, 2008.

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10. California Tomato Farmers. Food Safety Program. Available at *http://www.californiatomatofarmers.com/foodsafety.asp*. Accessed and printed on August 4, 2008.

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12. International Fresh-cut Produce Association, Produce Marketing Association, United Fresh Fruit and Vegetable Association, and Western Growers. 2006. Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain. 1st Edition. Available at *http://www.cfsan.fda.gov/~dms/lettsup.html*. Accessed and printed on August 7, 2008.

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14. Global Food Safety Initiative, GFSI Guidance Document, 5th Edition, September 2007. Available at *http://www.ciesnet.com/pfiles/programmes/foodsafety/GFSI_Guidance_Document_5th%20Edition%20_September%202007.pdf*. Accessed and printed on September 4, 2008.

15. Produce Marketing Association, Canadian Produce Marketing Association, and United Fresh Produce Association. 2007. Joint Release. Available at *http://www.cpma.ca/pdf/IndustryTech/Traceability_Joint_Release_PMA_CPMA_UFPA_Oct2007.pdf*. Accessed and printed on July 22, 2008.

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17. U.S. Government Accounting Office. 2008. Report to Congressional Requestors. Food Safety. Selected Countries Can Offer Insights into Ensuring Import Safety and Responding to Foodborne Illness. GAO 08–794. Available at *http://www.gao.gov/new.items/d08794.pdf*. Accessed and printed on July 18, 2008.

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19. Standing Committee On The Food Chain And Animal Health. Guidance On The Implementation Of Articles 11, 12, 16, 17, 18, 19 AND 20 of Regulation (EC) N° 178/2002 on General Food Law. Available at *http://ec.europa.eu/food/food/foodlaw/guidance/guidance_rev_7_en.pdf*. Accessed and printed on September 3, 2008.

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23. Letter dated July 3, 2008 from Michael F. Jacobson and Caroline Smith de Waal of the Center for Science in the Public Interest and Chris Waldrop of the Consumer Federation of America to Andrew C. von Eschenbach of the U.S. Food and Drug Administration. Available at *http://cspinet.org/new/pdf/von_eshenbach_traceability_letter.pdf*. Accessed and printed on July 19, 2008.

24. Letter dated July 3, 2008, from Thomas E. Stenzel of United Fresh Produce Association and Bryan Silbermann of Produce Marketing Association to Secretary Michael O. Leavitt of the U.S. Department of Health and Human Services. Available at *http://www.unitedfresh.org/assets/files/PMA_UFPA_2nd_HHS_Meeting_Request_7308.pdf*. Accessed and printed on July 21, 2008.

Dated: September 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–22430 Filed 9–19–08; 4:15 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60-Day Proposed Information Collection: Indian Health Service Background Investigations of Individuals in Positions Involving Regular Contact With or Control Over Indian Children, OPM–306

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 which requires 60 days for public comment on proposed information collection projects, the Indian Health Service (IHS) is publishing for comment a summary of a proposed information collection to be submitted to the Office of Management and Budget (OMB) for review.

Proposed Collection: Title: 0917–0028, ''IHS Background Investigations of Individuals in Positions Involving Regular Contact With or Control Over Indian Children, OPM–306. Type of Information Collection Request: Extension, without revision, of currently approved information collection, 0917–0028, ''IHS Background Investigations of Individuals in Positions Involving Regular Contact With or Control Over Indian Children, OPM–306.

Form Number: OPM–306. Forms: Declaration for Federal Employment. Need and Use of Information Collection: This is a request for approval of collection information required by Section 408 of the Indian Child Protection and Family Violence Prevention Act, Public Law 101–630, 104 Stat. 4544, and 25 U.S.C. 3201–3211. The IHS is required to compile a list of all authorized positions within the IRS where the duties and responsibilities involve regular contact with, or control over, Indian children; and to conduct an investigation of the character of each individual who is employed, or is being considered for employment in a position having regular contact with, or control over, Indian children. Section 3207(b) of the Indian Child Protection and Family Violence Prevention Act was amended by Section 814 of U.S.C. 3031, the Native American Laws Technical Corrections Act of 2000, which requires that the regulations prescribing the minimum standards of character ensure that none of the individuals appointed to positions involving regular contact with, or control over Indian children have been found guilty of, or entered a plea of nolo contendere or guilty to any felonious offense, or any of two or more misdemeanor offenses under Federal, State, or Tribal law involving crimes of violence; sexual assault, molestation, exploitation, contact or prostitution; crimes against persons; or offenses committed against children. In addition, 42 U.S.C. 13041 requires each agency of the Federal Government, and every facility operated by the Federal Government (or operated under contract with the Federal Government), that hires (or contracts for hire) individuals involved with children under the age of 18 or child care services to assure that all existing and newly hired employees undergo a criminal history background check. The background is to be initiated through the personnel program of the