

document and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Paperwork Reduction Act of 1995

This draft guidance contains proposed collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). As required by the PRA, FDA has published an analysis of the information collection concerning the submission of ingredient information (74 FR 45219, September 1, 2009, as corrected by 74 FR 47257, September 15, 2009) and will submit it for OMB approval.

V. Electronic Access

An electronic version of the guidance document is available on the Internet at <http://www.regulations.gov> and <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>

Dated: October 29, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–26466 Filed 10–30–09; 11:15 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Draft Guideline for the Prevention of Intravascular Catheter-Related Infections

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: Notice of availability and request for public comment.

SUMMARY: This notice is a request for review of and comment on the *Draft Guideline for the Prevention of Intravascular Catheter-Related Infections*, available on the following Web site: <http://www.cdc.gov/publiccomments/>.

This document is for use by infection prevention staff, healthcare epidemiologists, healthcare administrators, nurses, other healthcare providers, and persons responsible for developing, implementing, and evaluating infection prevention and control programs for healthcare settings across the continuum of care. The guideline updates and expands the *Guideline for the Prevention of*

Intravascular Device-Related Infections published in 2002. These guidelines provide evidence-based recommendations for preventing intravascular catheter-related infections.

DATES: Comments must be received on or before December 3, 2009.

ADDRESSES: Comments on the *Draft Guideline for the Prevention of Intravascular Catheter-Related Infections* should be submitted by e-mail to BSI@cdc.gov or by mail to CDC, Division of Healthcare Quality Promotion, Attn: Resource Center, 1600 Clifton Rd., NE., Mailstop A–31, Atlanta, Georgia 30333; or by fax 404–639–4049.

Dated: October 27, 2009.

Tanja Popovic,

Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–26393 Filed 11–2–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Career Development & Fellowship Applications.

Date: November 4, 2009.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call)

Contact Person: Raul A Saavedra, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Nsc; 6001 Executive Blvd., Ste. 3208, Bethesda, MD 20892–9529, 301–496–9223, saavedrr@ninds.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; K01 Conflict Review.

Date: November 19, 2009.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call)

Contact Person: Joann Mcconnell, PhD, Scientific Review Administrator, Scientific Review Branch, NIH/NINDS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, (301) 496–5324, mcconnej@ninds.nih.gov.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; K99 Special Review.

Date: November 20, 2009.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call)

Contact Person: Joann Mcconnell, PhD, Scientific Review Administrator, Scientific Review Branch, NIH/NINDS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, (301) 496–5324, mcconnej@ninds.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: October 21, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–25923 Filed 11–2–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0523]

Product Tracing Systems for Food; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comment.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the United States Department of Agriculture, Food Safety and Inspection Service (FSIS), is announcing a public meeting regarding product tracing systems for food intended for humans

and animals. The purpose of the meeting is to stimulate and focus a discussion about mechanisms to enhance product tracing systems for food. This discussion will help FDA and FSIS determine what short and long term steps the two agencies 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 electronic registration, electronic requests to make an oral presentation during the time allotted for public comment at the meeting, logistics, or to request a sign language interpreter or other special accommodation due to a disability: Sheila Johnson, Congressional and Public Affairs, 1400 Independence Ave., SW., Washington, DC, 20250, 202-690-6498, e-mail: Sheila.Johnson@fsis.usda.gov.

FSIS: For questions about meat, meat food products, poultry, poultry products, and egg products: William Smith, Assistant Administrator, Office of Program Evaluation, Enforcement & Review, rm. 3133, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC, 20250, 202-720-8609.

FDA: For non-electronic registration (i.e., registration by mail, fax, e-mail, or phone), for submission of written material for an oral presentation, and for questions about all other food: 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, toll-free FAX: 1-877-366-3322, e-mail: Juanita.Yates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Purpose of the Meeting

As discussed more fully in section IV.A of this document, Federal food safety agencies need to increase the speed and accuracy of traceback investigations and traceforward operations. FDA and FSIS intend the public meeting to stimulate and focus a discussion about the core elements of product tracing systems, gaps in current product tracing systems, and mechanisms to enhance product tracing systems for food. FDA and FSIS also intend the public meeting to improve the ability of FDA and FSIS to use the information in such systems to identify the source of contamination during outbreaks of foodborne illness, and to improve the ability of all persons in the supply chain to more quickly identify food that is (or potentially is) contaminated and remove it from the market during traceforward operations. This discussion will help FDA and FSIS

determine what short and long term steps each agency should take to enhance the current tracing system.

For purposes of this document, the term “food” applies to both food for humans and food for animals.¹ As defined by the Codex Alimentarius Commission (Codex),² traceability/product tracing is the ability to follow the movement of a food through specified stage(s) of production, processing, and distribution (Ref. 1).

II. How to Participate in the Meeting

Stakeholders will have an opportunity to provide oral comments. Due to limited space and time, and to facilitate entry to the building in light of security procedures, FDA and FSIS encourage all persons who wish to attend the meeting, including those requesting an opportunity to make an oral presentation during the time allotted for public comment at the meeting, to register in advance. Depending on the number of requests for such oral presentations, there may be a need to limit the time of each oral presentation (e.g., 5 minutes each). If time permits, requests may be granted for an opportunity to make such an oral 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 to the Docket established for the meeting.

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETINGS AND ON SUBMITTING COMMENTS

	Date	Address	Electronic Address	Other Information
Public meeting	December 9 and 10, 2009, from 9 a.m. until 5 p.m.	Jefferson Auditorium at the U.S. Department of Agriculture (South Building), 1400 Independence Ave., SW., Washington, DC, 20250 (Metro stop: Smithsonian Metro Station on the blue and orange lines, take the Independence Ave. exit)		Attendees must provide a picture ID to enter the building. The Jefferson auditorium is located at Wing 6 in the South Building. Attendees should enter the building at Wing 7 at the 14th Street entrance. Participation is also being made available via teleconference. The call-in information will be located at the bottom of the registration form.

¹ Under section 201(f) of the Federal Food, Drug, and Cosmetic Act (the FFDCFA), food is defined as (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

² 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.

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETINGS AND ON SUBMITTING COMMENTS—Continued

	Date	Address	Electronic Address	Other Information
Advance registration	December 2, 2009	We encourage you to use electronic registration if possible. ¹	http://www.fsis.usda.gov/News/Meetings_&Events . Please complete the registration form including all required fields.	A request for an oral presentation should specify whether the presentation will be directed to FDA, FSIS, or both. Depending on the number of requests, it may be possible to allot two presentation times to persons who request an opportunity to direct a presentation to both FDA and FSIS. Registration information and information on requests to make an oral presentation may be posted without change to http://www.regulations.gov , including any personal information provided.
Make a request for an oral presentation during the time allotted for public comment	November 23, 2009			
Provide a brief description of the oral presentation and any written material for the presentation	December 2, 2009	Juanita Yates (see FOR FURTHER INFORMATION CONTACT)		Written material associated with an oral presentation may be posted without change to http://www.regulations.gov , including any personal information provided.
Request a sign language interpreter or other special accommodation due to a disability	November 30, 2009	Sheila Johnson (see FOR FURTHER INFORMATION CONTACT)		
Submit comments	by March 3, 2010. 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 VII 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 Juanita Yates (see **FOR FURTHER INFORMATION CONTACT**).

III. 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.

IV. Background

A. Introduction

The public meeting is intended to address product tracing systems to facilitate traceback investigations and traceforward operations for food products. A traceback investigation is an investigation to determine and document the distribution and production chain, and the source(s), of contaminated (and potentially contaminated) food, often in the context of an outbreak of foodborne illness. A traceforward operation is an operation to determine the distribution of contaminated (and potentially contaminated) food. An outbreak of foodborne illness is the occurrence of

two or more cases of a similar illness resulting from the ingestion of a common food.

Food can become contaminated at many different steps in the farm-to-table continuum: On the farm; in packing, manufacturing/processing, or distribution facilities; during storage or transit; at retail establishments; in restaurants; and in the home. In recent years, FDA and FSIS have taken a number of actions to prevent both deliberate and unintentional contamination of food at each of these steps. FDA and FSIS have worked with other Federal, State, local, territory, 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. However, changes in consumer preferences, change in industry practices, and the rising volume of imports continue to pose significant challenges for FDA and FSIS (72 FR 8750, February 27, 2007; 73 FR 55115, September 24, 2008; 67 FR 62325, October 7, 2002; and Ref. 2). Recently, thousands of processed food products have been recalled due to contamination (and potential contamination) of ingredients (e.g., peanuts and peanut-derived products, pistachios, and dried milk) with a pathogenic microorganism (e.g., *Salmonella*) or chemical (e.g., melamine) (Refs. 3 through 6). In addition, contamination (and potential contamination) of ground beef with a pathogenic microorganism (e.g., *Escherichia coli* O157:H7) has led to recalls involving millions of pounds of ground beef (Ref. 7). These food contamination events, often involving foodborne illnesses, have emphasized the importance of efficient and effective product tracing systems, particularly the importance of linking shipments of contaminated (and potentially contaminated) food backward and forward through the supply chain through the efficient assembly and review of product tracing records.

In some cases, a firm that receives, manufactures, or distributes food, or a regulatory official detects contamination of a food in the market, without any known or suspected association between the food and reports of foodborne illness. When the contamination could cause foodborne illness, quick action is necessary to remove the food from the market. A traceforward operation to determine the distribution of all contaminated (and potentially contaminated) food may be initiated for any type of food in the market, e.g., a raw agricultural commodity, a food ingredient, or any single- or multi-ingredient processed food. In recent years, traceforward operations for food ingredients have highlighted the potentially large impact that contamination (or potential contamination) of a single food ingredient can have on thousands of food products containing that ingredient (Refs. 3 through 6).

In other cases, food that has become contaminated goes undetected until it is associated with an outbreak of foodborne illness. 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 (HHS), and State, local, territory and/or tribal health departments conduct epidemiologic investigations to identify the possible food(s) involved in an outbreak. In general, when it is concluded that the contamination occurred at the point of sale, such as a restaurant (e.g., due to illness of a food worker or environmental contamination at the point of sale), FDA or FSIS does not get involved with the investigation. If it appears that the contamination did not occur at the point of sale, CDC and/or the State/local/territory/tribal entity notify FDA, FSIS, or both about the outbreak and the specific food that is potentially associated with the outbreak.

After CDC and/or the State/local/territory/tribal entity notify FDA or FSIS that a specific food is potentially associated with an outbreak of foodborne illness, the notified agency (or agencies) reviews and evaluates the available data and information. Based upon the agency's review and evaluation of epidemiologic data and/or laboratory results, the notified agency may initiate a traceback investigation to identify the source of the food and, potentially, of the contamination. As with a traceforward operation, a traceback investigation may be initiated for any type of food in the market, e.g., a raw agricultural commodity, a food ingredient, or any single- or multi-ingredient processed food. Working with industry and with other domestic (and, in some cases, foreign) government agencies, the notified agency inspects or investigates each point throughout the supply chain to determine where the contamination likely occurred. In the course of an investigation, the notified agency may examine the facility, ingredients, finished products, packaging, and food handling practices (such as how long food is held before shipping, whether the facility practices "first in–first out" when selling products, and whether finished products or ingredients are shared or exchanged with other facilities).

Timely and accurate information gained from records available during a traceback investigation or traceforward operation may:

- Help limit the public health impact of a foodborne illness outbreak, for

example, by enabling a more rapid traceforward operation to remove the contaminated (or potentially contaminated) food 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 food safety;

- Help limit the source of the problem to a particular food (e.g., brand), or to a particular region or locality (e.g., as a source of contaminated (or potentially contaminated) fresh produce) so that firms or regions that are not connected to the contaminated (or potentially contaminated) food are not adversely affected by an outbreak investigation or by a recall; and

- Help prevent future outbreaks by enabling the applicable Federal or State regulatory agency to more rapidly investigate firms where contamination may have occurred, so that conditions and practices that may have been associated with the contamination can be observed and the lessons learned can be used to prevent contamination in the future.

Current records (maintained by the various persons in the supply chain) that contain product tracing information include external records (such as bills of lading, airway bills, manifests, invoices, shipping records, and packing lists) that a firm establishes to accompany commercial transactions and internal records (such as batch production records, inventory records, and distribution records) that a firm establishes for its own use and may consider proprietary. Existing FDA requirements to establish and maintain information to facilitate product tracing require a firm to make certain information available to FDA, within 24 hours, when FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals (see FDA's regulations entitled "Establishment, Maintenance, and Availability of Records" (21 CFR part 1, subpart J)).³ However, this information need not be kept as one record (see 21 CFR 1.330).

Similarly, FSIS requires certain classes of firms and corporations to maintain, retain, and make available to FSIS records that fully and correctly disclose all transactions involved in their businesses subject to the Federal Meat Inspection Act (21 U.S.C. 642), the

³ For more information on the recordkeeping regulations in 21 CFR part 1, subpart J, see Refs. 8 and 9).

Poultry Products Inspection Act (21 U.S.C. 460(b)), and the Egg Products Inspection Act (21 U.S.C. 1040). Records kept by FSIS-regulated businesses that may contain product tracing information include, but are not limited to, bills of sale, invoices, bills of lading, and receiving and shipping papers (see 9 CFR 320.1, 381.175, and 590.200). Upon the presentation of credentials by a representative of the Secretary of Agriculture, these records must be made available for examination and copying (see 9 CFR 320.4, 381.178, and 590.220).

In practice, reviewing multiple records to find information relevant to a particular traceback investigation or traceforward operation takes time and decreases the efficiency of product tracing. Recent traceforward operations have demonstrated that it can take months for foods containing a contaminated (or potentially contaminated) ingredient to be removed from the market (Refs. 3 through 6). Enhancing recordkeeping systems to be able to more rapidly link a specific lot of an incoming ingredient to all released food containing that specific lot of ingredient could improve the efficiency of traceforward operations for food products containing a contaminated (or potentially contaminated) food ingredient.

Likewise, recent traceback investigations conducted by FDA demonstrate that FDA's ability to identify the source of an outbreak can range from days to months after CDC notifies FDA that a specific food has been implicated in an outbreak (Ref. 10). At the start of a traceback investigation, FDA reviews records at the point of sale, such as a grocery store, where the product was purchased. The review of records at point of sale usually leads to the review of records at a distribution center. Key challenges at the point of sale include identifying shipments of interest and narrowing the number of shipments of potentially contaminated food. Key challenges at the distribution center include difficulties in linking a shipment released by a distribution center to the point of sale and difficulties linking outgoing shipments of food products released from the distribution center with incoming shipments of food products received by the distribution center. These challenges in the review of records at point of sale and at distribution centers delay the traceback investigation and may result in a wider scope of product potentially implicated.

Together these traceback investigations and traceforward operations have demonstrated that FDA needs to be able to respond to the size

and complexity of the food supply chain with a product tracing system that is more sophisticated, effective, and efficient in its capacity to link the contaminated food along the distribution chain and that reflects and responds to changing production and distribution patterns.

FSIS is also hindered by similar problems. FSIS relies heavily on records maintained by manufacturers, distributors, and retailers to aid in identifying and tracing back FSIS-regulated products associated with foodborne illness outbreaks, recalls, and other food safety incidents. Retail records are a critical component in traceback and traceforward activities. Quickly and effectively determining the source product in these situations is essential in identifying the product in commerce that presents a risk to the public and preventing additional illnesses.

Many investigations into human illness involve the consumption of raw beef products ground or chopped by FSIS-inspected establishments or retail facilities. FSIS investigators and public health officials frequently use records kept at all levels of the food distribution chain, including the retail level, to identify and traceback the product that is the source of the illness. In cases of *E. coli* O157:H7 complaints or illnesses, FSIS personnel often have to rely on raw beef grinding records kept by official meat establishments, retail facilities, and meat markets to gather the information needed to undertake traceback actions.

Recent illness outbreak investigations and other activities conducted by FSIS have demonstrated inadequate recordkeeping by some retail-level businesses and FSIS-inspected establishments that produce ground beef. The agency has found that the records kept by these establishments are often incomplete and have missing or inaccurate information. The lack of proper recordkeeping by these businesses has contributed to:

- Increasing the amount of time needed to identify products of interest,
- Inability to traceback product to the source material,
- Inability to identify all potentially adulterated products in distribution,
- Increasing the possibility that the wrong window of production is identified,
- Broader actions by the agency such as public health alerts and not directed recalls,
- Increased cost to the agency, and
- Increased risk to the consumer through the increased time delay, possibility of incorrect product

identification, and limited specificity in public health messages.

Like FDA, FSIS needs to take steps to change this situation. In particular, FSIS needs to assess the need to provide notice, outreach, compliance guides, or other information to industry to promote awareness of, and compliance with, records and food safety requirements.

While there are many significant challenges with traceback/traceforward investigations, there are successes. In 2007, the Minnesota Department of Health (MDH) conducted a traceback/traceforward investigation that resulted in the recall of approximately 117,500 pounds of beef trim products used to make ground beef. MDH conducted an epidemiological investigation of a cluster of nine *E. coli* O157:H7 case-patients with an indistinguishable pulsed field gel electrophoresis (PFGE) pattern combination who had reported eating ground beef. A case-control study conducted by MDH found that consuming ground beef purchased at retail outlets located in eight different States was significantly associated with illness. Leftover product from the case-patients collected and tested by the Minnesota Department of Agriculture (MDA) were found presumptive positive for *E. coli* O157:H7. In this case, the traceback/traceforward investigation was facilitated by MDA investigators' use of purchase date and store location information from case-patients, along with complete and accurate grinding logs from the retail stores. This enabled MDA to definitively identify the production date of the implicated product and the single federal meat establishment from which the product came.

B. Statutory and Regulatory Framework for Product Tracing Systems in the United States

1. FDA

Several sections in the FFDC (such as sections 301, 402, 403, 412, 414, 416, 417 and 704(a)) (21 U.S.C. 321, 342, 343, 350(a), 350(c), 350(e), 350(f), and 374(a)) and section 361 of the Public Health Service Act (42 U.S.C. 264) provide authority for, or are otherwise relevant to, product tracing systems. Using these authorities, FDA has established a number of regulations relevant to product tracing systems, such as those listed in table 2 of this document. Regulations established in 21 CFR part 1, subpart J apply to both human food and food for animals. The listed regulations established in 21 CFR parts 101, 106, 111, 113 and 114 apply to human food (21 CFR 500.23, however,

extends § 113's application to animal foods). The listed regulations

established in 21 CFR part 501 apply to food for animals.

TABLE 2—REGULATIONS RELEVANT TO PRODUCT TRACING SYSTEMS

Regulation(s)	Subject	Brief Description
21 CFR part 1, subpart J	Establishment, Maintenance, and Availability of Records	Requires certain persons who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain certain records identifying the immediate previous source of all food received, as well as the immediate subsequent recipient of all food released. The regulations describe the information that must be established and maintained, how long it must be maintained, and how quickly it must be available to FDA when FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. The regulations also describe persons (e.g., farms and restaurants) who are excluded from some or all of the requirements.
21 CFR 101.3 21 CFR 501.3	Identity labeling of food in packaged form	Requires the principal display panel of a food in package form to bear a statement of the identity of the commodity.
21 CFR 101.5 21 CFR 501.5	Food; name and place of business of manufacturer, packer, or distributor.	Requires the label of a food in packaged form to specify conspicuously the name and place of business of the manufacturer, packer, or distributor.
21 CFR 106.90	Infant Formula Quality Control Procedures	Requires product coding for all infant formulas.
21 CFR part 111	Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements	Requires, among other things, identification of each lot of received components in a manner that allows tracing the lot to the supplier and the date received; using this unique identifier when recording the disposition of the lot of received components; establishing a batch, lot or control number for each finished batch of dietary supplements; and being able to determine the complete manufacturing history and control of the packaged and labeled dietary supplement through distribution.
21 CFR 113.60(c); 21 CFR 114.80(b)	<ul style="list-style-type: none"> Thermally Processed Low-Acid Foods Packaged In Hermetically Sealed Containers; Acidified Foods 	A product code must be established and included on the package of a food that is a thermally processed low-acid food packaged in a hermetically sealed container (§ 113.60(c)) or an acidified food (§ 114.80(b)).

Section 417 of the FFDCFA establishes requirements for FDA to establish a Reportable Food Registry (RFR). A "reportable food" is an article of food (other than dietary supplements or infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals. The purpose of the RFR is to provide a "reliable mechanism to track patterns of adulteration in food [which] would support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health" (Public Law 110-085, section 1005(a)(4)). In accordance with section 417 of the FFDCFA, FDA implemented on September 8, 2009, the RFR electronic portal by which instances of reportable food must be submitted to FDA by responsible parties and may be submitted by public health officials. Information as to the immediate prior source of the food and/or ingredients and the immediate subsequent recipient(s) of the food may be required to be submitted through the electronic portal. FDA has issued a

guidance document (Ref. 11) containing questions and answers relating to the requirements under section 417 of the FFDCFA.

2. FSIS

Like FDA, FSIS' statutes have sections that are relevant to product tracing systems for meat, poultry, and egg products subject to FSIS' jurisdiction. Sections 642 of the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), 460(b) of the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), and 1040 of the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*) require certain classes of firms and corporations to maintain, retain, and make available full and correct business records or transactions in food. The regulations implementing those statutory sections, 9 CFR part 320, 9 CFR part 381, and 9 CFR 590.200, specify businesses and what types of basic records are required, such as bills of sale, bills of lading, receiving and shipping papers, receipts and inventories. Under the Federal Meat Inspection Act, FSIS also has the authority, under certain circumstances, to mandate specified recordkeeping by

retail stores for certain violations and to withdraw or modify statutory exemptions for public health reasons (21 U.S.C. 623 and 454, 9 CFR parts 301 and 381).

Under FSIS' Hazard Analysis and Critical Control Points (HACCP) regulations (9 CFR part 417), a meat or poultry establishment is required to keep records related to its HACCP plan, including all records associated with its operation (i.e., monitoring, verification, and corrective action). The records of these activities are subject to FSIS review and are to be made available to FSIS personnel (9 CFR 417.5(e) and (f)). Especially relevant are (1) all records, results, and supporting documentation associated with prerequisite programs; (2) the results and records associated with testing conducted for the establishment's business customer; and (3) results and records associated with an establishment's quality control program.

All of the records generated under the agency's statutory authority facilitate FSIS surveillance and investigation activities, and the control and removal of adulterated, misbranded, or otherwise

illegal or unsafe products from commerce. Failure to keep such records negatively affects consumers' health and FSIS food safety and response activities (e.g., foodborne illness investigations, product traceback, product traceforward, and product recall).

C. Considerations for an Effective Product Tracing System

A "whole chain" product tracing system consists of information elements provided by persons in the supply chain to other persons in the supply chain or to regulatory officials (e.g., during a traceback investigation). Key information elements of a "whole chain" product tracing system may include:

- Who manufactured the product,
- Who is sending the product forward in the supply chain and who is receiving the product,
- Who is transporting product in the supply chain,
- The physical location at which food is received or released,
- An adequate description of the food that is received or released,
- The date and time food is received or released,
- A lot or code number (or other identifier of the food),
- The quantity of food and how it is packaged,
- The specific source of each ingredient used to make every lot of finished product,
- A shipment identifier (such as an invoice number, airway bill number, or bill of lading, and
- A means to link information about food that is received to food that is released both internally and externally throughout the distribution chain.

A particular information element of a whole chain product tracing system may be available:

- In records (including internal and external records) that persons in the supply chain establish and maintain,
- On a label of packaged food (or on the container or package itself),
- On an individual item of unpackaged food (such as loose produce), and/or
- On a shipping case containing food.

The information available in the form of records associated with a whole chain product tracing system enables an interested person to identify, and link, at any specific stage of the supply chain, who manufactured a food product, what specific ingredients are in the product, where the product came from, where the product was or is, where the product went, and who transported the product.

Most product tracing systems (including FDA's regulations in 21 CFR

part 1, subpart J) are designed and implemented as "one up/one down" systems rather than as "whole chain" systems. In a "one up/one down" system, the focus is on the immediate previous source of food and the immediate subsequent recipient of food, as well as the immediate previous transporter and the immediate subsequent transporter.

The information available on the label or package⁴ of food has often been invaluable in enabling FDA to quickly identify the source of a food implicated in foodborne illness during a traceback investigation (73 FR 55115 at 55118). Likewise, such information can help FDA or FSIS to quickly determine the distribution of all identified lots of contaminated (and potentially contaminated) food during a traceforward operation. The practical utility of information available on the label or package of a food during a traceback investigation may be limited in some circumstances, e.g., if a consumer who became ill after eating a food product no longer has the package of food. However, information about when the consumer purchased the product, coupled with information maintained in records by the person who sold the product to the consumer, may help to narrow the scope of a traceback investigation.

In section V.A.4 of this document, FDA is seeking comment on whether some information in product tracing systems should be sent further in the supply chain than "one down."

D. International Product Tracing Systems

In 2008, FDA described some aspects of international product tracing systems (73 FR 55115 at 55119). For example:

- In 2006, Codex established principles for tracing food through production and distribution processes. The Codex principles are intended to assist government authorities in utilizing product tracing as a tool within their food inspection and certification system.
- The European Union (EU) requires all food and feed to be traceable "one step forward and one step back" in EU member states.
- In 2007 the International Standards Organization (ISO) issued ISO 22005:2007, which provides general principles and basic requirements for designing and implementing a product

⁴Note that 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)).

tracing system along a food processor's supply chain.⁵

- The GS1 Global Traceability Standard is a business process standard describing the traceability process independently from the choice of enabling technologies. It defines minimum requirements for companies of all sizes across industry sectors and corresponding GS1 Standards used within information management tools.

E. 2008 Public Meetings on Product Tracing Systems for Fresh Produce

In 2008, FDA held two public meetings to stimulate and focus a discussion about mechanisms to enhance product tracing systems for fresh produce intended for human consumption (73 FR 55115). Fresh produce includes fresh produce that is intact and whole (such as whole tomatoes), cut during harvest (such as heads of lettuce), or "fresh-cut" (i.e., minimally processed by actions such as peeling, slicing, or trimming before being packaged for use by the consumer or retail establishment). Examples of fresh-cut produce are shredded lettuce, sliced tomatoes, salad mixes, and cut melons. As discussed in the notice announcing the meetings, traceback investigations for fresh produce have highlighted several particular challenges associated with tracing fresh produce back through the supply chain (73 FR 55115 at 55118). For example:

- Fresh produce is perishable and may no longer be available for testing by the time the outbreak is detected;
- Fresh produce is often sold loose, without any packaging that would provide information about its source;
- Containers in which the fresh produce was shipped, which may have provided information about its source, may also have been discarded by the consumer or end user long before a traceback investigation is initiated; and
- Common industry practices add a layer of complexity. Examples of such practices are:
 - Repacking fresh produce from multiple sources;
 - Commingling food from different sources, shipments, or lots;
 - Exchanging food with other local farms or businesses;
 - Re-using and sharing shipment containers from other farms/businesses;

⁵ISO 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>.

- Using different names for the same fresh produce as it travels throughout the supply chain;⁶
- Substituting a different variety or size of fresh produce without documentation; and
- Not assigning a lot or code number (or other identifier of the food) to the fresh produce that goes forward into the supply chain.

As also discussed in the notice announcing the 2008 public meetings, in 2006 there was a multi-state outbreak of illnesses associated with the consumption of fresh spinach contaminated with *E. coli* O157:H7 (73 FR 55115 at 55118). In this situation, the traceback investigation was facilitated because several consumers who became ill still had packaged fresh spinach in their refrigerators. This traceback investigation was greatly facilitated by the information on the label of the packaged food and on the package itself, including a product code. Investigators were able to identify the processor through information required to be on the label of the packaged spinach (21 CFR 101.5(a)) and through a product code the processor had voluntarily placed on the package. In the early stage of the investigation, the investigators identified several potentially implicated farms associated with the production lot of bagged spinach based on the processor's records. Narrowing to the implicated farms from the processor records was more time consuming.

In the notice announcing the meetings (73 FR 55115 at 55120), FDA asked questions about nine topic areas relating to tracing systems for fresh produce. FDA received several dozen comments, submitted either directly to Division of Dockets Management, submitted in writing to accompany oral testimony provided at the meeting, or presented orally and captured in the written transcript of the meeting. In addressing FDA's questions, several comments support the approach recommended by the Produce Traceability Initiative (Refs. 12 through 14) for case identification based on GS1 standards for the effective management and control of supply chains for fresh produce. Information applied to the shipping case would identify the "brand owner" of the fresh produce in the case as well as various attributes of that fresh produce (such as what the fresh produce is and a lot number). Comments addressing the issue of commingling generally express

the view that commingling is an acceptable practice provided there are adequate records documenting the commingling to enable linking the incoming source and outgoing product.

Comments generally agree that information in a product tracing system should be human-readable and, where possible, in electronic form. However, some comments stress it is more important to have the information recorded in any form (including paper form) than to require product tracing records to be electronic. One comment notes that the common use of day labor, the pressure of productivity, and the challenges associated with handling perishable items make it difficult for persons who handle fresh produce to establish and maintain proper records. Some comments note that purchase records already maintained by retailers and restaurants (e.g., for accounting purposes) may be useful for product tracing.

Several comments mention the use of different product tracing systems by various persons in the supply chain, and the lack of interoperability of current systems, as significant barriers to whole-chain product tracing. Several comments describe products that offer solutions to some of the logistical challenges associated with tracing fresh produce. One comment notes that requiring a motor carrier to read a radio frequency identification (RFID) tag on each crate during the transportation process could be costly and burdensome to everyone in the supply chain. Comments generally agree that there would be significant startup costs associated with any system that uses a standard format, but that the impact on the industry would vary depending on an individual company's readiness.

Several comments both stress the importance of compliance with the existing requirements of the regulations in 21 CFR part 1, subpart J and assert that FDA should focus its efforts on enforcing these existing requirements for product tracing rather than on introducing new requirements. Some comments acknowledge that FDA's current legal authority to inspect records under 21 CFR part 1, subpart J is limited to situations for cause, i.e., when FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals (§ 1.361). Some of these comments express support for additional legal authority for FDA to inspect these records to evaluate compliance in addition to FDA's current legal authority to inspect these records for cause. Some comments point out

that the recordkeeping requirements of the Perishable Agricultural Commodities Act (PACA) have significance with respect to product tracing, e.g., that persons (such as handlers of fresh produce) subject to PACA already capture information that could be used for tracing purposes.

F. FDA's Activities Since the 2008 Public Meetings on Product Tracing Systems for Fresh Produce

In the spring of 2009, FDA engaged in a pilot project, through the Institute for Food Technologists (IFT) to conduct a mock traceback scenario on tomatoes with representatives of the industry, academia, States, and two technology companies. FDA also awarded a 1-year contract to IFT to review industry practices for product tracing and identify best practices employed by many different sectors regulated by FDA. The IFT report is expected to be delivered by November 2009.

Over the course of the last year, FDA has met extensively with many industry representatives on their product tracing initiatives as well as solution providers to gain a better understanding of the practices and technology available to enhance product tracing for foods. In addition, FDA has conducted several outreach efforts to share some of the challenges in traceback and traceforward investigations in foodborne illness outbreaks.

In May 2009, FDA provided an update on its efforts related to produce tracing systems at a joint symposium ("Symposium on Methods and Systems for Tracking, Tracing, and Verifying Foods") between the Food and Environment Research Agency of the EU and the Joint Institute for Food Safety and Applied Nutrition (JIFSAN, an academic partnership between FDA and the University of Maryland). FDA is monitoring the activities of the EU 6th Framework Research programs and various projects related to traceability. One such program is the EU TRACE program, which has developed a chain information management system (TraceCore XML). Another such program is the EU TRACEBACK program, which is currently developing a system based on micro-devices to implement food traceability in the food chain. This system will be pilot tested on two major product chains: Feed/dairy and tomatoes.

JIFSAN is collaborating with the Iowa State University's IOWA Grain Quality Initiative to incorporate a generic product traceability module into JIFSAN's Good Agricultural Practices train-the-trainer program.

⁶For example, a tomato may be referred to as a "red, round tomato" early in the supply chain, and be referred to as a "cooker tomato" at a later stage in the supply chain. This type of change in name reflects the degree of ripeness of the tomato, which varies over time.

G. 2009 Report of the Inspector General

In 2009, HHS' Office of Inspector General (OIG) issued a report entitled "Traceability in the Food Supply Chain" (Ref. 15). The purpose of the report was to (1) assess the traceability of selected food products and (2) determine the extent to which selected food facilities maintain information required by FDA in a food emergency. The report noted that not all facilities are required to maintain lot-specific information in their records, and those that are required to maintain lot-specific information are required to maintain it only if it exists. Thus, OIG was able to trace only 5 of the 40 products it investigated through each stage of the food supply chain.

For 31 of the other 35 products OIG investigated, OIG could identify the facilities that likely handled them (Ref. 15). Most facilities that handled these products did not maintain lot-specific information in their records and could only estimate a range of deliveries (from one or more facilities) that may have included the product OIG purchased. For the remaining four products, OIG could not even identify the facilities that likely handled them.

OIG identified several factors that prevented OIG from tracing the specific products through the food supply chain and observed that these factors would affect the speed with which FDA can trace specific food products through the food supply chain. The factors listed by OIG are:

- Manufacturers, processors, and packers, do not always maintain lot-specific information, as required;
- Other types of facilities do not maintain lot-specific information because it is not required;
- Retailers receive products not labeled with lot-specific information; and
- Products are mixed from a large number of farms.

V. Issues and Questions for Discussion for FDA

FDA welcomes public comments and/or data on the following issues related to product tracing systems.

*A. Core Information Elements of a Product Tracing System***1. Lot Code or Number (or Other Identifier of the Food)**

a. *Assigning a lot or code number (or other identifier of the food).* As discussed in section IV.E of this document, the traceback investigation for a 2006 multi-State outbreak of illnesses associated with the consumption of fresh spinach

contaminated with *E. coli* O157:H7 was greatly facilitated by the information on the label of a package of implicated spinach and on the package itself, including a product code. As also discussed in section IV.G of this document, the HHS OIG has found that the lack of a lot or code number (or other identifier) (either because such a number or code was not assigned, or because a facility either did not assign, or keep a record of, such a number or code) made it difficult to trace food throughout the supply chain.

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)?

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

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)?

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?

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?
- On the shipping container of packaged food, unpackaged food, or both?

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

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

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?

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

Records accompanying commercial transactions or documenting delivery or receipt of a product in commerce (such as a bill of lading, airway bill, invoice, shipping/receiving record, and packing list) contain product tracing information. For example, such records identify who is sending a product forward in the supply chain, who is receiving the product, what the product is, and how much of the product there is.⁷ In some cases, such records also identify the lot or code number (or other identifier of the food). Many of these records have their own identifier, e.g., an invoice number, airway bill number, or a bill of lading number. It may be efficient to associate product tracing information with a "shipment identifier," such as an invoice number, airway bill number, bill of lading, or some other identifier established by the shipper. For example, a firm that is sending product forward in the supply chain may retain some information (such as a lot or code number or other identifier of the food) in an internal inventory record and other information (such as the immediate subsequent recipient of the product) in shipping and distribution records. Including the shipment identifier in all of these records may help to link the records, particularly when records are in electronic form and can be searched using electronic means.

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?

Question 2b. Should any other information not already required by §§ 1.337 and 1.345 be considered an information element of an enhanced product tracing system?

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

⁷Note that § 1.352(a), (b), and (c) provide three options, each using slightly different terminology, for transporters to satisfy the recordkeeping requirements. For the purpose of the discussion here, FDA uses generic terms associated with the information element rather than the specific terms used in § 1.352(a), (b), and/or (c).

a shipping case be present on the package or shipping case?

Question 3b. If so, what additional product tracing information should be present on the package or shipping case?

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

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

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?

Question 4b. Should some information about packaged food⁸ (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?

5. Standardized Information Elements

The lack of standardization in the information in current product tracing systems can delay traceback investigations and traceforward operations largely due to the need to interpret and clarify information elements between varying product tracing systems and the lack of systems to link 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?

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

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

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?

B. Records

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

FDA's regulations in 21 CFR part 1, subpart J require persons who manufacture, process, or pack food to keep records on the lot or code number or other identifier of the food received from the nontransporter and transporter immediate previous sources of food, or released to the nontransporter and transporter immediate subsequent recipients of food, to the extent this information exists (§§ 1.337(a)(4) and 1.345(a)(4)). These regulations do not require persons who do not manufacture, process, or pack food to keep records on the lot or code 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?

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)?

2. Records to Facilitate Linkage

FDA's regulations in 21 CFR part 1, subpart J also require records kept by nontransporters to identify the immediate subsequent nontransporter and transporter recipients of food to include information reasonably available to the nontransporter to identify the specific source of each ingredient used to make every lot of finished product (§ 1.345(b)). In essence,

a record containing such information is a "linking record," because it links a specific lot of released food to specific lots of ingredient. FDA's regulations in 21 CFR part 1, subpart J have no corresponding requirement (under § 1.337) for a "linking record" that would link a specific lot of an incoming ingredient to all released food containing that specific lot of ingredient.

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?

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)?

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?

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

3. Records That Are Both Electronic and Human-Readable

As noted (see section IV.E of this document), comments to the 2008 notice of meeting on product tracing for fresh produce recommend that information in a product tracing system should be human-readable. Human-readable information would enable all persons in the supply chain to have access to the information. These comments also recommend that information in a product tracing system should, where possible, be in electronic form. Electronic systems could make it faster and easier to accurately record information, such as a lot or code number (or other identifier of the food) and link incoming with outgoing product and thus speed the course of a traceback investigation or traceforward operation. For example, a person making a paper record of a human-readable code expressed in numbers or letters may mistakenly transpose or omit numbers or letters, thus creating erroneous entries in the records. In

⁸Note that packaged produce is within the scope of both Question 4a and Question 4b.

contrast, the potential for such mistakes would be greatly reduced if the code is recorded using an automatic system, such as a bar code or RFID.

However, some persons may not have access to electronic technologies, particularly if the technology (such as the use of bar codes or RFID) requires an initial investment. Some persons may be reluctant to select a particular electronic technology if there is no industry standard for which electronic technology to use.

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?

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?

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)?

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?

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

Further enhancing the product tracing system for food could aid FDA in shortening the duration of outbreaks and limiting the number of people who become ill. It could also give FDA more information to use in preventing future outbreaks. However, net public health benefits from enhancements to current product tracing systems may vary by food category depending on the level of risk. The net public health benefits may also vary by the type and size of entity along the supply chain that would be covered by the enhanced product

tracing systems. FDA recognizes that enhancing product tracing for food may not be just a matter of keeping more or different records or adding more information to product or packaging, but also a matter of changing business practices.

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?

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?

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?

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?

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?

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?

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

E. Outreach

Shortly after the establishment of the product tracing requirements in 21 CFR part 1, subpart J, FDA held a series of public meetings to provide information on the rule to the public and to provide the public an opportunity to ask questions of clarification (69 FR 71655, December 9, 2004). Regardless of such outreach, the HHS OIG report (Ref. 15) noted that manufacturers, processors, and packers do not always maintain lot-specific information, as required.

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?

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?

VI. Issues and Questions for Discussion for FSIS

To address the specific causes of foodborne illness outbreaks associated with FSIS-regulated products, FSIS needs to develop a strategy to investigate and document them, and take enforcement action against firms for violations of FSIS' laws and regulations that impact public health. FSIS must also be able to fully investigate these complaints and reports of foodborne illness. With regard to investigations associated with ground beef consumption, product lot coding and beef manufacturing plant information are required to successfully conduct product traceback. In many circumstances, however, investigators are only provided with purchase information (e.g., date and location of purchase, type of ground beef). Investigators must then rely heavily on grinding records kept in retail stores, meat markets, and other operations to gather the information needed to undertake traceback actions. Unfortunately, investigators frequently find these grinding records to be incomplete because of missing or inaccurate information, thereby preventing the traceback of potentially adulterated products, which could result in additional illnesses.

FSIS is seeking comment on the following:

A. Core Information Elements of a Product Tracing System

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

With respect to the traceback and traceforward of ground beef, how can FSIS ensure that it will be able to obtain the following types of information from operations that grind beef:

- Production codes
- Total pounds ground with the same final label
- All source materials (such as full names and product codes of all source products used to formulate each lot of store ground product; Federal or State establishment numbers; sell-by, use-by, or other production date codes; use of bench trim and its source) used in each lot
- Special instructions or disclaimer statements on source material
- Other products ground from the same source

2. Standardized Information Elements

- Should FSIS focus on standardizing product codes?
- 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?

B. Role of Risk in Developing Regulations

- Should any or all enhancements to 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 enhancements to product tracing systems be developed or phased in based on risk?
- The need for adequate ground beef grinding records is based on risk. Should FSIS wait for other specific items to become public health issues or should FSIS use a broader approach and include all amenable product?
 - Should FSIS be concerned about ready-to-eat product or focus on raw product?
 - Should FSIS look at heat-treated, not fully cooked products?
 - Does formulation impact heat-treated, not fully cooked products to the extent that FSIS needs to traceback the source material or should FSIS focus more on the processing practices and labeling?

VII. 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 are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that all persons, including minorities, women, and persons with

disabilities are aware of this document, FSIS will announce it online through the FSIS Web page located at http://www.fsis.usda.gov/regulations_policies/2009_Notices_Index/index.asp. FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade and farm groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is available on the FSIS Web page. Through the Listserv and the Web page, FSIS is able to provide information to a much broader and more diverse audience. In addition, FSIS offers an e-mail subscription service that provides automatic and customized access to selected food safety news and information. This service is available at http://www.fsis.usda.gov/news_and_events/email_subscription/. Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password-protect their accounts.

IX. References

FDA has placed the following references on display in FDA's 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**.)

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3. FDA. 2009. Peanut Butter and other Peanut Containing Products Recall List. Information current as of 12 PM June 12,

2009. 3916 Entries in List. Available at <http://www.accessdata.fda.gov/scripts/peanutbutterrecall/index.cfm>.

4. FDA. 2009. Pistachios and other Pistachio Containing Products Recall List. Information current as of 12 noon June 23, 2009. 664 Entries in List. Available at <http://www.accessdata.fda.gov/scripts/pistachiorecall/index.cfm>.

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Dated: October 29, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-26479 Filed 11-2-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Brain Disorders in the Developing World 1.

Date: November 18, 2009.

Time: 3 p.m. to 10 p.m.

Agenda: To review and evaluate grant applications.

Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue, NW., Washington, DC 20036.

Contact Person: Dan D. Gerendasy, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5132, MSC 7843, Bethesda, MD 20892, 301-594-6830, gerendad@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Brain Disorders in the Developing World 2.

Date: November 19, 2009.

Time: 6 p.m. to 10 p.m.

Agenda: To review and evaluate grant applications.

Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue, NW., Washington, DC 20036.

Contact Person: Dan D. Gerendasy, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5132,

MSC 7843, Bethesda, MD 20892, 301-594-6830, gerendad@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 27, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-26424 Filed 11-2-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Health of the Population Fellowships.

Date: November 18-19, 2009.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting)

Contact Person: Karin F. Helmers, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 3166 MSC 7770, Bethesda, MD 20892, 301-435-1017, helmersk@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; NCRR Electron Microscopy Resource Review.

Date: November 30-December 2, 2009.

Time: 5 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza-Albany City Center, 30 Lodge Street, Albany, NY 12207.

Contact Person: Raymond Jacobson, PhD, Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5858, MSC 7849, Bethesda, MD 20892, 301-996-7702, jacobsonrh@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 27, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-26422 Filed 11-2-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; NIMH Brain Bank Resource.

Date: December 2, 2009.

Time: 3 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call)

Contact Person: Rebecca C Steiner, PhD., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd, Room 6149, MSC 9608, Bethesda, MD 20892-9608, 301-443-4525, steinerr@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)