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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

**Re: Comments on Proposed Recordkeeping Regulations,
68 Fed. Reg. 25,187 (May 7, 2003), Docket No. 2002N-0277**

The Food and Drug Administration (FDA) has published a notice of proposed rulemaking to implement section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). Section 306 adds a new section 414 to the Federal Food, Drug, and Cosmetic Act (FFDCA), giving FDA authority to require food facilities to keep and maintain certain records that will enhance FDA's ability to trace foods in the event of a bioterrorism threat. On behalf of the Center for Science in the Public Interest (CSPI), we are writing to comment on the proposed recordkeeping requirements necessary to protect the U.S. food supply from intentional contamination and adulteration. CSPI is a non-profit consumer advocacy and education organization that focuses primarily on food safety and nutrition issues and is supported principally by 800,000 subscribers to its *Nutrition Action Healthletter*.

In its recent report "Terrorist Threats to Food," the World Health Organization called effective traceback systems "critical."¹ In the event of a terrorist attack on the American food supply, it will be necessary for FDA to trace the suspected food back to its source as quickly as

¹ World Health Organization, Food Safety Department, *FOOD SAFETY ISSUES: Terrorist Threats to Food, Guidance for Establishing and Strengthening Prevention and Response Systems* (2002), at p. 16.

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possible to remove it from distribution channels and to trace it forward to aid in recalls to prevent human illnesses and death. Because the sufficiency of a trace back and trace forward will depend on the adequacy of records maintained by those involved in food production and distribution, it is particularly important that FDA impose strong recordkeeping requirements.

The recent discovery of a cow in Alberta, Canada, that tested positive for Bovine Spongiform Encephalopathy (BSE) offers an example of why effective recordkeeping is crucial to implementing an adequate traceback in the case of an emergency. The infected cow had been slaughtered and the carcass sent for rendering six months before the test results were obtained. Once the positive was confirmed, the Canadian Food Inspection Agency initiated a comprehensive investigation to determine how the cow became infected, including tracing the feed it had been given, its movement between herds, and how its remains were processed. However, lack of adequate recordkeeping hindered initial efforts to find the source of the cow's infection, as well as whether it produced any offspring that may have the disease.²

While it does not appear that any part of the infected cow entered the human food chain, the United States, Mexico, Japan, Australia, and other countries temporarily stopped importing Canadian beef.³ Newspapers reported that the Canadian cattle industry remained "paralyzed" as cattle prices plummeted.⁴ Not only was the cattle industry paralyzed, the stock prices of beef

² See Clifford Krauss, *Canada Extends Cattle Ranch Quarantine to British Columbia*, *The New York Times* (May 24, 2003), at A9.

³ Ultimately, it was determined that 10 Canadian feed mills received parts of the infected cow, and some of it was processed into dry dog food and chicken feed. See Kim Murphy, *Canada May Step Up its Livestock Controls*, *Los Angeles Times* (May 30, 2003).

⁴ Clifford Krauss, *200 in Herd Found Free of Mad Cow*, *The New York Times* (May 27, 2003), at A4. See also Jim Cote, *Cattle Futures Fall by Limit on Mad-Cow Case in Canada*, *Wall Street Journal* (May 21, 2003), at C13.

processors and fast food chains selling beef products were affected as well.⁵ This event demonstrates that if there is an intentional attack on the food supply, prompt action by regulatory and public health officials will be necessary to prevent both a public health crisis and an economic crisis.

While intentional contamination of the food supply has occurred infrequently, it is probable that it will happen again.⁶ Recently in Michigan, a supermarket employee was charged with poisoning 200 pounds of ground beef with an insecticide, Black Leaf 40, whose main ingredient is nicotine.⁷ Although this event was limited to a localized area since the contamination occurred at a single store, between 60 and 70 people became ill. By contrast, a terrorist attack on the food supply is likely to be more widespread, potentially sickening hundreds and thousands of consumers in many states over a wide part of the country and requiring a trace back and trace forward through a longer chain of distribution. For these reasons, we urge FDA to adopt the strongest recordkeeping provisions possible to assure that there are adequate systems in place to trace foods suspected of intentional contamination both backward and forward through the food distribution chain.

1. FDA Has a Duty Under Section 306 of the Bioterrorism Act to Impose Recordkeeping Requirements

Section 306(a) of the Bioterrorism Act provides that the Secretary “may by regulation”

⁵ Karen Talley, *McDonald's Falls on Mad-Cow Case*, Wall Street Journal (May 21, 2003), at C3.

⁶ The two most notable events involved a religious cult that contaminated salad bars in The Dalles, Oregon, with *Salmonella* Typhimurium in 1984, and a hospital lab worker who laced pastries with *Shigella dysenteriae* Type 2 in 1996. See 278 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION (Aug. 6, 1997).

⁷ CDC, *Nicotine Poisoning After Ingestion of Contaminated Ground Beef – Michigan, 2003*, 52 MORBIDITY AND MORTALITY WEEKLY REPORT 413-16 (May 9, 2003).

establish requirements regarding the establishment and maintenance, for not longer than two years, of records by food facilities which are needed by the FDA for inspection to identify the immediate previous sources and the immediate subsequent recipients of food, in order to address credible threats of serious adverse health consequences or death to humans or animals. At the same time, section 306(d) states that FDA "shall promulgate" regulations establishing recordkeeping requirements no later than 18 months after enactment of the Bioterrorism Act.

FDA construes these provisions to create an ambiguity and has asked for public comment on its interpretation that it is "required by section 306(d) of the Bioterrorism Act to exercise the authority in section 306(a)."⁸ Where as here, "an agency is charged with administering a statute, part of the authority it receives is the power to give reasonable content to the statute's textual ambiguities."⁹ The language in section 306, read as a whole, as well as the legislative history, confirm that Congress intended for FDA to exercise its new recordkeeping authority by promulgating regulations to require all persons who make, process or handle food to keep adequate records sufficient to enable the Agency to trace food back and forward through the distribution system in order to protect American consumers.

While the language of section 306(a) is permissive, the plain language of section 306(d) imposes a mandatory duty on FDA to promulgate regulations imposing recordkeeping requirements. Not only does the statute use the words "shall promulgate," it also imposes a deadline for accomplishing that task.¹⁰ By establishing a specific deadline for promulgation of

⁸ 68 Fed. Reg. 25,187, 25,190 (May 9, 2003).

⁹ Department of Treasury v. FLRA, 494 U.S. 922, 933 (1990).

¹⁰ It is generally true that the use of the word "shall" indicates the absence of discretion. See LO Shippers Action Comm. v. ICC, 857 F.2d 802, 806 (D.C. Cir. 1988), cert. denied, 490 U.S. 1089 (1989).

final recordkeeping requirements, Congress not only imposed on FDA a duty to take action, it also imposed an obligation to take that action within a specified time period. Thus, read as a whole, section 306 supports the FDA's interpretation that the duty to promulgate recordkeeping requirements is mandatory, not discretionary.¹¹

The conference report accompanying the Bioterrorism Act confirms that the managers intended that "those records that document the person from whom food was directly received, and to whom food was directly delivered, are adequate to enable identification of the source and distribution of food."¹² Such records will only be adequate if FDA identifies and prescribes the precise types of information it needs to conduct an adequate trace back in the event of a food emergency.

In fact, it would be an abuse of discretion if FDA were to change its interpretation and conclude that its authority under the recordkeeping provisions was discretionary and not mandatory. The Bioterrorism Act was a response to the events of September 11, 2001 and the need, among other things, to protect the American public against credible threats of serious adverse health consequences or death from intentionally contaminated food.¹³ FDA can only address such threats and protect the public if it can assure that food facilities maintain adequate

¹¹ See John Hancock Mut. Ins. Co. v. Harris Trust & Sav. Bank, 114 S. Ct. 517, 523 (1993) (finding that in interpreting statutes, first the language of the statute should be examined "not by a single sentence or member of a sentence, but looking to the provisions of the whole law, and its object and policy."). See also Bailey v. United States, 116 S. Ct. 501, 507 (1995) (quoting United Savings Ass'n v. Timbers of Inwood Forest Assocs., Ltd., 484 U.S. 365, 371 (1988) ("A provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme").

¹² H.R. Rep. No. 107-481, 107th Cong., 2d Sess., at 111.

¹³ The bioterrorism provisions amend portions of the Federal Food, Drug and Cosmetic Act. It is well settled that the FFDC is to be interpreted broadly so as to achieve its goal of public health protection. United States v. Bacto-Unidisk, 393 U.S. 784, 798 (1969).

records concerning the origins and destinations of the foods they make, process, handle and transport. Failure to exercise the recordkeeping authority given to FDA in section 306 would abnegate Congress' command to protect the public health and undermine the agency's ability to detect and trace intentionally adulterated foods. Such action would be inconsistent with the Act in general and with the recordkeeping provisions in particular.

2. There Is Sufficient Connection to Interstate Commerce to Warrant Recordkeeping Requirements on Persons Who Engage in Intrastate Activities Involving Food

Under the proposed rule, all persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to the recordkeeping requirements whether or not they directly engage in interstate activities involving food.¹⁴ This is a reasonable interpretation of the statutory requirements. As FDA has explained, the statute allows it to require domestic persons to keep records even if they do not engage in interstate commerce since a bioterrorist threat involving food would have the same effect on the public health regardless of whether the food originated from an out-of-state source or an in-state source.¹⁵

The manufacturing, processing, packing, distributing, receiving or holding food is clearly a commercial activity, even if performed solely within a state, that may substantially affect interstate commerce. It is an economic enterprise that can have a substantial effect on interstate commerce in several ways.¹⁶ For instance, the food could be consumed by out-of-state visitors or

¹⁴ 68 Fed. Reg. at 25,191.

¹⁵ 68 Fed. Reg. at 25,191.

¹⁶ The Supreme Court has upheld congressional acts regulating intrastate economic activity where it has concluded that the activity substantially affects interstate commerce. Thus, laws regulating local restaurants using substantial interstate supplies, *see Katzenbach v. McClung*, 379 U.S. 294 (1964), and inns and hotels catering to interstate guests, *see Heart of Atlanta Motel, Inc. v. United States*, 379 U.S. 241 (1964), have been upheld as legitimate exercises of Congress's power under the Commerce Clause of the Constitution.

tourists. Moreover, because people freely cross state borders, they could consume tainted food sold only within a state, but become sick and seek medical care in another state, thus causing an impact on an out-of-state health care system. In addition, a company may produce and sell its food or food products only within the state but the foods may, in turn, be processed into other products which are then sold in other states. Thus, the original ingredients, although produced and sold intrastate, could end up in products sold interstate. Or vice-versa, food components may be shipped in interstate commerce to one state, but all the processing and manufacturing takes place solely within that state.¹⁷

Finally, a finding that a certain food is intentionally contaminated – even if only distributed or sold locally – could have widespread, nationwide, even international, economic implications. As demonstrated by the recent “mad cow” episode in Canada, restrictions might be imposed on the distribution and sale of all such products, or consumers across the country may decide not to buy the product thus impacting the economy as a whole. As a result, we believe that FDA is correct in concluding that all persons who manufacture, process, pack, transport, distribute, receive, hold, or import food should be subject to the recordkeeping requirements whether or not they directly engage in interstate activities involving food.

3. FDA's Decision to Impose Separate Requirements on Transporters and Non-Transporters Is Reasonable

Subsection 306(b) authorizes FDA to establish requirements concerning records that it may need to identify the immediate previous sources and the immediate subsequent recipients of food in the event of a credible threat of serious adverse health consequences. To that end, FDA

¹⁷ For instance, in one case, the court found that the FFDCAs applies to foods processed within a state because the individual components had been shipped interstate. United States v. 40 Cases, More or Less of Six One Gallon Cans Articles Labeled in Part (Can) Pinocchio Brand 75% Corn, Peanut Oil and Soya Bean Oil Blended with 25% Pure Olive Oil, 289 F.2d 343 (2nd Cir. 1961).

has identified two sets of immediate previous sources and immediate subsequent recipients subject to regulation – non-transporters of food and transporters of food -- and has asked for comment on the reasonableness of this action.

We believe it is entirely reasonable for FDA to impose separate requirements on transporters and non-transporters of food. Under section 306(b), FDA may establish requirements applying to persons who manufacture, process, pack, transport, distribute, receive, hold or import food. Imposing separate recordkeeping requirements on transporters is critical to protecting the public for the following reasons:

- Persons who manufacture or process food may not always know who transports it;
- Food could be intentionally contaminated at any point in the distribution chain; and
- Several different companies could be involved in the chain of custody.

As FDA has explained, this recordkeeping will “increase the likelihood of a successful traceback by ensuring all those who handle the food are examined.”¹⁸

FDA also has requested suggestions for alternative recordkeeping arrangements that would allow for the complete and efficient investigation of food-related emergencies.¹⁹ We believe that source labeling, including country-of-origin labeling, should be a component of an effective traceback program in the event of a food emergency.²⁰

¹⁸ 68 Fed. Reg. at 25,194.

¹⁹ 68 Fed. Reg. at 25,194.

²⁰ Some industries have already developed technologies such as bar codes, stamps, stickers, or tags to identify the source of produce as well as software to assist in more accurate traceback to the grower/packer level.

4. An Effective Trace Back and Trace Forward Program Should Include Source Labeling

A. Source Labeling Is A Crucial Component of a Comprehensive Recordkeeping Program

Under FDA's proposed regulations, persons would be required to maintain information reasonably available to identify the specific source of each ingredient that was used to make every lot of finished product, so that incoming ingredients can be linked to the outgoing finished products.²¹ As FDA has explained, if it "cannot immediately narrow the trace back to a specific source, tracing becomes much more difficult, there is an increased risk to consumers, and some food sources are unfairly implicated."²²

Source labeling, which would follow the product from the farm to the consumer, could be an effective component in a trace back system and would have several advantages. First, while the proposed recordkeeping requirements undoubtedly will aid in establishing a chain of custody for purposes of traceback, if there is any break in that chain -- either through a facility's failure to keep records or a failure to maintain adequate records -- then FDA loses the ability to track a suspect food all the way through system. In that event, source labeling could be a crucial element in identifying the potential origin of contamination.²³

Second, if there is an intentional contamination event, time would be of the essence.

²¹ Proposed rule § 1.337(a).

²² 68 Fed. Reg. at 25,196.

²³ Last summer's ConAgra recall of *E. coli* O157:H7-contaminated ground beef was notable for the fact that USDA's Food Safety and Inspection Service had difficulty tracing where the contaminated meat had gone since there were inadequate records. If adequate records had been kept throughout the entire chain of production, including source labeling, such as stamping or labeling the product with the plant name and date of production, it would have been easier for the USDA to locate the source of contaminated meat, possibly resulting in a more effective recall.

Under the proposed recordkeeping regulations, facilities will have to produce records on request within 4 hours during normal work-week hours or 8 hours if the request is made at any other time.²⁴ However, even that time period may be too long in the event of a true emergency.

Depending on the length of the distribution chain involved in a contamination event, FDA may be required to examine the records of numerous food handling facilities. As a result, it could still take FDA several days to obtain needed records. Source labeling could help FDA determine the ultimate source faster.

Finally, source labeling, either on the shipping container or on the product itself, could be particularly important where there is product co-mingling or where packers or handlers recycle shipping containers. It would assist FDA in more quickly identifying a link between a suspect food vehicle and a specific food facility in the event of a terrorist attack. In addition, as FDA has noted, intentional attacks may be fundamentally more difficult to trace than natural outbreaks due to deliberate obfuscation of the source and possible multiple contamination events of different food types and food facilities.²⁵ Accordingly, mandatory source labeling could provide a deterrent to food bioterrorism by making a less attractive target.

The faster that the source of potentially contaminated food can be identified, the more illnesses can be prevented and more lives saved. From a public health perspective, improving the speed and accuracy of a traceback through source labeling to find implicated foods would help limit the population at risk.

²⁴ 68 Fed. Reg. at 25,199, proposed rule § 1.361.

²⁵ 68 Fed. Reg. at 25,225.

B. Country-Of-Origin Labeling Would Help Improve Traceback Of Potentially Contaminated Foods

Country of origin labeling, a form of source labeling, also could improve FDA's ability to trace food during a food emergency. Section 304 of the Tariff Act of 1930, as amended, requires that an article of foreign origin, including food, or its container be labeled to inform the ultimate U.S. purchaser of the country of origin of the foreign article.²⁶ However, certain food products that are in their natural, unprocessed state and that are offered for sale to the ultimate purchaser in bulk, as well as certain coffee, tea and spice products, are exempt from the marking requirement since they are difficult or impractical to mark.²⁷ These food items, commonly known as "J-list" articles, include natural products, such as fruits and vegetables, nuts, berries, and live or dead animals, fish and birds, maple sugar, and eggs.²⁸ As a result, the J-List exception from the country of origin marking requirement applies only to food goods that are in their natural, unprocessed state and that are offered for sale in bulk. For example, when fruits and vegetables enter the United States, their immediate containers must have country of origin labels.²⁹ In addition, consumer-ready packages, such as a cellophane-wrapped package of tomatoes, must have country of origin labels. However, a retailer may take loose produce out of

²⁶ The ultimate purchaser generally is defined as the last person in this country who will receive the article in the form in which it was imported. However, if the product undergoes some transformation, then it would not be required to bear a country of origin label.

²⁷ 19 U.S.C. §1304(a)(3)(J).

²⁸ 19 C.F.R. § 134.33

²⁹ Likewise, all meat products imported into the United States are required to bear the country of origin on the labeling of the container in which the products are shipped, as well as the establishment number assigned by the foreign meat inspection system and certified to USDA. If imported meat or meat products are intended to be sold intact to a processor, wholesaler, food service institution, grocer, or the household consumer, the country of origin labeling is conveyed to those recipients. If the imported meat or meat products are further processed in the United States, country of origin labeling is no longer required on the newly produced products.

a container and display it in an open bin, selling each individual piece of produce without a label. Likewise, produce may be commingled at the point of sale. As a result, the existing country of origin labeling requirements contain huge gaps, particularly for fresh produce.

In the Farm Security and Rural Investment Act of 2002, Congress recognized the importance of country of origin labeling for certain agricultural products.³⁰ The Act requires the Department of Agriculture (USDA) to issue voluntary country of origin labeling guidelines for use by retailers who wish to notify their customers of the origin of beef, lamb, pork, fish, perishable agricultural commodities (which includes fresh and frozen fruits and vegetables), and peanuts. Although the program initially is voluntary, the Act also requires USDA to promulgate regulations for a mandatory country of origin labeling program by September 30, 2004.³¹ When the mandatory labeling program takes effect, all retailers, as defined by the law, must comply with those requirements.

FDA should not wait until implementation of mandatory provisions of the Farm Security Act to impose country-of-origin labeling on *all* FDA-regulated imported foods as a means of assuring an effective trace back in the event of a food emergency and preventing the spread of foodborne illness.³² Illness outbreaks linked to contaminated imported foods, particularly produce, demonstrate the importance of the ability to trace contaminated products back to their

³⁰ Pub. Law No. 107-171, 7 U.S.C. §§ 1638-1638d. The Act amends the Agricultural Marketing Act of 1946.

³¹ Some states, such as Florida, already require country-of-origin labeling for fresh produce. Florida also requires such labels for honey and aqua-cultured products.

³² We recognize that there is current congressional debate over funding of the country of origin labeling provisions. See Scott Kilman, *Grocers, Meatpackers Fight Law to Label Origin of Foods* Wall Street Journal (June 26, 2003), at B1. This debate, however, does not impact FDA's authority to promulgate source labeling requirements.

source as quickly as possible. There are numerous examples where the regulatory agency has not been able to identify the source of contaminated food quickly enough and, sometimes, not at all.

For example, between May and June, 1998, there was a reported outbreak of *Salmonella oranienburg* in Ontario, Canada, resulting in twenty-two illnesses attributed to consumption of cantaloupes. Because cantaloupes were out of season in Canada, they were imported from numerous sources, including the United States, Mexico and Central America.³³ An attempted trace back of cantaloupes supplied to the retail outlets where the cantaloupes were purchased failed to identify a common supplier.³⁴

In 1996 there were almost 1,500 cases of cyclosporiasis in the United States linked to raspberries contaminated with *Cyclospora*. Although the Centers for Disease Control and Prevention declared Guatemalan raspberries as the likely source of the 1996 outbreaks, the FDA only issued an import alert after an additional 1,000 illnesses were reported in 1997. FDA itself has noted that it attempted to conduct approximately 38 tracebacks in the 1997 *Cyclospora* outbreak but was able to complete only 33 because of insufficient records.³⁵ Better labeling might have prevented many *Cyclospora* illnesses.

These are just two examples among many that demonstrate the need for quick and effective trace back for imported foods, particularly fresh produce, through country of origin

³³ Recently the Canadian Food Inspection Agency (CFIA) has imposed new requirements for country-of-origin labeling for cantaloupes imported from Mexico because of potential *Salmonella* contamination. Under the requirements, every container of cantaloupes must be identified by, among other things, the name and address of the certified grower and/or packer. In addition, CFIA will allow the importation of Mexican cantaloupes only if a comprehensive traceback system for the growers and/or packers has been established. See Canadian Food Inspection Agency, *Import Requirements for Mexican Cantaloupes* (May 16, 2003), at <<http://www.inspection.gc.ca/english/plaveg/fresh/mexcane.shtml>>

³⁴ Health Canada, Canada Communicable Disease Report, Vol. 24-22, *Salmonella Oranienburg, Ontario* (15 Nov. 1998).

³⁵ 68 Fed. Reg. at 25,227.

labeling. Identification of the country of origin through product labeling would have assisted regulatory and health officials in more quickly identifying the source of the tainted products to prevent additional illnesses and allowed for faster recalls. As consumption of fresh produce in the United States continues to increase, country of origin labeling will become even more important because of the potential commingling of fruits and vegetables during distribution to make up larger shipments and the accompanying difficulty in detecting the true source of the contamination.

Such labeling would also help minimize the business disruption for other similar products by assisting investigators in narrowing the scope of their investigation, leading them to a specific region, packinghouse, or field, rather than an entire commodity. For example, in the recent *Salmonella poona* outbreak linked to "Susie" brand cantaloupes imported from Mexico, it was reported that non-Susie brand cantaloupes were also being pulled from shelves because they had been intermingled with the recalled product.³⁶ Likewise, food producers and suppliers have a strong economic interest in isolating the source of a food safety problem as quickly as possible since early identification of suspect food would assure that their foods are not implicated and protect them from a false association with a particular outbreak.

C. The Act Provides FDA Authority to Require Source Labeling

Requiring source labeling as part of the recordkeeping requirements is within FDA's authority under the Bioterrorism Act. The language of section 306(b) authorizes the Secretary to establish "requirements regarding the establishment and maintenance . . . of records . . . which records are needed by the Secretary for inspection to allow the Secretary to identify the

³⁶ See *Mexican cantaloupe recall raises questions* (May 23, 2002), at http://www.foodmarketexchange.com/datacenter/news/dc_nc_index_detail.php3?newsid+710.

immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death” The statute fails to define “records,” thus giving FDA discretion to define the term.³⁷ In addition the statute gives FDA considerable discretion to identify which “records are needed” by the Agency for inspection to identify the immediate previous sources and subsequent recipients of potentially tainted food.³⁸

FDA should use this discretion to define a label as a “record” since such a label contains information concerning the food article. Moreover, as demonstrated by the Gautemalan raspberry and Mexican cantaloupe outbreaks, a label may be “needed” by the Secretary for inspection to allow him to identify the source of a food product as quickly as possible where it poses a threat of serious adverse health impacts. Labeling is important to ensure transparency in the chain of custody all the way to the consumer, particularly where there may be issues of commingling.

4. Where There is Doubt Concerning Whether Perishable Foods Will Be Processed Into Non-Perishable Foods, Facilities Should Retain Records for Two Years

FDA has proposed that records for perishable foods not intended to be processed into nonperishable foods be retained for one year after the date the records were created. For all other food, records must be retained for two years after the date the records were created. FDA has requested comment on whether a person subject to these regulations always or usually knows at the time perishable food is released whether or not it is intended to be processed into

³⁷ Likewise, the statute does not define the term “sources,” thus giving FDA discretion to define a country as a “source.”

³⁸ Congress may delegate policy making authority to an agency either through an express delegation or the introduction of an interpretative gap in the statutory structure. *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 696-97 (1991); *Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837, 864-66 (1984).

nonperishable food.³⁹ It is likely that some facilities will not always know whether the recipients of perishable foods intend to process them into nonperishable foods. Alternatively, they may know that some perishable foods they release are processed into nonperishable foods while others are not, but not know which. In those instances, facilities should be required to keep the records for two years. This is the only way FDA can assure that if there is subsequent problem that it will have records to conduct an adequate trace back.

Conclusion

Experience with past recalls for unintentionally contaminated foods has taught us the importance of adequate systems to identify and trace suspect foods as a means of protecting the public health. The recordkeeping requirements ultimately adopted by FDA should be strong enough to allow FDA to trace and track food throughout the distribution chain as quickly as possible in the event of a bioterrorist attack on the food supply. Only by tracking food quickly both forward and back through the chain of custody will FDA be able to prevent large numbers of illnesses and deaths.

Respectfully submitted,

s/s Karen Egbert



Karen L. Egbert
Senior Food Safety Attorney

Caroline Smith DeWaal
Director, Food Safety Program

³⁹ 68 Fed. Reg. at 25,190.