

March 7, 2002

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

Re: “Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance”; “Importers and Filers: Food Security Preventive Measures Guidance,” 67 Fed. Reg. 1224 (Jan. 9, 2002); Docket No. 01D-0583.

In response to the tragic events of September 11, 2001, and heightened concern over the safety of the domestic food supply, the Food and Drug Administration (FDA) has issued two guidance documents related to food security – “Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance” and “Importers and Filers: Food Security Preventive Measures Guidance.”

The Center for Science in the Public Interest (CSPI) appreciates the opportunity to provide comment on these two documents. 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*.

According to one news report, Secretary of Health and Human Services Tommy Thomson has testified before a House of Representatives subcommittee that he was “more fearful about [food safety] than anything else.”¹ While the guidance documents identify the kinds of preventive measures that operators can take to minimize the risk that food under their control will be subject to tampering or to criminal or terrorist actions, the suggested measures are too narrowly focused.

Accordingly, we recommend that the guidance be strengthened in the following ways.

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¹ Jill Carroll, *FDA Issues Guidelines to Protect Food*, Wall Street Journal (Jan. 8, 2002), at p. A2.

- **FDA should recommend that establishments conduct a formal review of areas of vulnerability**

Both guidance documents issued by FDA contain recommendations on appropriate measures that can be taken by food establishments to minimize the risk of food being subjected to tampering or criminal or terrorist actions. Recognizing that not all of the guidance is appropriate or practical for every food establishment or importer, the documents encourage operators to review the guidance and assess which preventive measures are suitable for their operation.

However, before an operator can determine the applicability of any particular measure, it must conduct an initial assessment, akin to the hazard identification component of the HACCP system, to determine areas of likely vulnerability. The guidance documents fail to recognize that the first step in management of any risk to food security must be an identification of what those risks are. Therefore, the guidance should be amended to recommend that each facility conduct a formal review of its company procedures, physical facility, processes, shipping and distribution systems to identify and list all relevant areas where it may be vulnerable to potential sabotage or terrorist attack. Only by first identifying potential vulnerabilities can an establishment be assured that it has adequate systems, procedures, and measures in place to address and manage those vulnerabilities. In addition, the guidance should recommend that each establishment conduct a periodic review of its vulnerability assessment, particularly when there has been a change in suppliers, production patterns, or distribution systems.

- **FDA should adopt guidance for special groups**

Food vendors and food sources for special groups, such as military bases, schools, and ships and aircraft, have been identified as probable targets for food bio-terrorism.² These sources rely on centralized kitchens or food production systems to provide food for large numbers of people, including children. Security measures in the transport of these foods to the point of distribution should be a matter of heightened concern, since there is increased potential for intentional adulteration or contamination of foods at this point. Accordingly, FDA should adopt additional guidance specifically to address the safety issues relating to food produced in centralized kitchens and its transport to the point of distribution.

- **FDA should encourage microbial testing requirements**

An adequate food safety program must do more than protect the physical security of buildings and facilities and conduct background checks on employees; it must include heightened inspection and verification of process controls to guard against intentional microbiological and chemical contamination. The Guidance for Food Producers suggests that food establishment

² Dr. Richard Lee, *Food As a Weapon*, presented at International Association for Food Protection Annual Meeting (Aug. 8, 2000), available at < <http://www.litigation.support.ene.com/bioterrorism/DrLee.pdf> >, at p. 2, Table 2.

operators should “consider” evaluating the utility of testing incoming ingredients. The guidance should go further. Because chemicals or infectious pathogens can be added at various points along the food chain, facilities should be encouraged (and required) to conduct testing of their products on a continuing basis to assure that there has not been intentional contamination of their products with biological or chemical agents.

The General Accounting Office (GAO) has determined that under the current structure, there are real doubts about the system’s ability to detect and quickly respond to a bioterrorist attack on the food supply.³ For example, in September 1984, approximately 751 people were sickened after eating at salad bars in The Dalles, Oregon. It took investigators over a year to discover that a religious cult had intentionally contaminated the food with *Salmonella Typhimurium*. If terrorists should ever decide to attack the American food supply, we cannot afford to wait a year to discover the source. This is particularly important since an intentional act of food adulteration could take place but remain undetected for days, even weeks, until there is an outbreak of illnesses. Accordingly, the guidance should do more to encourage food producers and processors to test their products on a routine basis for potential contamination, in particular, microbiological contamination. Testing of products both at processing and at points along the distribution chain will help better pinpoint where an act of deliberate contamination has actually occurred.

● **FDA should recommend that establishments implement both traceback and trace-forward regimes**

Product traceability is a key element of any food safety management system. The ability to traceback may be one of the most important weapons in the arsenal of determining the origin of contaminated or adulterated food since it assists public health and other authorities to determine the source of contamination once illnesses are discovered. Because the FDA does not have the authority to detain domestic food products, having systems in place for tracing a product (including input materials) back to the farm or to a particular animal in the case of intentional contamination is important. Therefore, the guidance should not only encourage food establishment operators to use only known suppliers and sources, it should encourage facilities to keep adequate and ongoing records of their supply sources, so they can trace back ingredients as well as end products. Importers, in particular, should be encouraged not only to use known, appropriately licensed or permitted sources for products, as the guidance recommends, but to demand that incoming products are accompanied by written documentation demonstrating a transparent chain of custody.

Among other things, the guidance should assure that companies are encouraged to use data management technologies to develop labels that accompany their products from farm to retail. All packers also should be required to keep records of farm/field conditions, sanitation, irrigation procedures, supplies, and product codes. Just as many countries are adopting ear or tail

³ General Accounting Office, *Food Safety: Agencies Should Further Test Plans for Responding to Deliberate Contamination*, GAO/RCED-00-3 (Oct. 1999).

tags that identify the herd of origin for animals, crates and boxes of vegetables, fruits, eggs and dairy products can bear, through product labeling or bar codes indicating farm of origin, date of harvest or processing, documentation of handling chain, packing house identification, and shipment date. Additional data can be added, including days in transit and temperatures. Once the product is ready to be shipped, it should be loaded into containers that are sealed by appropriate authorities and labeled with appropriate information. The case label should accompany the product until it is ready for distribution. The FDA should recommend that purchasing contracts include a requirement that suppliers will have commodity codes and expiration dates with written explanations provided for recalls and other food safety actions. Industry also should be encouraged to change its current practice of recycling shipping containers and co-mingling products during distribution and sale. If produce is to be co-mingled, it should bear a bar code or other label so that can be traced back to the source.

In addition, the guidance should focus not only on tracing a product back to its source but also on a facility's ability to trace a product forward through the food distribution chain in the event that problems with a product are detected after it leaves the processing or distribution facility. With an adequate trace forward system, an item can be recalled **before** it can sicken large numbers of consumers.

The trace forward ability is particularly important with respect to fresh produce, since it is often quickly consumed. Producers and distributors alike should be encouraged to use computer-generated bar-code labeling that includes time-coded information within the bar code so that facilities may more precisely trace their products to the point of distribution if a problem arises. At each element of the food distribution chain, food handlers should keep records as to the physical flow of the product, including date of acquisition. The FDA also should provide guidance with respect to methods to document rejected or returned products. If a product is prepared, repackaged and/or handled prior to distribution, service, or sale, companies should have written procedures in place to address this situation.

- **FDA should adopt more detailed guidance for monitoring products during shipping and delivery**

The guidance should be amended to recommend that all firms keep written and/or computerized records concerning deliveries from suppliers (incoming shipments), including the date that the raw or final products were received (not just logged in), time in transit, method of transport, origin, and condition, including shipping and storage temperatures.

We appreciate the opportunity to comment on the draft guidance documents.

Sincerely,

A handwritten signature in black ink that reads "Karen L. Egbert". The signature is written in a cursive style with a prominent initial "K" and a long horizontal stroke at the end.

Karen L. Egbert
Senior Food Safety Attorney

Caroline Smith DeWaal
Food Safety Director

March 7, 2002

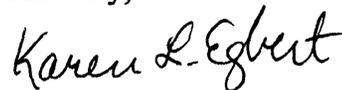
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Docket No. 01D-0583
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Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir or Madam:

Enclosed please find the original and two copies of CSPI's comments on "Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance" and "Importers and Filers: Food Security Preventive Measures Guidance." Please file these comments under Docket No. 01D-0583. Thank you very much.

Sincerely,



Karen Egbert
Senior Staff Attorney, Food Safety