Division of Dockets Management  
(HFA–305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

May 16, 2012

RE: Establishment, Maintenance, and Availability of Records: Amendment to Record Availability Requirements. [Docket No. FDA-2002-N-0153, RIN 0910-AG73]

The Center for Science in the Public Interest (“CSPI”) appreciates the opportunity to comment on the interim final rule amending regulations on establishment, maintenance and availability of records [Docket No. FDA-2002-N-0153, RIN 0910-AG73]. CSPI is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues, that is principally supported by the 850,000 subscribers to its Nutrition Action HealthLetter and by foundation grants.

CSPI supports the rule as published in the Feb. 23, 2012, Federal Register, and agrees with the Food and Drug Administration (“FDA”) that publication as an interim final rule with immediate effect is appropriate. We recommend, though, that FDA no longer view its authority to access business records as limited to conditions described in 21 U.S.C. §§ 350c and 374. Instead, changes made by the FDA Food Safety Modernization Act (“FSMA”) realign the purpose of these Bioterrorism Act provisions to focus them only on emergencies. FDA may look to other new authority under FSMA for records access during routine inspections.

The food industry has used the language of §§ 350c and 374 to prevent FDA from examining documentation on environmental and product testing, conditions in the facility, customer complaints, and traceability recordkeeping to hide problems. As a result, inspections have often been snapshots of conditions in the facility. In several instances, refusal to disclose records during a routine inspection preceded outbreaks.

Inspections in a preventive food safety system require access to records on testing, indications of problems and nonconforming conditions, and the facility management’s responses to these over time. This information is essential to assessing the effectiveness of a facility’s preventive controls, monitoring procedures and corrective actions.

1. FSMA Provides FDA Broad Access to Records Previously Protected by § 350c Limits

FSMA recognizes that inspections must be more than snapshots and gives FDA extensive new authority to access company records that, in the past, a facility could avoid disclosing except
in emergencies. Section 103 of FSMA adds a new requirement for food facilities to provide FDA with their written food safety plans and documentation on –

- Monitoring for preventive controls;
- Instances of nonconformance material to food safety;
- Environmental and product testing;
- Corrective actions taken; and
- The efficacy of their preventive controls and corrective actions.

21 U.S.C. § 350g(h)

Notably, the facility must make these records available upon oral or written request, whereas access under § 350c requires separate written authority. Under these provisions, a facility will no longer be able to refuse access to complaint logs, pest control records, HACCP plans and environmental testing results, as the Nestlé plant in Danville, VA, did prior to the 2009 *E. coli* O157:H7 outbreak from cookie dough that caused 76 reported illnesses.¹

A. Shipping Data Available Under § 350g(h) Access to Confirm Corrective Actions.

The change in how FDA may access records outside of § 350c has important public health implications so that FDA should read its new authority broadly. The records available under § 350g(h) in certain cases will overlap with those covered by the emergency authority in § 350c. For example, corrective actions that include a market withdrawal will of necessity include shipping data. Corrective actions taken in response to contamination from ingredients would require FDA to gather information on the sources of those ingredients. In the past, facilities could have protected such records unless FDA invoked the Bioterrorism Act. Facilities, now, must provide these records upon an inspector’s oral request. This access is important because it allows FDA to confirm distributors withdrew the food before its sale to the public and that suppliers took corrective steps after learning there was a problem.

B. Test Results Available as Records of Nonconformance Material to Food Safety.

Food facilities cannot refuse to provide FDA with records of positive tests conducted outside the facility’s preventive control plan. This is because § 350g(h) requires them to provide FDA with any records of nonconformance material to food safety. Two instances of food facilities hiding positive tests from FDA inspectors point to the importance of asserting this authority. The ConAgra peanut butter plant in Sylvester, GA, refused to turn over records of positive tests for pathogens unless FDA’s inspectors presented a written notice. This incident preceded the *Salmonella* tennessee outbreak in 2007 that sickened over 600 consumers.²

also had to invoke the Bioterrorism Act to discover that Peanut Corporation of America hid positive tests on its products before the *Salmonella* typhiurium outbreak in 2008-2009 that killed nine people and hospitalized more than 170.\(^3\)

C. Traceability Record Inspection Linked to Records Showing Efficacy of Controls.

FDA should also make clear that the efficacy of preventive controls and corrective actions are directly related to the strength of a facility’s traceability recordkeeping. Under § 350c, a facility is required to keep records of the immediate previous source and immediate subsequent recipient of food it processes. However, an Inspector General investigation in 2009 found that 25 percent of businesses were not aware of the recordkeeping requirement and almost 60 percent had incomplete records.\(^4\) Recommendations for addressing this problem included verifying compliance through routine access to traceability records. Linking the efficacy of a facility’s food safety plans to traceability recordkeeping would accomplish that.

2. Conclusion.

While outside the scope of this rulemaking, FDA should interpret its authority to access corporate records under § 350g(h) as superseding the limited access provided by §§ 350c and 374. Making a distinction between routine record access under § 350g(h) and emergency powers under §§ 350c and 374 would help the agency fulfill its public health mission of assuring facilities are meeting their responsibility to implement effective preventive food safety measures.

CSPI thanks the agency for taking these comments into consideration as it moves forward with its programs for assuring the safety of the U.S. food supply.

Sincerely,

David W. Plunkett, JD, JM
Senior Staff Attorney
Food Safety Department

---
