Food Safety Modernization Act Expanded Records Access Provisions: Implementation Through Interim Final Rule and Guidance

Kristi L. Wolff, Donnelly L. McDowell

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On February 23, 2012, the Food and Drug Administration ("FDA") published an interim final rule and guidance, which implement Food Safety Modernization Act ("FSMA") provisions regarding FDA's access to company records under the following situations:

(1) when FDA has a reasonable belief that a food article, and any other food that FDA reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals; or

(2) when FDA believes that there is a reasonable probability that use of or exposure to a food article, and any other food that FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals.[1]

Prior to FSMA, FDA could access and copy records only if there was a "reasonable belief that an article of food [was] adulterated ***and*** present[ed] a threat of serious adverse health consequences or death to humans or animals."[2] FSMA expands FDA authority to permit access to records when FDA believes there is a "reasonable probability" that an article of food, or any food likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals, regardless of adulteration. FSMA also expands access "beyond records relating to the specific suspect article of food to records relating to any other article of food that FDA reasonably believes is likely to be affected in a similar manner."[3]

Interim Final Rule Requires Companies to Turn Over Records Within 24 Hours

The FDA interim final rule requires companies to provide records relating to an article of food "that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals" or records "that are needed to assist the Secretary in determining whether there is a reasonable probability that the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals."[4] These records must be provided within "24 hours from the time of receipt of the official request, from the officer or employee duly designated by the Secretary of Health and Human Services who presents appropriate credentials and a written notice."[5] The interim final rule took effect on March 1, 2012 and FDA intends to begin enforcing the new requirements immediately.

The preamble accompanying the new rule indicates that FDA opted to implement the new FSMA requirements by means of an interim final rule, rather than through conventional notice and comment rulemaking procedures "[b]ecause FDA's expanded records access authority was effective upon the enactment of FSMA" on January 4, 2011. Therefore, FDA determined that "it is contrary to the public interest to require those members of the public whose records are requested under FDA's expanded authority to produce records without regulations explaining how to comply with FDA's new authority."[6]

While the interim final rule became effective on March 1, 2012, FDA will accept comments regarding the rule until May 23, 2012—which will afford interested parties an opportunity to discuss any concerns before a final rule is established. FDA will consider comments made during the comment period when FDA issues a final rule, which the FDA is expected to issue one year from the close of the comment period.

Notably, the interim final rule does not provide any information regarding when FDA will have a "reasonable belief" or "reasonable probability" that a food is adulterated and/or will cause serious adverse health consequences to human and animals.[7] In a separate document entitled "FDA Food Safety Modernization Act Frequently Asked Questions,"[8] FDA provides the following guidance:

"What constitutes a 'reasonable belief' that food is affected in a similar manner in the context of FDA records access?

Decisions regarding whether FDA 'reasonably believes' a food is affected in [a] similar manner so as to either be adulterated and present a threat of serious adverse health consequences or death to humans or animals or to pose a reasonably probability that the use of or exposure to such food will cause serious adverse health consequences or death to humans or animals will be made on a case-by-case basis because such decisions are fact-specific."

But, the current FDA guidance does not address how the agency intends its case-by-case approach to be implemented in a manner that abides by the procedural and evidentiary requirements of the FDCA, Administrative Procedure Act, and Fourth Amendment protections against unreasonable search and seizure. In the absence of more detailed guidance concerning how the agency will employ its standards and procedures to avoid overstepping these statutory and constitutional boundaries, the investigative demands of the agency are likely to impose undue legal and business risks on responsible companies.[9]

Draft Guidance for Industry: FDA Records Access Authority Under Sections 414 and 704 Federal Food, Drug, & Cosmetic Act

Along with the interim final rule, FDA also published an updated draft guidance document on February 23, 2012, that is entitled—"Draft Guidance for Industry: FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, & Cosmetic Act" ("Draft Guidance"). The new Draft Guidance updates FDA's November 2005 guidance entitled "Guidance for Industry and FDA Staff: Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Final Guidance,"[10] which described FDA authority to access records prior to FSMA under Section 306 of the Bioterrorism Act of 2002 (PL 107-188). Specifically, the new Draft Guidance explains FDA's position regarding (1) the circumstances permitting FDA records access; (2) the types of records that may be accessed and copied; (3) the types of records that may not be accessed and copied; and (4) the actions that FDA may take if access is inappropriately denied. The Draft Guidance also eliminates the November 2005 Guidance's explanation of the internal procedures that FDA followed prior to making a records access request.

Circumstances Permitting FDA Records Access

As described above, FSMA expands FDA authority to access records when FDA believes there is a "reasonable probability" that an article of food, or any food likely to be affected in a similar manner, will cause serious adverse health consequences or death to animals or humans, regardless of adulteration.

The Draft Guidance provides examples of situations in which food may cause serious adverse health consequences or death to humans or animals, including where food is contaminated with bacteria, where dry mix contains milk that is not declared as an ingredient, and where peanut contamination occurs due to cross-contact with another food containing peanuts.[11] The Draft Guidance also provides examples of situations in which FDA may access records of a food that is "likely to be affected in a similar manner" as a suspect food, such as for foods packed in the same processing line; processed in shared-use equipment; or generally "prepared, packed or held under similar conditions" as the suspect food. The authority would also permit access to a variety of foods when epidemiological data implicates multiple foods as potential sources of a bacteria outbreak such as *Salmonella*.[12] The Draft Guidance also makes clear that FDA records access applies to both human food and animal feed, as well as both domestic and foreign persons.

Types of Records That May be Accessed and Copied

The Draft Guidance explains that FDA records access extends to all records required to be kept under Section 414(b) of the FDCA and any other record related to the "manufacture, processing, packing, transporting, distribution, receipt, holding, or importation" of food.[13] The records may be in any format and may be located at a facility other than where the covered activities take place.

This section remains largely unchanged from the November 2005 Guidance, although the Draft Guidance does provide specific examples of records which FDA may access, including manufacturing records, raw materials (ingredients and packaging) receipt records, product distribution records, product inventory records, and test records.

Types of Records That May Not be Accessed or Copied

The Draft Guidance expands on the November 2005 Guidance by providing more detail concerning the types of records which may not be accessed or copied. Specifically, the Draft Guidance explains that FDA records access authority does not extend to the following:

- Records from farms, as defined in 21 C.F.R. § 1.328;

- Records from restaurants, as defined in 21 C.F.R. § 1.328;
- Records relating to food within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. § 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. § 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. § 1031 et seq.);
- Recipes, as defined in 21 C.F.R. § 1.328; and
- Financial, pricing, personnel, research and sales data other than shipment data regarding sales.

While these exemptions were not changed by FSMA, the Draft Guidance provides more context based on information contained in Section 1.328 of FDA regulations.[14]

FDA Actions if Access is Inappropriately Denied

The Draft Guidance also explains that refusal to permit access to requested records is a prohibited act under FDCA Section 301(e) and that FDA may initiate a civil or criminal action in response. Additionally, FDA may refuse admission of food offered for import into the United Statesby a firm that refused to permit FDA access to records.

The Draft Guidance further notes that additional FDA actions may be taken concurrently with, or prior to, a records access request. These actions include suspension of the food facility's registration, administrative detention or seizure of the food, or the issuance of a recall or injunction. FDA's authority to take such actions is unaffected by a records access request.[15]

Additional Information and Submission of Comments

Notably, the Draft Guidance deletes a section from the November 2005 Guidance, which explained the internal process that FDA intended to follow before requesting access to records. The process entailed reaching a consensus between either the Center for Food Safety and Applied Nutrition ("CFSAN") or the Center for Veterinary Medicine ("CVM"), and the Office of Enforcement ("OE") that a food article presented a threat of serious adverse health consequences or death. If agreement was reached, the appropriate Center would then have to consult with the Office of the General Counsel, Food and Drug Division for a determination as to whether there was a reasonable belief that the article of food was adulterated. Only after these determinations were made would the OE coordinate with the Director of the district where the food was located to request access to records. The Draft Guidance makes no mention of any process that FDA intends to follow when requesting access to records.

FDA urged interested parties to provide comments regarding the Draft Guidance by May 23, 2012 to ensure that FDA has adequate time to consider comments before publishing the final guidance.

Guidance for Industry: Questions and Answers Regarding Establishment and Maintenance of Records by Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food (Edition 5)

In conjunction with issuance of the records access interim final rule and Draft Guidance, FDA also issued an update to the corresponding guidance document--"Questions and Answers Regarding Establishment and Maintenance of Records By Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold or Import Food" ("Guidance").[16] The Guidance provides numerous question and answer examples designed to help a broad spectrum of food transport industry participants–from farm stands to airlines that haul food products–determine their recordkeeping obligations.

This Guidance remains largely the same as the previous edition, which was last updated in September 2006; however, FDA has updated the guidance to reflect the agency's expanded scope of records access and to provide additional information regarding records that are excluded from FDA access.[17] In general, the updated Guidance makes clear that "[t]he records access authority under Sections 414(a) and 704(a) does not extend to recipes for food, financial data, pricing data, personnel data, research data, or sales data other than shipment data regarding sales."[18] The Guidance also provides information regarding key terms, such as noting that "Recipe" is defined in Section 1.328 of FDA regulations as "the formula, including ingredients, quantities, and instructions necessary to manufacture a food product." Additionally, the Guidance notes that certain records may also be excluded from access under Section 116 of FSMA, but FDA has deferred specific guidance on this issue to a later date. While FDA's overall access to records has been expanded under FSMA, there are certain limitations. Entities should be aware of how these exemptions apply to their specific records before a records access request is made.

As FDA continues to implement FSMA provisions and provide guidance regarding these new requirements, entities subject to FSMA compliance should review their policies and procedures to ensure that they reflect FSMA's new requirements. In light of FDA expanded records access, specific steps that entities can take include (1) understanding the types of records that must be maintained given the type of food processing activities in which an entity is involved (*e.g.*, manufacturing,

transporting, packing, holding, etc.); (2) ensuring that recordkeeping systems are organized and allow appropriate personnel access to the records given that entities will only have 24 hours in which to respond to a request; and (3) understanding how records access exemptions apply to specific records for a food product. Entities should carefully monitor FDA developments regarding FSMA, as entities affected by this Act have the opportunity to influence FSMA requirements that ultimately will apply to their products and business practices.

Kelley Drye & Warren LLP

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For more information about this Client Advisory, please contact:

Donnelly L. McDowell
(202)342-8645
dmcdowell@kelleydrye.com

Kristi L. Wolff
(202) 342-8805
kwolff@kelleydrye.com

Appendix I: New or Revised Questions in Guidance for Industry: Questions and Answers Regarding Establishment and Maintenance of Records by Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food (Edition 5)[19]

8.2 Q: A transporter carries items that may or may not become food contact substances (*e.g.*, polyethylene bags). Is the transporter subject to the records access requirements?

A: In accordance with section 1.327(j), all persons who manufacture, process, pack, transport, distribute, receive, hold or import food contact substances other than the finished container that directly contacts food are excluded from all recordkeeping requirements except sections 1.361 and 1.363. Under these provisions, any existing relevant records must be made available to FDA **in response to an official request**, as soon as possible, not to exceed 24 hours from the time of FDA's request, **as required in sections 1.361 and 1.363**. If a transporter can reasonable expect that some or all of its cargo may become food contact substances, then that transporter must ensure that it has the capability to provide access within the specified time limit to records it normally maintains as a matter of business practice and that may be within the scope of a records access request by FDA.

29.6 Q: A manufacturing firm has multiple suppliers of particular ingredients and packaging materials. Is it sufficient to simply record all the potential suppliers that an ingredient or packaging material might have come from?

A: Persons who manufacture, process, or pack food are required to establish and maintain records regarding receipt of the lot or code number or other identifier of each ingredient and any finished container that they place in contact with food, if a lot or code number or other identifier exists, in accordance with section 1.337 and 1.327(k). When the food is released, records must be established and maintained that include the specific source of each ingredient used to make every lot of finished food and any finished container placed in contact with food, to the extent that the information is reasonably available (*e.g.*, does not require physical reconfiguration of the manufacturing facility), in accordance with section 1.345. "Packaging" is defined in section 1.328 as "the outer packaging of food that bears the label and does not contact the food." The manufacturer, processor or packer does not have to establish and maintain records for any packaging or for finished containers that it does not place in contact with the finished food, as stated in section 1.327(j). All existing relevant records must be made available as soon as possible to FDA on request, not to exceed 24 hours, as required by sections 1.361 and 1.363, ~~**if 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**~~. If information is reasonably available when food is released to narrow the possible sources of an ingredient, it is not sufficient to record all potential suppliers that an ingredient or packaging material might have come from if there is no expectation that that supplier's product would be in the finished product (*e.g.*, no shipments have been received from a vendor for months and onsite supply has been depleted).

32.4 Q: If a firm is a manufacturer, processor, and packer of a single product, would all lot numbers associated with this process (*e.g.*, lot numbers for individual cans, lot numbers for pallets, etc) have to be tracked?

A: Section 1.345 requires persons who manufacture, process or pack food to establish and maintain records when releasing the food to another person that include the lot or code number or other identifier (to the extent this information exists). FDA recommends that a vertically integrated company which generates several lot or code numbers or other identifiers in the course of its operations use the most specific one. Specific information about the food helps FDA narrow its investigation and increase the speed of the trace in the event that ~~**there is a reasonable belief that an article of food is adulterated and presents a threat of**~~ **the food may be associated with serious adverse health consequences or death to humans or animals.** However, another acceptable alternative would be for the firm to record identifiers of larger packages (such as pallets) but retain the ability to link these to lots of cans when necessary.

35.11 Q: Can a legal entity select a subset of facilities in the chain of custody to be a vertically integrated operation, and, if so, under what conditions? For example, can legal entity "T," who manufactures, packages and distributes product "M," designate the manufacturing facility and warehouse used to store newly made inventory10 milesaway as a one vertically integrated operation but exclude 4 T-owned regional warehouses that product will be subsequently shipped through before delivered to retailers?

A: As discussed in the response to Comment 13 inthe Final Rule preamble, a vertically integrated operation must establish and maintain records that identify the immediate previous sources of all food it receives, but does not have to establish and maintain records identifying immediate subsequent recipients of the food until that food is released to another person (including a transporter). However, the vertically integrated operation may choose to maintain records of some or all internal transfers of food as a matter of business practice. Sections 414(a) and 704(a) of the FD&C Act provide FDA with access to existing records relating to the manufacture, processing, packing, transportation, distribution, receipt, holding or importation of food ~~**when the records access requirements of the Bioterrorism Act are satisfied**~~ **under certain circumstances. Section 1.361 reiterates the circumstances in the statute and specifies that records must be made available to FDA within 24 hours from an official records request.**

41.1 Q: The regulation requires each nontransporter to establish and maintain records onsite or at a reasonably accessible location. The recordkeeping requirements may be a burden for smaller businesses that assist in product development and product sample testing. Can a larger firm that hires a smaller one for food development and testing maintain the records on behalf of the smaller firm?

A: Section 1.360 requires each nontransporter to establish and maintain records at the location where the covered activities described in the records occurred, or at a reasonably accessible location. FDA does not intend to specify the methods or system by which this was done. In this case, ~~**in the event that 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, relevant records must be made accessible onsite at the testing facility or at a reasonably accessible location as soon as possible upon request by FDA, not to exceed 24 hours, as required by §1.361 and §1.363**~~ **the larger firm may choose to maintain the required records on behalf of the smaller firm. However, when FDA requests access to records that meet the requirements of 414(a)(1) or (a)(2) of the FD&C Act, as explained in question 41.5 of this document, the relevant records must be made accessible onsite at the smaller firm, or at a reasonably accessible location. The records must be available as soon as possible, but not to exceed 24 hours after an official FDA request, as required in sections 1.361 and 1.363.** Regardless of the specific arrangements, the legal responsibility for establishing and maintaining records, and for producing them in a timely fashion, would remain with the smaller firm.

41.2 Q: Is it possible that an investigation may lead FDA to suspect that a product may have been tampered with inside a vertically integrated operation, for example en route between two facilities. If company systems are set up to establish records as a vertically integrated operation, what would be FDA's expectations if intra-company records were requested?

A: Sections 414(a) and 704(a) of the FD&C Act provide FDA access to existing records relating to manufacture, processing, packing, transportation, distribution, receipt, holding, or importation. If FDA requests intra-company records under ~~**the Bioterrorism**~~ **sections 414(a) and 704(a) of the FD&C Act**, FDA expects a vertically integrated operation to provide access to such existing records as soon a possible, not to exceed 24 hours from the time of receipt of the official request, as required by section 1.361.

42.1 Q What records are excluded from FDA's authority to access records under sections 414(a) and 704(a)?

A: The records access authority under sections 414(a) and 704(a) does not extend to recipes for food, financial data, pricing data, personnel data, research data, or sales data

other than shipment data regarding sales. "Recipe" is defined in section 1.328 as " the formula, including ingredients, quantities, and instructions necessary to manufacture a food product." Certain records may be excluded from access under section 116 of FSMA. FDA will provide guidance on the issue at a later date.

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[1] FSMA § 101(a)(2).

[2] FDCA § 414(a) (emphasis added).

[3] FDA Draft Guidance for Industry: FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, & Cosmetic Act (Feb. 2012), *available at*, http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyRespo

[4] FSMA § 101(a).

[5] *Establishment, Maintenance, and Availability of Records: Amendment to Record Availability Requirements*, 77 Fed.Reg.10658,10662 (Feb. 23, 2012) (publishing new Section 1.361).

[6] *Id.* at 10660.

[7] *Id.* at 10659 (in the preamble FDA only notes that "[d]ecisions regarding whether FDA 'reasonably believes' a food is affect in a similar manner to cause serious adverse health consequences or death to humans or animals would be made on a case-by-case basis because such decisions are fact-specific").

[8] Available at http://www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm#IC.

[9] *See* S. Roller, et al. *FDA's Expanding Postmarket Authority to Monitor and Publicize Food and Consumer Health Product Risks: The Need for Procedural Safeguards to Reduce "Transparency" Policy Harms in the Post-9/11 Regulatory Environment*, 64 Food & Drug L.J. 577 (2009) (discussing harm caused to entities when regulations are unclear or silent regarding the scope of an agency's statutory ability to demand records and other information).

[10] This guidance is available at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyRespo

[11] Draft Guidance at Question 5(a).

[12] *Id.* at Question 5(b).

[13] *Id.* at Question 6.

[14] *Id.* at Question 7.

[15] *Id.* at Question 8.

[16] Guidance for Industry: Questions and Answers Regarding Establishment and Maintenance of Records by Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food (Edition 5) (Feb. 2012), *available at*, http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyRespo

[17] *See* changes highlighted in Appendix I.

[18] *Id.* at 51.

[19] Changes from Edition 4 are in bold.