Further Protecting the Food Supply—FDA's Final Rule on Recordkeeping Requirements

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As required by section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act),[1] the Food and Drug Administration (FDA) published a final rule requiring persons who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish, maintain, and make available certain records.[2] This is the fourth rule to protect the food supply that stems from the Bioterrorism Act's mandates, with FDA already having promulgated a final rule for the administrative detention of food and interim final rules for food facility registration and prior notice for imported food shipments.[3]

The recordkeeping rule generally requires that persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States maintain records of the immediate previous sources and immediate subsequent recipients of food.[4] Upon written notice, the records must be made available to FDA for inspection and copying 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."[5] The regulation exempts numerous persons from some, and in certain cases all, parts of the regulation and permits companies to use both electronic and existing records to satisfy the requirements of the rule.[6]

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Scope of the Recordkeeping Regulation

The recordkeeping rule applies to food intended for consumption in the United States *and* food intended for export.[7] It also applies to food shipped solely in intrastate commerce.[8] The rule provides that "food" has the same meaning as that given in section 201(f) of the Federal Food, Drug, and Cosmetic Act (FDCA) and that "food" includes such items as alcohol, live food animals, and animal feed, including pet food.[9]

The types of records that must be established depend on whether the person is a "transporter" or "nontransporter." The rule defines "transporter," in pertinent part, as a person having "possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food."[10] A "nontransporter" is defined as a person "who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation."[11]

Persons deemed to "hold" food include warehouses, port facilities, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.[12] Brokers who facilitate only the distribution, sale, or transportation of food (i.e., they do not directly manufacture, process, pack, transport, distribute, receive, hold, or import food) are not subject to the record-

keeping requirements.[13] U.S. companies transporting food in their own trucks must comply with the recordkeeping requirements for nontransporters only.[14]

Foreign persons, except those who transport food in the United States, are exempt from the recordkeeping requirements.[15] FDA reasoned that, for foreign facilities, much of the information required by the recordkeeping regulation could be obtained through the prior notice requirements of 21 C.F.R. Part 1, Subpart 1.[16] If a foreign person transports food in the United States—even its own manufactured food—that person is considered a "transporter" and is subject to the transporter recordkeeping requirements.[17] A foreign person's partnership or contractual relationship with a U.S. company to transport food in the United States does not exempt the foreign company from the transporter recordkeeping requirements.[18]

The records required to be kept do *not* include food recipes, "financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales)."[19] Failure to comply with the recordkeeping rule requirements is a prohibited act under the FDCA.[20] Thus, noncompliance with the rule may result in an injunction or criminal penalties.[21]

Persons Exempt From the Recordkeeping Regulation

Although the rule is expansive in scope, it does exempt numerous persons from some, and in certain cases all, requirements of the recordkeeping regulation. Excluded from the regulation entirely are farms; restaurants; foreign persons (except those transporting food in the United States); persons who manufacture, process, pack, transport, distribute, receive, hold, or import packaging; persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for personal consumption or food that is within the exclusive jurisdiction of the U.S. Department of Agriculture; and persons who "receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food."[22]

Retail facilities (e.g., bakeries) fall under the exclusion afforded to restaurants, provided that more than 90% of their total food sales is for food they prepare and sell to consumers for immediate consumption.[23] Some convenience stores are "mixed-type" facilities, however, in that the food prepared and sold directly to consumers for immediate consumption (e.g., hot pretzels) is exempt from the recordkeeping rule via the restaurant exemption, but the stores must keep records of the nontransporter and transporter immediate previous sources for the rest of the food sold to consumers.[24]

The following persons are excluded from having to establish and maintain records but are not excluded from having to provide FDA with already existing records should FDA have "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": nonprofit food establishments; persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances, other than the finished container that directly contacts food; persons who manufacture, process, pack, transport, distribute, receive, hold, or import finished containers that directly contact food;[25] fishing vessels not engaged in processing; and retail food establishments that employ 10 or fewer full-time-equivalent employees (FTEs).[26] In addition, persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to the existing records availability requirement with respect to the food's packaging.[27]

The regulation also provides two partial exclusions. Persons who distribute food directly to consumers are excluded from the requirement to establish and maintain records to identify the immediate subsequent recipients, and persons who operate retail food establishments that distribute food to nonconsumers must establish and maintain records to identify the immediate subsequent recipients only to the extent the information is reasonably available.[28]

Records Required by Transporters and Nontransporters

To minimize the recordkeeping rule's burden on industry, FDA gives transporters five options to comply with the rule: 1) each transporter can establish and maintain records on its immediate previous source and immediate subsequent recipient; the origin and destination points; the date the shipment was received and released; a description of the freight, including the number of packages; the route of movement during the time the transporter shipped the food; and the transfer points through which the shipment moved;[29] 2) a transporter can enter into an agreement with the U.S. nontransporter immediate previous source and/or the U.S. nontransporter immediate subsequent recipient to establish and maintain certain records;[30] or 3) through 5) a transporter can establish and maintain records containing certain information already required by the Department of Transportation's (DOT's) Federal Motor Carrier Safety Administration, DOT's Surface

Transportation Board of rail and water interstate transporters, or the Warsaw Convention of international air transporters on air waybills.[31]

Transporters, and nontransporters maintaining records on behalf of a transporter, must retain records for six months after the dates of receipt and release of food having a "significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the transporter receives or releases the food."[32] The record retention time increases to one year if the food's risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days after the date the transporter receives or releases the food.[33]

Nontransporters must establish and maintain the following records for food received: the name, address, telephone number, and (if available) the fax number and email address of the nontransporter immediate previous source, whether domestic or foreign; an "adequate description" of the food received, including the brand name and specific variety, and the date the food was received; the quantity of food and information on how it was packaged; for manufacturers, processors, and packers only, the lot or code number or other identifier of the food, provided that this information exists; and the name, address, telephone number, and (if available) the fax number and email address of the transporter immediate previous source.[34]

These same records must be kept for food *released* except that they would pertain to the nontransporter and transporter immediate subsequent recipients of food.[35] In addition, for food released, nontransporters' records must contain information "reasonably available … to identify the specific source of each ingredient used to make every lot of finished product."[36]

FDA has not defined what it means by "reasonably available." In the preamble to the final rule, however, FDA illustrated when such information might *not* be "reasonably available." If a manufacturer makes cookies using flour from five different companies, and the flour from the companies is stored in one silo before being used to manufacture the cookies, then information "is not reasonably available to determine a single source of the flour used in a particular lot of cookies."[37] The information would be "reasonably available" if the manufacturer had dedicated silos for each supplier of flour.[38]

Although the rule requires nontransporters to maintain an "adequate description" of the food received from nontransporter and transporter immediate previous sources and released to nontransporter and transporter immediate subsequent recipients, FDA is permitting companies to "use existing abbreviation or code systems that identify the food very specifically, provided the abbreviations or codes can be readily deciphered at the time the records are made available to FDA."[39]

Regarding the recordkeeping of the quantity and packaging of bulk food, FDA stated that recording the gross quantity or weight is acceptable, as is providing a description such as "tank load" or "totes."[40]

Nontransporters are not required to establish and maintain records of the intermediate transporters; rather, they are required to keep records only of the transporter who brought the food to them or took the food from them.[41] The rule requires that transporters maintain records that identify intermediate transporters.[42]

Nontransporters must retain records for six months after the dates of receipt and release of food "having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date" the food is received or released; for one year if the risk of spoilage, loss of value, or loss of palatability of food occurs only after a minimum of 60 days but within six months of receipt or release of the food; and for two years if the risk of spoilage, loss of value, or loss of palatability of the food occurs not sooner than six months after the date the food (including frozen, dehydrated, or hermetically-sealed food) is received or released.[43] Nontransporters must retain records for animal food, including pet food, for one year after the date the food is received and released.[44]

Compliance Dates

The compliance dates for the recordkeeping rule are as follows: December 11, 2006, for very small businesses employing 10 or fewer FTEs; June 9, 2006, for small businesses employing fewer than 500 but more than 10 FTEs; and December 9, 2005, for all other businesses.[45]

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1 Pub. L. No. 107-188, 116 Stat. 594 (2002) (codified in various sections of 21 U.S.C.).

2 69 Fed. Reg. 71,562 (Dec. 9, 2004).

3 69 Fed. Reg. 31,660 (June 4, 2004) (Final Rule on Administrative Detention); 68 Fed. Reg. 58,894 (Oct. 10, 2003) (Interim Final Rule on Food Facility Registration); 68 Fed. Reg. 58,974 (Oct. 10, 2003) (Interim Final Rule on Prior Notice of Imported Food).

4 21 C.F.R. §§ 1.326(a), 1.337, 1.345, 1.352.

5 *Id.* § 1.361. The records must be made available as soon as possible, but no later than 24 hours from the time of receipt of the official request. *Id.* The request must be from an "officer or employee duly designated by the Secretary of Health and Human Services who presents appropriate credentials and written notice." *Id.*

6 *Id.* §§ 1.327, 1.330, 1.360(h).

7 69 Fed. Reg. at 71,571. FDA explained that "foods intended for export could easily be diverted into domestic commerce," and "not everyone in the food supply chain may know if the food is intended for consumption in the U.S." *Id.*

8 *Id.* at 71,572. FDA "concluded that the Bioterrorism Act gives FDA authority to

require persons to establish and maintain records, whether or not they engage in interstate commerce." *Id.*

[9] 21 C.F.R. § 1.328.

[10] *Id.* § 1.328.

[11] *Id.* § 1.328.

[12] 69 Fed. Reg. at 71,569.

[13] *Id.* at 71,570.

[14] *Id.*

[15] 21 C.F.R. § 1.327(h).

[16] 69 Fed. Reg. at 71,572.

[17] 21 C.F.R. § 1.327(h); 69 Fed. Reg. at 71,573.

[18] 69 Fed. Reg. at 71,573.

[19] 21 C.F.R. § 1.362.

[20] 21 U.S.C. § 331(e) (FDCA § 301(e)).

[21] *Id.* §§ 332(a), 333(a)(1) (FDCA §§ 302(a), 303(a)(1)).

[22] 21 C.F.R. § 1.327(a), (b), (g)-(i), (m), (n).

[23] *Id.* § 1.327(b). FDA has stated that food is "for immediate consumption when the food is capable of being eaten immediately with no further preparation." 69 Fed. Reg. at 71,580.

[24] 69 Fed. Reg. at 71,580.

[25] Note that "[p]ersons who place food directly in contact with its finished container," however, "are subject to all of the requirements of" the rule "as to the finished container that directly contacts that food." 21 C.F.R. § 1.327(k).

[26] *Id.* § 1.327(c), (f), (j), (k), (l).

[27] *Id.* § 1.327(i).

[28] *Id.* § 1.327(d), (e).

[29] *Id.* § 1.352(a).

[30] *Id.* § 1.352(e).

[31] *Id.* § 1.352(b)-(d).

[32] *Id.* § 1.360(f). The records must be created when the food is received and released, unless the requisite information is contained in existing records. *Id.* § 1.360(a).

[33] *Id.* § 1.360(f).

[34] *Id.* § 1.337(a)(1)-(6).

[35] *Id.* § 1.345(a)(1)-(6).

[36] *Id.* § 1.345(b).

[37] 69 Fed. Reg. at 71,598.

[38] *Id.*

[39] *Id.* at 71,599.

[40] *Id.* at 71,600.

[41] *Id.* at 71,596.

[42] *Id.*

[43] 21 C.F.R. § 1.360(b)-(d).

[44] *Id.* § 1.360(e).

[45] *Id.* § 1.368.