

FSMA Rule: Requirements for Additional Traceability Records for Certain Foods § 1.1305 Exemptions

Category	Description of the exemption	Reference
Farms	Certain produce farms exempt under § 112.4(a) in the Produce Safety Rule.	§ 1.1305 (a)(1)(i-ii)
	Exemption for farms when food is sold or donated directly to consumers.	§ 1.1305 (b)
	Partial exemption for farm to school and farm to institution programs.	§ 1.1305 (l)
Foods	Inapplicability to certain food produced and packaged on a farm. (1) The packaging of the food remains in place until the food reaches the consumer, and such packaging maintains the integrity of the product and prevents subsequent contamination or alteration of the product. (2) The labeling of the food that reaches the consumer includes the name, complete address, and business phone number of the farm on which the food was produced and packaged.	§ 1.1305 (c)(1)(2)
	Exemptions and partial exemptions for foods that receive certain types of processing. (1) Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance. (3) Food that you subject to a kill step, provided that you maintain records containing: (i) The information specified in § 1.1345 for your receipt of the food to which you apply the kill step. (ii) A record of your application of the kill step. (4) Food that you change such that the food is no longer on the Food Traceability List. (5) Food that you receive that has previously been subjected to a kill step or that has previously been changed such that the food is no longer on the Food Traceability List. (6) Food that will be subjected to a kill step by an entity other than a retail food establishment, restaurant, or consumer; or that will be changed by an entity other than a retail food establishment, restaurant, or consumer, such that the food will no longer be on the Food Traceability List.	§ 1.1305 (d)(1) (2) (3)(i-ii) (4) (5) (6)(i-iv)
	Exemption for produce that is rarely consumed raw listed as rarely consumed raw in § 112.2(a)	§ 1.1305 (e)
	Partial exemption for commingled raw agricultural commodities.	§ 1.1305 (h)(1) (2)(i-iv) (3)
	Exemption for food for research or evaluation.	§ 1.1305 ®
Retail operations	Exemption for small retail food establishments and small restaurants.	§ 1.1305 (i)
	Partial exemption for retail food establishments and restaurants purchasing directly from a farm.	§ 1.1305 (j)
	Partial exemption for retail food establishments and restaurants making certain purchases from another retail food establishment or restaurant.	§ 1.1305 (k)
Other operations	Exemption for persons who manufacture, process, pack, or hold certain foods subject to regulation by the U.S. Department of Agriculture (USDA).	§ 1.1305 (g)
	Exemption for nonprofit food establishments.	§ 1.1305 (o)
	Exemption for persons who manufacture, process, pack, or hold food for personal consumption.	§ 1.1305 (p)
	Exemption for certain persons who hold food on behalf of individual consumers.	§ 1.1305 (q)
Transporters	Exemption for transporters.	§ 1.1305 (n)

For full details see reference to FSMA Additional traceability record requirements for certain foods. The table presents a summary of the exemptions without being an exhaustive description of the exceptions.

<https://www.govinfo.gov/content/pkg/FR-2022-11-21/pdf/2022-24417.pdf>