

alternative approach should be used. Specifically, FDA is soliciting comments on the following questions: (1) Should we exempt all types of animal food entities from all or part of this proposed rule? (2) Should we exempt all pet food entities from all or part of this proposed rule? (3) Should we treat pet food the same as other types of animal food by requiring all pet food entities to meet the recordkeeping requirements under this regulation, not just those subject to the BSE rule? (4) Should we use criteria other than the scope of the BSE rule to determine which pet food entities should be exempt? If so, what should those criteria be?

2. Who is excluded from all or part of the regulations in this subpart? (Proposed § 1.327)

Proposed § 1.327(a) codifies the exemption for farms. This exemption is consistent with and required by the express language of the Bioterrorism Act.

Proposed § 1.327(b) codifies the exemption for restaurants. This exemption is consistent with and required by the express language of the Bioterrorism Act.

Proposed § 1.327(c) would exclude certain fishing vessels from all of the regulations in this subpart, except §§ 1.361 and 1.363. These vessels include those that not only harvest and transport fish, but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel. The Bioterrorism Act is silent with respect to exempting fishing vessels in section 306, the "Maintenance and Inspection of Records for Foods" provision, although the "Registration of Food Facilities" provision, section 305, expressly exempts fishing vessels, except such vessels engaged in processing as defined in § 123.3(k) (21 CFR 123.3(k)).

FDA has tentatively concluded that the records of fishing vessels as defined in § 123.3(k), like those of farms, are not a necessary component of an effective traceback investigation. Nevertheless, because the records of "fishing vessels otherwise engaged in processing fish, which for purposes of this subsection means handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding" are necessary to an effective traceback investigation, these would still be subject to all of the regulations in this subpart.

Proposed § 1.327(d)(1) would exclude retail facilities from the regulations in § 1.345 of this subpart. This limited exclusion is only from the requirement to establish and maintain records of the immediate subsequent recipients of food when the food is sold directly to consumers. The Bioterrorism Act expressly states that the Secretary may require the establishment and maintenance of records by persons who "distribute" food, and therefore retail facilities could be subject to all other regulations in this subpart if FDA required it. FDA has tentatively concluded that to require retail facilities to keep records of each individual recipient consumer would be too burdensome and not necessary in order to address credible threats of serious adverse health consequences or death to humans or animals.

Proposed § 1.327(d)(2) would exclude retail facilities, such as roadside stands, located in the same general physical location as farms, as defined in proposed § 1.328, that sell unprocessed food grown or raised on those farms directly to consumers. This exclusion only applies to those retail facilities that employ 10 or fewer full-time equivalent employees, which is consistent with the way FDA is proposing to define very small businesses in proposed § 1.368(a)(2). This exclusion applies only to unprocessed food, including fresh fruits and vegetables and other raw agricultural commodities for use as food, such as honeycomb. The exclusion also applies to fish raised on farms. Unprocessed food grown or raised on locations other than farms, or on farms not located in the same general physical location, are not excluded.

This exclusion does not apply to processed food, even if it is sold directly to consumers from a retail facility in the same general location as a farm, unless all of the ingredients in that processed food were grown or raised on that farm. Processed foods include, for example, baked goods, jams, jellies, and maple syrup. Retail facilities would be required to establish and maintain records of the immediate previous sources under proposed § 1.337 for processed food sold directly to consumers if any of the ingredients of that processed food were not grown on that farm.

FDA believes that the burden placed on these retail facilities to establish and maintain records for unprocessed food grown or raised on a nearby farm and sold directly to consumers would likely outweigh the risk to the public health that follows from this proposed exclusion. FDA has tentatively concluded that such records are not

needed in order to address credible threats of serious adverse health consequences or death to humans or animals. FDA believes it is necessary to narrow this exemption only to those retail facilities that remain close to the source farm in order to not compromise FDA's ability to trace adulterated food that has been transported over a distance greater than the same general physical location. The agency solicits comments on this proposed exemption.

FDA also is proposing in § 1.327(e) to exempt from all of the regulations in this subpart persons who manufacture, process, pack, transport, distribute, receive, hold, or import food that is regulated exclusively by the U.S. Department of Agriculture (USDA) under 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.*). This section complies with section 306(d)(2) of the Bioterrorism Act, which states that section 306 should not be construed to authorize FDA to promulgate regulations for records governing foods within the exclusive jurisdiction of USDA. It also complies with section 315 of the Bioterrorism Act, which states that nothing in Title III of the Bioterrorism Act, or an amendment made by Title III, shall be construed to alter the jurisdiction between USDA and the U.S. Department of Health and Human Services under applicable statutes and regulations.

This exemption is for food within the exclusive jurisdiction of the USDA. Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food that is jointly regulated by FDA and USDA would be required to keep records with regard to the food regulated by FDA. An example of food that is jointly regulated by FDA and USDA is frozen T.V. dinners containing both meat and fish.

Proposed § 1.327(f) would exclude foreign facilities that are also excluded from the requirement to register under section 305 of the Bioterrorism Act. As discussed previously in this document, FDA believes that requiring foreign facilities that must register to also establish and maintain records would be the most efficient and effective way to obtain information on food from foreign countries. Therefore, foreign facilities would not be required to establish and maintain records "if food from these facilities undergoes further manufacturing/processing (including packaging) by another foreign facility outside the United States." In other words, foreign facilities involved in the initial stages of manufacturing/