

manufacture, process, pack, transport, distribute, receive, hold or import food intended for human or animal consumption in the United States to comply with the regulations in this subpart, unless you qualify for one of the exclusions proposed in § 1.327. In addition, foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States are subject to these regulations, unless you qualify for one of the exclusions proposed in § 1.327.

However, even if you qualify for one of the exclusions proposed in § 1.327, if you conduct more than one type of activity at a location, and some of that activity is not exempt, you would be required to keep records with respect to the statutorily covered activities. For example, in addition to selling food to consumers, a retail facility may have an onsite restaurant or counter that prepares food it sells to consumers. The restaurant activity is exempt from all of the regulations in this subpart; however, the retail activities are covered by § 1.336. Similarly, a retail facility may sell both food and nonfood products, and may even sell primarily nonfood products. Regardless of what proportion of the retail facility sells nonfood products, these proposed regulations would require the retail facility to keep records of the immediate previous source for all food it receives that is not exempted by an exclusion. The regulations do not apply to the nonfood products the retail facility receives.

Proposed § 1.326(b) would require compliance by persons who engage either in interstate or in intrastate activities involving food. The Bioterrorism Act does not limit the establishment and maintenance of records requirement only to persons directly engaged in interstate commerce. To the contrary, the Bioterrorism Act provides FDA with the authority to require the establishment and maintenance of records by all "persons" who engage in specified activities involving food. Therefore, FDA tentatively concludes that the statute allows FDA to require domestic persons to keep records, whether or not they engage in interstate commerce. Because a bioterrorist threat involving food or other food-related emergency would have the same effect on the public health regardless of whether the food had originated from an out of state source, FDA is proposing in § 1.326(b) that all persons who manufacture, process, pack, transport, distribute, receive, hold, or import food be subject to these regulations, whether or not they directly engage in interstate activities involving food. Nonetheless, because

FDA recognizes that this is an important and controversial issue, the agency is seeking comment on whether its tentative conclusion that it has authority to require recordkeeping by persons engaged in only intrastate commerce is correct. FDA also seeks comment on how many intrastate persons are not covered by one of the exemptions from the recordkeeping requirement (e.g., the farm or retail exemption) and we invite recommendations on what screening questions the agency could ask to enable a person to easily determine whether the person is engaged in interstate or intrastate commerce.

Proposed § 1.326(a) would also require compliance by foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States unless the facilities qualify for an exclusion under proposed § 1.327(f). FDA is proposing that the foreign facilities that are required to register under section 305 of the Bioterrorism Act also be required to establish and maintain records under section 306 of the Bioterrorism Act. (The foreign facilities that would be excluded from both the proposed registration and recordkeeping requirements are described in the discussion of proposed § 1.327(f).) FDA believes if these foreign firms were not required to establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food, trace back of food products from outside the United States would be severely compromised. FDA believes that this approach provides the most efficient and effective strategy for obtaining needed information on food from foreign countries. FDA plans to take the appropriate steps and work closely with foreign governments to obtain access to the needed records if a threat of serious adverse health consequences or death to humans or animals from adulterated food necessitates inspection of records in foreign countries.

The provisions of this proposed rule apply to records of both human food and animal food. FDA believes that some recordkeeping requirements are necessary for food intended for food-producing animals, as well as for certain food for nonfood-producing animals (e.g., pet dogs and cats, horses, and zoo and circus animals). We define food for nonfood-producing animals as pet food. FDA believes, however, that the consequences of a potential terrorist attack or food-related emergency are greater for human food than for animal food. FDA also believes that the consequences of a potential terrorist attack or food-related emergency are

greater for food for food-producing animals than for pet food. FDA addressed certain animal food risks in our regulation for animal proteins prohibited in ruminant feed (21 CFR 589.2000), also referred to as the bovine spongiform encephalopathy (BSE) rule.

Although FDA acknowledges that the risk to humans from an attack on the animal food supply is lower than the risk to humans from an attack on the human food supply, there is some risk to both humans and animals from an attack on the animal food supply. Contaminated animal food can be a link to human foodborne illness. (Ref. 32). People could be at risk through direct contact with animal food or through unintentional cross-contamination of cooking surfaces or utensils. Animals may also become infected and serve as a reservoir for exposing other animals and humans. For example, in 1996, an organochlorine pesticide was intentionally introduced into an ingredient used in animal food, including pet food. In 2002, dog chew treats were contaminated with *Salmonella* and became a vehicle to transmit *Salmonella* into homes. As a consequence, many pet owners became ill and one person died.

We propose that (1) All entities that manufacture, process, pack, transport, distribute, receive, hold, or import food for food-producing animals must keep records under this proposed rule; and that (2) those entities that manufacture, process, pack, transport, distribute, receive, hold, or import pet food that must keep records under the BSE rule also keep records under this rule. Because of the concern that some pet food is diverted for use for food-producing animals, the BSE rule recordkeeping requirements apply to pet food. We believe this proposal to require recordkeeping under the Bioterrorism Act by pet food entities covered by the BSE rule will provide important safeguards needed to limit the impact of contamination of pet food while minimizing additional costs to industry.

As discussed below, we are proposing to exempt pet food entities that are not subject to the recordkeeping requirements of the BSE rule from the recordkeeping requirements of this proposed rule. We propose that all entities involved in animal food, including the pet food entities exempt from the recordkeeping requirements, remain subject to the proposed records access and availability requirements.

FDA is interested in comments on whether or not the proposal provides adequate tools to trace animal food affected by a terrorist attack or other food related emergency and whether an