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1. Registration of Food Facilities Interim Final Rule: The interim final rule requires the owner, operator, or agent in charge of a domestic or foreign facility that manufactures, processes, packs or holds “food” (as defined in the rule) for human or animal consumption in the U.S. to register with the FDA no later than December 12, 2003. In the rule, “facility” is defined as “any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States,” whether the food is produced domestically or abroad. Private residences of individuals are not facilities. The FDA is also clarifying that the definition of “facility” is not limited to a single building, but is also understood to include several contiguous structures. The Bioterrorism Act exempts farms, restaurants, other retail food establishments, nonprofit food establishments in which food is prepared for or served directly to the consumer, and fishing vessels (with some exceptions) from the requirement to register. Foreign facilities that manufacture/process food are also exempt if food from those facilities undergoes further processing or packaging of a more than de minimis nature at another foreign facility.

2. The Bioterrorism Act requires a foreign facility to provide the name of its U.S. agent. The U.S. agent acts as a communication link between the FDA and the foreign facility. The U.S. agent will be the person the FDA contacts if an emergency occurs, unless the facility has identified a different emergency contact. The interim final rule specifically requests additional comments on the costs of maintaining a U.S. agent.