

in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico because section 415(b)(2) of the Bioterrorism Act (21 U.S.C. 350d(b)(2)) defines the term "domestic facility" to mean a facility in any of the States or Territories. Facilities that manufacture/process, pack, or hold food for consumption in Hawaii and the Northern Mariana Islands are thus required to register because these locations are respectively a State and a Territory of the United States.

(Comment 9) Several commenters responded to FDA's request for comments on whether it has authority to exempt domestic facilities engaged only in intrastate commerce from the registration requirement and if so, whether the agency should use that authority. The commenters agree with FDA's decision in the proposed rule to require facilities engaged in intrastate commerce to register. One commenter states that intrastate facilities should not be excluded because individuals wanting to contaminate the food supply could choose key States from which to launch an attack. This commenter also points out that foreign facilities are not exempt, even if they only import food into one State. Several commenters argue that requiring these foreign facilities to register, while exempting facilities engaged in intrastate commerce, is discrimination against foreign facilities.

(Response) In the preamble to the proposed rule, FDA tentatively concluded that the Bioterrorism Act requires all domestic facilities to register, whether or not they engage in interstate commerce. Accordingly, proposed § 1.225(b) stated that a domestic facility must register (unless otherwise exempt) "whether or not the food from the facility enters interstate commerce."

FDA sought comment on whether the agency has authority to exempt domestic facilities engaged only in intrastate commerce from the registration requirement and, if so, whether FDA should use that authority. FDA also asked for comment on the number of so-called "intrastate" facilities that would not be covered by one of the exemptions from registration. No one asserted that Congress could not require such facilities to register. Similarly, no one identified intrastate facilities that would not already be covered by one of the exemptions. As noted in the preamble to the proposed rule, FDA believes that most facilities that do not engage directly in interstate commerce would be covered by an exemption in the interim final rule (e.g.,

residences of private individuals, farms, restaurants, retail food establishments.)

The comments received agreed with FDA's decision in proposed § 1.225 to require all nonexempt facilities to register even if food from the facility does not enter interstate commerce. They agreed with FDA's position that having a central database including all facilities that manufacture/process, pack, or hold food would help achieve the goals of the Bioterrorism Act. Moreover, the commenters gave additional reasons why excluding so-called "intrastate" facilities from the registration requirement could be detrimental or inappropriate. Importantly, no comments presented any reason for excluding facilities from the registration requirement solely on the basis of whether the food from the facility enters interstate commerce.

FDA is mindful that its interpretation of the Bioterrorism Act should not cast doubt on the constitutionality of the statute. (*See Solid Waste Agency of Northern Cook County v. U.S.*, 531 U.S. 159 (2001)). The agency has considered the relevant provisions of the Bioterrorism Act, the comments submitted on this issue, FDA's responsibilities in implementing the Bioterrorism Act, and the law interpreting the commerce clause of the Constitution (Article I, section 8). Based on these considerations, FDA is retaining § 1.225(b) as proposed, with the result that all facilities that manufacture/process, pack, or hold food (unless otherwise exempt) must register even if food from the facility does not enter interstate commerce.

Significantly, the plain language of new section 415 of the FD&C Act does not exclude a facility from registration because food from such facility does not enter interstate commerce. Notably, sections 301 and 304 of the FD&C Act (21 U.S.C 334) demonstrate that Congress has included a specific interstate commerce nexus in the provisions of the FD&C Act when that is its intent. Accordingly, it is reasonable to interpret the Bioterrorism Act as not limiting registration only to those facilities with a direct connection to interstate commerce. Congress's power to legislate under the commerce clause is very broad. However, such power is not without limits, *see United States v. Lopez*, 514 U.S. 549, 567 (1995); *U.S. v. Morrison*, 529 U.S. 598, 618 (2000), and these limits have been construed in light of relevant and enduring precedents.

In particular, in *Lopez*, *supra*, the Supreme Court acknowledged the continuing vitality of *Wickard v. Filburn*, 317 U.S. 111 (1942), noting that

"although Filburn's own contribution to the demand for wheat may have been trivial by itself, that was not 'enough to remove him from the scope of federal regulation where, as here, his contribution, taken together with that of many others similarly situated, is far from trivial.'" (514 U.S. at 556.) This principle applies squarely to the registration provision of the Bioterrorism Act. Accordingly, given the collective impact on commerce of so-called "intrastate" facilities that manufacture/process, pack, or hold food, FDA has concluded that each such facility should be required to register regardless of whether food from that facility enters interstate commerce. Thus, FDA is retaining § 1.225(b) as proposed.

This outcome is consistent with section 709 of the FD&C Act (21 U.S.C 379a), which states that in any action to enforce the act's requirements respecting foods, drugs, devices, and cosmetics, any necessary connection with interstate commerce is presumed. Likewise, this outcome is consistent with Congress's goal in enacting the Bioterrorism Act because the potential harm from bioterrorist attacks or other food emergencies can be great, whether or not the food moves from one state to another. The usefulness of the registration database can also be significant in food emergencies where interstate shipment has not occurred. Finally, as noted, FDA received no comments identifying so-called "intrastate" facilities that would not otherwise be exempt from registration. Thus, this outcome, as a practical matter, should have little if any impact on which facilities must register. Accordingly, FDA concludes that it is appropriate to require facilities that do not fall within an exemption to register regardless of whether the food from the facility enters interstate commerce.

(Comment 10) One commenter states that the proposed rule requires all foreign and domestic facilities with operations that have an effect or impact on food to register unless subject to specific exemptions. The commenter believes that this is vague and not specific for imported shipments, especially fresh produce, and would require all parties having any contact with the produce to register. This commenter also argues that the party registering with FDA for produce shipments should be the exporter.

(Response) The commenter misunderstands the proposed rule. First, the statement that the rule would require registration by all facilities that "have an effect on food" is not accurate. As stated previously, both the