

is reasonably expected to be directed to a food use.

(Comment 63) Several commenters assert that processing aids, such as defoaming agents and biocides, are used in the production of food but are not food in and of themselves and thus facilities that manufacture/process, pack, or hold such substances need not register.

(Response) FDA notes that there are a wide variety of processing aids, including processing aids used in packaging and other food contact materials and processing aids used in "traditional" foods. The commenters do not specify which type or types of processing aids they believe are not "food" such that establishments that manufacture/process, pack, or hold these substances should not be required to register.

Whether a facility that manufactures/processes, packs, or holds a processing aid must be registered depends upon whether such a substance is "food" under this rule. As noted, for purposes of the interim final rule, "food" excludes "food contact substances" (section 409(h)(6)). In addition, "food" excludes "pesticides" (7 U.S.C. 136(u)). Thus, if the processing aid is not a pesticide and is intended to have a technical effect in the food to which it is added, the substance is not exempt from the definition of "food" and the facility must be registered unless otherwise exempt under § 1.226 (*i.e.*, if it is a foreign facility, and food from such facility undergoes further manufacturing/processing (including packaging) by another facility outside the United States). In terms of processing aids, this means that, generally speaking, facilities that manufacture/process, pack, or hold processing aids used in the production of "traditional" food will be required to register. This is a reasonable result in that such processing aids are intentionally and directly added to "traditional" foods.

(Comment 64) Several commenters request an exemption for facilities dealing with agricultural chemicals (fertilizer, pesticides) since these are not food for consumption and they are already registered with EPA. Several other comments asked whether facilities that manufacture/process, pack, or hold anti-microbial pesticides used in or on food must register.

(Response) As discussed in the response to comment 58, the meaning of "food" in section 415 is ambiguous. Therefore, FDA may define "food" in a reasonable manner. FDA believes that excluding "pesticides" (7 U.S.C. 136(u)) from the definition of food is

reasonable. Agricultural pesticides, including those used in or on food for human or animal use, are comprehensively regulated by the Federal Government. Under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.*, all pesticides (both food and nonfood use) are registered with EPA. As part of the registration process, establishments in which pesticides are produced must register with EPA (40 CFR 167.3 and 167.20). As part of the importation process, prior notice of all pesticide shipments must be given to EPA (19 CFR 12.112).

Importantly, the Federal regulatory scheme for pesticides was substantially revised in 1996 by the Food Quality Protection Act (FQPA) (Public Law 104-170), and EPA's authority over pesticides was consolidated and also expanded. As a result of FQPA, pesticides and their residues are subject to substantial and comprehensive regulation by EPA. Where another Federal agency has the types of specific and comprehensive authority described above to regulate the safety of certain substances (here, pesticides), FDA believes that it is appropriate to interpret "food" in section 415 of the FD&C Act to not include such substances. Accordingly, FDA has revised the definition of "food" in § 1.227(b)(4) to exclude pesticides as defined by FIFRA (7 U.S.C. 136(u)). Therefore, FDA agrees that facilities that manufacture/process, pack, or hold "pesticides intended for use in or on food" need not register with FDA.

(Comment 65) Several comments asked whether facilities that manufacture/process, pack, or hold antimicrobial pesticides used in or on food must register.

(Response) As noted previously, for the purposes of this rule, the term "food" is defined to exclude any substance defined as a "pesticide" in FIFRA (7 U.S.C. 136(u)). Anti-microbial pesticides meet the FIFRA definition of "pesticide." Thus, facilities that manufacture/process, pack, or hold such substances are not required to register.

(Comment 66) Several commenters question how live food animals relate to the definition of food. One commenter indicates that many small animals are shipped to the United States with the intention to grow them in the United States for food and thus, such animals are not animals for food at the time they are imported. This commenter asks FDA to exempt live food animals from the definition of food.

(Response) As discussed in the response to comment 58, the meaning of "food" in section 415 is ambiguous.

Therefore, FDA may define "food" in a reasonable manner. FDA believes that it is reasonable to interpret "food" in section 415 to include live animals. First, such inclusion is consistent with the language in section 415(a), "food for consumption," in that live animals are raw material for, and thus reasonably considered components of, items traditionally consumed for taste, aroma, or nutritive value. Moreover, the products of live food animals are an integral part of the food consumed in the United States, and thus, it is logical to protect the raw materials (*i.e.*, the live animals) and such animal food products by including them under the Bioterrorism Act's safeguards. Second, Congress provided several statutory exemptions from the registration requirement, including "farms," section 415(b)(2), which would reasonably include those raising animals as well as those growing fruits and vegetables. By exempting farms, Congress indicates that, absent an exemption, establishments where fruits, vegetables, and animals are produced would be "food facilities" subject to registration. Third, the inclusion of live animals in the definition of "food" is consistent with the statutory language of the Bioterrorism Act as a whole. In particular, the recordkeeping, administrative detention, and prior notice provisions of the Bioterrorism Act all include an explicit reference to animals in the statutory standard, "serious adverse health consequences or death to humans or animals." (*See, e.g.*, 21 U.S.C. 334(h)(1)(A), 350c(a), and 381(m)(2)(B)(ii).) In each of these provisions, this standard serves as a trigger for FDA action. This standard does not appear in the registration provision, because there is no need for a trigger for FDA action in registration. FDA does not believe that the fact that this standard does not appear in the registration provision evidences the intent on the part of Congress that facilities that manufacture/process, pack, or hold live animals need not register. Accordingly, the interim final rule's definition of "food" includes live food animals.² FDA notes, however, that a facility that exports live food animals directly to the United States may be exempt as a "farm" if it satisfies the definition in § 1.227(b)(3).

(Comment 67) Some commenters ask that research and development (R&D) facilities and facilities that manufacture/

²Defining "food" to include live animals is also consistent with the case law interpreting the term "food" in the broader context of the act. (*See United State v. Tuente Livestock*, 888 F. Supp. 1416 (S. D. Ohio, 1995).)