

Importantly, FDA still considers food packaging and other food contact substances to be “food” within the meaning of section 201(f) of the FD&C Act when they, or their components, migrate into other food. Therefore, these items are still “food” for purposes of the other provisions of section 801 of the FD&C Act (with the exception of section 801(l), which shares the same definition of food as section 801(m)). Accordingly, although not subject to the section 801(m) of the FD&C Act requirement of prior notice, food packaging materials and other food contact substances will remain, as they have been, subject to determinations of admissibility under section 801(a) of the FD&C Act.

**b. Food processing aids.** (Comments) One comment argues that food processing aids and “indirect food additives” should not be considered food for purposes of section 801(m) of the FD&C Act. According to the commenter, these substances resemble food contact substances, which Congress, as evidenced by the prior notice legislative history of food contact substances, did not expect FDA to subject to prior notice.

(Response) Whether a food processing aid or “indirect additive” is subject to prior notice 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” as defined at section 409(h)(6) of the FD&C Act. Among other things, unlike food processing aids and “indirect additives,” “food contact substances” are not “intended to have any technical effect in food,” section 4091(h)(6) of the FD&C Act. In addition, “food” excludes pesticides as defined at 7 U.S.C. 136(u). Thus, if the substance is not a pesticide and is intended to have a technical effect in the food being processed, the substance is not exempt from the definition of “food” under § 1.276(b)(5) in the interim final rule. This is a reasonable result in that such processing aids are intentionally and directly added to “traditional” foods.

**c. Antimicrobial pesticides.** (Comments) One comment expresses concern about including antimicrobial pesticides within the scope of this regulation. The comment states that pesticides are imported pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), not the FD&C Act, and are subject to Environmental Protection Agency (EPA) approval before they are admitted to the United States. The comment asks that FDA clarify that this regulation is not applicable to antimicrobial pesticides with FDA and/or EPA approved food

contact uses. The comment states that including antimicrobial pesticides within the scope of this regulation would impose unnecessary burdens on antimicrobial pesticide registrants, without enhancing the protection of the food supply.

(Response) As discussed previously, the meaning of “food” in section 801(m) of the FD&C Act is ambiguous. Therefore, FDA may define “food” in a reasonable manner. FDA believes that excluding pesticides from the definition of food is reasonable. Pesticides, including those used in or on food for human or animal use, are comprehensively regulated by the Federal Government. Under FIFRA, 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 pesticide shipments must be provided 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) (Pub. L. 104–170), and EPA’s authority over pesticides was consolidated and 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 previously to regulate the safety of a substance, FDA believes that it is appropriate to interpret “food” in section 801(m) of the FD&C Act as not including that substance. Accordingly, FDA has revised the definition of “food” in § 1.276(b)(5) to exclude pesticides as defined by FIFRA.

**d. Chemicals** (Comments) One comment seeks clarification as to whether chemicals are considered “food.” The comment expects that chemicals intended for human consumption will likely be included in the requirements for prior notice.

(Response) We are not sure exactly what substances or products the comment refers to; “chemicals” is a very broad term. Unless excluded because they are food contact substances or pesticides, chemicals that are “used for food or drink” or are “used for components of any such articles” are “food” under section 201(f) of the FD&C Act and the definition in the interim final rule (§ 1.276(b)(5)). If the substance is used in some applications that make the substance “food” and some that do not, the principles applicable to further

processing and multi-use substances, set out in the following paragraphs, apply.

**e. Live animals.** (Comments) Two comments address inclusion of live animals. One comment urges FDA to exempt live food animals from this regulation, as it will have far-reaching impacts on all Canadian farmers who export live food animals to the United States. The other comment asks for clarification as to how prior notice applies to live food animals imported for further processing, such as finishing.

(Response) As discussed previously, the meaning of “food” in section 801(m) of the FD&C Act is ambiguous. Therefore, FDA may define “food” in a reasonable manner. FDA believes that it is reasonable to interpret “food” in section 801(m) of the FD&C Act to include live animals. Such inclusion is consistent with the explicit reference to animals in the statutory standard, “serious adverse health consequences or death to humans or animals” in section 801(m)(2)(B)(ii) of the FD&C Act—the provision that relates to FDA review of prior notices submitted for food refused for lack of adequate prior notice. In addition, it is consistent with the legislative history of section 801(m) of the FD&C Act that refers only to the exclusion of food contact substances. 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) by including them under the Bioterrorism Act’s safeguards. Finally, the inclusion of live animals in the definition of “food” is consistent with the reasonable interpretation of the registration provision, section 415 of the FD&C Act. Accordingly, the interim final rule’s definition of “food” includes live food animals. Defining “food” to include live animals is also consistent with the case law interpreting the term “food” in the broader context of the FD&C Act. See *United States v. Tuente Livestock*, 888 F. Supp. 1416 (S.D. Ohio, 1995).

**f. Articles for further processing or capable of multiple uses.** (Comments) Some comments ask that FDA clarify that the definition of “food” does not include substances that are not edible, but may be further processed to be rendered edible, for example, crude vegetable oils, crude petroleum, and minerals such as phosphates which may be refined and processed into food ingredients such as glycerin and phosphoric acid. The comments state that where bulk commodities have potential food and nonfood uses, there should be an exemption from import notification where these commodities have not been sufficiently refined to be