

§ 152.114

amended registration of a pesticide product, each of whose active ingredients is contained in one or more other registered pesticide products, only if the Agency has determined that:

(1) It possesses all data necessary to make the determinations required by FIFRA sec. 3(c)(7)(A) or (B) with respect to the pesticide product which is the subject of the application (including, at a minimum, data needed to characterize any incremental risk that would result from approval of the application);

(2) Approval of the application would not significantly increase the risk of any unreasonable adverse effect on the environment; and

(3) The criteria of §152.112(a), (d), and (f) through (h) have been satisfied.

(b) Notwithstanding the provisions of paragraph (a) of this section, the Agency will not approve the conditional registration of any pesticide under FIFRA sec. 3(c)(7)(A) unless the Agency has determined that the applicant's product and its proposed use are identical or substantially similar to a currently registered pesticide and use, or that the pesticide and its proposed use differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment.

(c) Notwithstanding the provisions of paragraph (a) of this section, the Agency will not approve the conditional registration of any pesticide product for a new use under FIFRA sec. 3(c)(7)(B) if:

(1) The pesticide is the subject of a special review, based on a use of the product that results in human dietary exposure; and

(2) The proposed new use involves use on a major food or feed crop, or involves use on a minor food or feed crop for which there is available an effective alternative registered pesticide which does not meet the risk criteria associated with human dietary exposure. The determination of available and effective alternatives shall be made with the concurrence of the Secretary of Agriculture.

40 CFR Ch. I (7-1-06 Edition)

§ 152.114 Approval of registration under FIFRA sec. 3(c)(7)—Products that contain a new active ingredient.

An application for registration of a pesticide containing an active ingredient not in any currently registered product may be conditionally approved for a period of time sufficient for the generation and submission of certain of the data necessary for a finding of registrability under FIFRA sec. 3(c)(5) if the Agency determines that:

(a) Insufficient time has elapsed since the imposition of the data requirement for those data to have been developed;

(b) All other required test data and materials have been submitted to the Agency;

(c) The criteria in §152.112(a), (b), (d), and (f) through (h) have been satisfied;

(d) The use of the pesticide product during the period of the conditional registration will not cause any unreasonable adverse effect on the environment; and

(e) The registration of the pesticide product and its subsequent use during the period of the conditional registration are in the public interest.

§ 152.115 Conditions of registration.

(a) *Substantially similar products and new uses.* Each registration issued under §152.113 shall be conditioned upon the submission or citation by the registrant of all data which are required for unconditional registration of his product under FIFRA sec. 3(c)(5), but which have not yet been submitted, no later than the time such data are required to be submitted for similar pesticide products already registered. If a notice requiring submission of such data has been issued under FIFRA sec. 3(c)(2)(B) prior to the date of approval of the application, the applicant must submit or cite the data described by that notice at the time specified by that notice. The applicant must agree to these conditions before the application may be approved.

(b) *New active ingredients.* Each registration issued under §152.114 shall be conditioned upon the applicant's agreement to each of the following conditions: