

“inert ingredients” or “other ingredients.” Under FIFRA, an “inert ingredient” is defined as “an ingredient which is not active.” FIFRA sec. 2(m). EPA uses the term, “formulation,” to refer to the particular combination of active and inert ingredients in a pesticide product. A pesticide “use” refers to the particular combination of circumstances under which a pesticide product may be applied, such as the rate, timing, method, and site of application.

1. *The statutory framework for regulation of new pesticide products.* FIFRA generally prohibits the sale or distribution of a pesticide product unless it has first been “registered” by EPA. FIFRA sec. 12(a)(1)(A). EPA issues a license, referred to as a “registration,” for each specific pesticide product allowed to be marketed; the registration approves sale of a product with a specific formulation, in a specific type of package, and with specific product labeling for a specific use. Each product is evaluated on a case-by-case basis.

FIFRA requires a person seeking to register a pesticide to demonstrate that the proposed product meets the statutory standard. EPA may approve the unconditional registration of a pesticide product only if the Agency determines, among other things, that use of the pesticide would not cause “unreasonable adverse effects on the environment.” FIFRA sec. 3(c)(5). The statute defines “unreasonable adverse effects on the environment” to include “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide. . . .” FIFRA sec. 2(bb).

When EPA registers a pesticide, it approves among other things a specific set of labeling for the product which contains directions for and restrictions on use of the product. Labeling includes any written or graphic material attached to the product container, i.e., the label, as well as other material accompanying the product or referenced on the label. FIFRA sec. 2(p). FIFRA makes it unlawful for any person “to use any registered pesticide in a manner inconsistent with its labeling.” FIFRA sec. 12(a)(2)(G). Thus, directions and restrictions appearing on, or referenced in, a pesticide product label become enforceable Federal requirements. Under FIFRA, most States have primary responsibility for enforcement against pesticide misuse. See FIFRA sec. 26.

While most regulatory decisions allowing entry of new pesticide products into the marketplace are made by EPA in its registration program, there are two other programs that can

authorize the use of new pesticides. Under section 18 of FIFRA, EPA may allow the use of an unregistered pesticide product by a State or Federal agency when necessary to address an emergency situation. Under EPA’s regulations, a petition for an exemption must establish that “emergency conditions” -- defined as “an urgent, non-routine situation that requires the use of a pesticide . . .” -- exist and that no effective, currently registered pesticide or non-pesticidal pest control method is available. 40 CFR 166.4(d). The emergency exemption regulations provide that EPA will not approve a request unless EPA determines, among other things, the use of the pesticide product will not cause unreasonable adverse effects on the environment. 40 CFR 166.25(b). In addition, under certain limited circumstances, States may approve a new use of a currently registered pesticide product to meet a “special local need.” FIFRA sec. 24(c). EPA’s regulations limit States’ exercise of this authority only to the approval of products that contain active ingredients that are present in a currently approved pesticide product and give EPA broad authority to disapprove products intended for uses that are not closely related to existing uses. See 40 CFR 162.152. States must notify EPA when they exercise this authority and a State’s registration shall not be effective for more than 90 days if disapproved by EPA within that period. FIFRA sec. 24(c)(2).

2. *The statutory framework for regulation of existing pesticide products.* In addition to a registration program for new pesticide products, EPA conducts a “reregistration” program. Reregistration focuses on currently registered pesticides and involves a systematic reexamination of the scientific data to determine whether the pesticides continue to meet contemporary scientific and regulatory standards. See FIFRA sec. 4. Among other things, EPA assesses whether there are adequate data to determine if the statutory standard is met. FIFRA gives EPA authority to require registrants to provide data if EPA “determines [the] additional data are required to maintain in effect an existing registration of a pesticide.” FIFRA sec. 3(c)(2)(B). (Imposition of such additional data requirements is subject to the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 - 3520). In the past, EPA has used this authority to require registrants to conduct studies that would provide additional data needed for the evaluation of potential hazards of and

exposures to pesticide products. EPA uses such data to assess pesticide risks and to determine whether changes in the terms and conditions of registration would be appropriate. In many cases, EPA’s reregistration review has concluded that additional risk mitigation measures were necessary to reduce potential harm to non-target plants and wildlife populations. Many registrants voluntarily have amended their products’ registrations to implement these risk mitigation measures. If, however, registrants do not adopt needed risk mitigation, EPA may impose the requirements through cancellation or suspension proceedings, conducted pursuant to FIFRA sec. 6 and 40 CFR part 164.

EPA may issue a Notice of Intent to Cancel the registration of a pesticide if it appears that the continued use of the pesticide “generally causes unreasonable adverse effects on the environment.” FIFRA sec. 6(b). Thus, the standard for approving a pesticide’s entry into the marketplace and the standard for retaining a pesticide on the market is based on a determination relative to “no unreasonable adverse effects” Because cancellation proceedings can be lengthy, FIFRA also contains provisions allowing EPA to “suspend” the registration and use of a pesticide, prior to the completion of a cancellation process, if use of the pesticide poses an “imminent hazard.” FIFRA sec. 6(c). FIFRA defines an “imminent hazard” as “a situation which exists when the continued use of a pesticide during the time required for [a] cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened under [the Endangered Species Act].” FIFRA sec. 2(l).

3. *Ecological risk assessment.* In deciding whether a pesticide product meets the statutory standards for registration or reregistration, EPA considers, among other things, the potential risks to non-target wildlife and plant species posed by use of the pesticide product. EPA’s evaluation of such environmental risks follows the principles contained in its Guidelines for Ecological Risk Assessment. (EPA 1998). In 1986, EPA developed detailed guidance for the review and analysis of potential environmental risks from use of pesticide products. See Standard Evaluation Procedures (SEP) for Ecological Risk Assessment (EPA 1986). Since 1986 EPA has made many additions and refinements to the basic approach outlined in the SEP. All of