

FIFRA GENETICALLY MODIFIED PLANT PESTICIDES

BACKGROUND

Recent advances in biological science allow the introduction of genetic material into plants to cause those plants to produce pesticidal substances. EPA has determined that genetically induced plant pesticides warrant regulatory oversight since there is a potential for novel dietary and environmental exposure of the pesticidal substances.

On November 23, 1994, (59 FR 60495) EPA published a statement of proposed policy and proposed rulemaking clarifying the status of plant pesticides. In this statement EPA indicated its intent to regulate plant pesticides other than those determined to be of low potential for risk, and proposed a regulatory framework, including definitions and proposed exemptions. EPA described in the proposed rule that it considers a plant pesticide to consist of a combination of both the pesticidal substance and the genetic material that induces its production in the plant. As of August, 2000, the final rule was anticipated to be published late in calendar year 2000. When final, the rule will be available on the OPP web site.

PLANT PESTICIDE REGULATION

EPA issued its first plant pesticide experimental use permit (EUP) in 1994 and its first registration in 1995. Since 1995 a limited number of registrations have been issued. As of year 2000 the majority of registrations have been for *Bacillus thuringiensis* (B.t.) in crops.

EPA has determined to place its regulatory oversight of plant pesticides prior to seed distribution, with the intention of

preventing potentially harmful genetic traits from entering the channels of trade. Close regulation occurs prior to registration. Conditions of experimental use permits, including permits that may allow increase in seed stock, control the distribution and use of experimental seed material. Experimental plant pesticide material is subject to FIFRA in the same manner as experimental chemicals, including record-keeping and production establishment production requirements.

When a registration is issued, it identifies the registered pesticide product as what is applied to the seed stock by the registrant at an early stage of crop seed production. The 'treated' seed is considered exempt from further FIFRA regulation as long as its use complies with the treated article exemption at 40 CFR 152.25(a). This means that subsequent seed production does not have to comply with requirements such as FIFRA sections 7 and 8. The seed that is sold does not have to be labeled as a pesticide, and the use of transgenic seed by farmers is not controlled by FIFRA.

Seed production and distribution which is exempted FIFRA may be reportable on a case-by-case basis by registrants as conditions of registration. The Office of Pesticides Programs, Biopesticides and Pollution Prevention Division may be contacted to obtain information regarding whether sales and use data are available for specific plant pesticides.

POTENTIALLY VIOLATIVE PLANT PESTICIDE ACTIVITIES

Since proper use of registered plant pesticides exempts products in commerce and use from FIFRA regulatory oversight, potential violations are generally likely only with respect to unregistered plant pesticides, including plant pesticides that are at pre-registration (e.g., experimental use permit) stages. The distribution or sale of unregistered plant pesticides is potentially violative under FIFRA section 12(a)(1)(A). The use of a plant pesticide under an experimental use permit in a manner contrary to the provisions of the permit is violative under section 12(a)(2)(H).

Plant pesticides may, as may any pesticide, be exempted by rule or by statute from FIFRA regulatory coverage. General exemptions (e.g., at 40 CFR 152.25 and 152.30) may apply to plant pesticides. Specific plant pesticides or categories of plant pesticides may be exempted by rulemaking. Statutory exemptions under FIFRA section 17, which apply to pesticides intended solely for export, also apply to plant pesticides intended solely for export.

Plant pesticides that are registered, or are under an experimental use permit, or that are unregistered but transferred under an exemption that allows transfer but does not categorically exempt the product from FIFRA oversight (e.g., exemptions at 40 CFR 152.30 and FIFRA section 17(a)), are subject to section 7 reporting and section 8 record-keeping, and if noncompliant are potentially violative under FIFRA sections 12(a)(2)(B) and (L). In the case of

registered pesticides, however, these requirements may apply to very limited circumstances, since seed treated with registered product are not subject to FIFRA.

COMPLIANCE MONITORING

Compliant product in the channels of trade is exempt from FIFRA and hence not subject to routine compliance monitoring. Tips or complaints will be the chief means for identifying product which is potentially not compliant and therefore subject to FIFRA. The linkage between section 3 registration compliance and FIFRA applicability requires that headquarters (OPP and OECA) be consulted on all investigations.

RESPONSES TO VIOLATIONS

Distribution or use of unregistered transgenic seed may trigger actionable violations under sections 12(a)(1)(A) or 12(a)(2)(H). The shipment may be subject to SSURO or seizure under section 13, and civil or criminal penalties as appropriate under section 14.