

5E-2.031 Pesticide Registration; Exemptions from Registration; Experimental Use Permits.

(1) For each application for any new, amended, or renewed pesticide registration, the department may require, in support of registration for sale and use in the State of Florida, summaries of data from pesticide efficacy studies and submission of scientific evidence that the pesticide will not cause any unreasonable adverse effects on public health or the environment.

(a) Material submitted to the department considered by the registrant to contain trade secrets or to be confidential shall be clearly marked "confidential" by the applicant or registrant. Confidential material shall not be distributed to any persons other than those specified by Chapter 487, F.S. Public disclosure of confidential data by any person to whom the data has been distributed shall be unlawful as provided in Section 487.031(5), F.S.

(b) Data considered confidential property of another registrant or manufacturer may be cited in an application to the department if written permission has been obtained from that registrant or manufacturer and is submitted to the department with the application.

(c) The department, upon finding that an applicant or registrant has withheld results or has submitted false or inaccurate data which precludes the department's ability to conduct valid risk assessments, shall initiate action to deny, cancel, or suspend registration pursuant to Section 487.041 and Chapter 120, F.S.

(d) Those registrants whose end-use product must be registered in Florida pursuant to Section 487.041(1), F.S., but which do not manufacture the federally registered basic technical grade material shall comply with the data requirements of this rule only as it pertains to the end-use product. Such registrants shall request the manufacturer supplying the basic technical grade material to provide the department with required data as it pertains to the technical grade material.

(e) The department will waive specific data requirement provisions of this rule for registration of products for which such data requirements are not pertinent to risk assessment procedures or for those applications for registration for which the department possesses a sufficient data base. The United States Environmental Protection Agency (EPA) "exclusive use of data" provisions of Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), September 28, 2012, which is hereby adopted and incorporated by reference and available online at <http://www.flrules.org/Gateway/reference.asp?No=Ref-04758> shall be recognized.

(2) Applications for Registration.

(a) Applications for Registration shall contain necessary scientific evidence in the form of data summaries accurately reflecting all scientific documents submitted to the U.S. Environmental Protection Agency (EPA) in support of federal registration under Section 3, FIFRA as adopted in paragraph (1)(e) of this rule.

(b) Upon determination that submitted data summaries are inadequate to complete public health and environmental assessments, the department shall require applicants or registrants to submit or generate additional data, as specified by the department, and by methods approved by the department. For standard tests, methods shall be those approved by the EPA in 40 CFR 158, July 1, 2013, which is incorporated by reference herein at <http://www.flrules.org/Gateway/reference.asp?No=Ref-04757>.

(3) Review of applications for registration shall consider, where applicable, criteria in the data summaries including:

(a) Product chemistry data, which shall provide information regarding key chemical properties that may influence a pesticide's relative susceptibility to leaching into groundwater and its relative stability in groundwater, shall describe the parent compound, degradation products, contaminants and impurities of toxicological concern. Chemistry data shall include but is not limited to: water solubility, vapor pressure, and soil partition coefficient based on organic carbon (K_{oc}) and octanol/water (K_{ow}). The product material safety data sheet and confidential statement of formula shall also be included. Formulators shall declare, on their submitted confidential statement of formula, the name(s) of the manufacturer(s) supplying the basic technical grade material for their end-use products and the EPA registration number for each technical grade material.

(b) Toxicological data, which shall provide information for human risk assessment and for environmental impact assessment of the pesticide on non-target organisms (plants, wildlife, aquatic and soil organisms). Toxicological data shall describe effects of the parent compound and degradation products, contaminants and impurities of toxicological concern.

(c) Environmental fate data, which shall describe the pesticide's behavior under Florida conditions or under laboratory or field protocol which adequately represents and reflects actual Florida hydrogeologic conditions. Environmental chemistry data shall include, information regarding physical and chemical degradation, metabolic transformation, persistence (half-life), bioaccumulation potential, and mobility of the pesticide. Degradation and metabolism data shall describe the behavior of the parent compound and degradation products, contaminants and impurities of toxicological concern in soil and water, under aerobic and anaerobic conditions.

(d) Residue chemistry data which describes pesticide residues detected in or on applicable crops, processed foods and animal feed in accordance with the provisions of 40 CFR 158, as adopted in paragraph (2)(b) of this rule. Registrants shall, where

applicable, submit methodology for determination of residues in soil and water (groundwater). Analytical methodology provided by the applicant for determination of residues must be acceptable to the department.

(e) Worker/applicator safety data, which shall provide evidence that use of the pesticide in accordance with the label does not pose any unreasonable risk to applicators or agricultural workers exposed to treated areas or commodities.

(4) The department shall consider data from authoritative sources in making determinations regarding a pesticide's impact on public health and the environment. "Authoritative sources" include pesticide experts in the United States (U.S.) Environmental Protection Agency's Office of Pesticide Programs, U.S. Fish and Wildlife Services, U.S. Food and Drug Administration, Centers for Disease Control and Prevention, pesticide registrants, the Florida Department of Environmental Protection, the Florida Fish and Wildlife Conservation Commission, the Florida Department of Health, the University of Florida's Institute of Food and Agricultural Sciences, the Florida Fruit and Vegetable Association, the Florida Fertilizer and Agricultural Association, and the University of Florida's County Extension Offices. Within the department, the Bureau of Scientific Evaluation and Technical Assistance shall identify those areas of concern for which further testing is needed.

(a) In those cases in which data are not available and require substantial time to generate (e.g., chronic toxicity data), the department shall either deny or conditionally approve registration pending generation of said data by the applicant, registrant or other sources, pursuant to paragraph (6)(c) of this rule. At such time as data become available, the department shall reevaluate any conditional registrations to which said data may pertain.

(b) When it is determined by the department that it is necessary that the applicant or registrant conduct Florida field testing of a restricted-use pesticide, that applicant or registrant shall apply to the department for an Experimental Use Permit. During the period of experimentation, the department may deny, revoke, suspend or conditionally accept the registration.

(5) The department shall subject applications for registration to timely review and evaluation. Upon notification of the applicant or registrant by the Bureau of Pesticides of additional data requests, pursuant to Section 120.60(2), F.S., the department shall specify the amount of time that will be provided for response to the request. If, upon expiration of the time allocated for response, the department has not received a complete written response from the applicant or registrant, the department may deny, cancel or suspend registration, or for good cause as demonstrated by the applicant or registrant, grant an extension to the time allocated to submit the requested data.

(6) The department, upon preliminary review of application data shall promptly register products accepted by the EPA under FIFRA, Section 3, as adopted in paragraph (1)(e) of this rule, provided submitted data are adequate to address Florida-specific concerns. The Bureau of Scientific Evaluation and Technical Assistance, within 90 days of receipt of complete data summaries, shall:

(a) Fully approve the registration; or

(b) Conditionally register the product subject to generation and submission of data designated by the Bureau of Scientific Evaluation and Technical Assistance within the department or require that certain restrictions or limitations be placed on the use or sale of the pesticide in Florida. Such restrictions or limitations shall be described to the applicant or registrant by the department as part of this notification; or

(c) Notify the applicant or registrant of intent to deny registration, and the basis for denial, pursuant to Chapter 120, F.S.

(7) In cases where the department determines that restrictions, limitations, or conditions attached to registration are warranted, such restrictions, limitations or conditions shall be accomplished.

(a) By label: registrants may list restrictions, limitations or conditions as pertains to Florida on the product label; or

(b) By rule: restrictions, limitations or conditions may be promulgated into rules of the department which regulate the sale and use of the product. Registrants shall cooperate with the department to disseminate the contents of those rules which apply to their product.

(8) If during the registration process, or at any time after full or conditional registration is accepted, the registrant determines that there is preliminary or conclusive scientific evidence of any adverse effects or risk to public health or the environment from use of the pesticide, the registrant shall immediately submit to the department the data and conclusions made by the registrant with respect to said evidence.

(9) The department may, at any time, review and evaluate any registered pesticide, if new information is made available which indicates that use of a pesticide has caused or may cause any unreasonable adverse effect on public health or the environment. Such review and evaluation may result in revocation, cancellation or suspension of a pesticide registration, if risk assessment procedures deem such actions appropriate.

(10) As a result of review of a registered pesticide or application for registration, the department may require that the applicant or registrant design a groundwater and/or surface water and soil monitoring program which will monitor pesticide use locations for groundwater and/or surface water contamination, and accumulation of soil residues. Such monitoring programs shall be designed and implemented in coordination with appropriate state agencies.

(11)(a) Applicants for new or amended pesticide brand registration must submit electronically an application and any pesticide registration fees, including supplemental fees and late fees via the Department's online payment website at www.FreshFromFlorida.com. An applicant will be required to submit online at this website the following information for registration of a new or amended pesticide product brand: the name of the applicant, including whether it is a division or subsidiary and if so, the name of the parent company; the business mailing address and business street address of the applicant; the name of the primary contact person for the applicant and contact information, including e-mail address, telephone number and fax number; the product name and the EPA/Florida number; the registration type; the signal word for the product; and the registration year. Upon completion of this transaction, a confirmation of payment letter shall be mailed to the Florida Department of Agriculture and Consumer Services, Bureau of Scientific Evaluation and Technical Assistance, 3125 Conner Boulevard, Building 6, MS #L6, Tallahassee, Florida 32399-1650 together with the following documents:

1. One final printed label (that which appears on the product container);
2. One EPA stamped accepted label including a copy of any EPA comment, notification and amendment letter(s) issued in connection with acceptance of the label;
3. One Safety Data Sheet (SDS) as defined in Section 487.2031, F.S., which includes a statement of emergency treatment;
4. For sub-registrations, the information required in item 2. above must be obtained from or submitted by the manufacturer along with the EPA form entitled, "Notice of Supplemental Distribution of a Registered Pesticide Product" EPA Form 8570-5, (Rev. 8-94), which is hereby adopted and incorporated by reference and available online at <http://www.flrules.org/Gateway/reference.asp?No=Ref-04759>.

(b) Applicants for pesticide brand product re-registration must submit electronically an application for re-registration via the Department's online payment website at www.FreshFromFlorida.com. The applicant will be required to submit the same information online set forth in paragraph (11)(a) of this rule as an applicant for a new or amended product brand registration.

Rulemaking Authority 487.041, 487.051, 570.07(23) FS. Law Implemented 487.041, 487.042, 487.051 FS. History—New 2-20-85, Formerly 5E-2.31, Amended 8-2-89, 7-18-95, 8-26-10, 11-30-14.