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REGISTRATION OF PESTICIDES BY EPA
SECTION 3

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As mentioned by Mr. Matheny, Section 3 Regulations of FIFRA, published July 3, 1975 (40FR28267), require the submission of chemistry, toxicology, and efficacy data for registration. The EPA uses these data to determine if a product, when used according to label directions, is effective for the purpose claimed without causing unreasonable effects on man or the environment. Described below are the basic types of data required.

General Chemistry

The purpose of general chemistry data is to characterize the basic properties of the formulated product and its components and to determine physical or chemical hazards of the product. These requirements include information on the complete composition of the technical chemical, including the chemical names and percentages of impurities; the basic manufacturing process of the technical chemical; the purity of the starting and intermediate materials used in the manufacturing process; the basic physical and chemical characteristics of each active ingredient; and the analytical methods for the principal components and impurities. Also included is information on the complete composition of the formulated product, including the name and percentage of each active or inert ingredient; the basic manufacturing process of the pesticide formulation; the storage stability of the product, under the anticipated exposure conditions during the expected shelf-life period; and the method of analysis for identifying and quantifying each active ingredient in the pesticide formulation.

Environmental Chemistry

The purpose of environmental chemistry data is to assess the fate of the formulated product and its degradation products in the environment. These requirements cover field stability data on each active ingredient, indicating the dissipation time and its modes of degradation or metabolism; accumulation data for target or non-target species for each active ingredient, metabolite, or degradation product; and mobility data, including volatility and leaching properties. If significant potential for movement in soil can reasonably be anticipated, then additional data on movement will be required. The requirements also cover data on the safe methods for disposal of the pesticide product and container.

Human and Domestic Animal Toxicology

The purpose of human and domestic animal toxicology data is to determine the hazard

of the product to man and domestic animals. These requirements include acute toxicity data based upon oral, dermal, inhalation, and ocular routes of exposure; subacute and chronic data for specific chemicals and use patterns; diagnostic, first aid, palliative or antidotal data; and reentry data for cholinesterase-inhibiting chemicals.

Fish and Wildlife Toxicology

The purpose of fish and wildlife data is to assess the hazard of the product to fish, bird, and other non-target animals. These requirements encompass acute and subacute data on avian species (upland game and waterfowl) and acute toxicity on fish species (cold water and warm water). Depending on the use pattern and chemical, these requirements may also include studies on avian reproduction, aquatic invertebrates, simulated field tests, or field monitoring and observation.

Phytotoxicity

The purpose of phytotoxicity data is to reveal the toxic effects of a product to plants. These requirements cover data for target plants when the product is applied on or near the plant and data for non-target plants if volatilization, leaching or lateral movement in soil is involved.

Efficacy

The purpose of efficacy data is to substantiate effectiveness claims made for the product. For rodenticides applied as baits and ground sprays in orchards, the requirements include acute and subacute toxicity studies; laboratory acceptance studies for baits; laboratory efficacy studies; and field efficacy studies.

Registration Guidelines

The amended FIFRA requires the EPA to publish guidelines for pesticide registration. The purpose of these guidelines is to provide the Agency, the registrant, and the general public with the types of data upon which registration decisions are being made. The EPA published proposed guidelines on June 25, 1975 (40FR26802). Based on comments reveived from the general public, industry, and universities, we are revising these guidelines. When published in their final form, they will provide specific guidance on the data requirements for major groups of pesticides, including rodenticides applied in orchards.