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CALIFORNIA REGISTRATION PROCEDURES RELATIVE TO VERTEBRATE PESTICIDES

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I am very happy to be here today and to have the opportunity to talk to you about the Department of Food and Agriculture, with particular emphasis on the Department's role in registering pesticides and how this relates to Federal registration. My comments will address all pesticides including vertebrate pesticides.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Environmental Protection Agency (EPA) has broad and flexible authority. The FIFRA is a comprehensive regulatory statute and under it the EPA determines the pesticides that may be registered and for what uses. New chemicals, new uses of established products, new combinations, new formulations of active ingredients, and previously registered pesticides are evaluated.

Section 24. Authority of States.

> "A) A State may regulate the sale of any Federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act."

Within the California Department of Food and Agriculture, the Pesticide Registration and Agricultural Productivity Unit (PR&AP) is responsible for the evaluation and registration of pesticide products.

Let me explain briefly how the work of the Registration Unit is organized. It is composed of three basic segments: The Information Center, Registration Specialists staff, and the Scientific Evaluation staff.

The Evaluation segment of the Registration Unit consists of 16 individuals under the supervision and direction of a Program Supervisor. I am one of 13 of these individuals who has responsibility for evaluating data submitted in support of registration in the disciplines of toxicology, entomology, microbiology, biology, chemistry, and plant physiology. These evaluations are documented to show if the data will or will not support registration, identifying any additional data required, and identifying any adverse impacts.

To complete the organizational structure, you should know that there are 3 other Units within the Division of Pest Management. They consist of Worker Health and Safety, Pesticide Enforcement, and Integrated Pest Management/Environmental Monitoring. Each of these Units plays a specific role in the registration decision-making process.

The decision-making process goes beyond the Department of Food and Agriculture and into 5 other governmental agencies which have jurisdiction and control over the impacts of pesticides. These agencies include the Department of Health Services, Fish and Game, Industrial Relations, Air Resources Board, and the Water Quality Control Board. They do not routinely evaluate every pesticide, but take an interest in those products that might affect their area of responsibility and concern.

REGISTRATION

The registration of pesticides involves five basic types of requests. We deal with:

1. New Product Registrations.

   These products are referred to by their FIFRA designation as Section 3 registrations and involve full registration of labels pertaining to new active ingredients or subregistrations of presently registered active ingredients. Data we require in order to register these products are presently summaries of the data submitted to EPA, plus any of the California-only data outlined in Article 5 of the California Administrative Code. We have recently amended our regulations to allow waiver of the EPA summaries in selected cases.

2. Amended Labels.

   These actions involve the addition of, or expansion of, uses not presently on the Section 3 label, and involve the entire realm of possible changes of the presently registered label. Data required are those which support the amended use or change. We receive numerous changes, that we designate as nonsubstantive changes, in this area. Nonsubstantive changes do not require data submission and are handled by the Registration Specialists (i.e., Brand Name Changes, Company Name Changes, or slight Formulation Changes that do not affect the pesticidal properties of the product.

3. 24(c), Special Local Need (SLN).

These registrations are usually issued for a period of 5 years and involve both first and third party requests. Section 24(c) of the Federal Insecticide, Fungicide, and Rodenticide Act gives states the authority to request an additional use of a Federally-registered product to meet a Special Local Need. First party SLNs are those requested by the primary registrant of the product. Third party SLNs are those requested by someone other than the chemical company holding the basic registration. Although anyone can submit an application for a third party SLN, the majority of requests come from other governmental agencies or agricultural organizations. The majority of the third party SLN requests come from county agricultural commissioners. Data required are that which supports the new use pattern, and for agricultural uses, usually efficacy and residue information. One basic requirement for registration of any third party SLN is approval for that use by the basic registrant of the product. This is standard procedure due to the liability inherent in its new use. Another requirement of Section 24(c) is that we substantiate to EPA the reason and provide a justification for the issuance of the SLN.

4. Experimental Use Permits (EUP).

EUPs are issued by both Federal and State governments. Federal EUPs normally allow rather largescale applications of the product, although the total poundage is limited. These are handled the same as Section 3 full registration requests.

State EUPs are designed to allow development of data to support full registration. They normally involve application of the product to small, replicated test plots with prior identification of what they will be testing for, with concurrent notification of the local agricultural commissioner, and final reports submitted to the Department. The product, when used under a Federal EUP, may be sold to the user whereas the product must be provided free of charge when used under the State EUP. When these experiments take place on a food crop, the crop may not be harvested unless there is an existing food tolerance established.

5. Section 18, Emergency Exemptions.

Section 18 of FIFRA gives states the authority to authorize a new use of a Federally-registered pesticide in cases where an emergency is justified and documented. By far, the majority of Emergency Exemptions are submitted to EPA for approval prior to implementation. These are designated as specific exemptions. There is, however, authorization for states to issue a crisis exemption, which authorizes the immediate use. We are required to notify EPA of that type of decision within 36 hours and submit an application for a specific exemption and an appropriate residue action level within 10 days of the first application along with the normal justification and documentation of the emergency. As a point of information, Section 18 requests have continued to increase. During 1980, we received 24 requests and, so far this year, we have received 48 requests (as of 2/11/82).

Data required to support a Section 18 may be minimal or extensive depending upon the nature of the emergency and the parameters of the known hazards of use setting and that particular pesticide. A couple of things you should know about Section 18 requests are that we are cautious in issuing emergency exemptions on products containing active ingredients not previously registered in this State, and second, on issuing crisis exemptions on food crops for which an action level tolerance has not been established. If we issued such a use, and data were not available for EPA to establish a temporary tolerance and any residues were found on the harvested crop, the crop would have to be destroyed.

All Registration recommendations and data requests flow back to the Registration Specialist who put the product into evaluation. If additional data are requested, the request is submitted by the Specialist to the applicant. After the evaluation is completed and we have written recommendations from each Evaluator involved, the recommendations are then reviewed by the Program Supervisor of the Evaluation Program.

Once a Registration decision has been made within the Division, the proposed decision to register or deny registration must be posted for 45 days to allow for public comments. The proposed decisions are posted in specifically designated offices of the State and the county agricultural commissioners. Any comments received must be responded to prior to a final decision being posted with the Secretary of Resources.

SPECIAL REQUIREMENTS

California Registration requirements for vertebrate pesticides differ from the Environmental Protection Agency requirements in the following areas:

Efficacy

Product performance data evaluation has recently been waived by EPA but these data are necessary for California registration.

Biochemical Data

Each applicant to register a pesticide product that is a rodenticide shall submit biochemical data describing the metabolic pathway and the mode of action in animal models suitable for extrapolation of the data to man.

Rodenticide Bait Safety

Anticoagulant rodenticide baits intended for home use shall contain a color additive of such intensity as to be readily evident.

Suggested dyes for anticoagulant baits are listed in the Department's Operational Protocol for Pesticide Registration and Evaluation Manual.

Baits containing strychnine shall be dyed with a green color additive as specified in the Department's Vertebrate Pest Control Handbook.

GOAL OF UNIT

The goal of the Registration Unit in discharging its duties is to assure that its data requests and its registration actions are logical, reasonable, and legal.

This does not present an unbearable burden on registrants and the Department is willing to, and has, met with and worked with registrants to produce data that meet the legal requirements but remain logical and reasonable.