

DEPARTMENT OF PESTICIDE REGULATION

James W. Wells, Director



1020 N Street, Room 332  
Sacramento, California 95814

California Notice 94-7

NOTICE TO REGISTRANTS AND INTERESTED PERSONS  
REGARDING SUBMISSION OF AN APPLICATION FOR  
INTERIM REGISTRATION OF A PESTICIDE PRODUCT

Effective January 1, 1994, Assembly Bill 771 added Article 16 of Chapter 2 of Division 7 (Sections 13161-13170) entitled "The Interim Data Gap Exemption for Qualified Federally Registered Pesticides" to the Food and Agricultural Code (FAC). Article 16 establishes an interim registration process whereby applicants for registration of a pesticide product or label amendment of a pesticide product may apply for a certificate of interim registration. Under the interim registration process, the submission of certain data may be deferred for up to three years. Article 16 does not give requests for interim registration priority in the review process; therefore, requests for interim registration will be reviewed in the order received along with all other requests for registration.

WHO MAY APPLY FOR A CERTIFICATE OF INTERIM REGISTRATION

FAC Section 13164 provides that any registrant or user group of any pesticide registered with the U. S. Environmental Protection Agency (USEPA) may apply for a certificate of interim registration. The application may be for registration of a new product, an amendment to the label of a currently registered product, or an amendment to the label of a product which is currently registered under a certificate of interim registration.

WHAT TYPES OF DATA MAY BE DEFERRED

FAC Section 13163 provides that the director may defer no more than three of the following data requirements:

1. Efficacy studies.
2. Octanol-Water Partition Coefficient (Kow) - as required by FAC Section 13143(a)(3).
3. Soil photolysis - as required by FAC Section 13143(a)(6).
4. A field dissipation study - as required by FAC Section 13143(a)(6).

5. A study required pursuant to Section 13143(a) that will be redone to correct errors or a study conducted under California conditions or guidelines.

WHAT NEEDS TO BE SUBMITTED TO APPLY FOR A CERTIFICATE OF INTERIM REGISTRATION

1. A completed Application for Registration of Economic Poison (Pesticide) (not required if the request is for a label amendment);
2. If the application is being submitted by a user group, a single contact person and telephone number must be designated;
3. The \$200 application fee and the \$5,000 fee for review and processing of the application for interim registration (the \$200 application fee is not required for label amendments);
4. Six copies of the product labeling;
5. Proof that the product is federally registered and that the label has been approved by the USEPA;
6. All of the data required for registration in California except the data for which a deferral is being requested;
7. If the applicant is a user group, written authorization from the owner of the product. In addition, the user group will need to either submit all of the required data, have the federal registrant submit all of the required data, or submit a written authorization from the data owner to use data on file to support the registration of the product;
8. A cover letter which includes the following:
  - A. A statement that a certificate of interim registration is being requested;
  - B. The brand name and USEPA Registration Number of the product for which the certificate of interim registration is being requested; and
  - C. A list of the data requirements for which deferral is requested and a proposed date for submission of the data;

9. The following information required by FAC Section 13164(a) to show that the product will fill a need and significantly enhance a system's approach to pest management:
- A. Information showing that the product will be a significant component in a pest management system. FAC Section 13161(b) defines a pest management system as " . . . a systematic approach to pest control that stresses the application of biological and cultural pest control techniques with the selective use of pesticides when necessary to achieve acceptable levels of control with the least possible harm to nontarget organisms and the environment . . . ." Attachment A provides guidance as to the type of information that should be submitted; and
  - B. Identify and provide information to support one (or more) of the following conclusions that pertain to the product:
    - (1) The product will reduce risks to the public health, the pesticide work place, or the environment by reducing the overall use of chemical controls within a pest management system.
    - (2) The product will reduce risks to the public health, the pesticide work place, or the environment by providing a more benign alternative to an existing use pattern.
    - (3) The product will reduce risks of pest resistance problems such as loss of economic efficacy and increased amounts or frequency of chemical applications by providing better integrated management of a pest or pest complex.
    - (4) The product will reduce a substantial economic hardship to a segment of California's agricultural industry due to a pest infestation for which there is no feasible alternative.

The product only needs to meet one of the above conclusions in order to meet this criteria for interim registration. Provide a separate explanation for each conclusion which you believe applies to your product. Your explanation should draw upon the information you have provided in response to 9A above.

In addition, if you claim that the product will reduce risks to the public health or the pesticide work place by

providing a more benign alternative to an existing use pattern, you must provide a comparison of the toxicity of the product proposed for interim registration and alternative control measures. If you claim that the pesticide will reduce a substantial economic hardship to a segment of California's agricultural industry due to a pest infestation for which there is no other feasible alternative, you must provide substantiation of an economic impact in addition to information on alternative control measures. Any additional information in support of these conclusions should be referenced with bibliographic citations and personal communications (names and telephone numbers of those providing expert opinion) to support the answers given.

#### LIMITATIONS ON THE CERTIFICATE OF INTERIM REGISTRATION

FAC Section 13166 requires the director to limit the use of any pesticide granted a certificate of interim registration to specific uses within a pest management system. The director may also place additional restrictions on the use of any pesticide granted a certificate of interim registration, including, but not limited to, requiring a restricted material permit or the written recommendation of a specially trained pest control advisor or a specially trained certified private applicator, or limiting the quantity, area, and manner of application.

#### OTHER REQUIREMENTS

1. Within 90 days of approval of a product for interim registration, the registrant is required to submit a written commitment to conduct the deferred studies. The commitment must include for each deferred study: (1) the name and address of the person/organization conducting the study; (2) the initiation and expected completion date of the study; (3) a schedule for submission of quarterly progress reports, and (4) a commitment to submit the completed study by the date previously set by the Department.
2. A certificate of interim registration will expire on December 31 of each year unless it is renewed annually pursuant to FAC Section 12817.

#### REASONS FOR REVOCATION OF A CERTIFICATE OF INTERIM REGISTRATION

1. Product no longer meets the requirements of Article 16 FAC;
2. Failure to submit a progress report on any deferred study;

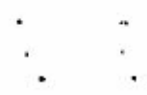
3. Failure to show in the progress report that a good faith effort is being made to complete the study; or
4. The period of time from the issuance of the certificate has exceeded the three-year limit.

A pesticide product for which the certificate of interim registration has been revoked may not be sold by the registrant. The product may be possessed or sold by a dealer for two years after the date of the revocation and may be possessed or used in accordance with the directions on the label, unless the director determines that protection of human health or the environment require otherwise. The conditions under which the product may be sold or used will be specified in the revocation letter.

If you need further information, please contact James Herota at (916) 324-3915.

  
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Barry Cortez Chief

9-16-94  
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Date



## Attachment A

### PEST MANAGEMENT SYSTEMS INFORMATION

To determine whether the product proposed for interim registration will be a significant component of a pest management system, general information is needed on alternative control options in that system. A table is provided, with descriptions of each element, to help in providing a summary of control options. Include bibliographic citations and personal communications (names and telephone numbers of those providing expert opinion) supporting the answers given.

Instructions for Control Alternatives Data Table - Use additional copies of the table as necessary.

#### 1. Site(s) or Crop(s) :

Identify the site or crop on which the product is intended to be applied. Be as specific as possible. For example, "corn," "alfalfa," "wheat," "tomatoes," "golf courses," and "industrial sites" are nonspecific entries. Use instead "corn for silage," "alfalfa for hay," "wheat for seed," "tomatoes for processing," etc., indicating the specific use of the pesticide in a site. Use a separate table for each site or crop, unless all of the information in the table applies to all of the crops or sites listed on that table.

#### 2. California Region:

Use the map provided (see figure 1) to identify the California region(s) in which the particular crop/site-pest combination will be treated with the product. Circle the appropriate region number(s) on the table. Use a separate table for each region of intended use, unless all of the information in the table applies to all of the regions listed.

#### 3. Target Pests:

Identify the pest or group of pests which the product is intended to control. Be as specific as possible, using scientific names and/or common names which are officially recognized by the American Phytopathological Society, the Entomological Society of America, or the Weed Science Society of America. Use a separate table for each target pest or group of target pests, unless all of the information in the table applies to all of the pests listed.

#### 4. Control Options:

Identify each of the control options currently available to control the target pest(s) in each California region. Include the following options:

- Each pesticide (active ingredient) currently registered and used in the last three years to control the target pest(s);
- Each cultural control method currently used to control the target pest(s);
- Each biological control agent currently used to control the target pest(s); and
- The product proposed for interim registration.

Cultural control refers to the manipulation of the environment to mitigate pest damage. This includes, but is not limited to, planting dates and plant varieties, interplanting, plant spacing, sanitation, soil preparation, tillage, crop rotation, irrigation and fertilizer management. Biological control refers to the use of predators and parasites (living organisms) to mitigate pest damage. Pesticides includes chemicals, pathogens, growth regulators, and other products which are required to be registered by the Department.

Identify biological control agents by using scientific names and/or common names which are officially recognized by the American Phytopathological Society or the Entomological Society of America. Identify chemical names by common chemical names for active ingredients in pesticide products.

#### 5. Pest Resistance:

Identify any documented pest resistance associated with the use of each control option listed column 4 of the table. Submit any documentation that the pest has developed resistance to a particular control option and circle "yes" on the data table. Provide explanations, including (1) locations, (2) first report of resistance development, and (3) present level of resistance in pest population. If the pest is not documented as having developed resistance to a particular control option, circle "no."

#### 6. Adverse Impact on Beneficial Organisms:

Identify any adverse impacts associated with the use of each control option listed in column 4 of the table. Beneficial organisms include, but are not limited to, predators and parasites of pest species. If adverse effects on beneficial species are documented to be associated with a particular control



option circle "yes." Provide explanations for answers given. If no adverse impacts are known on beneficial organisms, circle "no".

7. Feasible Alternatives:

A "feasible alternative", as defined in law, means "other chemical or nonchemical procedures that can reasonably accomplish the same pest control function as existing procedures with comparable effectiveness and reliability, taking into account economic, environmental, sociological, technological, and ecological factors, including impact on beneficial and nontarget organisms, pest resistance to pesticides, and timeliness of control."

Identify whether each control option identified in column 4 is a "feasible alternative" to the product proposed for interim registration. If the control option is a feasible alternative, circle "yes," if not, circle "no."

If the control option is not a feasible alternative, explain why it is not, and cite a source for the information. Provide explanations for answers given.

**Control Alternatives Data Table.**

1. Site(s) or Crop(s), be as specific as possible (corn for silage, alfalfa for seed, etc):			
2. California Region (See map) 1 2 3 4 5 6 7			
3. List Target Pests (Be as specific as possible):			
4. Identify Control Options (Alternatives)	5. Has Pest Resistance Developed?	6. Is There an Impact on Beneficial Organisms?	7. Is This a Feasible Alternative?
	yes / no	yes / no	yes / no
	yes / no	yes / no	yes / no
	yes / no	yes / no	yes / no
	yes / no	yes / no	yes / no
	yes / no	yes / no	yes / no
	yes / no	yes / no	yes / no
	yes / no	yes / no	yes / no
	yes / no	yes / no	yes / no
	yes / no	yes / no	yes / no
Product Proposed for Interim Registration:	yes / no	yes / no	yes / no

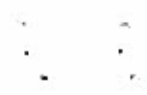
On a separate sheet of paper, please provide explanations of answers circled along with associated information sources for all responses consisting of personal communications (names and telephone numbers of those providing expert opinion), and bibliographic citations.

Product Use Information:

In addition to the information provided in the table, please provide the following:

1. List the number of applications of the product which are expected for a given field/site per year;
2. List the restrictions on the label that may impact the use of the product in pest management systems;
3. Provide information regarding whether and how the product will help mitigate pest resistance to available alternative pesticides; and
4. In terms of total pounds of active ingredient used, number of acres treated, and number of applications per field/site, list the potential changes in use patterns for currently used control options that are likely to occur if the product received an interim registration. Include any pesticide use that would be reduced or eliminated. Provide an assessment of changes in pesticide use patterns on pest resistance, beneficial organisms, and the environment compared with existing use patterns if the product were to receive interim registration. Consider each applicable California region independently.

Include bibliographic citations and personal communications (names and telephone numbers of those providing expert opinion) supporting the answers given.



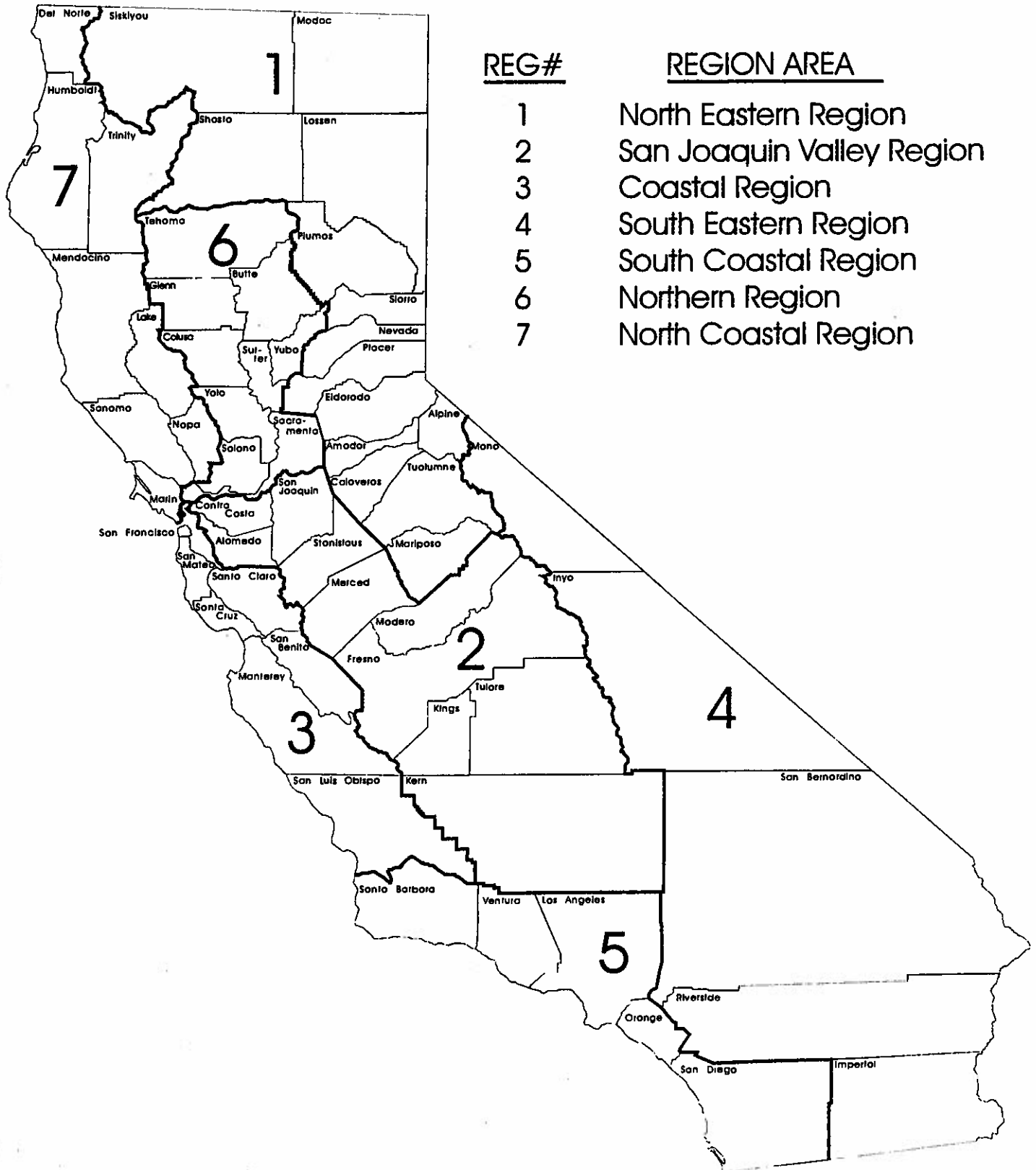


Figure 1. Map of California regions.

