



Mary-Ann Warmerdam
Director

Arnold Schwarzenegger
Governor

California Notice 2008-2

NOTICE TO PESTICIDE REGISTRANTS REGARDING PRIORITIZATION OF PESTICIDE ACTIVE INGREDIENTS FOR RISK ASSESSMENT

This notice announces the Department of Pesticide Regulation's (DPR) intention to conduct risk assessments on the following pesticide active ingredients:

Spirotetramat**	High Priority
Flubendiamide**	Moderate Priority
Fluoxastrobin**	Moderate Priority
Spinetoram*	Moderate Priority
Tetraconazole**	Moderate Priority

* New active ingredient

** New active ingredient not currently registered

Food and Agricultural (FAC) sections 13121-13130 require DPR to review the toxicology database of all registered pesticide active ingredients. If DPR identifies possible adverse effects, then it evaluates the significance of the adverse effects. DPR determines the significance of the adverse health effects by conducting a risk assessment. If DPR decides that the use of a pesticide results in a significant adverse effect, the law requires DPR to suspend or cancel the pesticide. In addition, FAC section 12824 requires DPR to endeavor to eliminate from use in California any pesticide that endangers the agricultural or nonagricultural environment.

DPR intends to complete risk assessments on the active ingredients identified as high priority first, before conducting risk assessments on those identified as moderate or low priority.

Unless registrants or other persons submit additional data, DPR plans to use data currently on file to conduct risk assessments on each of the active ingredients listed above. Submission of the following data would be useful:

1. Metabolism studies conducted in a mammal, such as a rat. Please include the active ingredient and major metabolites in the study. Use the U.S. Environmental Protection Agency/Office of Pesticide Programs (U.S. EPA/OPP) study protocol. The studies should characterize the pharmacokinetics of the active ingredient and metabolites and include oral absorption, tissue distribution, biotransformation, and excretion properties.
2. Dermal absorption studies using doses relevant to expected human exposures on one or more appropriate laboratory animal species (rat and/or monkey). The studies need to characterize the dermal absorption time between eight to ten hours. Use the U.S. EPA/OPP pesticide assessment guidelines, subdivision F, Hazard Evaluation, Human and



Domestic Animals, Series 85-3 (August 30, 1994), or those recommended in Regulatory Toxicology and Pharmacology, 29:37-43 (1999), or the Journal of Toxicology and Environmental Health, 16:25-37 (1985). Before initiating the study, we recommend submitting the protocol to DPR for review.

3. Data on studies of handler exposure (e.g., mixer-loader; applicator; mixer-loader-applicator) using a product containing the active ingredient. Conduct the studies with pesticide product formulations and application methods used in California (e.g., aerial, airblast, groundboom, handgun). Please measure potential dermal and inhalation exposure. Measure the use of the pesticide product anticipated to provide the maximum human exposure consistent with current and proposed label instructions for use in California. If possible, provide urinary metabolite data on the persons exposed. Use the U.S. EPA Office of Prevention, Pesticides, and Toxic Substances Harmonized Test Guidelines 875.1000-1600. Before initiating the study, we recommend submitting the protocol to DPR for review.
4. If the pesticide is applied to the foliage of crops, provide data on dislodgeable foliar residue decay for crops on which the chemical will be used in California, e.g., vegetables, field crops (such as cotton), citrus, deciduous tree crops, vine crops (such as grapes) and greenhouse crops. Dislodgeable foliar residue studies should conform to the guidance provided by DPR (Edmiston, S., Powell, S., Spencer, J., and Curtis, C. 2002. Guidance for determination of dislodgeable foliar residue. HS-1600, Revision 1. Sacramento, CA: Worker Health and Safety Branch, Dept. of Pesticide Regulation, California Environmental Protection Agency).
5. If the pesticide is used on turf, provide transferable turf residue data. If the pesticide has indoor residential uses, provide dislodgeable surface residue data on indoor surfaces (e.g., carpet, hardwood or linoleum floors). We strongly encourage the registrants to involve DPR in the protocol development phase of these studies.

DPR may not have on file the types of data described above. Additionally, many studies already submitted to DPR do not meet the criteria described above. Without acceptable data on dermal absorption and worker exposure, DPR intends to assume a dermal absorption rate of 50 percent and use the highest estimated human exposure in conducting the risk assessment.

DPR intends to notify registrants when it initiates the risk assessment process for any of the pesticide active ingredients listed above. When DPR initiates the risk assessment process, it is unlikely that you will have sufficient time to conduct additional studies. Therefore, do not wait for DPR's notification of initiation of the risk assessment before conducting and/or submitting all data that you want DPR to consider during the risk assessment process.

Please address all data submissions as follows:

Risk Assessment
Attn: Victoria Hornbaker
Pesticide Registration Branch
California Department of Pesticide Regulation
1001 I Street, P.O. Box 4015
Sacramento, California 95812-4015

Please address all requests for additional information to Ms. Victoria Hornbaker, by telephone at (916) 323-5143 or by e-mail at <vhornbaker@cdpr.ca.gov>.

Original Signed by Charles M. Andrews
Charles M. Andrews, Chief
Pesticide Registration Branch
(916) 445-4377

2/04/2008
Date

cc: Ms. Ann Prichard
Ms. Victoria Hornbaker