



Department of Pesticide Regulation



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California Notice 2004-7

TO: Pesticide Registrants And Other Interested Persons

SUBJECT: Changes to Residue Data Requirements for Food or Feed Use Pesticide Products

Effective immediately, the Department of Pesticide Regulation (DPR) will no longer require applicants to submit certain types of residue data to support the registration of new pesticide products intended for use on food or feed crops, or amendments to add a new food or feed crop or change the use directions of a registered pesticide product. DPR has discontinued its evaluation of residue data currently submitted to DPR, and will file this data in its library.

DPR will no longer require the following types of data:

- Nature of the Residue in Plants and Livestock (OPPTS Test Guideline 860.1300)
- Magnitude of Residue:
 - Crop Field Trials (OPPTS Test Guideline 860.1500)
 - Processed Food/Feed (OPPTS Test Guideline 860.1520)
 - Meat/Milk/Poultry/Eggs (OPPTS Test Guideline 860.1480)
 - Water, Fish, Irrigated Crops (OPPTS Test Guideline 860.1400)
 - Food Handling (OPPTS Test Guideline 860.1460)
 - Storage Stability (Freezer) (OPPTS Test Guideline 860.1380)
- Accumulation Studies:
 - Confined Rotational Crops (OPPTS Test Guideline 860.1850)
 - Field Rotational Crops (OPPTS Test Guideline 860.1900)

DPR will continue to require the following types of residue data, when applicable to the registration action requested:

- Chemical Identity (OPPTS Test Guideline 860.1100)
- Direction for Use (OPPTS Test Guideline 860.1200)
- Residue Analytical Method (OPPTS Test Guideline 860.1340)
- Multiresidue Method (OPPTS Test Guideline 860.1360)
- Analytical Reference Standards (OPPTS Test Guideline 860.1650)

In addition, DPR will continue to confirm the existence of a federal tolerance or exemption from the requirement of a tolerance for each food or feed crop listed on the pesticide product label.

Applicants for an Emergency Exemption from Registration (FIFRA section 18) must still provide DPR with sufficient residue data for U.S. EPA to establish a time-limited tolerance.



DPR does not intend to amend its data requirement regulations. Therefore, DPR retains its authority to require an applicant to submit residue data on a case-by-case basis at any time, either during evaluation of a pesticide product or after registration.

Historically, both the U.S. Environmental Protection Agency (U.S. EPA) and DPR required the submission of residue data. However, each agency's purpose for requiring/reviewing the data was slightly different. U.S. EPA uses the results of residues studies to establish tolerances. DPR reviewed residue data to determine whether use of a pesticide on a specific food or feed crop in accordance with label directions would result in residues, at the time of harvest, above the federally established tolerance level. DPR also used the results of residue studies to determine whether certain types of amendments to the use directions of a registered product (i.e, shortening the pre-harvest interval, increasing application rates) were likely to result in over tolerances.

In the past, states had the authority to establish tolerances. Therefore, DPR's review of residue data was critical when tolerances set by U.S. EPA were not based on acceptable risks. The Food Quality Protection Act (FQPA) of 1996 now preempts states from establishing separate tolerances. In addition, FQPA requires U.S. EPA to set tolerances specifically to ensure that all food uses of a pesticide active ingredient pose a reasonable certainty of no harm. U.S. EPA establishes tolerances for individual food crops at a level that is far more stringent than necessary to protect public health. Accordingly, when DPR finds residues above the established tolerance for a given food crop, no appreciable health threat results. However, produce with residues above tolerance cannot enter the channels of trade until pesticide residue levels are at or below the federally established tolerance. Such over tolerances may result in an economic loss to growers, despite full compliance with pesticide label requirements.

DPR staff are currently working with U. S. EPA, Health Canada, and the European Union (EU) to develop a standardized statistical method for establishing pesticide tolerances using residue data.

DPR has determined that certain types of residue data are no longer necessary. DPR will instead put its resources toward reducing the current registration backlog and conducting more work share activities with U.S. EPA, such as DPR's review of IR-4 minor crop residue data.

If you have any questions, please contact Dr. David Supkoff by e-mail at <dsupkoff@cdpr.ca.gov>, or by telephone at (916) 324-4185.

Original Signed by Barry Cortez

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Date