**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**WASHINGTON, D.C. 20460**
**April 3, 2003**

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES



**CERTIFIED MAIL # 7001 1140 0001 4913 6709**

Dear Registrant:

This is the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for 4-Chlorophenoxyacetic Acid (4-CPA), which was approved on April 3, 2003. A Notice of Availability of this TRED will be published in the *Federal Register* (*FR*).

The Federal Food, Drug and Cosmetic Act (FFDCA), as amended by FQPA, requires EPA to reassess all the tolerances for registered chemicals in effect on or before the date of the enactment of the FQPA, which was in August of 1996. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. Once a safety finding has been made that aggregate risks are not of concern, the tolerances are considered reassessed. A reregistration eligibility decision (RED) for 4-CPA was completed in March 1995, prior to FQPA enactment. Therefore, the tolerances need to be reassessed to meet the FQPA standard.

The pesticide 4-CPA is used indoors to restrict root growth during seed germination of mung beans. The only exposure anticipated is via the food pathway. There is no exposure expected through consumption of drinking water given the enclosed nature of the chemical's use, and there are no registered residential uses. Therefore, aggregating exposures from the food, drinking water, and residential pathways of exposure is not necessary. As a result, the Agency has only evaluated the dietary (food) risk associated with the use of 4-CPA, and has determined that there is a reasonable certainty that no harm to any population subgroup will result from this potential exposure. Therefore, no mitigation measures are needed, and the tolerances established for residues of 4-CPA in/on raw agricultural commodities are now considered reassessed as safe under §408(q) of the FFDCA.

FQPA requires that EPA consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for considering other substances is because of the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect, as would a higher level of exposure to any of the other substances individually.

Although the Agency compared toxicities of other chlorophenoxy acetic acids to 4-CPA to improve the hazard characterization, EPA does not have, at this time, available data to determine whether 4-CPA has a common mechanism of toxicity with other substances. For the purposes of this TRED, EPA is assuming there is no common mechanism of toxicity, and that the tolerances established for residues of 4-CPA in/on raw agricultural commodities are considered reassessed as safe under §408(q) of the FFDCA.

The Agency also reviewed 4-CPA to determine if its use pattern could cause adverse impacts on endangered and threatened species. Approximately 20 pounds of 4-CPA active ingredient (ai) are used per year for indoor treatment of mung beans at a single production facility. Due to the limited usage of this chemical in total annual pounds used and geographic area used, there are unlikely to be risks to endangered species associated with 4-CPA. Additionally, waste water discharges containing 4-CPA resulting from this registered use are subject to pre-treatment requirements and are likely to be significantly diminished through this process. Any residues of 4-CPA leaving the production facility are likely to be further reduced (if not eliminated) at a publicly owned treatment works prior to entering surface water. Therefore, EPA believes that the exposures and risks to endangered species from the registered use of 4-CPA are likely to be low and not of concern to the Agency.

The Agency's human health findings for the plant growth regulator 4-CPA are summarized in the enclosed human health risk assessment. The risk assessment and other technical support documents pertaining to the 4-CPA TRED are listed in Attachment One of this document and are available for viewing in the OPP public docket and on the Internet at http://www.epa.gov/edocket/. The 4-CPA docket ID number is OPP-2003-0124.

The tolerances for residues of 4-CPA in/on raw agricultural commodities are for the parent compound, 4-CPA *per se*. No metabolites or degradates are included in the tolerance expression. The existing tolerances for 4-CPA have been reassessed. One tolerance for tomatoes (no longer supported or on the label) will be revoked, and the tolerance for mung bean sprouts will be reduced from 2.0 to 0.2 ppm based upon previously reviewed and accepted residue chemistry studies. No maximum residue limits (MRLs) for 4-CPA have been established or proposed by Codex. Therefore, there are no international compatibility issues with respect to the U.S. tolerances. A summary of the reassessed tolerances for residues of 4-CPA are found in Table 1.

**Table 1. Tolerance Reassessment Summary for 4-CPA**

| Commodity | Established Tolerance (ppm) | Reassessed Tolerance (ppm) | Comments *[Correct Commodity Definition]* |
|---|---|---|---|
| bean, mung, seed | 2.0 | 0.2 | Bean, mung, seed |
| tomatoes | 0.05 | None | Revoke, use deleted |

The food use subject to this TRED is listed in Table 2. The Agency has not identified any label amendments which should be implemented as a result of this TRED.

**Table 2. Food/Feed Use Patterns Subject to Tolerance Reassessment for 4-CPA**

| Application<br>a) Type<br>b) Timing<br>c) Equipment | Formulation<br>[EPA Reg. No.] | Application Rate | Use Directions and Limitations |
|---|---|---|---|
| beans, mung, seed | | | |
| a) immersion bath<br>b) seedling germination<br>c) water bath | Soluble concentrate<br>96.2 % ai [8906-1] | 7.4 X $10^{-4}$ lb ai / 100 lbs bean seeds | Do not feed treated hulls or bean parts to livestock. |

This letter summarizes the Agency's decision on the tolerance reassessment for 4-CPA. Please contact Mark Howard of my staff with any questions regarding this decision. He may be reached by phone at (703)308-8172 or by e-mail at howard.markt@epa.gov.

Sincerely,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosure: Human Health Risk Assessment for the 4-CPA TRED

**Attachment One**

**Technical Support Documents**
**for the 4-CPA TRED**

1. Anderson, Dave (USEPA/OPPTS/OPP/HED) Toxicity Studies with 4-Chlorophenoxyacetic acid (4-CPA) and Structures Related to 4-CPA. September 10, 2002.

2. Christensen, Carol (USEPA/OPPTS/OPP/HED) 4-Chlorophenoxyacetic acid. HED Human Health Risk Assessment for the Tolerance Reassessment Eligibility Document (TRED). March 12, 2003.

3. Corbin, Mark (USEPA/OPPTS/OPP/EFED) 4-Chlorophenoxyacetic acid TRED. Estimated Drinking Water Concentrations for 4-CPA for use in the Human Health Risk Assessment. September 11, 2002.

4. Corbin, Mark (USEPA/OPPTS/OPP/EFED) 4-CPA – Evaluation of Endangered Species for the Tolerance Reassessment Decision (TRED) Document for 4-CPA. Addendum to the September 11, 2002 EFED Drinking Water Concentrations. March 24, 2003