MEMORANDUM

Date: 5/27/99

Subject: PP#7F04864 - AMENDMENT TO HUMAN HEALTH ASSESSMENT FOR AZOXYSTROBIN. PETITION FOR TOLERANCE ON PISTACHIO NUTS AND THE TREE NUTS CROP GROUP

DP Barcodes: D256308  Caswell#: none
PRAT Case#: 289006  Chemical#: 128810
Submission#: S526775  40 CFR: 180.507
Class: Fungicide
Trade Names: Heritage Fungicide (EPA Reg. No. 10182-408)
ICIA5504 80WG Fungicide (EPA Reg. No. 10182-416)
Abound Flowable Fungicide (EPA Reg. No. 10182-415)

To: Cynthia Giles-Parker, John Bazuin, PM Team 22
Registration Division/Herbicide Branch (7505C)

From: Douglas Dotson, Chemist
Health Effects Division/Registration Action Branch 2 (7509C)

Through: Michael Doherty, Peer Reviewer
Donna Davis, Branch Chief
Health Effects Division/Registration Action Branch 2 (7509C)

I. BACKGROUND

A tolerance of 0.01 ppm was recently established for residues of azoxystrobine (methyl(E)-2-(2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl)-3-methoxyacrylate) and its Z isomer (R230310) in/on the tree nuts crop group and pistachio nuts (Memo, D. Dotson, PP#7F4864, D248888, 1/28/99). The California Department of Pesticide Regulation (CDPR) has requested that the tolerance be increased to 0.02 ppm. HED has determined that available field trial data warrant the increased tolerance.

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The maximum application rate and PHI appearing on the labels for tree nuts and pistachios are 0.2 lb a.i./A and 45 days, respectively. Although almonds are a member of the tree nuts crop group, they appear separately on the labels. The maximum application rate and PHI for almonds are 0.25 lb a.i./A and 28 days, respectively. The registrant submitted field trial data in which two different PHIs were used (i.e., 28 days and 45 days). The field trial data from the samples which had a 45-day PHI were reviewed, and although the label was approved for a 28-day PHI, the field trial data from the samples with this PHI were not reviewed. The data were subsequently reviewed (Memo, D. Dotson, D256297, in preparation). HED determined that a tolerance of 0.02 ppm for the combined residues of azoxystrobin and R230310 was adequate to support the lower PHI.

The approved use pattern for pistachios is currently the same as that for the tree nuts crop group (i.e., maximum application rate: 0.2 lb a.i./A; maximum number of applications: 6; PHI: 45 days). The petitioner is requesting that the use pattern for pistachios be the same as that for almonds, and not that of the other tree nuts. That is, the petitioner is requesting that the maximum application rate be increased to 0.25 lb a.i./A and the PHI be decreased to 28 days.

II. EXECUTIVE SUMMARY

HED recommends in favor of amending the pistachio nut and tree nuts crop group tolerance from 0.01 ppm to 0.02 ppm. HED has determined that the submitted field trial data support the approved 28-day PHI for almonds. HED also recommends in favor of approving the following changes with respect to pistachio nuts: an increase in the application rate from 0.2 to 0.25 lb a.i./A, and a decrease in PHI from 45 to 28 days.

III. SCIENCE ASSESSMENT

HED has determined that a tolerance of 0.02 ppm is appropriate for the tree nuts crop group based on field trial data from the representative commodities: almonds and pecans. HED has also determined that a tolerance of 0.02 ppm is adequate to support the change in use pattern of pistachio nuts (Memo, D. Dotson, D256297, in preparation). Therefore, a DEEM™ analysis has been performed using a value of 0.02 ppm for the combined residues of azoxystrobin and R230310 in/on tree nuts and pistachios (Memo, D. Dotson, D256300, 5/21/99). Tolerance level residues and 100% crop treated assumptions were made for all commodities just as they were in the DEEM™ analysis done in conjunction with the original risk assessment. In the original risk assessment a tolerance level of 0.01 ppm was used for the combined residues of azoxystrobin and R230310. The increase in the tree nuts and pistachios tolerance from 0.01 to 0.02 ppm has a negligible effect on exposure for the U.S. population and all population subgroups. The theoretical maximum residue contribution (TMRC) remained the same to 4 significant figures in all groups except one (Males 20+ years). In this group the TMRC was the same to 3 significant figures. As a result, the %RfD values did not change. There are no changes in the drinking water levels of comparison and the risk is still acceptable. As a result, HED recommends in favor of increasing the tolerance for the combined residues of azoxystrobin and R230310.
in/on the tree nuts crop group and pistachio nuts from 0.01 ppm to 0.02 ppm. In addition, HED recommends in favor of approving the proposed label amendment for pistachio nuts.