UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 4 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Dwight Welch, President
Dr. Arthur Chiu, Vice-President
Dr. William Hirzy, Vice-President
The National Treasury Employees Union
Ben Franklin Station Box 7672
Washington, DC 20044

Dear Sirs:

Thank you for your letter of November 22, 2004, addressed to U.S. Environmental Protection Agency (EPA) Administrator Mike Leavitt and Stephen L. Johnson, Deputy Administrator, on behalf of Dr. Brian Dementi. Mr. Johnson, now the Acting Administrator, asked that I respond on his behalf.

With your letter, you provided a copy of a letter from Dr. Dementi also dated November 22, 2004, to Messrs. Leavitt and Johnson, in which Dr. Dementi expresses concern about the findings of a study submitted and funded by Cheminova entitled, "A Pathology Working Group Review of Liver Slides from the 24-month Toxicity/Oncogenicity Study in the Rat."

Under FIFRA, Congress has placed the burden of toxicity testing on the companies that make and sell pesticide products. Thus, the pesticide companies, rather than the taxpayers, bear the cost of studies required by EPA for pesticide registration.

You have asked that the Agency consider Dr. Dementi's recommendation for a re-read of disputed histopathology slides by a panel of pathologists not employed by the malathion registrants, and that Dr. Robert Maronpot of the National Toxicology Program be included in the panel. Members of my pesticide program staff have reviewed your letter and the enclosures and provided me with their findings.

First let me say that it is not unusual for a registrant to request, based on a reevaluation of pathology readings, that EPA reconsider a decision made by the Pesticide Program's Cancer Assessment Review Committee. In this case, Cheminova requested a review of EPA's cancer classification based on the Pathology Working Group (PWG) study cited above. EPA scientists evaluated the PWG study and concluded that the appropriate classification is "Suggestive Evidence of Carcinogenicity."

Dr. Dementi has expressed concern regarding the PWG rat study on previous occasions, including several memoranda. To address Dr. Dementi's concerns, Agency staff held a meeting with Dr. Hardisty (PWG Chair) on April 11, 2000, at which Dr. Dementi was present. Dr. Hardisty presented his responses to many of Dr. Dementi's questions in writing and at the meeting. In addition, the Agency Consulting Pathologist, Dr. John Pletcher, reviewed the PWG report, taking Dr. Dementi's questions into consideration. Finally, after an in-depth review of the above information, EPA's Drs. Diwan and Copley prepared a memorandum dated July 21, 2000, summarizing their findings and concluding that the PWG followed Agency procedures outlined in Pesticide Registration (PR) notice 94-5 (copy enclosed) for submitting a pathology re-read to the Agency for reconsideration of carcinogenicity peer review decisions based on changes in pathology diagnoses.

After reviewing the information you have provided, we continue to believe that the PWG report on tumor evaluation is consistent with acceptable scientific practices specified in the Agency's PR Notice 94-5 and used in PWG reports submitted for other chemicals.

Dr. Dementi is correct in pointing out that the PWG Chair, Dr. Hardisty, apparently did not evaluate all slides with hepatocellular alterations (i.e., noncancer histopathologic changes in the liver). The PWG process requires as a first step that one PWG member (called the "peer review pathologist") read all the slides of potential interest as an initial "second opinion." The next step is for the PWG chair to compare the findings reported by the peer review pathologist to those of the initial pathologist (i.e., the study pathologist, who is not part of the PWG) to determine which slides need to be brought before the full PWG. Thus, all liver slides were read by two different pathologists (the study pathologist and the PWG peer review pathologist). In this case, the PWG Chair made the decision to re-read only those slides that showed moderate and severe lesions. For the purposes of the cancer assessment, we believe this decision was appropriate. Therefore, we believe that initiating another evaluation will not affect the tumor incidence, cancer classification, quantification of cancer risk, or the overall risk assessment.

Thank you for your interest in this important matter. You may wish to contact Marty Monell at 703-305-7090 if you have questions or would like to discuss these issues.

Sincerely,

Susan B. Hazen
Acting Assistant Administrator

Enclosures:

1. EPA Pesticide Registration (PR) notice 94-5, August 24, 1994
2. EPA Memorandum, February 24, 2005, responsive to NTEU letter dated November 22, 2004