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WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

October 8, 1999

MEMORANDUM

SUBJECT: EFED rebuttal response to SKW Trostberg AG's rebuttal to the rainbow trout early life stage study (MRID No.:44076701; DP Barcode: D228813) classification conducted with **Hydrogen Cyanamide**.
PC Code No. 014002; CAS No. 420-04-2; DP Barcode: D258799; Case: 193715

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THROUGH: Aquatic Biology Technical Team Co-chairs
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THROUGH: Patricia Jennings, Acting Branch Chief
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This memo addresses the rebuttal to the classification of the rainbow trout early life stage (ELS) study (MRID No.:44076701). This study was initially classified as supplemental/irreparable because a NOAEL was not determined. Wildlife International, the registrant's contract lab, provided a rationale for determining an NOAEL for the most sensitive test endpoints of weight and length. The method they used to determine an NOAEL was an estimate that was extrapolated from information provided through multiple means testing using Dunnett's critical value.

This issue was brought before the EFED Aquatic Biology Technical Team (ABTT). The ABTT reviewed the data and concluded that the study should remain classified as supplemental; however, the study does not have to be repeated. The rationale for this study's classification is that EFED policy requires that the chronic toxicity endpoint, *i.e.*, the NOAEL, is to be based on empirical data and not an estimate. However, the ABTT has performed a regression analysis of



the weight data based on the lower 95% confidence limits for weight in the lowest treatment group and estimated that the NOAEL is 0.8 ppm. This value will be used as the freshwater fish chronic toxicity endpoint for hydrogen cyanamide.

Both the registrant and Wildlife International should be reminded that it is EFED's policy that NOAEL be based on empirical data and that a better effort should be made in range finding tests to establish treatment concentrations that are likely to provide an empirically-based NOAEL. Estimates of NOAEL based on Dunnett's critical value or even regression analysis are subject to a considerable amount of variability and do not compare to actual data indicating that an effect was not observed at a particular treatment level.