May 11, 2000

MEMORANDUM

SUBJECT:  MOLINATE - Registrant's 30-Day Response to Draft HED Chapter for RED

DP Barcode: D265730
PC Code: 041402
Case: 818845
Submission: S579331

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THRU:  Whang Phang, Ph.D., Branch Senior Scientist
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and

Michael Metzger, Branch Chief
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Action Requested: Review Zeneca Ag Products 30-Day Response to the Draft HED Chapter of the RED for Molinate.

Recommendations: The registrant's comments have been reviewed. While many issues are identified by the registrant, RRBI considers the majority of them as a difference of scientific opinion and/or interpretation, rather than errors. The errors recognized by RRBI include the following:
1) Zeneca states that there are four end-use products, rather than the six specified in the\nhuman health risk assessment. The Federal Register notice announcing the voluntary cancellations\nof 10182-171 and 10182-174 was published on April 26, 2000. There is a 180-day comment period,\nwhich means that the cancellations will be finalized October 25, 2000. The cancellation of these\nproducts will be acknowledged in the final risk assessment.

2) Concerning the Toxicology Chapter for the RED (Page 6, 21 day dermal study), Zeneca states that\nthe study is identified as a rabbit study in the heading, whereas it is a rat study. This is an error;\nhowever, the text below the heading accurately indicates that the study was conducted in rats. Zeneca\nalso states that the study was classified as unacceptable due to the lack of data on plasma and brain\ncholinesterase; however, this is an error as both plasma and erythrocyte cholinesterase measurements\nwere made and reported in this study. The classification should have been based on the lack of brain\ncholinesterase alone.

3) Also in the Toxicology Chapter (Page 13, 4-part investigative study, Part IV), Zeneca states that\nthe NOAEL is given as 0.2 mg/kg, whereas it should be 0.26 mg/kg. RRB1 acknowledges this error\nand will make the correction.