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MEMORANDUM

SUBJECT: Review of "Endangered species analysis for BAS 670 336SC in field corn (including both conventional and herbicide resistant/tolerant varieties), popcorn, seed corn, and sweet corn crops" submitted by BASF on 01/28/2005.

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BASF submitted an endangered species assessment (MRID 46460701, 01/28/2005) in support of registration of the new herbicide, BAS 670 336SC (Topremazone). The assessment concluded that a buffer strip of 30 feet would provide sufficient protection for terrestrial plants, and that no buffer is needed to protect aquatic plants because "exposure does not approach levels of concern for them". EFED disagrees with these conclusions. EFED conducted an independent endangered species assessment in its ecological risk assessment (D290065, 290068, 290076) and concluded that a buffer strip of 1000 feet (the limit of Agdrift) would not be sufficiently protective of endangered terrestrial plants. EFED concluded that risk to endangered aquatic plants was higher than levels of concern to the Agency for both aerial and ground applications.

The different conclusions reached by the two analyses appear to be caused primarily from the use of different toxicity values in the assessments conducted by EFED and BASF. EFED used a NOEC of 1 ppb (*Lemna gibba*; MRID 45902329) for the endangered aquatic plant species assessment and an EC05 of 9E-6 lbs a.i./Acre (soybean, vegetative vigor; MRID 45902328) for the terrestrial plant endangered species assessment. In contrast, BASF used an aquatic plant NOEC of 2 ppb and a terrestrial plant NOEC of 0.008 lbs a.i./Acre (peas) in the endangered

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species assessment. EFED does not believe that the use of either of these toxicity values are justified as discussed below. Additional deficiencies in BASF's endangered species assessment are also described below.

- Aquatic plant endangered species assessment: An acceptable study in *Lemna gibba* conducted using technical grade topremazone produced a NOEC of 1 ppb (MRID 45902329). This study was used by EFED to estimate risk to endangered aquatic plants. A study based on the formulated product (MRID 45901821) produced a NOEC of 2 ppb, which served as the basis of BASF's assessment. BASF reported that the formulated product study produces a more realistic exposure regime than the technical material. EFED believes that 1 ppb is a more appropriate toxicity value because 1 ppb and 2 ppb are essentially equivalent toxicity values and likely represent biological variability or differences in study conditions or designs and not differences in toxicity between the technical grade material and formulated product. Also, the environmental fate of the active ingredient is likely distinct from the fate of the other substances in the formulated product. Therefore, outside of spray drift, which is expected to contribute a relatively small amount of the total surface water EECs, aquatic exposure to the active ingredient will likely occur separately from the other substances in the formulated product. For these reasons, 1 ppb is considered to be the more appropriate toxicity value for the endangered aquatic plant species risk assessment.

BASF also supported the conclusion that endangered aquatic plants are not likely at risk from topremazone because EFED's surface water exposure models over-estimate potential exposures to aquatic plants. BASF calculated "over-prediction factors" that were based on a linear regression equation relating application rate to an over-prediction ratio reported in Jackson et al. (2004). These over-prediction ratios were determined by comparing PRZM/EXAMS predicted EECs to monitoring data for the same chemical (over-prediction ratio = PRZM/EXAMS EEC / monitoring value). The modeling exercise was based on a single model run for each pesticide included in the analysis, performed using a nationally-vulnerable crop/site scenario, maximum label rates, national percent crop area, and 100% acres treated. The monitoring data was from a composite of monitoring from 12 reservoirs scattered across the country that represented a wide range of conditions. The data were from approximately 1.5 years of monitoring. The over-prediction ratio calculated for topremazone was 2.7, which was used to adjust the PRZM/EXAMS EECs downward. This analysis was used to support BASF's conclusion that their endangered species assessment for aquatic plants was adequately safe. EFED has identified several concerns with the methodology in BASF's analysis that preclude its use in ecological risk assessment:

- No attempt was made to determine the extent of pesticide usage in any of the reservoir watersheds in order to relate them back to detections. In fact, no attempt was made to determine whether the pesticides used in the comparison were used in the watersheds during the time of the study.



- Jackson et al. compared screening model estimates against 1.5 years of USGS monitoring of a handful of drinking water reservoirs. Drinking water reservoirs are not representative of ecologically-significant water bodies. Further, aquatic EECs are based on 1-in-10 year values over a 30-year period, which are not comparable to 1.5 years of monitoring data. No attempt to make a more relevant comparison of modeling vs. monitoring by (a) using model scenarios that were regionally representative of the reservoir watersheds, (b) accounting for differences in weather patterns (many of the reservoirs experienced drier-than-normal years during most of the study, with extreme weather events such as a hurricane interrupting the study) to allow for a comparison with 1-in-10-year concentrations, or (c) modeling actual use rates, crop areas, or acres treated in the reservoirs in a way that would make for relevant comparisons.

- Terrestrial plant endangered species assessment: BASF used a NOEC of 0.008 lbs a.i./Acre from a non-GLP field vegetative vigor study in peas as the basis for the endangered plant species assessment. EFED believes that this value is inappropriate for use in ecological risk assessment because peas were not used in the laboratory studies to allow for a comparison of the results from the laboratory and field studies. Therefore, conclusions cannot be made regarding the relative sensitivity of each study. It is possible that field studies conducted using the most sensitive species tested in laboratory studies (soybeans; MRID 45902328) may produce similar or lower toxicity values if tested in adequately conducted field studies. Also, a number of deficiencies were noted in the field study (see D290065) including lack of control plants. Therefore, the EC05 from soybeans is considered the most appropriate value available for use in ecological risk assessment.