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OFFICE OF
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MEMORANDUM

SUBJECT: Environmental Fate and Effects Division Response to Comments made by Syngenta on EFED's Drinking Water Assessment for Metolachlor/S-Metolachlor

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EFED has reviewed Syngenta's comments (letter dated April 29, 2002) on the preliminary drinking water assessment for metolachlor/s-metolachlor. We have addressed these comments and made the appropriate changes to the attached exposure assessment. Note that the preliminary drinking water assessment evaluated exposure to racemic metolachlor and s-metolachlor. All references in this document and the revised drinking water assessment to metolachlor are for the racemic form (50% s-isomer : 50% r-isomer) whereas all references to s-metolachlor refer to the enriched isomer form (88% s-isomer : 12% r-isomer). Where the enantiomeric ratio has not been determined the reference is for metolachlor/s-metolachlor.

It is important to note that overall the revised exposure assessment results in lower estimated exposure concentrations (EEC) than those presented in the preliminary drinking water assessment. Table 1 below presents a summary of the original acute EECs from the TRED along with revised EECs. Table 2 presents similar summary of the chronic EECs.

Table 1. Acute EECs for metolachlor/s-metolachlor TRED

Media	EEC used in TRED dated January 30, 2002	Source	Revised EEC dated May 14, 2002	Source
metolachlor/s-metolachlor in Surface Water	138.8 ppb	STORET	77.6 ppb	NAWQA
ESA in Surface Water	64.2 ppb	FIRST	31.9 ppb	FIRST
OA in Surface Water	180.7 ppb	FIRST	91.4 ppb	FIRST
metolachlor/s-metolachlor in Groundwater	6.9 ppb	SCI-GROW	5.5 ppb	SCI-GROW
ESA in Groundwater	50.7 ppb	SCI-GROW	65.8 ppb	SCI-GROW
OA in Groundwater	90.2 ppb	SCI-GROW	31.7 ppb	SCI-GROW

Table 2. Chronic EECs for metolachlor/s-metolachlor TRED

Media	EEC used in TRED dated January 30, 2002	Source	Revised EEC dated May 14, 2002	Source
metolachlor/s-metolachlor in Surface Water	4.3 ppb	NAWQA	4.3 ppb	NAWQA
ESA in Surface Water	45.9 ppb	FIRST	22.8 ppb	FIRST
OA in Surface Water	129.2 ppb	FIRST	65.1 ppb	FIRST
metolachlor/s-metolachlor in Groundwater	6.9 ppb	SCI-GROW	5.5 ppb	SCI-GROW
ESA in Groundwater	50.7 ppb	SCI-GROW	65.8 ppb	SCI-GROW
OA in Groundwater	90.2 ppb	SCI-GROW	31.7 ppb	SCI-GROW

Modeling: Rates and Product

Rates

Syngenta comment, (page 82 of 98): EPA modeled metolachlor rather than S-metolachlor uses. Specifically, the rates modeled were incorrect for corn, sorghum, cotton, soybeans, peanuts, and turf. Since the s-metolachlor rates are 35% less than historical metolachlor application rates, this results in a significant error in the EEC. The result of this error is that the TRED EEC's were inappropriately inflated. In addition, modeling for some uses like turf do not reflect current approved labels.

EFED response: Rates used were the metolachlor rates which reflected maximum rates at time of assessment. However, given the current status of registration of metolachlor and s-metolachlor, revised modeling has been completed with current label rates for both metolachlor and s-metolachlor.

Modeling: Koc's, Conversion Factors, and PCA's

Syngenta comment, (page 82-83 of 98): In many of the modeled exposure estimates the Agency did not use all the currently available data in a way consistent with current Agency guidance. According to the TRED, EFATE data from the 1994 RED was used. It is not clear what recent S-metolachlor half-life and Koc data were included in the TRED. At the very least, all data accepted by EPA in previous submissions should be included in the evaluation given current EPA standard operating procedures for conducting aggregate risk assessments.

EFED response: EFED has reviewed the comments provided in Syngenta's *Response to EPA Draft TRED for S-metolachlor* dated April 29, 2002. EFED has addressed several comments which have resulted in changes in the EEC's presented in the preliminary assessment. In particular, EFED has revised model inputs and relied on currently approved application rates for both metolachlor and s-metolachlor.

Syngenta is correct that an incomplete fate dataset was used to generate inputs in the preliminary assessment. This has been corrected. All fate data submitted has been used, in accordance with current EFED guidance, to generate revised input parameters. Revised modeling has been completed with current application rates for both metolachlor and s-metolachlor.

Syngenta comment, (page 82-83 of 98): According to the TRED the aerobic soil metabolism half-lives for ESA and OA were estimated from the decline portion of the kinetics curve. This is inappropriate because the degradates are still being formed during this portion of the decay curve.

EFED response: EFED appreciates the comments made concerning the method used to approximate the degrade half-lives. The use of the decline portion of the formation and decline data from the study "Comparative Aerobic Soil Metabolism of Phenyl-¹⁴C-CGA-77102 and Phenyl-¹⁴C-Metolachlor (MRID 43928936) is intended to provide a conservative estimate of

degradate half-lives in the absence of actual aerobic soil metabolism data. Refinement of the degradate half-lives include completion of individual aerobic soil metabolism studies for metolachlor ESA and metolachlor OA. Another approach is to estimate rate constants for metolachlor ESA and metolachlor OA degradates from available software (e.g. Model Maker) which can provide simultaneous solutions for the formation and decline of parent and degradates. Alternatively, the use of a "total residue" approach for estimating total residue concentration in drinking water could be considered. The "total residue" approach estimates a lumped degradation rate for all residues of metolachlor/s-metolachlor (parent, ESA, and OA) which can be used in models (FIRST and SCI-GROW in this instance) to provide an aggregate EEC for parent plus ESA and OA.

EFED evaluated the use of Model Maker software for estimating individual rate constants taking into account the formation and decline of co-occurring degradates found in MRID 43928936. However, EFED believes that the effort is complicated by the co-occurrence of multiple degradates within the study, that a precursor degradate to OA is proposed, and an incomplete pathway for the ESA (see page 91 of MRID 43928936) was presented. Refined half lives estimated in this manner would likely introduce additional uncertainty to the assessment. EFED elected to forgo the use of this approach because of the uncertainties listed above until the necessary information is available.

Alternatively, EFED estimated a "total residue" half life for parent metolachlor/s-metolachlor, metolachlor ESA, and metolachlor OA from the data in MRID 43928936. The approach gives a lumped half life for the residues and is considered by EFED as a conservative upper bound means of estimating degradate exposure when fate data are limited. A "total residue" half life was estimated from the metolachlor/s-metolachlor data by summing the parent plus ESA and OA degradate data and estimating a total residue half life using log transformed data. Half lives for "total residues" were 65.7 days for metolachlor and 68.5 days for s-metolachlor (71.4 days for 90th percentile). Use of these half lives to estimate a "total residue" EEC (sum of parent, ESA, and OA) in surface water yields concentrations of 300 ppb for acute exposure and 214 ppb for chronic exposure. For comparison from the revised exposure assessment the combined acute EEC for parent (NAWQA), ESA (FIRST) and OA (FIRST) in surface water was 200.9 ppb and the combined chronic EEC in surface water was 92.2 ppb using the half-lives generated from the decline curve of MRID 43928936.

Therefore, EFED has relied on the original estimates of degradation rates for the ESA and OA degradates in the absence of individual Subdivision N aerobic soil metabolism studies on the degradates, the uncertainty associated with Model Maker, and the fact that we believe the "total residue" approach is more conservative.

OA Conversion Rate

*Syngenta comment, (page 83 of 98): The 28% conversion ratio cited by EPA for OA was taken from the original metolachlor aerobic soil metabolism study (MRID 41309801). In this study the formation of OA is exaggerated because the extraction procedure converted **all** of the ESA to OA (simple hydrolysis of the sulfonic acid to the carboxylic acid). In the metolachlor / S-metolachlor*

side by side aerobic soil metabolism (MRID 43928936) the extraction methodology was not as harsh and both degradates (OA and ESA) were extracted intact.

After day 60, the total level of ESA and OA starts dropping (i.e., maximum conversion rate occurs within the first 60 days in this experiment). Therefore, Syngenta respectfully submits EPA should use 10.3% rather than 28% for an OA conversion rate.

EFED response: EFED reviewed the original study (MRID 41309801) from which the 28% conversion factor was selected. The study does document that multiple extractions of the soil to capture bound residues were used. However, it is impossible to confirm the conclusions that extraction procedures resulted in the conversion of ESA (which was not analyzed for in the study) to OA. Further analysis on the part of the registrant would be required to support the contention. Until such time that Syngenta can demonstrate more clearly the effect of the extraction on OA and ESA formation, EFED will rely on the 28% conversion factor used in the original assessment. However, if confirmed, a lower conversion factor will decrease the EECs for metolachlor OA by approximately two thirds (reducing acute EEC in surface water predicted by FIRST from 91.4 ppb to 32.6 ppb).

ESA and OA Koc values

Syngenta comment, (page 83 of 98): On page 12 of the FQPA drinking water assessment the Agency cites 0.83 as the lowest Koc for both the ESA and OA degradates. **The origin of this value is unknown.** The Koc's reported for ESA are 22, 2, 3, and 6. For OA the values are 3, 8, 12, and 6. The input values and subsequent model outputs should be corrected, accordingly.

EFED response: Corrected Koc values will be used in the revised drinking water assessment. Guidance calls for using the lowest Koc in SCI-GROW when greater than 3 fold variation is noted and using the lowest non-sand Koc in FIRST. The data used by EFED for determining the Koc values for OA (MRID 40494605) exhibit greater than 3 fold variation. Therefore, the lowest value (2.85) is used in SCI-GROW. EFED did not use the Koc data for ESA at the time of the original drinking water assessment and, therefore used the OA value for modeling ESA.

EFED has screened the data and is currently conducting a full review of the Adsorption/Desorption study for CGA-354743 (metolachlor ESA). Based on the screen, EFED believes the data presented in the study (MRID 44931722) is appropriate for use in the revised assessment. It is worth noting that the reported Koc values (22, 2, 3, and 6) also show greater than 3 fold variation, thus the value of 2 (recalculated by EFED to 2.01) would be used in SCI-GROW which is lower than the OA value used in the original assessment.

Use of PCA values

Syngenta comment, (page 83 of 98): The Agency used a default value of 0.87 as the PCA for individual crops whether the model being run was FIRST or PRZM/EXAMS. For crops grown in rotation on the same area within a watershed (e.g. corn and soybean), this is clearly a considerable overestimate of the actual crop acreage. EPA has standard PCA's for these crops

and Syngenta Crop Protection respectfully submits that these figures should be used.

EFED response: EFED disagrees with Syngenta's comment of the PCA factor used. EFED's concerns for the occurrence of multiple crops in a given watershed were clearly explained in the drinking water assessment. The standard PCA's referenced by the registrant were for single crops within a watershed. Because of the widespread use of metolachlor, EFED feels that the default PCA is protective of those watersheds where metolachlor may be used on multiple crops other than those for which PCA's have been determined. The use of the default PCA adjustment factor is in accordance with EFED policies and procedures which have been subjected to peer review by the science advisory panel, the scientific community, and the public. A more detailed description of how the watershed-based percent crop areas (PCA) were derived can be found in the May 1999 presentation to the FIFRA Scientific Advisory Panel (SAP), *Proposed Methods For Determining Watershed-derived Percent Crop Areas And Considerations For Applying Crop Area Adjustments to Surface Water Screening Models*. This document and the SAP's response are available at: <http://www.epa.gov/scipoly/sap/1999/#may>.

Additional Modeling

Syngenta comment, (page 83 of 98): The agency should consider running additional modeling (Tier 2) for the turf exposure.

EFED response: EFED has incorporated an additional Tier II scenario for turf in Florida for the modeling of s-metolachlor (no turf use for metolachlor). However, EFED believes that the fate database is incomplete for the ESA and OA degradates at this time. Tier I modeling of the degradates was completed to provide a conservative, screening level assessment of the degradates in surface water. Given that EFED was not requested to refine these estimates, higher tiered modeling was considered unnecessary.

Monitoring: Sample Frequency

Syngenta comment, (page 84 of 98): A consistent theme throughout the document is the claim that the sampling regime for both acute and chronic datasets is not frequent enough. The implication is that if more frequent sampling had occurred, the environmental concentrations would be higher. This comment occurs on pages 3, 18, 19, and 26 with regard to both acute and chronic exposure time frames.

EFED response: The intent of the comment in the drinking water assessment was to make clear that EFED was relying on a large body of surface water and groundwater monitoring data collected at different times, by different groups, for different objectives. EFED was concerned that no single monitoring study evaluated as part of this assessment was focused on metolachlor/s-metolachlor use. Sample frequencies varied from dataset to dataset and therefore, EFED feels that this lends an element of uncertainty to the assessment. The comment was meant to indicate that there was uncertainty with estimating acute (peak) concentrations from monitoring data which had varying sample frequencies. It was not meant to imply that the time weighted mean concentrations (used for chronic exposure estimates) were impacted.

Clarification should be presented regarding the analysis done in the USGS Open-File Report 01-456, Pesticides in Selected Water-Supply Reservoirs and Finished Drinking Water, 1999-2000: Summary of Results from a Pilot Monitoring Program (hereafter referred to as Pilot Monitoring Program). The registrant implies that the analysis done by USGS was intended to develop a "paradigm" for the Agency on the issue of sample frequency. The analysis done was intended to address the specific requirements of the Pilot Monitoring Program and not represent a "thoroughly evaluated" issue as the registrant implies. In fact, the analysis indicated that for compounds of differing half lives (compare the results for bromoxynil with atrazine) different sample frequencies may be required. Specifically, the analysis indicated that more frequent sampling was required to capture the peak concentration for bromoxynil, with a shorter half life, than atrazine. Finally, the analysis does not account for temporal variability. The authors relied on a single year of the PRZM/EXAMS daily estimated concentrations and oversampled on a weekly (and bi-weekly basis) by randomly repeating the sample exercise for the same year, thereby missing any temporal variability which would be in the 36 year predictions from PRZM/EXAMS. This minimizes the effect of climate on the analysis by using the same year of data.

In addition to this general concern, EFED's specific concern with sampling frequency centers on two facts. First, none of the surface water or groundwater data evaluated (with the exception of the PGW studies) were targeted to metolachlor/s-metolachlor use. Second the Ohio Tributary study relied on reported values which were averages of multiple samples on a given day. Which samples were averaged and what effect the averaging had on determining peak concentrations was not reported in this study. Therefore, EFED is concerned that reporting peak concentrations from this data may underestimate concentrations actually detected. The study did not indicate which samples were averages or what the variation was around the average.

PLEX Database

Syngenta comment, (page 84-85 of 98): In the review of Syngenta's PLEX database (p 17), which is the monitoring database collected for the Safe Drinking Water Act, the Agency commented that: "The infrequent sampling means that the reported annual maximum metolachlor concentration in the PLEX database for any given CWS in any given year is likely to be substantially less than the actual annual maximum metolachlor concentration."

EFED response: The intent of the statement was to point out that estimating acute concentrations from data collected on a quarterly basis may be biased low due to the infrequent sampling frequency. Syngenta acknowledges this fact on page 85 of the response document. The comment will be revised in the drinking water assessment to clarify that the comment was for acute exposure only.

Heidelberg Database

Syngenta comment, (page 84-85 of 98): With regard to the Heidelberg College Dataset provided by the registrant, EPA stated: "Therefore, these maximum concentrations from the data may under predict the actual maximum concentrations detected in the entire dataset."

EFED response: The intent of the statement was to point out that estimating acute concentrations from data reported with daily averages without reporting the full data set from which the average was calculated will under-report the actual maximum detected in the data (unless all averages were based on equal values). Also, the study did not indicate which reported values were averages and which were single concentrations. The comment will be revised in the drinking water assessment to reflect this fact.

Monitoring: Declining Concentration in the Environment

Trends

Syngenta comment, (page 84-85 of 98): The Metolachlor monitoring data EPA used does not reflect the observed decline in concentrations in recent years. The databases used in the TRED include STORET (1982-87, OH and MI), USGS NAWQA (1993-99, 34 states), ARP (1995, 12 state), and USGS PILOT (2001, 12 states). The high concentrations in the old STORET database monitored in the 80s were used in the assessment as the worst case and as a validation of the regulatory models. Recent monitoring data have demonstrated a clear and consistent downward trend. As concluded in a recent Syngenta study (MRID 45527503, Syngenta Study no. 1663-01) and other scientific publications (e.g., Battaglin and Goolsby, 1999), the reduction in the overall metolachlor environmental concentrations is primarily due to the decreased use of Metolachlor. This downward trend has resulted from the phase-in of the lower application rate S-metolachlor end-use products and other factors such as the increasing environmental stewardship effort and best management practices.

The overall trend of declining concentrations is also evident in the data cited by EPA in the TRED document. Plotted in Figure 5 and 6 below are data directly from Appendix C (NAWQA), Appendix D (STORET), Appendix E (ARP), and Appendix F (USGS Midwestern Reservoir) in the EPA document. The annual maximum and time weighted metolachlor concentrations are grouped according to the year sampled. For the NAWQA data, the annual time weighted calculation were used. For the ARP data, both upper bound (setting <LOQ data to the LOQ values) and lower bound (setting <LOQ data to 0) annual time weighted means were included in the plots.

As shown in the box plots in Figure 5 and 6, a clear declining trend is confirmed in the rather diverse monitoring datasets. The data distribution between the 10th and 90th percentiles were orders of magnitude lower in the 90s than in the 80s. The median annual maximum in the 80s ranged 10 - 39 ppb, which declined to 0.04 - 1.1 ppb in 90s. And the median annual time weighted means ranged 0.6 - 1.5 ppb in the 80s declining to 0.012 - 0.26 ppb in the 90s.

Using more detailed monitoring data and product use information in several Ohio Lake Erie tributary watersheds, Syngenta has further shown that Metolachlor residues in the Ohio watersheds have further declined since 1998, the first large amount of S-Metolachlor use year, comparing to the mid 1990s (MRID 45527503, Syngenta Study no. 1663-01).

The general declining trend of Metolachlor concentrations is also seen from the percentile data

calculated for each database by EPA (TRED Table 11, 12, 13). As shown in Figures 7 and 8, the old monitoring data values (e.g. STORET, 1982-87) were far higher than the most recent monitoring data. Syngenta strongly believes that the total environmental residues of Metolachlor are rapidly declining and will decline further as the replacement of metolachlor by S-Metolachlor continues. Ultimately a reduction of more than 1/3 is anticipated, reflecting better product stewardship and the use of S-metolachlor and the registration of metolachlor at use rates equivalent to those established for S-metolachlor..

It is important to point out that the trend analyses presented to EPA in previous submissions were not exclusively meant to provide information that could be directly utilized in a refined or probabilistic risk assessment. If risk assessment refinement was the goal – instead of documentation of a downward trend – then Syngenta would agree that some of the questions raised by the Agency are relevant.

Syngenta utilized two separate strategies in order to demonstrate a downward trend in surface or ground water monitoring data sets. This was necessary, given that any change in application rate – even as dramatic as 35% - perhaps would be confounded by complex natural variability (i.e., amount of rainfall occurring right after applications, variance in planting times). This type of variability occurs in two different dimensions. The first dimension of variability is that of time (i.e., temporal variation). Natural variations in weather and climate patterns from year to year can be extreme, making any kind of trend analysis of environmental loading very difficult.

The second dimension of variability involves variation in local climate conditions from place to place in the same year. In any given year, specific regions may be considerably wetter or dryer, warmer or cooler, which also may change planting times and cultural practices. Rainfall, temperatures, and planting time in South Dakota are different than in Mississippi. Thus, any attempt to evaluate the environmental effect of a given use rate across the entire country in a given year over many different weather and climate based zones must contend with this high level of background natural variability.

To address the confounding effects of climate across time and across regions separately, Syngenta applied two different, yet complimentary strategies to perform a trend analysis.

In the first instance, a tightly defined region (Maumee & Sandusky Watersheds in Ohio) was used in which the climate and cropping patterns are relatively uniform across the region, and detailed systematically sampled monitoring data are available. To account for and remove the climatic temporal variation in this region, we used atrazine as an internal standard. This approach is valid because atrazine and metolachlor are applied simultaneously 81-91% of the time in this region. Additionally, during the timeframe of interest atrazine use is relatively constant or decreasing slightly. We evaluated the effects of S-metolachlor introduction by both concentration and mass flow. In doing so we were able to demonstrate that the use volume reduction caused by the change to S-metolachlor significantly decreased surface water loading of residues as measured by concentration and mass flow.

The second strategy which is used to deal with local climate variations was to integrate data

spatially over all major use areas in the United States (PLEX database). By looking at a large number of states we can take into account the spatial and temporal variability at individual sites. This approach also accounts for the entire volume of chemical that is used in a year, irrespective of where it is used. Since the analysis covers such a wide region and over several years, the natural climate variations (including hydrologic and use patterns) will average out allowing for a meaningful trend analysis. In doing so we were able to demonstrate a reduction in frequency of detection as well as concentration.

An analysis of spatial subgroups as e.g., individual states or regions may not be feasible. The number of samples is small (reducing statistical power) and without an internal reference (as was used in the previous example) it is difficult to overcome the background natural variation across regions. Thus, the analysis of SDWA data by state may or may not provide sufficient statistical power to answer the question unless additional noise reduction measures are adopted.

In short, by adopting these two strategies Syngenta was able to demonstrate a downward trend for environmental loading and water residues since the introduction of S-metolachlor. This is consistent with the expected results that reducing the overall use rate by 35% would ultimately reduce the overall environmental burden. We believe that the benefit from the rate reduction will manifest itself in a long-term reduction in environmental and human exposure.

EFED response: It is important to note here that Syngenta suggests that the Agency rejects their claim that the reduction in application rates reflected in the phase-in of s-metolachlor in the late 1990's will reduce loadings into the environment. EFED agrees that the label rate reduction should result in less loading to the environment. Where EFED does not agree with Syngenta is that the data submitted demonstrate a clear downward trend or reduction in concentrations in surface water and groundwater as a result of the phase-in of the lower rate s-metolachlor.

EFED did not agree or disagree with the conclusions presented in the studies cited, but found the analysis inconclusive as to whether the reduction demonstrated in the PLEX data could distinguish between reduction due to label change and other factors. Also, as noted below, EFED does not believe that the analysis of the Ohio Tributary data was conclusive to support the contention that a clear cause and effect could be demonstrated between rate reduction and the changes seen in the regression. Confounding this was the fact that analysis of the actual concentration/loadings data in this study was not performed and EFED's cursory analysis suggested that mean concentrations did not decrease over time.

EFED agrees that the use of older data should be avoided when more recent data are available. The revised assessment includes a recommendation that a more recent value, 77.6 ppb, from the NAWQA data be used for a peak EEC. It should be pointed out however that the National Contaminant Occurrence Database (NCOD) indicates a maximum concentration detected in drinking water derived from surface water of 130 ppb. However, because the source of this data has not been confirmed it is not recommended for the peak EEC. No change in the chronic EEC, 4.3 ppb, is recommended as this value was selected from NAWQA.

EFED does not disagree with Syngenta that there appears to be a decrease in concentrations over time as reported in the data evaluated in this assessment. However, EFED cannot confirm the "cause and effect" between the reduction in loadings due to phase in of s-metolachlor and the decrease in concentration. EFED's concern is most clearly demonstrated in the PLEX database derived from CWS data. The CWS data shows a decrease over time (both as a function of decrease in frequency of detection and concentration profile) but no attempt was made to demonstrate how much of total decrease (between 35% and 65% as reported by Syngenta) seen in CWS data is due to the 15% to 20% reduction in loadings due to s-metolachlor phase-in (estimated using Syngenta's use data which reports between 40% and 60% phase-in of s-metolachlor by 2000).

Comparison of PRZM/EXAMS and Monitoring Data

Syngenta comment. (page 87-88 of 98): When comparing the PRZM/EXAMS model predictions (the EPA worst corn scenario, Appendix B) with all the percentiles of the monitoring data processed by EPA in the TRED document (TRED Table 11, 12, 13), these simulations are not predictive. See Figures 7 and 8. The model simulations grossly and consistently over-predicted all data, generally by orders of magnitude for both annual maximums and time weighted means. Even compared to the out of date STORET database from the 1980s, the model grossly over-predicted the monitoring data. The unrealistically high model predictions probably resulted from a number of well recognized fundamental differences between the field scale models and the real-life watershed scale processes. Artificial bias to unrealistic worst case assumptions, particularly when these worst case assumptions are added on the top of each other, and improper use of environmental fate parameters are the most likely reasons for this failure to predict.

EFED response: PRZM/EXAMS is intended to provide upper bound estimates of surface water concentrations as a screening tool. In this assessment, the intention was to provide screening level estimates to compare against the monitoring data. Syngenta implies that the intent was to use monitoring to validate the model results. The opposite was the case. EFED did not use the model results for metolachlor/s-metolachlor (even though they were higher for chronic exposure) in this assessment for surface water EEC's for either the acute (annual maximum) or the chronic (time weighted mean) exposure. The model results were intended to provide confidence that the monitoring data were appropriate indicators of exposure.

On page 6 of the preliminary drinking water assessment it states that "In order to augment the existing data, an additional set of drinking water exposure assessments were completed using modeling predictions." The Tier II model runs using PRZM/EXAMS for metolachlor/s-metolachlor were completed as a check against the EECs which were selected from monitoring data. The monitoring data were not used to validate the model runs. The acute and chronic EECs for metolachlor/s-metolachlor recommended in the drinking water assessment were selected from monitoring data.

Also, EFED acknowledged on page 9 of the drinking water assessment that "the long term chronic exposure estimates tend to over predict the time weighted mean concentrations detected

in the monitoring data.” However, with the exception of the Mississippi cotton scenario modeled, the revised model runs predict EECs that are comparable with those selected from monitoring data.

Monitoring: Drinking Water

Treatment Process Effects

Syngenta comment, (page 88 of 98): EPA was not convinced that treatment processes remove S-metolachlor from raw water and given the uncertainty with this analysis EFED did not incorporate treatment effects into the drinking water assessment (page. 3 and 15).

EFED response: EFED reviewed the data from the USGS Reservoir study which suggests some treatment effect may be occurring. Research is currently underway and EFED has given priority to research into treatment effects and how this data may be used in future risk assessments including effects on specific acetanilides. Any information that the registrant wishes to provide in this research area would be greatly appreciated by EFED.

Enantioselective Analysis

Syngenta comment, (page 88-89 of 98): EPA was concerned that no data were available on the stereochemistry of metolachlor or its two primary degradates in monitoring data. The Agency was concerned by the lack of stereospecific data from groundwater and surface water monitoring studies for both parent and degradates and the lack of stereospecific data for the ESA and OA degradates are a source of uncertainty in this assessment (page 4). Since metolachlor is a racemic mixture of the S- and R-isomers, there was no need for stereospecific analysis prior to the registration of S-metolachlor in 1997 as only racemic product was in the marketplace.

Syngenta has been actively developing enantioselective analytical methods since the introduction of S-metolachlor to allow differentiation of different stereoisomers of metolachlor and degrade residues in water. We now have methods available for s-metolachlor, R-metolachlor, S-metolachlor ESA and R,S-metolachlor ESA. However, it should be noted that stereospecific data from groundwater and surface water monitoring studies are not critical for exposure assessment because the S- and R-isomers of metolachlor according to EPA reviews have similar toxicity and environmental profiles and, therefore, the portion of the drinking water assessment that relies on monitoring can logically be based on the summation of the R,S-isomer concentrations. Surface water monitoring studies have clearly indicated a shift towards increasing the S/R isomer ratios (H. Buser, et. al., Environmental Sci. Technol., 200, 34: 2690-2696) and a decreasing trend in the total isomer concentrations detected in both the surface and ground water after the introduction of s-metolachlor.

Syngenta believes that if there is any uncertainty associated with the lack of stereospecific data, the uncertainty would be the mixed use of both R- and S-metolachlor that could be complicated by the concurrent registration as two separate active ingredients. The amount of

benefit of reducing the total environmental residue concentrations by using S-metolachlor will be directly proportional to how much the old racemic metolachlor products are replaced by the new ones. Syngenta respectfully disagrees with EPA's constant denial of the fact that the more than 1/3 lower use rate of S-Metolachlor is reducing the overall environmental load. Given the current state where approvals of metolachlor products are limited by the use rates established for S-metolachlor, the pattern of decline in water residues should continue.

EFED response: EFED believes chiral specific analysis for monitoring data will not enhance the ability to illustrate a downward trend in metolachlor concentration and loadings. However, it would allow direct analysis of the source of metolachlor (racemic or s-metolachlor) detected in surface water and groundwater. This is supported by Buser, et. al., who documented the change towards increasing S/R ratios and also noted that at least in the short term concentration was not a good indicator of the phase-in of s-metolachlor.

Frequency of Detection

Syngenta comment, (page 89 of 98): In the cover letter of the drinking water assessment, EPA states that the frequency of detection of metolachlor from the entirety of the monitoring data evaluated (NAWQA, ARP, STORET, and USGS Reservoir studies) suggest that metolachlor contamination in drinking water sources (both surface and ground water) is widespread (cover letter). Syngenta agrees that Metolachlor has been detected in surface water because it is one of the most effective and widely used herbicides for corn and soybeans in the United States. It is well known that use intensity is a principal driver influencing the magnitude and detection frequency of pesticides in surface waters on a watershed. However, metolachlor has been detected only at trace levels in surface drinking water and well below its health advisory level under normal agricultural conditions.

EFED response: EFED acknowledges that metolachlor/s-metolachlor is a widely used herbicide. The data summarized in this assessment does not support the contention that metolachlor/s-metolachlor has only been detected in trace levels.

As noted previously, EFED agrees that the CWS data submitted by Syngenta indicates that both the frequency of detection and concentration profiles for metolachlor/s-metolachlor have decreased since the early 1990's. It should be noted (and was stated on page 18 of the drinking water assessment) that data from CWS with groundwater sources may not be good indicators of exposure due to the fact that typical CWS groundwater sources are deep and travel time from surficial aquifers to groundwater sources of drinking water may be long. This suggests that the effect of metolachlor/s-metolachlor use on groundwater supplied CWS may not be evident yet. NAWQA groundwater data and recent data reported by the Suffolk County, New York Department of Health Services, Bureau of Groundwater Resources suggest that metolachlor/s-metolachlor and its degradates are impacting shallow groundwater.

Outlier

Syngenta comment, (page 90 of 98): In the EPA TRED, the maximum metolachlor concentration

from all reported groundwater data was given at the 10,000 ppb level, while the average concentration from all reported data was 82.9 ppb. EFED believes that the reported maximum (10,000 ppb) and average concentration (82.9 ppb) should be viewed with caution because no information is available at this time to evaluate timing and location of the reported detections.

Upon further investigation in SDWIS, Syngenta was able to trace the alleged 10,000 ppb detection to a trailer park CWS in Pennsylvania. However, neither the State of Pennsylvania nor the CWS has any record of such a detection. Since no existing source can verify the data point, it should be removed from the database and not discussed in the TRED. (see Attachment A).

EFED response: EFED reported the 10,000 ppb value from the NCOD but did not recommend the use of this value as an EEC in risk assessment. The NCOD is maintained by the Office of Water. A re-check the NCOD indicates that the 10,000 ppb detection is still reported in the database. EFED cannot simply ignore the reported value and cannot therefore change the summary statistics as reported in NCOD. However, EFED does agree that the information provided by Syngenta indicate that the reported value is in error. EFED recommends that a copy of the report of Syngenta's investigation of this occurrence should be forwarded to the Office of Water for correction.