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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Memorandum

Subject: Consideration of Novartis' Document "Comments on 'Equivalency of Pesticides Metolachlor and S-metolachlor with Respect to Ground Water Contamination'"

From: Kevin Costello, Geologist/Risk Assessment Process Leader
Environmental Risk Branch I
Environmental Fate and Effects Division (7507C)

Kevin Costello
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Through: Sid Abel, Acting Chief
Environmental Risk Branch I/EFED

Sid Abel 8/29/2000

and

Denise Keehner
Acting Division Director, EFED

Denise Keehner

To: Arthur-Jean Williams
FEAD

In Novartis' document "Comments on 'Equivalency of Pesticides Metolachlor and S-metolachlor with Respect to Ground Water Contamination'", which was published in the Federal Register on February 23, 2000, the company advances the arguments that: 1) metolachlor and s-metolachlor have the same environmental fate profile, 2) the environmental fate properties of these chemicals indicate that metolachlor is less likely to leach to ground water than EFED previously thought, 3) ground-water monitoring studies indicate that when metolachlor is detected in ground water the concentrations would rarely approach even one-fifth of the Health Advisory Level of 70 ppb, and 4) the reduced application rate of s-metolachlor makes it even less likely that metolachlor will be detected in ground water at levels approaching the HAL.

Novartis is correct on essentially all of these points, but the data presented by Novartis also indicate that one does not fully understand the environmental fate of metolachlor by focusing on parent metolachlor alone. Degradates of metolachlor, especially metolachlor ethanesulfonic acid (ESA), are much more likely to be detected in ground water, and at higher concentrations. In fact, recent studies indicate that metolachlor

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ESA may be one of the most prevalent pesticide contaminants of ground water (e.g. Kahlkhoff, et al, 1998).

A short evaluation of Novartis' major comments on metolachlor and ground water follows.

Issue

1. Metolachlor and s-metolachlor have the same environmental fate profile.

This appears to be true, and EFED has agreed with this position since before the rebuttal was submitted. The major point outstanding from EFED's previous review was that the fate properties of metolachlor and s-metolachlor were similar to each other, but different than the values calculated earlier for racemic metolachlor.

2. The lower application rate of s-metolachlor makes it less likely that it will be detected in ground water at levels approaching the HAL of 70 ppb.

Since the application rate of s-metolachlor is 1/3 less than that of the racemic mixture, it is true that as a result less metolachlor (generically) would be expected to get to ground water. Since the toxicity of s-metolachlor is indistinguishable from the racemic mixture (except for plants), it is reasonable to compare concentrations of s-metolachlor to the HAL of 70 ppb.

However, it is not clear (nor likely) that the racemic metolachlor will be removed from the market, even though Novartis will no longer sell it. Therefore, since the relative future market share of the two products is unknown, the effect of the reduced application rate for s-metolachlor can't be predicted, but will likely be less than the overall 1/3 reduction predicted by Novartis.

3. The most recent environmental fate studies for metolachlor indicate that it is much less likely to leach than EFED previously believed.

The aerobic soil metabolism and photolysis half-lives calculated by Novartis do in fact suggest that metolachlor may be less persistent than suggested by data in the early 1990s. For instance, the recent EFED review of the environmental fate of metolachlor (8/17/2000, DP Barcode D236884, attached) concurs that the biphasic aerobic soil-metabolism half-life proposed by Novartis is reasonable, with half lives between 7 to 66 days depending on the half-life estimation.

However, degradation of metolachlor makes it more of a ground-water problem, not less. Metolachlor ethanesulfonic acid (ESA) is the most prevalent contaminant in several recent ground-water studies (methods of distinguishing metolachlor ESA from metolachlor and other ESAs have only been developed within the last 5 years or so). Metolachlor oxanilic acid (OA) has also been detected in ground-water, although at

lower concentrations than metolachlor ESA. Metolachlor ESA and metolachlor OA are not currently in the Pesticide Management Plan.

The fact that metolachlor degradates are much more likely to get to ground water than metolachlor lessens the likelihood that damage to non-target plants could occur by contaminated drinking water. Like metolachlor itself, metolachlor ESA and metolachlor OA should have different isomers corresponding to those of the parent. However, recent toxicity studies for metolachlor ESA (which did not distinguish between isomers of the degradate) indicate that it did not cause damage to non-target terrestrial plants tested.

4. The soil partitioning coefficient for s-metolachlor is greater than that of metolachlor, indicating that the isomer is less likely to leach than than the racemic mixture.

EFED disagrees with this assessment. The apparent difference in Koc values for the two species of metolachlor is an artifact of the different organic carbon contents of the soil in which the metolachlor and s-metolachlor adsorption/desorption studies were performed. The data suggest that metolachlor and s-metolachlor would be equivalently mobile to highly mobile in soil and water environments.

5. When normalized for the amount of pesticide used, metolachlor has a smaller percentage of detections than any other pesticide for which detections in at least 100 wells was reported in the 1992 Pesticides in Ground Water Database.

This is not a meaningful statistic. The PGWDB is not a single study within which one can compare different pesticides statistically, but rather a compendium of ground-water monitoring results that were voluntarily provided to the Agency. Furthermore, the usage data from 1992 can not be used with the monitoring data in the PGWDB, which date from the early 1980s to 1991 at latest.

6. The NAWQA database indicates a very low detection rate of metolachlor in ground water, with very low concentrations in the samples that had detections.

Metolachlor was detected in 18.4% of shallow ground-water sampling sites within the first 20 study units of the NAWQA program cited by Novartis. However, of the 924 such sites sampled, only 3.1% had detections at concentrations greater than 0.05 ppb. The maximum concentration found in any well was 5.4 ppb. Metolachlor was detected in 5.5% of 933 deeper aquifer wells, with a maximum concentration of 2.47 ppb. Metolachlor ESA was not an analyte in these study units.

However, metolachlor ESA and metolachlor OA are included as analytes in more recent NAWQA studies. One such study unit is the Lower Illinois River Basin, in which a NAWQA program was begun in 1994. The results of the ground-water monitoring program (which will be published in 2000) include metolachlor ESA detections as high as 39 ppb and metolachlor OA concentrations as high as 11 ppb in one well

(http://il.water.usgs.gov/proj/lirb/gw/results/metlchr_tbl.html). These combined concentrations of metolachlor degradates (metolachlor was found at < 1.0 ppb in that well) are greater than 2/3 the HAL of 70 ppb for parent metolachlor.

It is not clear how far sampled wells were from actual use of metolachlor. The vulnerability of the chosen sites to ground-water contamination is also not readily determined without a detailed evaluation of the entire monitoring well network. However, the results suggest that in a generic survey, metolachlor will indeed be detected in ground water. As Novartis asserts, the data also suggest that metolachlor will not often be found at levels approaching the HAL of 70 ppb.

7. Two prospective ground-water monitoring studies have not produced metolachlor ground-water detections anywhere near the HAL of 70 ppb, or even 7 ppb.

EFED has not yet reviewed these studies in detail, but indications are that Novartis is correct. The primary metolachlor species found in these studies are metolachlor degradates metolachlor ESA and metolachlor oxanilic acid (OA).

8. "Metolachlor was detected in less than one percent of Community Water Systems (CWS) wells in nine major use states between 1993 and 1998, and was at least an order of magnitude below the Health Advisory Level of 70 ppb in all samples."

EFED has not reviewed this data to which Novartis is referring, but these results are consistent with the other data cited by the registrant. It is unlikely that metolachlor ESA was included as an analyte at the CWS laboratories, since it is not on the unregulated contaminant monitoring list. A full understanding of the data is not possible given the level of detail presented by the registrant. The registrant did not indicate how many of the wells it cited drew water solely from ground-water sources. Other information such as the depth of the wells and the "age" of the ground water (time it took sampled water to reach the sampling depth from surface, as determined by a series of tracers) would be useful for further interpretation of the data.

In any case, other studies from the open literature also indicate that metolachlor ESA and metolachlor OA are more likely to be found than metolachlor, and at higher concentrations. In a study for the USGS in Suffolk County, New York, Phillips, et al (http://www.dnyalb.er.usgs.gov/projects/nypesticides/reports/Phi_WRIR99-4018.pdf) measured the ratios of metolachlor ESA to metolachlor and to metolachlor OA in ground water and in tile drains. The median ratio of metolachlor ESA to metolachlor in Suffolk County wells was 30. The median ratio in tile drains sampled further upsite were 460 and 950, with some values over 1000. The authors attribute the difference in the ratios to differences in soil texture; coarse soils such as those in Suffolk County seem more likely to allow leaching of metolachlor before more complete conversion to its degradates. This hypothesis is consistent with lower ratios seen in tile drains from storm events following metolachlor application.

Therefore, metolachlor has been detected in ground water, but is likely to be detected less often and at lesser concentrations than its degradates, especially metolachlor ESA. Metolachlor is more likely to be detected in areas with coarse-grained soils (the highest concentrations detected have been mostly in Florida). Although metolachlor has not been detected in the prospective ground-water studies, it follows that metolachlor as parent compound would most likely be detected in shallow wells to which there is rapid recharge. However, although many people in agricultural areas draw their drinking water from shallow wells, it is still much more likely that exposure to metolachlor would be in the form of degradates metolachlor ESA and metolachlor OA.