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ACETOCHLOR REGISTRATION PARTNERSHIP

C/O MONSANTO COMPANY

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April 9, 2010

Secretary Matt Frank
Wisconsin Department of Natural Resources
101 South Webster Street AD/8
Madison, WI 53703

Secretary Karen Timberlake
Wisconsin Department of Health Services
1 West Wilson Street 650
Madison, WI 53703

Subject: NR 140 groundwater standards for acetochlor

Dear Secretary Frank and Secretary Timberlake:

Last December, the Acetochlor Registration Partnership (ARP) submitted written comments on the proposed groundwater standards for Acetochlor contained in the NR 140 Rule revision. Those comments pointed out that DHS had used a cancer assessment, which had been withdrawn by the US EPA, when calculating the proposed ES and PAL for acetochlor. In our comments we identified outdated EPA Office of Pesticide Program reviews that were used in establishing the proposed standard and provided the appropriate/most current Federal Number and supporting documents.

In response to ARP's comments, last month the DHS issued a revised proposal for an ES and PAL for acetochlor. We appreciate the DHS reviewing our comments and making revisions to the Cycle 9 document. However, from the available record it appears that the methodology used by DHS to calculate the newly revised ES and PAL for acetochlor does not follow the very specific process mandated by WI statutes. As such, we are providing additional comments, to again clarify the appropriate Federal Number and resulting ES (200 ug/L) and PAL (40 ug/L) that should be utilized for the NR 140 rule revision. We would welcome the opportunity to meet with you if you need any additional clarification or to discuss this further.

As you know, NR 140 was initially promulgated by the Natural Resources Board in 1986 to comply with Chapter 160 of the Wisconsin state statutes ("the WI Statute"). The WI Statute stipulates a very specific process for developing state groundwater quality standards. Chapter 160 [160.07(4)(a)] states that "If a single Federal Number exists for a substance the number shall be the enforcement standard." ARP believes a Federal Number as defined by the WI Statute exists for acetochlor. As such, that Federal Number (i.e., the Reference Dose or RfD) should be relied upon as the basis for the ES and PAL. Previous DHS actions on other chemicals, in addition to internal DHS communications, have established a DHS precedent that an RfD is a Federal Number (see attached emails from Lynda Knobeloch to Henry Anderson and from Sandra Esrael to Mark Werner). As pointed out in our previous comments, the EPA Office of Pesticide Programs derived the acetochlor RfD and has reconfirmed this value in subsequent rules published in recent Federal Register announcements (May 2007 and September 2009).

Even if the well-established precedent of considering an RfD a Federal Number is not followed, the WI Statute [160.07(4)(c)] further mandates "the department of health and social services shall develop a recommended enforcement standard using the methodology under s. 160.13." As detailed in s. 160.13(2)(b)1, "If an acceptable daily intake for the substance is established by the office of pesticide programs or the office of drinking water in the federal environmental protection agency, that federal value shall be the acceptable daily intake." The RfD for acetochlor was derived by the Office of Pesticide Programs as the acceptable daily intake for acetochlor. As such, even if the current RfD is not considered a Federal Number, under 160.13(2)(b)1 it must still be used directly to calculate the ES and PAL.

Finally, according to the WI Statute [160.13(3)] "If no acceptable daily intake for the substance is established by the office of pesticide programs or office of drinking water in the federal environmental protection agency, the department shall determine the acceptable daily intake for the substance by dividing the substance's no-observable-effect level by a suitable uncertainty factor." Based on the available record, it appears that this is the approach that DHS took when revising the ES and PAL for acetochlor. As indicated above, that approach is inappropriate for acetochlor, since US EPA has established a RfD / average daily intake value for acetochlor. It is noteworthy that DHS relied upon the same no-observed-effect-level (NOEL) relied upon by the US EPA Office of Pesticide Programs to derive the Federal Number, but applied a 3,000-fold uncertainty factor to the NOEL rather than the 100-fold uncertainty fold factor applied by US EPA. The result of this approach was to inappropriately lower the ES and PAL by 30-fold with no statutory authority to do so. DHS provided no additional information in the revised standards to justify applying a number different from the Federal Number, as would be allowed under 160.09 (e) and 160.13 2 (b) 2, nor was any significant technical information identified, which is scientifically valid and which was not considered when the Federal Number was established.

In summary, WI Statute prescribes a very specific process for developing state groundwater quality standards. Considerable precedent has been set by DHS that the process requires using the US EPA RfD to calculate the standards and the record is clear that US EPA has established and reconfirmed recently the RfD / average daily intake value for acetochlor. However, DHS has presented DNR with a proposal that substantially deviates from established precedent and the statutory process. ARP again requests that the ES and PAL for acetochlor be revised to 200 and 40 ug/L, respectively, as outlined in our original comments on the proposed Cycle 9 revisions, using the current Federal Number/USEPA RfD and following the process mandated by the WI statute. We urge DNR to not proceed with promulgating the acetochlor standards proposed by DHS, until those proposed standards comply with the WI Statute.

Again, we appreciate your consideration of the points raised in this letter. Please contact us if additional clarification is desired, or if you would like to discuss this further.

Sincerely,

Gregory Watson, Ph.D.

**Chemical Regulatory Affairs Lead** 

**Monsanto Company** 

cc. Mike Lemcke (DNR)

Judy Ohm (DNR)

Michael Scott (DNR)

Lynda Knobeloch (DHS)

Diane Welsh (DHS)

James Matson (DATCP)