



(FORM UPDATED: 08/11/2010)

**WISCONSIN STATE LEGISLATURE ...
PUBLIC HEARING - COMMITTEE RECORDS**

2005-06

(session year)

Senate

(Assembly, Senate or Joint)

**Committee on Natural Resources and
Transportation...**

COMMITTEE NOTICES ...

- Committee Reports ... **CR**
- Executive Sessions ... **ES**
- Public Hearings ... **PH**

INFORMATION COLLECTED BY COMMITTEE FOR AND AGAINST PROPOSAL

- Appointments ... **Appt** (w/Record of Comm. Proceedings)
- Clearinghouse Rules ... **CRule** (w/Record of Comm. Proceedings)
- Hearing Records ... bills and resolutions (w/Record of Comm. Proceedings)
(**ab** = Assembly Bill) (**ar** = Assembly Resolution) (**ajr** = Assembly Joint Resolution)
(**sb** = Senate Bill) (**sr** = Senate Resolution) (**sjr** = Senate Joint Resolution)
- Miscellaneous ... **Misc**

MONSANTO
imagine™



MONSANTO COMPANY
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ST. LOUIS, MISSOURI 63167
<http://www.monsanto.com>

November 23, 2005*

Secretary Scott Hassett
Wisconsin Department of Natural Resources
101 S. Webster St.
Madison, WI 53703

RE: Clearinghouse Rule 02-095 related to establishment of Groundwater Standards for Alachlor ESA

Dear Secretary Hassett:

On November 16, 2005, the Wisconsin Assembly Committee on Natural Resources requested that DNR convene an independent scientific peer review panel, to be paid for by Monsanto Company, to review the proposed groundwater standard for alachlor ESA, an environmental degradate of the herbicide alachlor. Monsanto is hopeful that DNR will agree to this request to resolve this long-standing dispute and would like to work with DNR to ensure a timely and objective evaluation. Accordingly, Monsanto proposes the following for consideration by DNR:

1. The scientific peer review should answer the following three questions:
 - a) Does the Scientific Support Documentation accurately summarize the available information regarding the potential toxicity and carcinogenicity of alachlor ESA, and the potential carcinogenicity of parent alachlor?
 - b) Based on the available information, and the requirements of section 160.13 of Wisconsin's Groundwater Protection Standards, what value should be utilized as a "No-observable-effect-level" (NOEL) for determining an "acceptable daily intake" for alachlor ESA?
 - c) Based on the available information, and the requirements of section 160.13 of Wisconsin's Groundwater Protection Standards, what value should be utilized as a "suitable uncertainty factor" for determining an "acceptable daily intake" for alachlor ESA?
2. The scientific peer review shall be organized by a neutral, independent third party expert acceptable to DNR, DHFS and Monsanto Company. This expert should have significant experience in regulatory toxicology and risk assessment (preferably the establishment of health-based standards), and in conducting and/or coordinating these types of scientific peer reviews. One possible candidate would be Dr. Michael Dourson, an internationally

recognized expert in toxicology and risk assessment. Formerly with the USEPA, Dr. Dourson is now Director of a non-profit corporation, Toxicology Excellence for Risk Assessment (TERA), which specializes in the conduct and/or coordination of peer review of risk assessments similar to the one requested for alachlor ESA. Details regarding the qualifications of Dr. Dourson and TERA can be found at www.tera.org. Other possibilities might include Drs. Penny Fenner-Crisp (retired, formerly with USEPA and the International Life Sciences Institute), Roger McClellan (Toxicology and Human Health Risk Analysis), and Dennis Paustenbach (ChemRisk).

3. The peer review panel should consist of 4-5 independent scientists, selected by the above third-party expert, with well-recognized expertise in regulatory toxicology and/or risk assessment, especially regarding the determination of NOELs from animal studies and selection of Uncertainty Factors for use in risk assessment and health-based standards.
4. Information to be available for the peer review shall include, but not necessarily be limited to, the following:
 - a) Scientific Support Documentation for Cycle 8, March 2005 (revised August 2005), pertaining to alachlor ESA
 - b) Chapter 160, Wisconsin Stats., Groundwater Protection Standards
 - c) Final reports for all toxicology studies conducted with alachlor ESA
 - d) Statements from consulting pathologist and veterinary ophthalmologist regarding the results of the 91-day drinking water study with alachlor ESA
 - e) Peer-reviewed scientific publications on alachlor ESA
 - f) EPA Reregistration Eligibility Decision document for alachlor (December 1998) or relevant portions thereof.
 - g) EPA Carcinogenicity Peer Review (4th) of Alachlor (June 1997)

Further details regarding the nature of the scientific peer review should be agreed between DNR, DHFS, Monsanto and the expert coordinating the peer review. It is our expectation that the results of this peer review would be available within about 6 months of initiation.

Please contact Amy Winters (608-235-8443) or me (314-694-8853) if you have any questions.

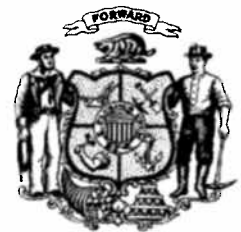
Thank you.

Sincerely,

Joel Kronenberg, Ph.D., D.A.B.T.
Lead, Food & Chemical Toxicology
Monsanto Company



WISCONSIN STATE LEGISLATURE





State of Wisconsin \ DEPARTMENT OF NATURAL RESOURCES

Jim Doyle, Governor
Scott Hassett, Secretary

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November 28, 2005

Honorable Scott Gunderson, Chair
Assembly Committee on Natural Resources
Room 7 West
State Capitol

Re: Clearinghouse Rule No. 02-095
Groundwater quality standards

Dear Representative Gunderson:

In response to your letter dated November 17, 2005, the Department of Natural Resources agrees to consider modifications to Clearinghouse Rule No. 02-095 relating to groundwater quality standards.

As required by s. 227.19(4)(b), Stats., the Department will notify your Committee when a decision has been made on the proposed modifications.

Sincerely,

Scott Hassett
Secretary

cc: Mike Lemcke – DG/2
Bill Phelps – DG/2
Carol Turner – LS/5



MEMORANDUM/CORRESPONDENCE

State of Wisconsin
Division of Public Health
Bureau of Environmental and Occupational Health
608 / 266-7480

Date: November 30, 2005
To: Henry Anderson, M.D.
From: Mark A. Werner, Ph.D. *MAW*
Subject: Health-based risk value comparison for alachlor-ESA

Per your request, I have developed a brief comparison of the methods used by our agency and those used by the Minnesota Department of Health in establishing health-based risk values for the ethane sulfonic acid metabolite of alachlor in drinking water.

Our recommendation to DNR is for the adoption of an enforcement standard of 20 µg/L for alachlor-ESA. The Minnesota Department of Health has developed a recommendation for a health-based risk value of 40 µg/L. The recommendations are based on similar no-observed-effect level values. Our NOEL is 20 mg/kg/day and the MN NOAEL is 16 mg/kg/day; both are based on hematological effects observed at the middle and high doses in the 90-day rat study sponsored by Monsanto in 1993. From there, differences are observed in four areas as displayed in the table below.

| | WI DHFS | MN DOH |
|---|---------|--------|
| Recommendation (µg/L) | 20 | 40 |
| NOEL or NOAEL (mg/kg/day) | 20 | 16 |
| Uncertainty Factor | 10,000 | 1000 |
| Water Intake (L/day) | 1 | 2 |
| Body Weight (kg) | 10 | 70 |
| Fraction of Exposure Allocated to Water | 100% | 20% |
| Child Intake Adjustment Factor | None | 3 |

- (1) **Uncertainty Factor.** The Minnesota recommendation incorporates an uncertainty factor of 1000 based on three areas of uncertainty: interspecies variability (10), intraspecies variability (10) and "database uncertainty" (10). Our recommendation incorporates an uncertainty factor of 10,000 based on four areas of uncertainty. Our values for interspecies and intraspecies variability are identical to those adopted by Minnesota. Our

recommendation includes tenfold uncertainty factors for use of a subchronic study and for data gaps, particularly the lack of a carcinogenicity study for a metabolite of a potentially carcinogenic compound.

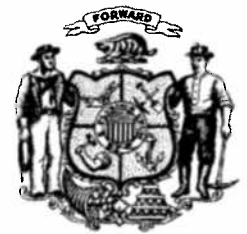
- (2) **Relative Source Contribution (RSC).** The Minnesota recommendation includes a value to account for exposure to the compound of interest and related compounds that may be incurred by routes of exposure other than drinking water. In this case, an RSC value of 0.2 represents a scenario in which 20% of overall exposure is considered to be derived from drinking water. This term is commonly applied by the U.S. Environmental Protection Agency in drinking water risk assessment, and its inclusion in this case effectively reduces the resulting risk value by a factor of five. There is no provision for applying RSC values in Chapter 160 Stats.; accordingly, such exposure is not accounted for in the Wisconsin statutory formula.
- (3) **Water Consumption and Body Weight Assumptions.** The Wisconsin assessment is based on the model of a 10-kg (22 lb.) child who consumes 1 liter of water per day. The Minnesota formula is based on the model of a 70-kg (155 lb.) adult who consumes 2 liters of water per day, resulting in a larger risk value than the Wisconsin model.
- (4) **Child Intake Adjustment Factor.** In its assessment, Minnesota includes a "child intake adjustment factor" of three. This value is applied to account for the difference highlighted in (3) above between the level of protection afforded when a child model is used vs. when an adult model. The use of this factor effectively negates the difference between the Wisconsin and Minnesota approaches as described in (3) above.

I was also able to find documentation on North Carolina's recommended health-based drinking water quality advisory for alachlor and related metabolites. The North Carolina approach is based on a cancer slope factor of 0.08/(mg/kg/day) for alachlor published in 1997 in EPA's Health Effects Assessment Summary Tables (HEAST). Based on the use of a 1×10^{-6} cancer risk level, an assumed body weight of 70 kg and a daily water intake of 2 L, a recommended total interim maximum allowable concentration for alachlor and related metabolites was calculated at 0.4 µg/L. This value is applied to the sum of observed concentrations of alachlor and related metabolites such as alachlor-ESA.

Please let me know if you have any questions about this assessment.



WISCONSIN STATE LEGISLATURE





Wisconsin Agribusiness Council, Inc.

P.O. Box 46100 • Madison, WI 53744-6100 • Phone (877) WIS-AGRI • Fax (877) 947-2475

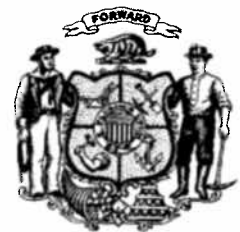
November 31, 2005

TO: Members of the Natural Resource Committee of the Wisconsin Senate
FROM: Ferron Havens, President/CEO
RE: Clearinghouse Rule 02-095

The Wisconsin Agribusiness Council opposes the passage of clearinghouse rule 02-095 as it is currently drafted. We all want to protect Wisconsin groundwater, however after reviewing all the material, there seems to be a number of issues that are not clearly resolved regarding the data and recommendations as it relates to the use of thealachlor ESA groundwater standard and its impact on farmers and small businesses in Wisconsin. To that end, we request that, prior to taking final rulemaking action, DNR convene an independent scientific peer review of the proposed standard and the data and methodology utilized to establish it.



WISCONSIN STATE LEGISLATURE





Capitol Strategies, LLC

Government relations and Public Policy Consulting Firm

**Senate Natural Resources Committee
December 1, 2005**

Testimony of Amy Winters, Contract lobbyist for CropLife America and Monsanto Company on Clearinghouse Rule 02-095 Establishing a Groundwater Standard for alachlor ESA.

Chairman Kedzie, members of the committee, thank you for this opportunity to testify on Clearinghouse Rule 02-095, and more specifically on the proposal to establish a groundwater standard for ethane sulfonic acid (alachlor ESA).

My client, CropLife America, is a national trade association that represents the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CropLife America's member companies produce, sell and distribute virtually all the crop protection, pest management and plant biotechnology products used by American farmers. Monsanto Company is a leading provider of agricultural products and solutions and is the manufacturer of alachlor ESA.

CropLife America and Monsanto fully supports Wisconsin's goal of protecting groundwater resources and ensuring the safety of drinking water and has no objection to the establishment of scientifically sound, health-based groundwater quality standards. However, we strongly **oppose** the proposal to establish a 20 ppb Enforcement Standard and 4 ppb Preventive Action Limit for alachlor ESA as it is not based on sound science nor is it consistent with standard scientific or regulatory practices. It also conflicts with the conclusions of other state, federal and international regulatory agencies.

Some of the issues we will outline are specific to alachlor ESA but many will also apply to other chemicals, including environmental degradates of other agricultural products, for which groundwater standards may need to be established in the next few years. The state clearly needs to take appropriate caution to ensure public health, however, erroneous decisions by DHFS may unnecessarily alarm Wisconsin residents about the safety of their drinking water supplies and could have a significant impact on Wisconsin's agricultural industry. It also sets an irresponsible precedent for establishing groundwater standards in Wisconsin.

Wisconsin's new data quality statute the legislature overwhelmingly supported and that Governor Doyle signed into law last year (state statute 227.14 2m) requires that each agency **shall** ensure the accuracy, integrity, objectivity, and consistency of the data that is used when preparing a proposed rule. Under this law, it is essential that any regulatory standard be based on the most accurate and comprehensive scientific evaluation available.

To comply with this statute, we request that the committee object to the portion of the rule that establishes this standard for alachlor ESA and recommend that prior to taking final rulemaking action, DNR convene an independent, scientific review panel to conduct a peer review of the toxicology data on alachlor ESA, and of the methodology used and conclusions drawn by DHFS.

This request is based upon our belief that DHFS did not ensure the accuracy, integrity, objectivity and consistency of the data underpinning its recommendations. We believe an objective review of the data, consistent with the State's Data Quality statute, will show that DHFS 1) misinterpreted a key study concerning the toxicity of alachlor ESA, 2) disregarded the results of a follow-up study that was specifically designed and conducted to address DHFS' concerns, 3) did not utilize U.S. Environmental Protection Agency (EPA) conclusions concerning the toxicity of alachlor and alachlor ESA; and 4) did not follow standard scientific and regulatory practices or EPA guidelines with regard to selection of a suitable uncertainty factor.

The use of a peer review panel is not unprecedented for groundwater standards in Wisconsin. In 1999 after the objection of this committee to a proposed ammonia standard, the DNR did proceed with a peer review of that proposal; the result was that the panel did not concur with the Wisconsin Department of Health and Family Services conclusions/science and the state did not proceed with the rule/groundwater standard.

On November 16th, the Assembly Natural Resources Committee unanimously voted on a motion requesting DNR to consider removing the alachlor ESA groundwater standard from the rule and have it peer reviewed; if the DNR does not agree to do so, the committee objects to the entire rule. I have attached that motion and a copy of the committee record.

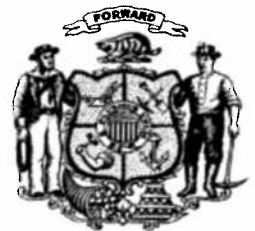
On November 28th, Secretary Hassett sent a letter to Chairman Gunderson agreeing to consider modifications; we ask that this committee reinforce this action and also request the peer review be done.

Thank you for your time and consideration.

Monson wants a peer review panel



WISCONSIN STATE LEGISLATURE



**Testimony of the Department of Natural Resources
Relating to Draft Clearinghouse Rule 02-095
Senate Committee on Natural Resources and Transportation
December 1, 2005**

Thank you for the opportunity to provide comments on administrative rule changes proposed in Clearinghouse Rule 02-095. My name is Mike Lemcke and I am the Chief of the Groundwater Management Section in the Department of Natural Resources.

I am appearing today in support of the rule changes proposed in this legislation. The objective of these proposed administrative rule revisions is to comply with the Department's charge to develop state groundwater quality standards for substances found in Wisconsin's groundwater and to implement the provisions of Chapter 160, Wisconsin's groundwater protection law. Proposed are rule revisions to establish new public health related groundwater quality standards for alachlor ethane sulfonic acid (alachlor-ESA) and molybdenum, and revised public health related groundwater quality standards for butylate, dacthal and naphthalene.

Butylate and dacthal are crop herbicides used in Wisconsin and alachlor-ESA is a breakdown product of alachlor, another herbicide used in the state. Molybdenum is a metallic element used in the manufacture of steel alloys and in a variety of other industrial processes. Naphthalene is a hydrocarbon compound found in coal tar, wood preservatives and insect repellents.

The existing state groundwater standards for butylate, dacthal and naphthalene are based on established federal reference dose levels. Because the federal reference dose levels for these substances have been revised, changes are being proposed to state groundwater standards to reflect the new federal numbers. Alachlor-ESA and molybdenum have been found in Wisconsin groundwater but state groundwater standards have not yet been established for these substances. In accordance with Chapter 160, the DHFS has developed recommendations for groundwater quality standards for these substances and the Department is proposing that these new standards be adopted.

In accordance with Chapter 160 the Department is required, for substances of public health concern, to propose rules establishing recommendations from the DHFS as state groundwater quality enforcement standards. The Department has proposed rules establishing the DHFS enforcement standard recommendations for alachlor-ESA, butylate, dacthal, molybdenum and naphthalene as ch. NR 140, Wis. Adm. Code, state groundwater quality enforcement standards, and has proposed rules establishing ch. NR 140, Wis. Adm. Code, state groundwater quality preventive action limits for these substances in accordance with applicable provisions of Chapter 160.

The Department began rulemaking to include these new and revised groundwater quality standards in chapter NR 140 in 2002. The Natural Resources Board approved public hearings on the proposed rule revisions and a series of hearings were held around the state in the fall of 2002. The Monsanto Company, the manufacturer of the herbicide alachlor, informed the Department that it was funding a new alachlor-ESA toxicity study and requested that the Department postpone final rule revisions until this study was finished. The company also requested a peer review of the methodology used by DHFS to develop its alachlor-ESA standard recommendation. The Department agreed to wait until the Monsanto funded study was completed. The DHFS reviewed the final results of the new alachlor-ESA toxicological study and provided the Department updated recommendations for groundwater quality

standards in August, 2005. The enforcement standard recommended by DHFS for alachlor-ESA did not change. A standard of 20 ug/L was still recommended. The Department requested that the Natural Resources Board adopt the proposed groundwater quality standards and the Board unanimously approved adoption at their September, 2005 meeting.

There has been some controversy associated with the proposed groundwater quality standards for alachlor-ESA. The alachlor-ESA breakdown product of the herbicide alachlor has been found to leach through the upper unsaturated soil zone and into groundwater. Alachlor is a corn and soybean herbicide used fairly extensively in Wisconsin in the early 1990s. Federal and state drinking water and groundwater protection standards have been established for alachlor at 2 ppb (ug/L). No federal or state drinking water standard has yet been established for alachlor-ESA.

Groundwater monitoring done at Department of Agriculture, Trade and Consumer Protection (DATCP) field sites in the early 1990s showed the presence of the alachlor-ESA metabolite of alachlor in groundwater, even at locations where the parent herbicide was not detected. In December of 1993 the Wisconsin Department of Health (Dept. of Health and Social Services) developed an interim health advisory level of 20 ppb (ug/L) for alachlor-ESA. An interim health advisory level provided rural homeowners with a health protection standard and also allowed them to apply for state well compensation program well replacement funds.

A 1994 Department of Agriculture, Trade and Consumer Protection (DATCP) well sampling survey done in high alachlor use areas of southern Wisconsin showed the alachlor-ESA breakdown product of alachlor to be present in approximately 32% of sampled wells and the parent herbicide, alachlor, present in approximately 2% of sampled wells. In a second 1994 well sampling survey, completed in areas of agricultural chemical use around the state, alachlor-ESA was found in about 13.5% of the sampled wells and alachlor was found in about 1.4% of the sampled wells.

In August, 1994 a letter from the Secretaries of DATCP, DHFS and the Department was sent to the Monsanto Company requesting that they initiate additional study, including chronic and reproductive feeding studies of alachlor-ESA to assess its long term effects and carcinogenic potential. In January, 1995 the company sent a letter to DATCP stating that their position was that no further toxicologic study of alachlor-ESA was warranted.

In recent, DATCP groundwater sampling, alachlor-ESA has been found in 28% of randomly selected water supply wells statewide, and in 91% of private water supply wells, and 48% of public water supply wells, known to be susceptible to impacts from agricultural chemicals (wells with past herbicide or nitrate detects).

Use of alachlor in Wisconsin, and in the Midwest, has decreased significantly over the last thirteen years. Wisconsin usage of alachlor in 1992 was reported to have been 2,358,000 lbs., or on an estimated 30% of the state "corn acreage". Since 1992, corn and soybean growers have switched to other herbicide products and alachlor use has steadily declined. Reported use in Wisconsin in 2001, 2002 and 2003 (the latest year for which corn crop agricultural chemical use data is available) was on 3% or less of state "corn acreage". Reported use of alachlor on all Midwestern soybean crops during this time period was "on less than 1%" of the total soybean planted acreage.

Past results from the DATCP well sampling database had shown that approximately 1% of water supply wells tested (13 of 1,288) were above the proposed alachlor-ESA groundwater

quality enforcement standard level of 20 ppb. These wells were subsequently replaced, or "follow up" sampling indicated that alachlor-ESA levels have dropped below 20 ppb. There are currently no wells in the DATCP sampling database showing alachlor-ESA levels above 20 ppb.

Because no water supply wells are currently testing above the proposed alachlor-ESA groundwater enforcement standard, and as use of the alachlor herbicide has declined in Wisconsin to relatively low levels, the Department has determined that any management practice restrictions placed on alachlor, to prevent exceedances of state groundwater enforcement standards for alachlor-ESA, are unlikely to have any significant economic impacts on Wisconsin agriculture.

No federal reference dose (RfD), health advisory level or drinking water standard for alachlor-ESA has yet been established by the United States Environmental Protection Agency (US EPA). Alachlor-ESA is however now on US EPA's Contaminant Candidate List (CCL). The US EPA is now reviewing alachlor-ESA occurrence and toxicology information to see if development of federal drinking water standards for the substance is warranted. Some analysis of alachlor-ESA toxicology was done by the US EPA Office of Pesticide Programs in 1998, when alachlor was reregistered as an approved herbicide "active ingredient". This analysis was reviewed by DHFS during their development of a recommended alachlor-ESA groundwater standard.

Health based advisory levels for alachlor-ESA have been established in Minnesota and North Carolina. The Minnesota health based advisory level (Health Based Value) for alachlor-ESA has been set at 40 ppb (ug/L). This level was lowered from 100 ppb to 40 ppb on Oct. 31, 2005. A North Carolina health based advisory level (Interim Maximum Allowable Concentration) has been established for total alachlor plus its metabolite breakdown products. The North Carolina advisory level for total alachlor plus its breakdown products is 0.4 ppb (ug/L). The European Union has also completed some review of alachlor-ESA toxicity information but has not set a specific standard for the substance. All herbicide breakdown products in groundwater are regulated by the European Union at 0.1 ppb (ug/L).

Some issues have been raised related to the proposed alachlor-ESA groundwater quality standards. It has been pointed out that the methodology used by the Wisconsin DHFS to develop its recommendation for an alachlor-ESA groundwater quality enforcement standard differs from the risk assessment and standard setting methodologies used by US EPA and in other states. Health risk assessment and groundwater protection standard methodologies used by the federal government, and by various states, differ. For example some states, including Wisconsin, set groundwater protection standards at levels to protect children while other states do not. Because the US EPA and states use different methodologies, protection factors and computational algorithms, risk assessment levels and established standards differ. Chapter 160, Wisconsin's groundwater law establishes a risk assessment methodology and standard setting procedure that must be used in Wisconsin to develop groundwater quality standards.

It has been suggested that a scientific panel be convened to review the data, methodology and conclusions used by DHFS in developing their alachlor-ESA enforcement standard recommendation. The scientific validity of the data used to develop the recommended alachlor-ESA groundwater standards has not been questioned. No concerns have been expressed regarding the results of scientific studies used by DHFS to develop their recommendations. DHFS followed the risk assessment methodology and standard setting procedure required under chapter 160, Stats. and their recommendation for an alachlor-ESA groundwater quality enforcement standard is scientifically valid and consistent with past established Wisconsin

groundwater quality standards. A review of the established risk assessment methodology and standard setting procedure that is specifically required under Wisconsin state statute would be of little value.

Alachlor-ESA is in Wisconsin drinking water. A groundwater protection standard is needed to provide the state with the tools to address past contamination of the resource and the ability to minimize any potential future impacts. The process established in our state statute allows our groundwater quality standards to be revised if new, relevant information becomes available.





State of Wisconsin \ DEPARTMENT OF NATURAL RESOURCES

Jim Doyle, Governor
Scott Hassett, Secretary

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July 10, 2006

Honorable Scott Gunderson, Chair
Assembly Committee on Natural Resources
Room 7 West
State Capitol

Re: Clearinghouse Rule No. 02-095 - Groundwater quality standards

Dear Representative Gunderson:

On November 17, 2005, the Assembly Committee on Natural Resources requested the Department of Natural Resources to consider modifications to Clearinghouse Rule No. 02-095 relating to groundwater quality standards.

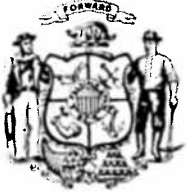
At the June 28, 2006 Natural Resources Board meeting the Board reviewed your request to consider rule modification. The Natural Resources Board took your request very seriously and carefully considered the information available on this issue. Attached is a letter from the Natural Resources Board outlining the steps taken since receiving your letter upon which the Board based their decision. After careful consideration of all information the Natural Resources Board voted not to modify the rule.

Under s. 227.19(4)(b)2., Stats., the Department of Natural Resources refers this rule to your Committee for an additional 10 working day review on this decision. If the Department does not hear from you within 10 working days of the receipt of this notification, the Department will continue processing this rule.

Sincerely,

Scott Hassett
Secretary

cc: Sen. Neal Kedzie
Mike Lemcke - DG/2
Mike Scott - LS/5
Carol Turner - LSL/5



State of Wisconsin \ NATURAL RESOURCES BOARD

July 10, 2006

Honorable Scott Gunderson, Chair
Assembly Committee on Natural Resources
Room 7 West
State Capitol

Re: Clearinghouse Rule No. 02-095 - Groundwater Quality Standards

Dear Representative Gunderson:

On November 17, 2005, the Assembly Committee on Natural Resources requested that the Department of Natural Resources (DNR) consider modifications to Clearinghouse Rule No. 02-095 relating to groundwater quality standards. These modifications included removing the proposed state groundwater quality standard foralachlor ethane sulfonic acid (alachlor-ESA) from the rule package and convening a scientific review panel.

At the June 28, 2006 Natural Resources Board meeting the Board reviewed your request to consider rule modification. The Natural Resources Board took your request very seriously and on behalf of the Board I wanted to share with you the details of the process we followed in making our decision.

After receiving your request the DNR asked technical toxicological experts at the Department of Health & Family Services (DHFS) to determine if the proposed scientific review foralachlor – ESA would be useful. (attached letter dated November 23, 2005) DHFS provides the primary science/toxicological review for the development of Wisconsin's Groundwater Standards. The groundwater setting process was designed such that DHFS, the agency that develops the numeric standards, works independently from agencies who apply the standards at regulated facilities or contamination sites. DHFS followed the statutory mandated process to develop a proposed standard for Alachlor-ESA when the rule was initially proposed.

Upon receipt of the DNR's letter DHFS took the request and initiated a new thorough scientific review to confirm their original recommendation for analachlor-ESA standard. They had several toxicologists review the technical information used prior to the public hearing process, the information received at the public hearings, and an additional toxicological study that was completed during the rule development process. The toxicologists then applied the methodology set forth in Wisconsin Statutes ch. 160 for development of groundwater standards and determined that the original proposed standard was appropriate. Additionally, during this process DHFS staff contacted their counterparts in North Carolina and Minnesota to discuss the health basedalachlor-ESA values established in those states. North Carolina established a 0.4 ug/L standard for thealachlor parent plus its metabolites. Minnesota established a 40 ug/L standard foralachlor-ESA. Wisconsin's proposed standard of 20 ug/L is in the regulatory middle of these two other states.

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After this extensive review was completed the DHFS's Secretary Helene Nelson responded to the Department of Natural Resource's request indicating that their agency had completed a comprehensive and professional review and they had determined that an additional external review was not necessary. (attached letter dated May 15, 2006)

At the June 28, 2006 Natural Resources Board meeting the Board reviewed DHFS's response and unanimously voted not to modify the rule. I hope I have transmitted enough information in this letter to adequately impart the lengths to which the two agencies and the Natural Resources Board went to respond to the Committee's request. If you have any additional questions DHFS and DNR staff are available to brief you and the legislative committees on this issue.

Sincerely,

A handwritten signature in black ink, appearing to read "G. M. O'Brien", written in a cursive style.

Gerald M. O'Brien
Chair

cc: Sen. Neal Kedzie
Natural Resources Board Members
Scott Hassett, Secretary DNR
Helene Nelson, Secretary DHFS



State of Wisconsin
Department of Health and Family Services

Jim Doyle, Governor
Helene Nelson, Secretary

May 15, 2006

Mr. Scott Hassett
Secretary
Department of Natural Resources
101 South Webster Street
Madison, WI 53707

Dear Secretary Hassett:

Thank you for your letter detailing actions of the Wisconsin Assembly's Committee on Natural Resources requesting that your agency consider revisions to Clearinghouse Rule 02-095, which contain the Department of Health and Family Service's recommendations for new and revised groundwater enforcement standards.

The Department of Health and Family Services (DHFS) staff conducted an extensive multi-year review and analysis of existing data. Staff have carefully considered and responded to comments received in writing or verbally at public hearings, and have responded to questions raised by the DNR Board and elected officials.

After completing this comprehensive and professional review, it is my opinion that the resulting groundwater standard properly interprets Ch. 160 Stats., which guides the process by which recommendations for groundwater enforcement standards are established. I do not believe that an external review of the proposed standard is necessary.

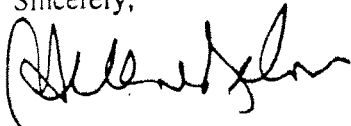
However, I am aware of the legislative committee's specific recommendation that Department of Natural Resources (DNR) pursue an external scientific panel review of the proposed standard for the ethane sulfonic acid degradate of alachlor (alachlor-ESA). I strongly believe that if it is determined necessary to conduct such a review, that it must be done entirely independent of any special interest group with an interest in its outcome.

I am concerned that the completion of a review paid for by a particular stakeholder creates a regulatory development process open only to those who have the ability to pay and sets an unhealthy precedent inconsistent with protecting the health, safety and welfare of Wisconsin's residents. Any review panel to support Ch 160 Stats standards should be the responsibility of the state and not based on whether an external party can fund the activity.

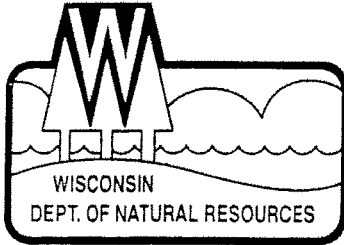
Wisconsin.gov

Thank you for the opportunity to comment on this proposed review. I am confident that the proposed standard appropriately protects the health of Wisconsin's citizens.

Sincerely,

A handwritten signature in black ink, appearing to read "Helene Nelson". The signature is fluid and cursive, with a large initial "H" and "N".

Helene Nelson
Secretary



State of Wisconsin \ DEPARTMENT OF NATURAL RESOURCES

Jim Doyle, Governor
Scott Hassett, Secretary

101 S. Webster St.
Box 7921
Madison, Wisconsin 53707-7921
Telephone 608-266-2621
FAX 608-267-3579
TTY Access via relay - 711

November 23, 2005

Ms. Helene Nelson, Secretary
Department of Health and Family Services
1 W. Wilson Street
Madison, WI 53707-7850

Subject: Review of proposed Alachlor-ESA groundwater quality standards

Dear Ms. Nelson:

I am writing you as your agency provides the primary science/toxicological review for the development of Wisconsin's Groundwater Standards. On November 16, 2005 the Wisconsin Assembly Committee on Natural Resources held a public hearing on proposed legislation and rule revisions. This hearing included Clearinghouse Rule 02-095, proposed new and revised state groundwater quality standards. The proposed groundwater quality standards for alachlor ethane sulfonic acid (alachlor-ESA) were discussed at the hearing and the Committee adopted a motion (attached), requesting that the Department consider modifying Clearinghouse Rule 02-095 to remove the proposed alachlor-ESA groundwater standards and commence a scientific review panel to review those proposed standards. The Department has agreed to consider modification of Clearing House Rule 02-095 as requested.

Your agency developed a recommendation for an alachlor-ESA groundwater quality enforcement standard (ES) in accordance with ss. 160.07 & 160.13, Stats. This recommendation was provided to the Department in August, 2005. The Department proposed adoption of the ES recommendation, along with an alachlor-ESA preventive action limit, developed in accordance with s. 160.15, Stats. Adoption of these proposed standards was unanimously approved by the Natural Resources Board at their Sept., 2005 meeting.

The Assembly Committee on Natural Resources has requested that the Department consider coordinating a review of the proposed alachlor-ESA groundwater quality standards by a scientific review panel. Before I make a final decision to agree or disagree with the Committee's action I need to be aware of your position as the agency responsible for developing this standard. I need to know if your agency believes this proposed review would be useful. In addition, if you could provide any rationale you used in making your decision, supporting or opposing a review, it would be appreciated.

Thank you for your assistance in this matter.

Sincerely,

Scott Hassett
Secretary



Scott Gunderson



STATE REPRESENTATIVE • 83RD DISTRICT

July 20, 2006

Senator Neal Kedzie
313 South, State Capitol
Madison, WI 53708

Dear Senator Kedzie,

I am writing to inform you that on July 20, 2006 the Assembly Natural Resources Committee, pursuant to s. 227.19 (4) (b) 5. and (d), Stats., objected to a portion of Clearinghouse Rule 02-095.

MOVED: that the Assembly Committee on Natural Resources, pursuant to s. 227.19 (4) (d) 6., Stats., objects to that portion of Clearinghouse Rule 02-095, relating to groundwater protection standards, that creates an enforcement standard and a preventive action limit for Alachlor ethane sulfonic acid (Alachlor ESA) on the grounds that the proposed standards for Alachlor ESA are arbitrary and capricious, and impose an undue hardship.

This motion was adopted on a vote of Ayes, 7; Noes, 5 (Ott, Steinbrink, Molepske, Van Akkeren, Hebl); Absent, 3 (Moulton, Black, and Gronemus).

Sincerely,

Representative Scott Gunderson
83rd District
Wisconsin State Assembly

State Capitol:

P.O. Box 8952
Madison, WI 53708
(608) 266-3363

Toll-Free:
(888) 534-0083

Fax:
(608) 282-3683

E-Mail:
Rep.Gunderson@
legis.state.wi.us

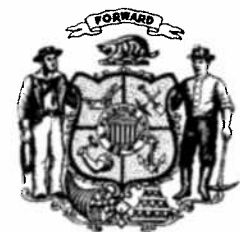
83rd District:

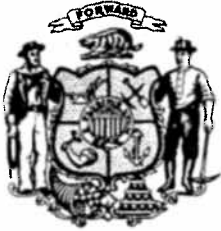
P.O. Box 7
Waterford, WI
53185

(262) 895-6254



WISCONSIN STATE LEGISLATURE





STATE OF WISCONSIN

July 17, 2006

Honorable Scott Gunderson, Chair
Assembly Committee on Natural Resources
Room 7 West
State Capitol

Dear Representative Gunderson:

The Natural Resources Board recently returned Clearinghouse Rule No. 02-095 on groundwater quality standards to the Assembly Committee on Natural Resources without modification. The Rule is included for possible executive action on the Committee's July 20th agenda.

Your committee had requested that the Department of Natural Resources (DNR) consider modifications to the rule, including an external peer review of the proposed groundwater standard for Alachlor-Ethane Sulfonic Acid (Alachlor-ESA). In accordance with state statute, the numeric standard proposed for Alachlor-ESA was developed by toxicologists at the Department of Health & Family Services (DHFS).

In response to your request the DHFS, conducted a review/audit of the scientific data, methodology used, and final recommended numeric value. Upon completing this review/audit DHFS determined that their original recommended standard was appropriate.

Currently there is no promulgated state groundwater quality standard for Alachlor-ESA. The Department of Agriculture Trade & Consumer Protection (DATCP) has conducted monitoring studies that show Alachlor-ESA is present in approximately 28% of water supply wells sampled. As this indicates a potential for long term exposure of the state's citizens to this contaminant DATCP has requested that a state groundwater quality standard for Alachlor-ESA be established.

The three agencies support the adoption of this groundwater quality standard for the protection of state groundwater resources, water supplies, and citizen's health. We believe the internal review/audit completed by DHFS has met the intent of your request and hope that the rule making process on Clearinghouse Rule No. 02-095 may now continue.

Sincerely,

Scott Hassett, Secretary
Department of Natural Resources

Helene Nelson, Secretary
Department of Health & Family

Rod Nilsestuen, Secretary
Department of Agriculture
Trade & Consumer Protection

cc: Assembly Committee on Natural Resources Members
Sen. Neal Kedzie - 313 J.



ATTACHMENT I - General Comments

1. Scientific Objection

We believe that the DHFS recommendation is at odds with the scientific evidence and is therefore seriously flawed in two key respects:

- (1) DHFS's conclusions regarding the toxicity of alachlor ESA, particularly DHFS' determination of a No Observable Effect Level (NOEL) and their decision to ignore recent study results.
- (2) DHFS did not select an appropriate uncertainty factor for use in calculating an Enforcement Standard.

In both instances, DHFS' conclusions are at odds with and considerably more conservative than those of USEPA and other federal, state, and international regulatory agencies.

The net effect of these two decisions by DHFS is a proposed Enforcement Standard (20 ppb) that is at least 30-fold, and perhaps over 100-fold, more restrictive than would have been set had the DHFS followed EPA's guidance for conducting risk assessments and setting water quality standards or utilized EPA's conclusions regarding the toxicity of alachlor and alachlor ESA.

2. An Independent Scientific Peer Review is Needed

There is a mechanism available to resolve such scientific disputes. This mechanism – **peer review by an independent, scientific review panel** -- is supported by Wisconsin statutes and has been used successfully in prior instances.

On July 1, 2004, state statutory requirements to assure the quality of agency data utilized in rulemaking went into effect (2003 Wisconsin Act 145, Small Business Regulatory Reform). Section 227.14(2m), sometimes called the Data Quality Act, provides as follows:

“Each agency shall, in cooperation with the department of administration, ensure **the accuracy, integrity, objectivity and consistency of the data** that is used when preparing a proposed rule and when completing an analysis of the proposed rule under sub. (2).”

This law mirrors the important policy choice made in the Federal Data Quality Act that imposes a similar obligation on federal agencies to assure the scientific soundness of data utilized in federal regulations. This newly enacted obligation applies to all Wisconsin state agency rulemaking. Yet despite a wealth of new data submitted to DHFS, and official USEPA statements to the contrary, DHFS has steadfastly refused to reconsider the 20 ppb interim standard for alachlor ESA first recommended over a decade ago. Internal department correspondence from DHFS also suggests that DHFS was unwilling to objectively consider-- as required by statute-- any new information or scientific opinion.

Under these circumstances, we believe the establishment of a peer review panel to objectively review DHFS' recommendations is essential. DHFS and DNR are both obligated to comply with the state Data Quality Act, yet the proposed rule and analysis for alachlor ESA clearly fail to meet its requirements. DNR staff is in error when it rejects a peer review panel on the grounds that "there is no provision in Chapter 160, Stats., for peer review of groundwater standard recommendations developed by DHFS" and that the result will provide "little service to the citizens of the state." (DNR Response to Public Comments, pp. 6, 11; Comments 20, 44)

Scientific peer review is often utilized by state, national and international regulatory agencies to resolve difficult and/or controversial scientific issues. DNR previously convened such a review panel to assess the proposed groundwater standard for ammonia. A scientific peer review panel is also now being convened by the Minnesota Department of Health to resolve scientific controversies associated with their establishment of Health Risk Limits (HRLs) for contaminants found in groundwater.

Contrary to DNR staff's assertion, convening an independent peer review panel to resolve the scientific disputes over the proposed rule for alachlor ESA will provide significant value to Wisconsin citizens by demonstrating the integrity of the regulatory process, and ensuring that whatever standards are ultimately adopted are scientifically sound and fully protective of public health. Delaying adoption of a formal Enforcement Standard and Preventive Action Limit for alachlor ESA pending completion of such a peer review will have no impact on public health because the State has in place an interim health advisory level of 20 ppb for alachlor ESA, the same value now being proposed as the Enforcement Standard.

3. Small Business Impact

Monsanto also believes that DNR improperly certified the proposed rule by not fully assessing the potential impact of this rule on small businesses and Wisconsin's agricultural industry. Alachlor is an important and particularly cost-effective herbicide for the state's grain and silage producers, most of who are small business owners. The analysis fails to account for all of the potential economic effects the proposed standard may have on these important members of Wisconsin's agricultural economy.

In addition to the Data Quality Act, Act 145 also created the Small Business Regulatory Review Board, charged to review rules to determine whether they "place an unnecessary burden on the ability of small businesses . . . to conduct their affairs." (S. 227.30(1), Stats.) Rules that "may have a significant economic impact on small businesses" must be submitted to the Small Business Regulatory Review Board at the same time those rules are filed with the Legislature. (S. 227.24(3), Stats.). **The proposed groundwater standards for alachlor ESA meet this test and should be considered by the Small Business Regulatory Review Board (SBRRB).**

4. Monsanto's Prior Comments Remain Unaddressed

Monsanto provided extensive scientific and legal comments on this proposal during the public hearing process. As DNR's Response to Public Comments document shows, many of our

comments were supported by other agricultural interests, including small business owners, through public testimony and written comments. We are disappointed to see that these comments had no impact on the proposal. DHFS' recommendations for the Enforcement Standard and Preventive Action Limit remain unchanged. We also note that many of these comments appear to have been summarily dismissed without sufficient rationale.

Monsanto's September 2002 written comments also detailed the many ways in which the procedures followed by DHFS in developing its recommendation fail to comply with the requirements of Chapter 160, the state groundwater law. (See September 2002 comments attached)

Attachment II

Response to DHFS Responses to Public Comments and Cycle 8 Scientific Support Documentation

1. Determination of the NOEL

(a) DHFS has concluded that the NOEL for the 1993 rat study conducted with alachlor ESA was 20 mg/kg/day. **This value is almost 10-fold lower than the NOEL (182 mg/kg/day) determined for the same study by USEPA and by the European Union.** DHFS has now acknowledged the USEPA conclusion, but justified its conclusion on the basis of the “criteria specified in Ch. 160” (see Green Sheet Attachment 2, DHFS responses #1, 8 and 21). It appears that DHFS is referring to section 160.13(c), which defines the term NOEL. However, this definition is essentially the same as that used by USEPA as well as other regulatory agencies and toxicologists throughout the world, and does not justify DHFS’ decision to ignore USEPA’s conclusion.

(b) DHFS previously justified its NOEL decision on the basis of statistics (see November 2001 draft Recommendation, included as Attachment B to Monsanto’s September 20, 2002 written comments). However, as discussed in Monsanto’s written comments of September 20, 2002, that position conflicted with a previous DHFS statement that statistical significance was not intended to be used as the sole determinant of whether or not a finding is biologically significant or meaningful. The reference to statistical significance has now been dropped from DHFS’ August 2005 Scientific Support Documentation for Cycle 8 Revisions of NR 140.10 (2005 DHFS Recommendation) but DHFS’ conclusion regarding the NOEL remains the same. DHFS provides no alternative explanation in either the 2005 DHFS Recommendation or in DHFS’ Response To Public Comments other than to assert that the conclusion results from “application of the criteria in Ch. 160”.

(c) As alluded to in DHFS response #8, and previously expressed in both written and verbal statements to Monsanto, DHFS appears to consider suspect the fact that USEPA has revised its conclusions about the 1993 study.

Monsanto believes these concerns are unwarranted. USEPA revised its conclusions after receipt of additional information and further scientific input and review. This is not an unusual occurrence. **In addition, the final USEPA conclusions regarding the NOEL for this study were included in the alachlor Reregistration Eligibility Decision (RED) document that was published in 1998 following both internal USEPA peer review and a standard public comment period.** DHFS had previously been in contact with USEPA about this study and any further concerns should have been expressed at that time.

(d) In 2002, following a series of meetings with and **at the suggestion of DHFS,** Monsanto initiated a new 90-day rat study with alachlor ESA (at a cost of approximately \$200,000), in an attempt to resolve this issue. The results of the 2003 study clearly demonstrated that alachlor ESA is markedly (10- to 40-fold) less toxic than believed by DHFS. DHFS has acknowledged this marked difference but has chosen to ignore the new

results and to continue to base their calculations only on their original conclusions from the 1993 study. DHFS justifies this decision (2005 DHFS Recommendation, page 5) on the basis that alachlor ESA was administered via the drinking water in the first study and via the diet in the second study. However, dietary administration was utilized in the second study to avoid the water palatability problem that greatly complicated the interpretation of the results in the first study. It is highly unlikely that this difference in methodology, **which was discussed with and agreed to by DHFS prior to study initiation**, would have had a significant impact on the study results. Furthermore, results from studies conducted via dietary administration have been used by state, national and international authorities to establish numerous groundwater standards, including the overwhelming majority of those for pesticides (including alachlor).

2. Selection of a Suitable Uncertainty Factor

(e) DHFS' utilization of a 10,000-fold uncertainty factor differs greatly from the 1000-fold uncertainty factor used for alachlor ESA in the alachlor RED and thus violates 160.13(2)(b) which requires DHFS to utilize available information from USEPA. Please also see our September 2002 comments for detailed explanation of the specific deficiencies.

(f) Contrary to the statement on page *viii* of the 2005 DHFS Recommendation, uncertainty factors of 10,000 are not typically used, even in cases where the data are limited or there are some unresolved concerns. EPA's general guidance is that uncertainty factors greater than 3000 should not be used in establishing standards because they are "too uncertain." (*e.g.*, EPA Office of Drinking Water, 2000).

(g) DHFS's response to the above two comments (DHFS Responses #6 and 10) is only that they are "required to employ the methodology outlined in Ch. 160 for deriving uncertainty factors". The methodology provided in Ch. 160 does not justify this decision. Section 160.13 lists the *types* of information that should be considered when determining a suitable uncertainty factor; it does not provide any guidance as to what the *magnitude* of such a factor should be.

(h) The use of an additional ten-fold uncertainty factor to account for DHFS' concern about *possible* carcinogenicity of alachlor ESA is contrary to a specific recommendation made to DHFS by USEPA in 1994, and ignores the USEPA conclusion that "alachlor ESA is unlikely to be carcinogenic" (alachlor RED, 1998), a conclusion that DHFS agreed to in a 2001 meeting. It is also contrary to the policies expressed in the USEPA Guidelines for Carcinogen Risk Assessment (USEPA, 2005). In fact, there are numerous examples of USEPA Category B2 (Probable) or C (Possible) carcinogens for which no additional uncertainty factor has been applied.

(i) DHFS either does not fully understand or does not accept USEPA's revised cancer classification for alachlor. This classification was changed in late 1997 following extensive peer review of the data by numerous senior scientists at USEPA, as well as the USEPA Science Advisory Panel. This classification now represents the official USEPA regulatory position. **However, the 2005 DHFS Recommendation as well as DHFS' Response #9 continues to rely on the outdated, B2 (Probable Human Carcinogen) classification that was assigned in 1986.**

(j) DHFS continues to rely on highly misleading and outdated examples as precedent for use of a 10,000-fold uncertainty factor (DHFS Responses #5 and 23). All four examples cited in the 2005 DHFS Recommendation were based on decisions prior to the USEPA policy decision in the year 2000 that uncertainty factors greater than 3000 should not be employed. More importantly, the unusually large uncertainty factor DHFS utilized for these chemicals was based either on the fact that a NOEL for the chemicals had not been determined or because the chemicals were classified by the USEPA as a Probable (B2) and/or Possible (C) human carcinogens. Neither of these situations applies to alachlor ESA.

(k) In addition to not addressing any of the factual issues raised about the four examples, DHFS' Response #23 erroneously states that Monsanto claims "EPA has no RfDs with a UF of 10,000 based on a subchronic LOAEL". This is incorrect. Monsanto commented that the **only** examples in which USEPA applied a 10,000-fold uncertainty factor in determining the RfD were a few chemicals for which a subchronic NOEL could not be determined and a subchronic LOEAL had to be used instead. As previously explained, this is not the situation for alachlor ESA. USEPA has established numerous RfD's based on subchronic toxicity studies and uncertainty factors of 1000 or 3000.

3. Rejection Of A Peer Review Panel

(l) DNR's Response to Comments rejects the idea of peer review by an independent, scientific panel on the grounds that "there is no provision in Chapter 160, Stats., for peer review of groundwater standard recommendations developed by DHFS." (DNR Response to Public Comments, pp. 6, 11; Comments 20, 44) This position misunderstands the law. On July 1, 2004, state statutory requirements to assure the quality of agency data utilized in rulemaking went into effect (2003 Wisconsin Act 145, Small Business Regulatory Reform). Section 227.14(2m), sometimes called the Data Quality Act, provides as follows:

"Each agency shall, in cooperation with the department of administration, ensure **the accuracy, integrity, objectivity and consistency of the data** that is used when preparing a proposed rule and when completing an analysis of the proposed rule under sub. (2)."

S. 227.14(2m) mirrors the important policy choice made in the Federal Data Quality Act that imposes a similar obligation on federal agencies to assure the scientific soundness of data utilized in federal regulations. This newly enacted obligation applies to all Wisconsin state agency rulemaking. The fact that it is not specifically included in the provisions of Chapter 160 does not make it inapplicable to groundwater standards rulemaking, nor does it relieve DHFS and DNR of the obligation to comply with the new law.

(m) DNR's Response to Public Comments also rejects the idea of peer review on the basis that "peer review of the proposed ammonia nitrogen groundwater standard reclassification to a public health standard was difficult to accomplish, and the resulting evaluation provided little service to the citizens of the state." (DNR Response to Comments, pp. 6, 11; Comments 20, 44) DNR's response also misunderstands the important public policy purpose, which underlies Wisconsin's adoption of the Data Quality Act. That the peer review process might be difficult is neither surprising – given the nature of the scientific disputes – nor justification

for not doing it. The citizens of Wisconsin are well served by assurance that regulations are based on sound science, and the regulatory process has the integrity of independent review by qualified experts. None of these explanations justifies failure to comply with the state Data Quality Act.

4. Impact on Farmers and Small Businesses

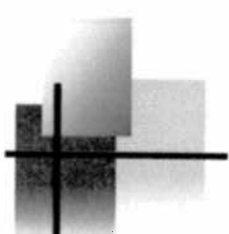
(n) The analysis of this rule's potential impact on small businesses has serious omissions, as it fails to account for all of the potentially harmful economic impacts on Wisconsin's agricultural industry. Alachlor is an important and particularly cost-effective herbicide for the state's grain and silage producers, most of who are small business owners. According to Doane Market Research, just over 1500 of the state's growers used alachlor in 2004 on at least some of their row crops.

Wisconsin's corn growers have two problem weeds, Woolly Cupgrass and Wild Proso Millet, for which higher application rates of alachlor are required to provide suppression. This product is used in both conventional and Roundup Ready Corn 2, the latter of which is increasingly being planted as a tool to provide season long control of Wisconsin's most troublesome weeds. Alachlor provides critical early season suppression of these weeds, followed by highly effective glyphosate applications to the Roundup Ready Corn 2 crop. This system has been very effective over the last 5-6 years. A geographic restriction in the use of alachlor or merely a reduction in its maximum application rate could impose a serious economic burden on such alachlor users, who would then be forced to try more expensive weed treatment systems, or simply accept the costly reductions in yield that these problem weeds can cause.

In addition to these growers, there is an important group of small businesses not included in the analysis – Wisconsin's livestock producers. As consumers of corn silage, these producers have a direct economic interest in the availability of cost-effective herbicides such as alachlor, which enable silage to be provided to livestock at an affordable price.

The proposed rule could lead to requirements to implement mitigation measures for alachlor similar to those now in place for atrazine, including rate reductions and use prohibition areas. According to DATCP's most recent public reports, over 100 wells exceed the proposed PAL of 4 ppb for alachlor ESA. This could lead DATCP to create an alachlor use prohibition area of over half a million acres. Impacted alachlor users would then be forced to choose more expensive herbicides, without serving any real benefit to public health or the environment. This looming economic burden to the state's small business community should trigger the involvement of the Small Business Regulatory Review Board (SBRRB).





Minnesota Health Based Value (HBV)

- HBV is MN's non-enforceable, interim groundwater standard
- Alachlor ESA HBV just lowered (10/31/05) from 100 to 40 ppb
- However, lower value based primarily on MDH's proposed new exposure methodology, which is currently undergoing external peer review, not on change in Acceptable Daily Intake (ADI)
- Minnesota ADI = 8x higher than Wisconsin ADI, without considering results of new rat study
- Using MN ADI with exposure methodology mandated by WI 160.13, Stats., would result in ES of 160 ppb vs. DNR proposal of 20 ppb

Minnesota Health Based Value (HBV)

ADI = Acceptable Daily Intake (also called RfD or Reference Dose)

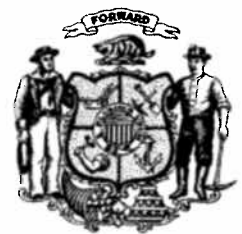
$$ADI = \frac{NOEL}{UF} \quad (WI = 2, MN = 16 \mu\text{g}/\text{kg}/\text{day})$$

$$\text{Wisconsin ES} = ADI \times \frac{10 \text{ kg bodyweight}}{1 \text{ L/day}} \times 100\%$$

$$\text{Minnesota HBV} = ADI \times \frac{70 \text{ kg bodyweight}}{2\text{L/day} \times 3} \times 20\%$$



WISCONSIN STATE LEGISLATURE



- "Less on a scale... accountability"
Can discuss as "Monsanto's"

- EPA:
'NO ETC
2. Unnecessary FURTHER

✓ DMS/DTPS not comparing
their (EPA) (??)

✓ The peer review has
been before on DTPS?

✓ What possible chance
do farmers have?

✓ USEPA - March 1984
"Unlikely to be a carcinogen"

① New Study

✓ Peer Review

① 1984 request 3 studies
Monsanto said not needed

- 2002 - 2004 Monsanto
said they would do a
study. Although not requested
by EPA in writing?

② Peer Reviews:
IS DTPS following
the rest of EPA law?
Monsanto asking for peer review

Q Does Missouri's infrastructure
remain strong on the edge?
Are we standards for services?

Q Do you disagree?
(w/ the other panel)

P (Have you disagreed before w/ wT DHS?
(A) Not comparable

~~Look at standards~~

Q Are you looking at other states??
No -> and in general for standards

~~but...~~

~~why...~~

P (\$200,000,000,000)

Missouri says DNR ignored?
True?

What does it mean for
Missouri -> just answer.
More concerned w/ procedures

Peer review on
existing data only.