

 **07hr\_SC-ENR\_CRule\_07-034\_pt01**



(FORM UPDATED: 08/11/2010)

WISCONSIN STATE LEGISLATURE ...  
PUBLIC HEARING - COMMITTEE RECORDS

**2007-08**

(session year)

**Senate**

(Assembly, Senate, or Joint)

**Committee on ...  
Environment and Natural Resources  
(SC-ENR)**

**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 ... **HR** ... **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**

\* Contents organized for archiving by: Mike Barman (LRB) (July/2014)

Senate

Record of Committee Proceedings

**Committee on Environment and Natural Resources**

**Clearinghouse Rule 07-034**

Relating to groundwater quality standards.  
Submitted by Department of Natural Resources.

August 22, 2007 Referred to Committee on Environment and Natural Resources.

August 28, 2007 **PUBLIC HEARING HELD**

Present: (4) Senators Miller, Wirch, Kedzie and Schultz.  
Absent: (1) Senator Jauch.

Appearances For

- Mike Lemcke, Madison — Department of Natural Resources
- Henry Anderson, Madison — DHFS
- Mark Werner, Madison — DHFS
- Bruce Rheineck, Madison — DATCP

Appearances Against

- None.

Appearances for Information Only

- None.

Registrations For

- Anne Sayers, Madison — Wisconsin League of Conservation Voters

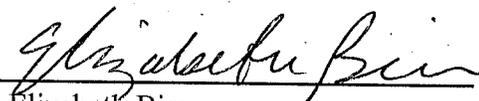
Registrations Against

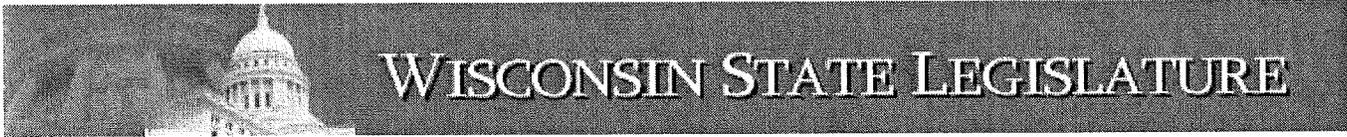
- None.

Registrations for Information Only

- None.

October 22, 2007 No action taken.

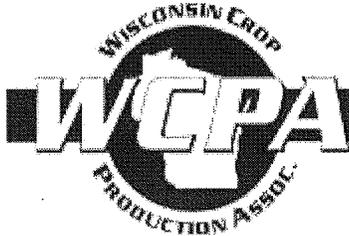
  
Elizabeth Bier  
Committee Clerk



**Bier, Beth**

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**From:** Mike Turner [wcpa@tds.net]  
**Sent:** Friday, May 18, 2007 8:31 AM  
**To:** \*Legislative Assembly Democrats; \*Legislative Assembly Republicans; \*Legislative Senate Democrats; \*Legislative Senate Republicans  
**Subject:** Objection to Proposed NR 140 Groundwater Standards for Alachlor ESA



2317 International Lane, Suite 102, Madison, WI 53704-315  
Phone: 608 249-4070 Fax: 608 249-5311

May 17, 2007

Mr. William Phelps  
Wisconsin Department of Natural Resources  
Bureau of Drinking Water and Groundwater  
P.O. Box 7921  
Madison, WI 53707

**RE: Proposed NR 140 Groundwater Standards for Alachlor ESA - CR07-034**

Dear Mr. Phelps:

On behalf of the undersigned agricultural organizations that comprise the agribusiness and farming communities within Wisconsin, we are writing to you in reference to the DNR's proposal to establish groundwater standards for alachlor ESA.

The undersigned business representatives oppose the establishment of an Enforcement Standard of 20 ppb and a Preventive Action Limit of 4 ppb for the following reasons:

1. The United States Environmental Protection Agency has concluded that alachlor ESA and the parent compound alachlor are not likely to pose significant cancer risk to humans.
2. The proposed standards are based on use of an uncertainty factor for the possibility that alachlor ESA may be carcinogenic. Use of the uncertainty factor is inappropriate, making the standards based on it unjustified.
3. We are also concerned about unjustified regulatory actions that needlessly risk causing public concern and unnecessarily tap into limited State resources.

We also believe that it is essential that any regulatory standard be based on the most accurate and comprehensive scientific evaluation available. Before any groundwater standards are set for alachlor ESA:

1. DNR/DHFS should reconsider its recommendation of 20 ppb and propose a more reasonable and science based alternative as is required under section 227.14 (2m) of the Wisconsin State Statutes.
2. Conduct an Independent unbiased scientific peer review of the proposed groundwater standard for

alachlor ESA.

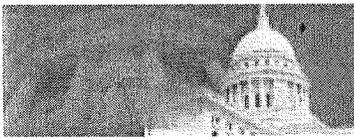
3. Place a "trigger" in the rule that would automatically/immediately revise the groundwater standard and PAL as soon as a health advisory level or reference dose (acceptable daily intake) for Alachlor-ESA is established by the federal environmental protection agency.

We ask that you put these comments in the record and consider them before taking any further action on the proposedalachlor ESA groundwater standard. Thank you very much.

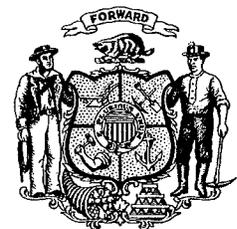
Wisconsin Crop Production Association, Mike Turner, Executive Director  
Wisconsin River Agronomy, LLC, Scott Firlus, Agronomy Manager  
Chilton Co-op, Steve Zutz, General Manager  
Knutzen Crop Consulting, Paul Knutzen, President/Owner  
Country Horizons Cooperative, Robert Lowe, General Manager  
Vogel Seed and Fertilizer, Randall Vogel, President/Owner  
Federation Co-op, Jeff Polivka, General Manager  
North Pacific Ag Products, Joel Cox, Regional Sales Representative  
Greg's Feed and Seed, Greg Seffrood, Owner  
Ag-Tech, Ron Smith, President/Owner  
Bullseye Ag, Jim Sutter, Owner  
Middleton Farmers Co-op, Dave DeVriendt, Agronomy Manager  
Syngenta, David Flakne, State Government Relations Manager  
Landmark Services Cooperative, Jim Shelton, Agronomy Manager  
FS Co-op, Bruce Barganz, Operations Manager  
Twin-State, Frank Masters, Operations Manager  
Cooperative Plus, Inc, Pat Vogel, General Manager  
Reabe Aerial Application, Jeff Reabe, President/Owner  
Lentz Fertilizer, Donald Lentz, President/Owner  
Kettle-Lakes Cooperative, Andy Walsh, Agronomy Manager  
Linco Equipment, Lyn Dolan, Manager  
UAP Distribution, David Kampen, Operations Manager  
The WeatherTime Ag Weather Radio Network, Marv Holewinski, News Director  
CountrySide Co-op, Brad Mikelson, Agronomy Manager  
Hartung Brothers, Dan Hartung, President  
Larson Cooperative Company, Scott Jones, Agronomy Manager  
Na-Churs Alpine Solutions, Zip Reagan, State Sales Manager  
Ag Ventures, LLC, Mike Mleziva, General Manager  
Gundrum Brothers Farm Supply, Mark Gundrum, President  
Ag Systems Inc, Guy Mathias, Manager  
Agri-Land Co-op, Dennis Halbach, Manager  
Farmers Co-op Oil Company, Skip Nordahl, Agronomy Manager  
United Suppliers, Aaron Burke, Manager  
Fertilizer Dealer Supply, Todd Yeazel, State Director

*Mike Turner*  
*Executive Director*  
*WCPA*  
*2317 International Lane, Suite 102*  
*Madison, WI 53704*  
*Phone: 608-249-4070*  
*Fax: 608-249-5311*  
*Get Connected On-Line - [www.wicrops.org](http://www.wicrops.org)*

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# WISCONSIN STATE LEGISLATURE



## Memorandum

August 28, 2007

To: Beth Bier

From: Heather Libbey

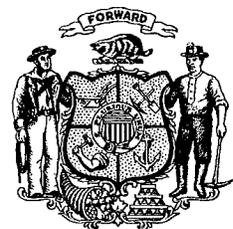
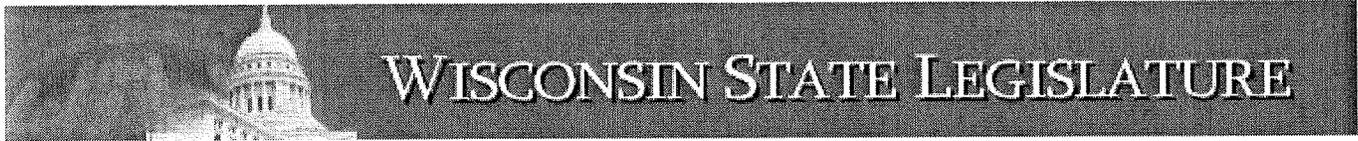
Re: Committee Hearing on SB 197, SB 198, and Clearing House Rule 07-034

The hearing began with discussion of SB 198. Representatives from both the DNR and the WI Wildlife Federation spoke in favor of repealing the outdated three-day waiting period for a bow-hunting license. There was no one speaking in opposition.

The hearing continued with the discussion of SB 197. There were representatives from several groups present to speak in favor of the bill. Some of these were the Association of WI Lakes, WI Land and Water Conservation, WI Wildlife Federation, and various other groups, as well as residents who live on Wisconsin lakes.

Three speakers spoke in favor of the bill, but proposed amendments. The representative from the Crop Production Association spoke in favor of the bill, but proposed an amendment that would allow the state law to pre-empt local ordinances and prevent local governments from passing more stringent ordinances. They also spoke against wording in the bill that would make it the responsibility of the retailers to prevent illegal purchase of the product. The WI Green Industry Federation also spoke in favor of the bill, but suggested an amendment that would only allow local governments to pass stricter ordinances if they are first approved by the state. They also proposed an amendment that would allow retailers to display fertilizer that contains phosphorus, but they would have to post a sign detailing the restrictions and exemptions of the fertilizer's use. The representative from the MMSD also spoke in favor of the bill, but asked for certain amendments. One of the suggested amendments would exempt bio-solids, such as Milorganite. The suggested amendment would also allow for an exemption for fertilizers which contain less than 3% total phosphorus, so long as less than 1% of that is "plant available" phosphorus.

The hearing concluded with discussion of Clearinghouse Rule 07-034. Representatives from Health and Family Services, the Department of Agriculture, the DNR and the Department of Public Health all spoke in support of the amendment to the groundwater quality standard. They argued that a standard was needed for Alacore-ESA in order to increase public access for well compensation as well as create an enforcement standard for the Department of Agriculture. There was no one to speak against the amendment.



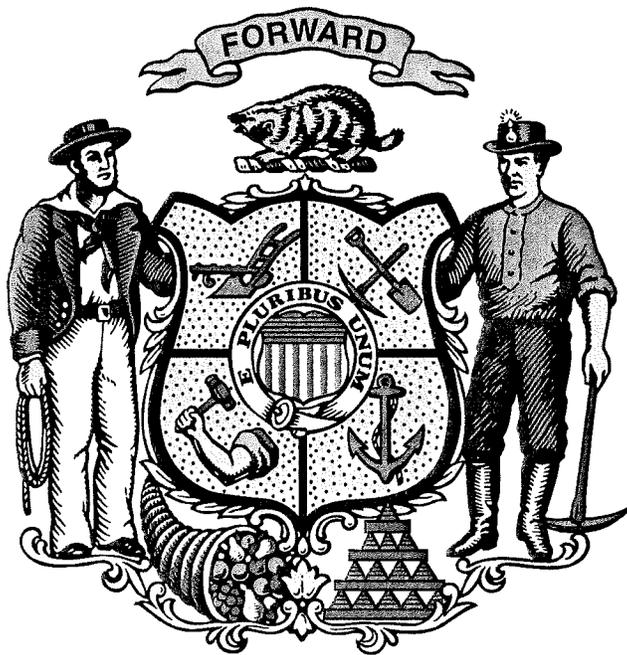
**DATCP Testimony to the  
Senate Environment and Natural Resources Committee  
Regarding CR-07-034, Groundwater Quality Standards  
August 28, 2007**

The Department of Agriculture, Trade and Consumer Protection is the lead agency in the state for the regulation of pesticide use. We asked the DNR and DHFS to set a standard for alachlor ethane sulfonic acid (alachlor ESA) based on our findings of this herbicide metabolite in Wisconsin's groundwater.

DATCP has detected alachlor ESA in Wisconsin's groundwater for well over a decade. We estimate that across the state as a whole, 28% of groundwater contains detectable levels of alachlor ESA, and in areas with a higher proportion of agriculture more than 40% of the groundwater has detectable levels. These estimates are based on a statistically valid, random statewide survey conducted in 2001, utilizing 336 wells primarily serving rural homes, farms and small businesses. Historically, eleven wells in Wisconsin have tested above the proposed ES of 20 parts per billion (ppb). Over the last two years DATCP has attempted to determine the present status of these 11 wells. Four of the wells have been abandoned, six of the wells were resampled and test below the proposed standard, and one of the wells was not available for sampling by the well owner. Since the Assembly Committee on Natural Resources on July 20, 2006, Portage County has reported well results from one well above the proposed standard.

According to a 2005 USDA survey of agricultural chemical usage, alachlor is not listed as a corn herbicide in Wisconsin, which means that the product is used on less than 1% of the Wisconsin corn acreage. Alachlor had been used more extensively in the state in the 1990's, with about 30% of the corn acreage receiving alachlor applications in 1992. The predominance of detects of alachlor ESA (the breakdown product) in groundwater today is due to the long half life of the metabolite.

DATCP's response to an alachlor ESA enforcement standard (ES) and preventive action limit (PAL) will depend on the standards that are set and a thorough analysis at that time of the number and distribution of locations where groundwater contains alachlor ESA above the ES and PAL. In general, DATCP will conduct an investigation around wells that exceed an ES to determine the cause of the groundwater contamination. Our goal is to find the least onerous way for producers to reduce the impacts to groundwater to levels below the ES. We look for solutions on a local level before we evaluate the need for regional control options, such as establishing areas where use is prohibited.



### Fiscal Estimate — 2007 Session

<input checked="" type="checkbox"/> Original	<input type="checkbox"/> Updated	LRB Number	Amendment Number if Applicable
<input type="checkbox"/> Corrected	<input type="checkbox"/> Supplemental	Bill Number	Administrative Rule Number NR 140, Wis. Adm. Code

Subject  
 Amendments to ch. NR 140, Wis. Adm. Code (Groundwater Quality)

**Fiscal Effect**

State:  No State Fiscal Effect  
 Indeterminate

Check columns below only if bill makes a direct appropriation or affects a sum sufficient appropriation.

- |  |   |
|--|---|
| <input type="checkbox"/> Increase Existing Appropriation | <input type="checkbox"/> Increase Existing Revenues |
| <input type="checkbox"/> Decrease Existing Appropriation | <input type="checkbox"/> Decrease Existing Revenues |
| <input type="checkbox"/> Create New Appropriation        |   |

- Increase Costs — May be possible to absorb within agency's budget.  
 Yes  No
- Decrease Costs

Local:  No Local Government Costs  
 Indeterminate

1.  Increase Costs  
 Permissive  Mandatory
2.  Decrease Costs  
 Permissive  Mandatory

3.  Increase Revenues  
 Permissive  Mandatory
4.  Decrease Revenues  
 Permissive  Mandatory

5. Types of Local Governmental Units Affected:  
 Towns  Villages  Cities  
 Counties  Others  
 School Districts  WTCS Districts

**Fund Sources Affected**

- GPR  FED  PRO  PRS  SEG  SEG-S

**Affected Chapter 20 Appropriations**

**Assumptions Used in Arriving at Fiscal Estimate**

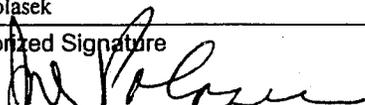
SUMMARY OF RULE - Chapter NR 140, Wis. Adm. Code, establishes Wisconsin state groundwater quality standards and creates a framework for implementing those standards in compliance with Wis. Stat. Ch. 160. These proposed amendments to NR 140 add a new enforcement standard (ES) and preventive action limit (PAL) for Alachlor ethane sulfonic acid (Alachlor-ESA). In accordance with Wis. Stat. Ch. 160, these proposed amendments to NR 140 groundwater quality standards are based on recommendations from the Department of Health and Family Services (DHFS).

Chapter NR 140 currently contains groundwater standards for 122 substances of public health concern, 8 substances of public welfare concern and 15 indicator parameters. The proposed groundwater standards would apply to all regulated facilities, practices and activities which may impact groundwater quality. Regulated facilities, practices and activities, which are sources of the substances for which groundwater standards are proposed, are, for the most part, likely sources of substances for which groundwater standards already exist. Consequently, there should be few cases where the proposed standards would be exceeded where existing standards are not currently being exceeded. Thus, the Department does not anticipate significant additional costs to the regulated community associated with establishing these NR 140 standards. Also, any additional monitoring costs to the regulated community should be minimal, and the workload of state regulatory agencies should not change substantially.

FISCAL IMPACT - Although additional monitoring costs may be imposed upon the state or local government entities that are within the regulated community, the extent of such monitoring and any costs associated with it--while too speculative to quantify at this time--are not expected to be significant. Thus, the Department believes it is unlikely that there will be additional costs to state and local governments resulting from adopting these groundwater standards.

**Long-Range Fiscal Implications**

None.

Prepared By: Joe Polasek	Telephone No. 266-2794	Agency Department of Natural Resources
Authorized Signature 	Telephone No. 266-2794	Date (mm/dd/ccyy) 07-13-07



# WISCONSIN STATE LEGISLATURE



- **[August 2007]** - [Natural Resources Board Meeting (Bayfield) Aug. 14 & 15, 2007; ... ]
- **July 27, 2007** - Natural Resources Natural Board Agenda Item ("Green Sheet") requesting NRB adoption of proposed Alachlor-ESA groundwater standards (Board Order DG-18-07, Clearinghouse number CR07-034); Department and DHFS response to public comments included in Green Sheet package.
- **June 2007** - updated DHFS Scientific Support Document for Alachlor-ESA; titled *Scientific Support Documentation for Groundwater Enforcement Standard and Preventive Action Limit for Ethane Sulfonic Acid metabolite of Alachlor (Alachlor-ESA)*.
- **May 2007** - public hearing held on May 11, 2007, in Madison, Wisconsin; one member of the public attended the hearing and signed a hearing appearance slip "in opposition" to the proposed amendments; no oral comments were presented at the public hearing. Written comments on the proposed rule revisions were accepted through May 18, 2007; four comment letters/memos were received by the Department from: Alachlor ESA Coalition, Wisconsin Crop Production Association, Monsanto Company and Wisconsin Farmers Union. Comments received both in opposition to, and supporting, proposed standards; comments in opposition focused on the methodology used by DHFS to develop their ES standard recommendation.
- **March 28, 2007** - Wed., March 28, 2007 Natural Resources Board Meeting (Madison) - NRB authorized public hearings for proposed amendments to NR 140, Wis. Adm. Code, that establish groundwater quality standards for Alachlor-ESA (Board Order DG-18-07).
- **March 14, 2007** - updated results from DATCP's water supply well sampling database; per March 14, 2007 e-mail from DATCP (Bruce Rheineck), DATCP's water supply well sampling database (sample results from both private and municipal wells) shows detections of Alachlor ESA in 617 of 1434 non-monitoring wells sampled (approximately 43 % with detects). Approximately 2% (11 wells) of sampled wells with Alachlor-ESA detects show sample result values equal to or exceeding the proposed NR 140 ES of 20 ug/L. Approximately 38% (230 wells) of sampled wells with Alachlor-ESA detects show sample result values equal to or exceeding the proposed NR 140 PAL of 4 ug/L.
- **Feb. 26, 2007** - Natural Resources Board Agenda Item ("Green Sheet") package for March NRB meeting requesting that the Board authorize public hearings on amendments to NR 140 that establish groundwater quality standards for Alachlor-ESA (Board Order DG-18-07).
- **Feb. 22, 2007** - Natural Resources Board Rule Agenda/Board Action Checklist ("Pink Sheet") and Scope Statement memo. Department proposes to again establish state groundwater quality standards for Alachlor ethane sulfonic acid (Alachlor-ESA). Proposed is ES of 20 ug/L and PAL of 4 ug/L [per DHFS scientific support document recommendation (*Scientific Support Documentation for Cycle 8 Revisions of NR 140.10 Groundwater Enforcement Standard & Preventive Action Limit Recommendations*)].
- **Jan. 11, 2007** - E-mail from WI Legislative Council (Ron Sklansky) to Dept. (Carol Turner) re: 1) JCRAR failure to meet its statutory responsibility (within 30 days of its action, to take executive action on objection sustaining legislation) and 2) automatic purging, or withdrawal,

of a rule on December 31 of the 4th year after the year in which it is submitted to the legislative council staff (unless already filed with the revisor or already withdrawn by the agency) per s. 227.14 (6) (c), Stats. Portion of DNR rule related to Alachlor-ESA ("rule remainder") therefore automatically withdrawn December 31, 2006 and new proposed rulemaking must be initiated to promulgate groundwater quality standards for Alachlor-ESA.

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- **Dec. 31, 2006** - Alachlor-ESA portion of rule (CR 02-095) withdrawn [per s. 227.14(6)(c), Stats.] - proposed rule considered withdrawn if not filed with the office of the revisor on Dec. 31 of the fourth year after the year in which it was submitted to the legislative council staff.
- **Sept. 6, 2006** - Sept. 6, 2006 letter from JCRAR to Dept. objecting to portion of rule related to alachlor-ESA standard.
- **Sept. 5, 2006** - Natural Resources Board held teleconference meeting to consider JCRAR motion. Recommendation made by Dept. to not eliminate alachlor-ESA standard from rule and to not conduct a scientific review panel review of proposed standard. Natural Resources Board considered the JCRAR motion and voted to authorize the Dept. to conduct and implement a structured peer review of the proposed alachlor-ESA standard, without any controlling influence by any outside party, if the proposed standard is allowed to "move forward" and be adopted (Sept. 5, 2006 letter from NRB to JCRAR & Sept. 5, 2006 letter from Dept. to JCRAR).
- **August 22, 2006** - Joint Committee for Review of Administrative Rules (JCRAR) - held Public Hearing on rule (portion of rule objected to by Assembly Committee on Natural Resources - proposed alachlor-ESA standards) on August 22, 2006 - passed motion to request that Dept. eliminate alachlor-ESA standard from rule and commence external scientific review of proposed standard, or Committee would object to portion of rule related to alachlor-ESA standard (Aug. 23, 2006 & Aug. 28, 2006 letters).
- **July 20, 2006** Assembly's committee on Natural Resources Executive Session. Executive session discussion on aspects of the rule package related to proposed alachlor-ESA standard. Committee adopted motion (7 to 5) to object to portion of the rule relating to groundwater standards for alachlor-ESA on grounds that proposed standards are arbitrary and capricious, and impose an undue hardship. Rule sent on to Joint Committee for Review of Administrative Rules (JCRAR).
- **July 17, 2006** Joint letter from DATCP, DHFS, & DNR Secretaries to Representative Gunderson expressing support for recommended DHFS alachlor-ESA standard.
- **July 10, 2006** Letter from DNR to Representative Gunderson, which accompanied Natural Resources Board letter, notifying him of the Natural Resources Board's decision to not modify rule.
- **July 10, 2006** Letter from Natural Resources Board to Representative Gunderson detailing the steps taken in consideration of Assembly Natural Resources Committee rule modification request.
- **June 28, 2006 Natural Resources Board meeting – UW River Falls** After extensive discussion the Natural Resources Board voted unanimously not to modify the rule. The Board

sent a letter to Representative Gunderson detailing the steps taken to fully evaluate the need for additional review.

- **May 15, 2006** - Letter from DHFS to Dept. responding to request for opinion on usefulness of scientific review of proposed alachlor-ESA groundwater standard. DHFS responded to the Department of Natural Resource's request indicating that their agency had 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 and that additional external review was not necessary.
- **Dec. 1, 2005 - Senate Natural Resources and Transportation Committee Public Hearing**  
- The Senate Committee on Natural Resources and Transportation held Public Hearings on Clearinghouse Rule 02-095. "No Action Taken" by Senate Committee on rule (12/21/2005 Committee Report).
- **Nov. 28, 2005** - Letter from Dept. to Assembly Committee on Natural Resources (Representative Gunderson) informing them that Dept. would consider Committee motion.
- **Nov. 23, 2005** - Letter from Dept. to DHFS requesting that technical toxicological experts at DHFS determine if proposed scientific review of proposed alachlor-ESA groundwater standard would be useful.
- **Nov. 16, 2005 - Assembly Natural Resources Committee Public Hearing** - The Assembly Committee on Natural Resources held Public Hearings on Clearinghouse Rule 02-095. The Committee adopted a motion (Nov. 17, 2006 letter to Dept.) requesting that the Department consider modifications to Clearinghouse Rule 02-095 to remove the proposed groundwater quality standard for alachlor-ESA, and convene a scientific review panel to review that proposed standard.
- **Sept 28, 2005 - Proposed Cycle 8 Standards to NRB – Port Washington** Natural Resources Board voted unanimously to adopt proposed standards.
- **Aug, 2005 - DHFS revised Scientific Support Document** – Minor revisions made to the March 2005 – DHFS scientific support document *Scientific Support Documentation for Cycle 8 Revisions of NR 140.10 Groundwater Enforcement Standard & Preventive Action Limit Recommendations*
- **March 2005 - DHFS recommendations for NR 140 groundwater quality standards for Alachlor ESA** In March, 2005 DHFS completed their review of the new Monsanto Alachlor ESA rat toxicity study, and of additional information related to Alachlor ESA submitted by the Monsanto Co. during the public hearing comment period. After completing it's review of this "new" information DHFS finalized their *Scientific Support Documentation for Cycle 8 Revisions of NR 140.10 Groundwater Enforcement Standard & Preventive Action Limit Recommendations* (dated March 2005) document. The March 2005 Scientific Support Documentation for Cycle 8 includes references to new submitted information and study results. After review of all available, relevant information DHFS has recommended that the groundwater quality standards proposed in Nov. 2001 for Alachlor ESA, NR 140 enforcement standard (ES) of **20 ug/L** and a preventive action limit (PAL) of **4 ug/L**, be established as ch. NR 140 standards.

- **Sept. 2003 - Results in DATCP's Water Supply Well Sampling Database** In Sept., 2003 DATCP's water supply well sampling database, which includes sample results from both private and municipal wells, showed detections of Alachlor ESA in 610 wells. Approximately **2%** (13 wells - all privately owned water supply wells) had sample values exceeding the proposed NR 140 ES of 20 ug/L. Approximately **39%** (239 wells) had reported sample values exceeding the proposed NR 140 PAL of 4 ug/L.
- **June 2003 - Completion of "New" Alachlor ESA Toxicity Study** A "new" Monsanto Co. sponsored Alachlor ESA toxicity study, titled *A 90-Day Oral (Diet) Toxicity Study of MON 5775 in Rats*, was completed by WIL Research Laboratories, Inc., on June 20, 2003. This study, the "Monsanto 90-day study", is similar to the 1993 Springborn Labs "91-day" rat toxicity study, but differs in two significant ways: a different species of rat was used for the Monsanto 90-day study (CrI:CD(SD)IGS BR for the Monsanto 90-day study vs Fischer F-344 rats for the Springborn Labs 91-day study) and the Monsanto 90-day study assessed the effect of Alachlor ESA in food while the Springborn Labs 91-day study evaluated the effect of Alachlor ESA in drinking water. The official results of the Monsanto 90-day Alachlor ESA toxicity study were submitted by Monsanto to DHFS for review.
- **Aug. & Sept 2002 - Public Hearings on proposed Cycle 8 Groundwater Standards held** At the June 2002 Natural Resources Board Meeting, the Board authorized public hearings on proposed NR 140 amendments that included the Alachlor ESA groundwater quality standards. Public hearings were held in Aug. and Sept. of 2002 at: Madison, Dodgeville (2 hearings) and Stevens Point (2 hearings), and a video hearing was broadcast from Madison to video conference sites in: La Crosse, Fond du Lac, Spooner, Kenosha, Eau Claire and Rhinelander. Comments were received at the 2002 public hearings (and during the public comment period) both in support of the proposed Alachlor ESA groundwater standards and in opposition to them. The comments in opposition to proceeding forward with the proposed Alachlor ESA groundwater quality standards focused primarily on two issues: the methodology (NOEL & UF selection) DHFS used in establishing its recommended standards, and the fact that the Monsanto Co. had funded a new Alachlor ESA toxicity study providing additional toxicity information that should be considered before state Alachlor ESA groundwater quality standards were finalized. Comments were also expressed suggesting that a peer review should be conducted, by an "independent panel", of the studies and methodology used by DHFS to establish its Alachlor ESA groundwater standard recommendations.
- **Spring 2002 - Meeting w/Monsanto Co.** In the spring of 2002 DNR & DHFS staff met with representatives of the Monsanto Co., the Monsanto Co.'s local legal council (Michael Best & Friedrich), and a representative of the Agricultural Business Council (Ms. Amy Winters) to discuss Monsanto's concerns with the proposed 20 ug/L NR 140 Alachlor ESA groundwater ES. The Monsanto Co. submitted a letter (dated 12/14/2001) to the Department stating its position disagreeing with the DHFS recommendation of 20 ug/L for an Alachlor ESA NR 140 ES.
- **February 20, 2002 - Rule Agenda/Board Action Checklist ("Pink Sheet")** - Board Action Checklist ("Pink Sheet") and scope memo prepared for rulemaking to establish/revise groundwater standards for "Cycle 8" substances (Alachlor-ESA, Molybdenum, Butylate, Dacthal & Naphthalene).
- **Nov. 2001 DHFS Recommendations for NR 140 groundwater quality standards for Alachlor ESA** In Nov., 2001 DHFS completed their *Scientific Support Documentation for Cycle 8* with recommendations for NR 140 groundwater quality standards for "cycle 8"

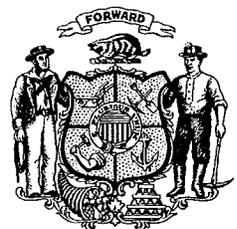
substances, including Alachlor ESA. DHFS recommended an Alachlor ESA NR 140 enforcement standard (ES) of **20 ug/L** and a preventive action limit (PAL) of **4 ug/L**. As no "federal number" (maximum contaminant level drinking water standard or no-adverse-response level), or state drinking water standard exists for Alachlor ESA, DHFS calculated a recommended NR 140 ES using the methodology specified in Ch. 160, Stats. (s. 160.13, Stats). DHFS established an acceptable daily intake level of 0.002 mg/kg/day for Alachlor ESA, based on the results of a 1993 (Springborn Labs) 91-day rat Alachlor ESA toxicity study. DHFS used a 20 mg/kg/day "no observable effect level" (NOEL) from the Springborn Labs study, and a 10,000 "uncertainty factor" (UF), to establish an acceptable daily intake level for Alachlor ESA. They then based their recommended NR 140 ES for Alachlor ESA on this acceptable daily intake level intake, assuming [per s. 160.13(2)(c), Stats.] consumption of 1 liter of water per day by a person weighing 10 kilograms.

- **May 2000 Request for Recommendations for NR 140 Standards** In May, 2000 (letter dated 5/2/2000) the Department requested that DHFS review existing toxicological information and develop recommendations for state groundwater standards for Alachlor ESA.
- **2000 survey in agricultural chemical use areas statewide** - In a 2000 statewide survey in agricultural chemical use areas, Alachlor ESA was detected in approximately **28%** of 336 private water supply wells sampled. The mean concentration of Alachlor ESA detected in the survey wells was 1.0 ug/L (with detected Alachlor ESA levels ranging from 0.101 ug/L to 14.8 ug/L).
- **2000 statewide survey focused on wells likely to be contaminated with pesticides** - In a 2000 statewide survey that focused on wells likely to be contaminated with pesticides, Alachlor ESA was detected in **91%** of 22 sampled private water supply wells, **81%** of 27 sampled monitoring wells and **48%** of 23 sampled municipal water supply wells. Wells were selected for this survey based on previous detections of pesticides or proximity to agricultural fields. The mean Alachlor ESA concentrations (and highest detected level) in the survey wells were: private water supply wells 3.5 ug/L (highest detect = 9.0 ug/L), monitoring wells 4.7 ug/L (highest detect = 33 ug/L) and municipal wells 1.9 ug/L (highest detect = 4.4 ug/L).
- **Dec. 1998 Alachlor Reregistration Eligibility Decision (RED)** EPA's Dec. 1998 Alachlor Reregistration Eligibility Decision (RED) document included some evaluation of the ESA metabolite of Alachlor. No federal acceptable daily intake level/Reference Dose (RfD) for Alachlor ESA has been established, but the Alachlor RED document suggested two approaches that might be used to set an RfD for Alachlor ESA. One of those suggested approaches was to use the 0.01 mg/kg/day RfD established for the "parent" pesticide, Alachlor. The other approach suggested was to establish a RfD based on the results of the 1993 Springborn Labs 91-day (rat) Alachlor ESA toxicity study. Using this approach, a NOEL of 157 mg/kg/day from the Springborn Labs study, and a UF of 1,000, an Alachlor ESA acceptable daily intake level/RfD of 0.16 mg/kg/day could be calculated.
- **Jan 1995 - Response to Request for Additional Study** In Jan., 1995 Monsanto sent a letter (dated 1/30/95) to the Secretary of DATCP stating that their position was that no further toxicological study was needed for Alachlor ESA.
- **Aug, 1994 - Request for Additional Alachlor ESA Study** In Aug., 1994 the Secretaries of the DNR, DATCP and DHFS (then DHSS) sent a letter (dated 8/3/94) to the Monsanto Co. requesting that the company initiate additional studies to assess the chronic, reproductive and carcinogenic effects of Alachlor ESA.

- **1994 DATCP survey in southern Wisconsin high Alachlor use areas** - In a 1994 DATCP survey of 669 private water supply wells that focused on high Alachlor use areas of southern Wisconsin, Alachlor ESA was detected in approximately **32%** of wells sampled. The mean Alachlor ESA concentration detected in the survey wells was 4.9 ug/L (with detected Alachlor ESA levels ranging from 1.1 ug/L to 26.7 ug/L).
  - **Sept, 1993 – State Health Advisory Level (HAL) for Alachlor ESA** In Sept., 1993 DHFS (then DHSS) set a state health advisory level (state drinking water guideline) for Alachlor ESA at **20 ug/L** and emphasized the need for additional toxicological studies to evaluate the long-term chronic effects and carcinogenicity of Alachlor ESA (memo dated 9/8/93).
  - **July, 1992 – Revision to NR 140 groundwater quantity standards for Alachlor, the parent.** Enforcement standard revised to conform with established federal MCL of 2 ug/L (ppb) The preventive action limit (PAL) revised to 0.2 ug/L
  - **1988 – NR 140 Groundwater Quality Standards established for Alachlor (the "parent" compound).** NR 140 ES for alachlor established at 0.5 ug/L; PAL set at 0.05 ug/L.
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# WISCONSIN STATE LEGISLATURE



## REPORT TO LEGISLATURE

NR 140, Wis. Adm. Code  
Groundwater quality standards (Alachlor ESA)

Board Order No. DG-18-07  
Clearinghouse Rule No. 07-034

### Basis and Purpose of the Proposed Rule

Amendments are being proposed to Wisconsin Administrative Code Chapter NR 140, Groundwater Quality. Chapter NR 140, Wis. Adm. Code, establishes Wisconsin state groundwater quality standards for substances of public health and welfare concern. Amendments to NR 140 are proposed to add groundwater quality standards for a substance of public health concern, alachlor ethane sulfonic acid (alachlor-ESA).

Wisconsin's groundwater law, State Statute Chapter 160, was created in May of 1984, as part of the 1983 Wisconsin Act 410. NR 140 was adopted by the Natural Resources Board in 1985 to comply with ch. 160, Stats. Chapter 160, Stats., requires the Department to develop groundwater quality standards for substances detected in, or having a reasonable probability of entering, the groundwater resources of the state. Alachlor-ESA has been detected in Wisconsin in a significant number of water supply wells.

Alachlor-ESA is a degradation product of the broadleaf herbicide alachlor. Alachlor has been used in Wisconsin primarily on corn and soybean crops. Alachlor-ESA was detected in approximately 28% of the private water supply wells tested in a 2000/2001 Wisconsin Department of Agriculture and Consumer Protection (DATCP) statewide groundwater sampling survey. In a 1999/2000 DATCP groundwater sampling survey of wells known or suspected to be impacted by agricultural chemicals, alachlor-ESA was detected in 91% of private water supply wells tested and 48% of the municipal water supply wells tested.

NR 140 establishes groundwater quality standards at two levels, enforcement standard (ES) and preventive action limit (PAL). In accordance with ch. 160, Stats., health based ES groundwater quality standards are established based on recommendations developed by the Department of Health and Family Services (DHFS). PAL groundwater quality standards for substances of public health concern are set at either 20% of the concentration of the established ES, or at 10% of the concentration of the established ES if the substance has carcinogenic, mutagenic or teratogenic properties or interactive effects.

These proposed amendments to NR 140, to establish state groundwater standards for alachlor-ESA, are based on recommendations received from DHFS. Because no federal number, as defined by statute, or health based reference dose (acceptable daily intake level) has been established for alachlor-ESA, DHFS developed their recommendations for an alachlor-ESA ES using the applicable methodology in s. 160.13, Stats. DHFS has recommended an alachlor-ESA ES of 20 micrograms per liter ( $\mu\text{g/L}$ ), and a PAL, set at 20% of the recommended ES, of 4  $\mu\text{g/L}$ .

The Natural Resources Board has approved amendments to NR 140 in: 1988, 1990, 1991, 1993, 1995, 1996, 1998, 1999, 2003 and 2006. These amendments were made to add and revise groundwater quality standards and to clarify rule language. There are currently groundwater quality standards for 122 substances of public health concern, 8 substances of public welfare concern and 15 indicator parameters in NR 140.

### SUMMARY OF THE RULE

New NR 140 public health based groundwater quality standards are proposed for alachlor-ESA, a degradation product of the broadleaf herbicide alachlor. DHFS has recommended an ES of 20  $\mu\text{g/L}$  and

a PAL of 4 µg/L for alachlor-ESA. A concentration of 20 µg/L has been used as an interim health advisory level for alachlor-ESA in Wisconsin since 1993.

Amendments to NR 140 are proposed to add groundwater quality standards for alachlor-ESA, as indicated below:

<u>Substance</u>	<u>Current Standards (in µg/L)</u>		<u>Proposed Standards (in µg/L)</u>	
	<u>ES</u>	<u>PAL</u>	<u>ES</u>	<u>PAL</u>
<b>Alachlor-ESA</b>	no standard	no standard	<b>20</b>	<b>4</b>

Summary of Public Comments

In March of 2007, the Natural Resources Board authorized the Department to hold public hearings and solicit comments on the proposed amendments to NR 140. A public hearing was held on May 11, 2007, in Madison, Wisconsin. One member of the public attended the hearing and signed a hearing appearance slip "in opposition" to the proposed amendments. No oral comments were presented at the public hearing.

**5. Summary of Written Public Comments**

Written comments on the proposed rule revisions were accepted through May 18, 2007. Correspondence was received by the Department expressing comments on the proposed NR 140 amendments. A total of four comment letters/memos were received by the Department:

- 1) a memo, dated 5/14/2007, from the Alachlor ESA Coalition
- 2) a letter, dated 5/17/2007, from the Wisconsin Crop Production Association
- 3) a letter, dated 5/16/2007, from the Monsanto Company
- 4) a letter, dated 5/18/2007, from the Wisconsin Farmers Union

The Department received written comments both in opposition to, and in support of, the proposed NR 140 alachlor-ESA groundwater quality standards.

Comments received in opposition to the proposed groundwater quality standards for alachlor ESA focused on the methodology used by DHFS to develop their ES groundwater standard recommendation. Because no federal number (federal drinking water standard, suggested no adverse response level or cancer risk level) or Wisconsin state drinking water standard has been established for alachlor-ESA, DHFS, in accordance with Wisconsin's groundwater law, used the methodology specified in ss. 160.07 and 160.13, Stats., to develop it's recommended alachlor-ESA ES.

Use of the s. 160.13, Stats., methodology to develop a NR 140 ES recommendation requires DHFS to determine a no-observable-effect level (NOEL) for alachlor-ESA, and a "suitable" uncertainty factor that the NOEL can be divided by to calculate a reference dose (RfD)/acceptable daily intake (ADI) value. The calculated RfD/ADI is then used to develop a recommended enforcement standard. The majority of the comments received in opposition to the proposed alachlor-ESA groundwater standards challenged DHFS' determination of an alachlor-ESA NOEL, and the uncertainty factor used in the RfD/ADI calculations.

DHFS reviewed relevant toxicological studies and determined an alachlor-ESA NOEL from the results of a 1993 91-day rat study of the toxicity of alachlor-ESA administered in drinking water. Different opinions have been expressed on the selection of a NOEL from the results of this study. Comments were received suggesting that an alternative NOEL from the 1993 rat study be used by DHFS to develop their recommended alachlor-ESA enforcement standard. The Monsanto Company, the manufacturer of alachlor, initiated a new (2003) 90-day rat study of the toxicity of alachlor-ESA administered in food. Comments were received suggesting that the results of this study be used, instead of the results of the 1993 drinking water study, as the basis for an alachlor-ESA ES recommendation.

The enforcement standard development methodology in s. 160.13, Stats., requires DHFS to determine a suitable uncertainty factor to be used in the calculation of a recommended enforcement standard. DHFS is required to consider a number of specific factors, listed in the statute, when establishing a suitable uncertainty factor. Comments were received questioning DHFS' determination of the uncertainty factor used to develop their recommended alachlor-ESA enforcement standard and suggesting that a different uncertainty factor would be more appropriate.

In determining the uncertainty factor used to calculate their alachlor-ESA ES recommendation DHFS included a factor for "data gaps, including lack of a carcinogenicity study for the metabolite of a potentially carcinogenic parent compound". Comments were received questioning use of this specific factor in determining the uncertainty factor to be used in development of an alachlor-ESA ES recommendation. Commenters suggested that DHFS reconsider use of this factor based on the current EPA alachlor cancer classification.

Because of concerns with DHFS' determination of the NOEL and uncertainty factor used to develop their recommended alachlor-ESA ES, commenters suggested that an independent panel conduct a peer review of the studies and methodology used by DHFS to develop their recommended standard.

Commenters also asked that a "trigger" be placed in the rule that would automatically/immediately revise alachlor-ESA groundwater quality standards as soon as a health advisory level or reference dose (acceptable daily intake) for alachlor-ESA was established by the U.S. Environmental Protection Agency.

Comments were received generally supporting the protection of groundwater resources in Wisconsin. Comments were also made supporting the proposed groundwater standards for alachlor-ESA and stating that farm family health is critical to the health of Wisconsin's rural economy.

A separate Response to Public Comments (Attachment 1) provides responses to comments received on the proposed NR 140 amendments. DHFS has provided responses to comments received related to their development of groundwater standard recommendations for alachlor-ESA (Attachment 2). DHFS has also updated the scientific support documentation that was prepared for their alachlor-ESA groundwater standard recommendations (Attachment 3).

#### Modifications Made

No modifications were made as a result of the public hearing. The Natural Resources Board requested the Department to add a directive that the Department was required to initiate rulemaking to revise the existing state groundwater quality standards for Alachlor-ESA if a new reference dose or federal number was adopted by the U.S. Environmental Protection Agency.

#### Appearances at the Public Hearing

In support – none

In opposition

Amy Winters, Monsanto, P.O. Box 771, Madison, WI 53701

As interest may appear - none

#### Changes to Rule Analysis and Fiscal Estimate

None were required.

Response to Legislative Council Rules Clearinghouse Report

The recommendations were accepted.

Final Regulatory Flexibility Analysis

The Department does not believe that the proposed rule will have a significant economic impact on a substantial number of small businesses. The compliance and reporting requirements in NR 140 are not changed by the proposed amendments. If a groundwater quality standard is exceeded, the owner or operator of a facility, practice or activity, including any small business, must report the violation to the appropriate regulatory agency. The proposed amendments to NR 140 would add one new substance that a facility may have to monitor for, and report exceedances of, if sampled levels attain or exceed proposed standards.

Chapter 160, Stats., requires establishment of both design and performance standards. Individual regulatory programs (DATCP, COMM, DNR-Waste Management, DNR-Watershed Management, etc.) establish design and operational standards in their program rules. Performance standards (groundwater quality standards) are contained in NR 140. Chapter 160, Stats., does not allow for less stringent schedules, deadlines or reporting requirements, or for exemptions to remedial action, when a groundwater quality standard is attained or exceeded, based on the size of the business causing the contamination.

There would be adverse impacts on public health, welfare, safety and the environment if small businesses were not required to meet regulatory reporting requirements and implement remedial responses. The more quickly contamination can be evaluated and responses initiated, the less likely that public health, safety and welfare will be adversely affected. If small businesses were exempt from these requirements groundwater contamination would continue unabated at least until the Department could appropriate

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## Response to Legislative Council Rules Clearinghouse Report

The recommendations were accepted.

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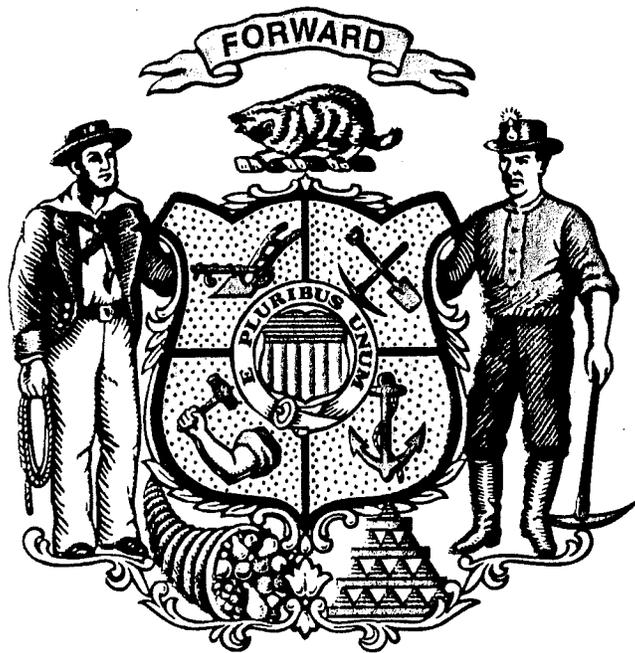
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There would be adverse impacts on public health, welfare, safety and the environment if small businesses were not required to meet regulatory reporting requirements and implement remedial responses. The more quickly contamination can be evaluated and responses initiated, the less likely that public health, safety and welfare will be adversely affected. If small businesses were exempt from these requirements groundwater contamination would continue unabated at least until the Department could appropriate sufficient resources to undertake this work. The delay, or possibility that nothing would be done, would lead to adverse impacts on public health, welfare, safety and the environment.

The type of small businesses that are typically impacted by NR 140 include dry cleaners, small manufacturers, agricultural cooperatives, farmers, underground storage tank owners, small solid waste disposal facilities, small wastewater treatment operations, as well as others. In effect, any small business that has an authorized or unauthorized discharge of a substance exceeding the health or welfare groundwater quality standards listed in NR 140 is responsible for responding to the release consistent with the requirements of NR 140.

With the proposed amendments to NR 140 there would be new groundwater quality standards for one new substance. The new groundwater standards would be used, along with existing NR 140 standards, to establish system and facility design standards, for compliance purposes, and as clean up goals in the event of a spill or unpermitted discharge. If remedial action or other response is necessary, the individual programs which regulate the facility, practice or activity would determine the appropriate level of clean-up required. As the cost of remedial options varies, the cost of remediation of groundwater contamination for small businesses will vary, depending on the complexity of the site, the contamination at the facility, practice or activity, and the federal and state laws being used to guide the remedial action.

The new substance for which groundwater quality standards are proposed has been detected in groundwater in Wisconsin. The adoption of state groundwater quality standards that can be used for design, compliance and clean-up activity purposes might aid small businesses in number of ways. Groundwater standards provide specifications for facility and activity design and management, as well as inform a business whether or not substance concentrations detected in groundwater exceed levels determined to be protective of public health and welfare. If concentrations of a substance in a potential drinking water source are elevated and remediation is required, established groundwater quality standards let a small business know when clean-up efforts are completed. When substances are detected in groundwater for which a NR 140 standard does not exist, the Department may require clean-up of groundwater "to the extent practicable". This may result in overly conservative clean-up depending upon the actual toxicity of the substance detected.



Attachment #1

**RESPONSE TO PUBLIC COMMENTS  
July 13, 2007**

**Revisions to ch. NR 140, Wis. Adm. Code, to amend  
NR 140.10 Table 1 and Appendix 1, relating to groundwater quality standards for Alachlor-ESA  
Natural Resources Board Order No. DG-18-07**

**Introduction**

In March of 2007, the Natural Resources Board (NRB) authorized the Department to hold public hearings and solicit comments on proposed revisions to Ch. NR 140, "Groundwater Quality", that would establish new state groundwater quality standards for alachlor ethane sulfonic acid (alachlor-ESA).

A public hearing on proposed revisions to NR 140 was held on Friday May 11, 2007. One person attended the hearing. That hearing attendee did not present oral comments, but did register "in opposition" to the proposed NR 140 revisions.

Written comments on the proposed rule revisions were accepted through May 18, 2007. Correspondence was received by the Department expressing comments on the proposed NR 140 revisions. A total of four comment letters/memos were received by the Department:

- 1) a memo, dated 5/14/2007, from the Alachlor ESA Coalition [submitted attached to 5/17/2007 e-mail (from Ms. Amy Winters, President, Capitol Strategies, LLC)]
- 2) a letter, dated 5/17/2007, from the Wisconsin Crop Production Association [submitted attached to 5/17/2007 e-mail (from Mr. Mike Turner, Executive Director, Wisconsin Crop Production Association); copy of letter also submitted via conventional mail]
- 3) a letter, dated 5/16/2007, from the Monsanto Company [submitted attached to 5/18/2007 e-mail (from Ms. Amy Winters, President, Capitol Strategies, LLC and Monsanto Contract Lobbyist)]
- 4) a letter, dated 5/18/2007, from the Wisconsin Farmers Union [submitted via fax on 5/18/2007]

The following acronyms and abbreviations are used to identify commenting organizations below:

<b>AEC</b>	Alachlor ESA Coalition
<b>WCPA</b>	Wisconsin Crop Production Association
<b>MON</b>	Monsanto Company
<b>WFU</b>	Wisconsin Farmers Union

The majority of comments that were received by the Department on this rule relate to DHFS' development of recommendations for alachlor-ESA groundwater quality standards. A copy of comments received by the Department were forwarded to DHFS for their review and response. DHFS has prepared a document with responses to comments related to their development of alachlor-ESA groundwater standard recommendations. This document is attached to the NRB Agenda Item (Green Sheet) background memo as Attachment 2. DHFS has also revised its alachlor-ESA scientific support documentation. The revised DHFS scientific support documentation is attached to the NRB Agenda Item background memo as Attachment 3.

Below are responses to comments received by the Department on the proposed rule, with DHFS responses (from their response to comments document) referenced as appropriate. Comments related to rule language clarity, grammar, punctuation and use of plain language were also received from the Wisconsin Legislative Council Rules Clearinghouse.

**I. Written comments received on proposed ch. NR 140, Wis. Adm. Code, revisions:**

1. **Comment:** (AEC) "As we have previously stated during the CR 02-095 rule review, we fully support Wisconsin's goal of protecting groundwater resources and ensuring the safety of drinking water and have no objection to the establishment of a scientifically sound, health-based groundwater quality standard. We only ask that the state ensure that sound science is being utilized in establishing this standard and that the state is ensuring the accuracy, integrity, objectivity, and consistency of the data that is being used to prepare the rule as required by the Data Quality Act (State statute 227.14 2m)."

**Response:** *The Department is proposing that the groundwater quality standard recommendations developed by the Wisconsin Department of Health and Family Services (DHFS) for alachlor-ESA be adopted in ch. NR 140, Wis. Adm. Code. As required under Wisconsin's groundwater law, DHFS followed the methodology in s. 160.13, Stats., in developing its recommendation for an alachlor-ESA groundwater quality enforcement standard.*

*Section 227.14(2m), Stats., addresses the quality of data used in the preparation and analysis of a proposed rule. The scientific data that DHFS used in developing their recommendation for an alachlor-ESA groundwater quality enforcement standard were primarily the results of toxicology studies funded by the Monsanto Company, the manufacturer of alachlor. The standard recommended by DHFS is based on the results of valid scientific studies, and the methodology used to develop it is specified in state statute. There is no reason to believe that the accuracy, integrity, objectivity or consistency of the data used by DHFS in developing its alachlor-ESA enforcement standard recommendation is in question.*

2. **Comment:** (AEC, MON) "... believe that the DHFS recommendations are at odds with the scientific evidence and are therefore erroneous in two key respects: (1) DHFS's conclusions regarding the toxicity of alachlor ESA, particularly DHFS' determination of a No Observable Effect Level (NOEL) 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 (20ppb) 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."

**Response:** *DHFS has reviewed comments related to the NOEL and uncertainty factor used to develop its recommendation for an alachlor-ESA groundwater quality enforcement standard. DHFS has provided responses to comments related to the NOEL and uncertainty factor it utilized - see DHFS (NRB Agenda Item background memo - Attachment 2) response to comments: A, B, D, E & G.*

3. **Comment:** (AEC) "DHFS has justified the additional 10-fold uncertainty factor on the basis of the carcinogenicity of the parent alachlor. However, contrary to DHFS' justification, alachlor is NOT classified by EPA as a "probable human carcinogen". In 1997, following review of extensive mechanistic information and evaluation by the Science Advisory Panel, the EPA re-classified alachlor as "likely to be a human carcinogen at high doses, but not likely at low doses." The scientific justification for this reclassification was clearly outlined in the RED [Dec. 1998 EPA Reregistration Eligibility Decision (RED) Alachlor]."

**Response:** *DHFS has reviewed comments related to the uncertainty factor used to develop its recommendation for an alachlor-ESA groundwater quality enforcement standard. DHFS has provided responses to comments related to the uncertainty factor it utilized - see DHFS (NRB Agenda Item background memo - Attachment 2) response to comments: B, C & F.*

4. **Comment:** (AEC, MON) "The March 2006 EPA Cumulative Risk Assessment for Chloroacetanilides was also not utilized in establishing the proposed standard. The assessment summarizes the latest EPA cancer risk assessment for combined residues from alachlor and acetochlor in food and water. 2 key elements in this assessment are: (1). The ESA and OXA metabolites were not included in the cancer risk assessment. As stated in the third paragraph on page 19, "These compounds [the metabolites] ... are not included in this cumulative risk assessment because extensive data are available (USEPA 2004b) to show that these compounds show a different toxicological profile than the respective parents and do not contribute to the development of nasal olfactory epithelium tumors in rats." (2). The EPA did NOT apply any additional safety factor for carcinogenicity, even though both alachlor and acetochlor are known to be carcinogenic to rats. As indicated at the top of pages 5 and 30, the Agency considers a Margin of Exposure greater than 100 to be outside their "level of concern" (LOC) for the tumors produced by these chemicals. This is equivalent to utilizing a total uncertainty factor (UF) of 100, based on two values of 10 each to account for interspecies and intraspecies differences. No additional uncertainty factor was applied due to concerns about carcinogenicity. This is clearly in contrast to the WI approach of adding an extra 10X due to the DHFS/DNR "concern" about potential carcinogenicity of alachlor ESA."

**Response:** DHFS has reviewed the March 2006 EPA Cumulative Risk Assessment for Chloroacetanilides document and has provided a response to comments related to this document - see DHFS (NRB Agenda Item background memo - Attachment 2) response to comments G.

5. **Comment:** (AEC) "... we believe that the proposed rule/groundwater standard is not based on sound science and will needlessly alarm Wisconsin residents. It will also set an irresponsible precedent for the groundwater standard process and potentially unnecessarily tap into limited financial resources for remediation efforts."

**Response:** The alachlor-ESA groundwater quality standards recommended by DHFS were developed using the appropriate methodology specified in Wisconsin's groundwater law, ch. 160, Stats. The scientific data used in developing the recommendations were primarily the results of toxicology studies funded by the Monsanto Company, the manufacturer of alachlor. The standard recommended by DHFS is based on the results of valid scientific studies, and the methodology used to develop it is specified in state statute. There is no reason to believe that the data or methodology used by DHFS is in question. The alachlor-ESA enforcement standard recommended by DHFS is consistent with past standards, and is based on review and consideration of the best science available.

6. **Comment:** (AEC, WCPA) ... ask that "DNR/DHFS reconsider its recommendation of 20 ppb and propose a more reasonable and science based alternative as is required under section 227.14 (2m) of the Wisconsin State Statutes."

**Response:** This comment is somewhat vague and confusing. Section 227.14(2m), Stats., addresses the quality of data used in the preparation and analysis of a proposed rule. The comment presented is related to the 20 part per billion (ppb)/milligram per liter (mg/L) alachlor-ESA groundwater quality enforcement standard recommendation developed by DHFS. As required under Wisconsin's groundwater law, DHFS followed the methodology in s. 160.13, Stats., in developing its recommendation for an alachlor-ESA groundwater quality enforcement standard.

The comment appears to suggest that the 20 mg/L enforcement standard recommendation developed by DHFS is unreasonable and not science based. In developing their recommendation DHFS followed the applicable methodology specified in Wisconsin's groundwater law, ch. 160, Stats. The scientific data used in developing the recommendation were primarily the results of toxicology studies funded by the Monsanto Company, the manufacturer of alachlor. The standard recommended by DHFS is based on the results of valid scientific studies, and the methodology used to develop it is specified in state statute. There is no reason to believe that the accuracy, integrity, objectivity or consistency of the data used by DHFS in developing its alachlor-ESA enforcement standard

*recommendation is in question. The alachlor-ESA enforcement standard recommended by DHFS is reasonable, consistent with past standards, and is based on the best science available.*

7. **Comment:** (AEC, WCPA) ... ask that DNR/DHFS conduct "an unbiased independent scientific peer review of the proposed groundwater standard for alachlor ESA".

(MON) "Monsanto requests that prior to taking final rulemaking action DNR convene an independent, scientific review panel to conduct an external unbiased scientific peer review of the toxicology data on alachlor ESA, and of the methodology used and conclusions drawn by DHFS."

**Response:** *The recommendation for an alachlor-ESA groundwater quality enforcement standard was developed by DHFS in accordance with the methodology specified in s. 160.13, Stats. This methodology is applicable in cases where no federal number or state drinking water standard has been established for a substance. DHFS is required by state statute to utilize this methodology, and it has consistently been employed by DHFS in the past to establish state groundwater quality standards.*

*There is no provision in ch. 160, Stats., for peer review of state groundwater standard recommendations developed by DHFS. DHFS' recommendation for an alachlor-ESA groundwater quality enforcement standard of 20 µg/L was established in accordance with the applicable provisions of ch. 160, Stats., and it is consistent with past development of state groundwater quality standards. There is no justification for requiring a peer review of the scientific studies and methodology used by DHFS to develop their recommended standard.*

8. **Comment:** (AEC, WCPA, MON) ... ask that a "trigger" be placed in the rule that would automatically/immediately revise the groundwater standard and PAL as soon as a health advisory level or reference dose (acceptable daily intake) for Alachlor-ESA is established by the federal environmental protection agency.

**Response:** *Ch. 160 Stats. directs that Wisconsin state groundwater enforcement standards are generally established based on "federal numbers" which represent EPA consensus risk-based values such as maximum contaminant levels, cancer potency factors and health-based reference doses. However, the statute directs that groundwater standard recommendations are initiated at DHFS to ensure their adequacy and appropriateness for a particular compound. The imposition of a trigger that would bypass the authority of DHFS to review and recommend appropriate ES and PAL values would represent a violation of the statute. Wisconsin groundwater quality standards are routinely adjusted to reflect new or revised federal guidance. A "trigger", as proposed in the comments, would not conform with Wisconsin law and, as revisions to state groundwater standards are now routinely made, is not necessary.*

9. **Comment:** (MON) "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."

**Response:** *The Wisconsin state groundwater quality standards proposed for alachlor-ESA are based on recommendations developed by DHFS. These recommendations were developed in accordance with methodologies specified in state statute. DHFS considered all available, applicable scientific information related to the toxicology of alachlor-ESA when it developed its recommendations. No federal or international standards or health advisory levels have been established for alachlor-ESA.*

*At least two states, Minnesota and North Carolina, have established health based guidance levels for alachlor-ESA. The health based guidance level (Health Based Value) established for alachlor-ESA in Minnesota is 40 µg/L. The health based guidance level (recommended Interim Maximum Allowable Concentration) established in North Carolina for total alachlor plus its metabolites (including alachlor-ESA) is 0.4 µg/L. The health based groundwater quality standards for alachlor-ESA recommended by DHFS are not inconsistent with the health advisory levels established in these states.*

10. **Comment:** (MON) "The state clearly needs to take appropriate caution to ensure public health, however, erroneous decisions by DHFS, if adopted, 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."

*Response: The Department is charged with establishing state groundwater quality standards for substances detected in, or having a reasonable probability of entering, the groundwater resources of the state. Water supply well sampling, done by the Wisconsin Department of Agriculture, Trade and Consumer Protection, has shown alachlor-ESA to be one of the most commonly detected pesticide related compounds in Wisconsin groundwater. Alachlor-ESA has been found in approximately 28% of the water supply wells tested in alachlor use areas.*

*In order to provide adequate safeguards for public health and welfare, state groundwater law clearly justifies development of state groundwater standards for alachlor-ESA. Chapter 160, Stats., establishes a strict process for generating and promulgating state groundwater quality standards that ensures that these standards are based on sound science, and that available, pertinent information is considered in their development. This statutory process has been followed in the development of the proposed state groundwater quality standards for alachlor-ESA.*

11. **Comment:** (MON) "... 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."

*Response: Section 227.14(2m), Stats., addresses the quality of data used in the preparation and analysis of a proposed rule. The scientific data used by DHFS in developing its recommendation for an alachlor-ESA enforcement standard were primarily the results of toxicology studies funded by the Monsanto Company. The standard recommended by DHFS is based on the results of valid scientific studies, and the methodology used to develop it is specified in state statute. There is no reason to believe that the accuracy, integrity, objectivity or consistency of the data used by DHFS in developing its alachlor-ESA enforcement standard recommendation is in question.*

12. **Comment:** (MON) "Monsanto provided extensive scientific and legal comments on this proposal during the public hearing process on CR02-095. As DNR's Response to Public Comments on CR02-095 document shows, many of our comments were supported by other agricultural interests, 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 (attached) 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. We ask that those comments be reconsidered/utilized in the review/reassessment of CR07-034".

**Response:** DHFS has received a copy of all comments that were sent to the Department related to this rule. DHFS has reviewed those comments and has provided responses to comments related to their development of recommendations for alachlor-ESA groundwater quality standards - see DHFS response to comments document (NRB Agenda Item background memo - Attachment 2). DHFS has also revised the scientific support documentation that details the development of its alachlor-ESA groundwater standard recommendations - see DHFS June 2007 alachlor-ESA scientific support documentation (NRB Agenda Item background memo - Attachment 3).

13. **Comment:** (MON) "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 September 2005 Green Sheet Attachment 2, DHFS responses [to comments received on Natural Resources Board Order No. DG-37-02] #1, 8 and 21 (attached). 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."

**Response:** DHFS has reviewed comments related to the NOEL used to develop its recommendation for an alachlor-ESA groundwater quality enforcement standard. DHFS has provided responses to comments related to the NOEL it utilized - see DHFS (NRB Agenda Item background memo - Attachment 2) response to comments: A & E.

14. **Comment:** (MON) "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"."

**Response:** DHFS has reviewed comments related to the NOEL used to develop its recommendation for an alachlor-ESA groundwater quality enforcement standard. DHFS has provided responses to comments related to the NOEL it utilized - see DHFS (NRB Agenda Item background memo - Attachment 2) response to comments: A & E.

15. **Comment:** (MON) "... 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."

**Response:** DHFS has reviewed comments related to the NOEL used to develop its recommendation for an alachlor-ESA groundwater quality enforcement standard. DHFS has provided responses to comments related to the NOEL it utilized - see DHFS (NRB Agenda Item background memo - Attachment 2) response to comments: A & E.

16. **Comment:** (MON) "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)."

*Response: DHFS has reviewed and considered the results of all available scientific studies related to the toxicity of alachlor-ESA. These studies included the new Monsanto initiated 90-day rat study [A 90-day oral (diet) toxicity study of MON 5775 in rats, conducted by WIL Research Laboratories] - see DHFS June 2007 alachlor-ESA scientific support documentation (NRB Agenda Item background memo - Attachment 3).*

17. **Comment:** (MON) "DHFS' utilization of a 10,000-fold uncertainty factor differs greatly from the 1000-fold uncertainty factor used for alachlor ESA in the alachlor RfD 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."

*Response: DHFS has reviewed comments related to the uncertainty factor used to develop its recommendation for an alachlor-ESA groundwater quality enforcement standard. DHFS has provided responses to comments related to the uncertainty factor it utilized - see DHFS (NRB Agenda Item background memo - Attachment 2) response to comments: B, C & D.*

18. **Comment:** (MON) "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)."

*Response: DHFS has reviewed comments related to the uncertainty factor used to develop its recommendation for an alachlor-ESA groundwater quality enforcement standard. DHFS has provided responses to comments related to the uncertainty factor it utilized - see DHFS (NRB Agenda Item background memo - Attachment 2) response to comments D.*

19. **Comment:** (MON) "DHFS's response to the above two comments [Monsanto comments on Natural Resources Board Order No. DG-37-02 related to DHFS' use of a 10,000-fold uncertainty factor] (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."

*Response: Chapter 160 does not provide guidance on the magnitude of the uncertainty factor used in the calculation of an acceptable daily intake/RfD. Section 160.13(2)(b)3, Stats., lists the types of information that must be considered in establishing a suitable uncertainty factor. This information was considered by DHFS in establishing a suitable uncertainty factor to be used to calculate an acceptable daily intake/RfD value for alachlor-ESA - see DHFS June 2007 alachlor-ESA scientific support documentation (NRB Agenda Item background memo - Attachment 3)*

20. **Comment:** (MON) "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."

*Response:* DHFS has reviewed comments related to the uncertainty factor used to develop its recommendation for an alachlor-ESA groundwater quality enforcement standard. DHFS has provided responses to comments related to the uncertainty factor it utilized - see DHFS (NRB Agenda Item background memo - Attachment 2) response to comments: B, C & F.

21. **Comment:** (MON) "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 [to comments received on Natural Resources Board Order No. DG-37-02] continues to rely on the outdated, B2 (Probable Human Carcinogen) classification that was assigned in 1986."

*Response:* DHFS has reviewed comments related to the uncertainty factor used to develop its recommendation for an alachlor-ESA groundwater quality enforcement standard. DHFS has provided responses to comments related to the uncertainty factor it utilized -see DHFS (NRB Agenda Item background memo - Attachment 2) response to comments F.

22. **Comment:** (MON) "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 [to comments received on Natural Resources Board Order No. DG-37-02]). 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."

*Response:* DHFS has reviewed comments related to the uncertainty factor used to develop its recommendation for an alachlor-ESA groundwater quality enforcement standard. DHFS has provided responses to comments related to the uncertainty factor it utilized - see DHFS (NRB Agenda Item background memo - Attachment 2) response to comments: D & F.

23. **Comment:** (MON) "In addition to not addressing any of the factual issues raised about the four examples, DHFS' Response #23 [to comments received on Natural Resources Board Order No. DG-37-02] 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."

*Response:* Thank you for clarification of Monsanto's position on this issue.

24. **Comment:** (MON) "Comments at September 5th 2006 DNR Board Meeting by Dr. Anderson - Dr. Anderson, Department of Health and Family Services, stated that "The rats who were fed this [Alachlor ESA] in their drinking water suffered from anemia." and that ".....Monsanto argues that

anemia is not a serious enough affect [sic] to base the standard on." Monsanto has never argued that anemia is not a serious health effect or that it shouldn't be used to establish health-based standards. Rather, Monsanto disagrees with the DHFS/DNR conclusion that alachlor ESA caused anemia in rats, especially at the dose levels cited by DHFS. The DHFS conclusion is also in contrast to the conclusions of the USEPA and EU, both of which concluded that the slight numerical differences cited by DHFS were not biologically relevant and/or were not caused by alachlor ESA. This conclusion is further supported by the clear lack of anemia in a repeat study conducted at the request of DHFS with even higher dose levels of alachlor ESA."

*Response: Thank you for clarification of Monsanto's position on this issue.*

25. **Comment:** (MON) "In addition, the rule background statement that current levels of alachlor ESA in WI groundwater would lead to adverse impacts on public health is in contrast to the following statement by USEPA: "Chronic dietary risk from alachlor from food containing residues of alachlor and from consumption of water containing residues of alachlor per se and/or residues of alachlor ESA is not of concern." By their overly conservative proposal, DHFS/DNR will create a false public health concern and trigger unnecessary mitigation expenses that will have no meaningful impact on public health."

*Response: The (Feb. 26, 2007) rule background memo statement that refers to "adverse impacts" (page 4, second paragraph) is a discussion of adverse impacts on public health, welfare, safety and the environment that would result if small businesses were not required to meet the regulatory requirements (reporting, remedial response) of Wisconsin's groundwater law, ch. 160, Stats. The rule background memo does not state that current levels of alachlor ESA in WI groundwater would lead to adverse impacts on public health.*

26. **Comment:** (WFU) "Wisconsin Farmers Union supports the DHFS groundwater standard for alachlor ESA as proposed. The standard was developed as required in the Wisconsin Groundwater Protection law, just as it has been for more than 100 other chemicals. It uses the best science available and has been 15 years in the making. Farm family health is critical to the health of Wisconsin's rural economy and our well waters are important."

*Response: Thank you for the comment supporting the proposed groundwater quality standards for alachlor-ESA. See DHFS (NRB Agenda Item background memo - Attachment 2) response to comments H.*

Attachment #2

**Recommendation for Groundwater Enforcement Standard  
and Preventive Action Limit for Alachlor-ESA**

**Summary of Comments  
June, 2007**

- A. *DHFS' conclusions regarding the NOEL for alachlor-ESA are in direct conflict with the conclusions of the U.S. EPA and the European Commission.***

In the most recent opinion of EPA's Office of Pesticide Programs about the toxicity of alachlor-ESA, it was concluded that the effects observed at the middle dose of 200 mg/kg/day in the 1993 subchronic toxicity study were "minor, generally not dose-related, and not biologically meaningful." In reviewing the data provided by Monsanto from this study in accordance with the criteria established in Ch. 160 Stats., DHFS continues to find that the effects observed at the 200 mg/kg/day dose level constitute a lowest observed effect level (LOEL) and an appropriate endpoint for deriving an enforcement standard and preventive action limit for this compound.

- B. *DHFS' use of an uncertainty factor of 10,000 is flawed and unsupported, and does not meet the criteria in Stats. 160.13(2)(b)3. The use of an additional UF for concern about possible carcinogenic potential is inappropriate since the acceptable daily intake is typically based only on non-cancer endpoints and is not intended to address carcinogenic risk, which should be evaluated separately.***

As in the case of several compounds for which enforcement standards have been recommended by DHFS and ultimately adopted, uncertainty and suspicion about carcinogenic activity has been addressed by inclusion of an uncertainty factor where one was deemed necessary to protect public health. In this case, no suitable data exist on which to evaluate the carcinogenic potency of alachlor-ESA in a quantitative way.

- C. *DHFS' assessment ignores the substantial body of evidence that demonstrates that alachlor ESA is less toxic than parent alachlor and is unlikely to be carcinogenic.***

DHFS is recommending an enforcement standard for alachlor-ESA that is ten times higher than the corresponding enforcement standard for alachlor. While the database for alachlor-ESA is not robust enough to warrant a reduction of the uncertainty factor, DHFS finds the data sufficient to derive a separate standard for alachlor-ESA rather than to recommend that it be regulated in tandem with its parent compound at the more restrictive ES level of 2 µg/L. D. DHFS ignores substantial regulatory precedent for utilizing uncertainty factors of 1000 to 3000 when establishing an ADI or RfD based on a NOEL from a subchronic toxicity study. No appropriate regulatory precedent exists for applying an uncertainty factor of 10,000 in this situation.

The background document lists several compounds for which uncertainty factors of 10,000 have been incorporated into recommendations for enforcement standards. As described in Monsanto's comments on the proposed rule, DHFS has only rarely made recommendations that incorporate such a large uncertainty factor. Each of the previous cases where DHFS has employed a UF of 10,000 has been for a compound for which there was a reasonable amount of data about the health effects related to exposure, but there were specific data gaps that required the use of a larger uncertainty factor. The known carcinogenic potential of alachlor and the absence of data on the carcinogenicity of a closely-related degradate of

alachlor represents a uniquely troubling gap in the database that, in the view of DHFS, requires that particular caution be taken in regulation.

**E. *DHFS fails to consider the most recent and scientifically available information, including its current opinion on the establishment of a NOEL for alachlor-ESA.***

As described in the background document, DHFS' application of the criteria in Ch. 160 yields a different no-observed-effect level (NOEL) than was determined by EPA in the most recent of the three opinions offered by their Office of Pesticide Programs.

**F. *DHFS fails to recognize EPA's classification of alachlor under its new cancer classification system and its conclusion that alachlor is unlikely to be carcinogenic at low doses.***

EPA has proposed revisions to the system by which it classifies carcinogens. At the same time, EPA has maintained its maximum contaminant limit goal (MCLG) of zero for alachlor, a value reserved for compounds that are considered by EPA to be carcinogenic. As such, it is concluded that EPA's current regulatory position about the carcinogenicity of alachlor as a drinking water contaminant reflects sufficient concern to warrant classification as a carcinogen. Alachlor is listed as a B2 carcinogen in EPA's 2006 table of drinking water standards and health advisories. Revised cancer descriptors based on its new approach to cancer classifications are provided in this table for several compounds. However, no such revision is noted for alachlor.

A reference to the opinion of EPA's Office of Pesticide Programs that alachlor is unlikely to be carcinogenic at low doses is included in the background document. No guidance is provided, however, to determine the threshold at which a dose is to be considered 'low'. Opinions such as this may ultimately be considered in a revision of how alachlor is regulated by EPA as a drinking water contaminant. Giving such a finding priority over an existing EPA drinking water regulation would, however, be premature.

**G. *DHFS has not considered all available studies on alachlor-ESA, including EPA's recently-published "Cumulative Risk from Chloroacetanilide Pesticides".***

DHFS staff were not aware of the publication of this document until May of 2007, and a reference to the document has been added to the background document. This document summarizes the findings of a screening-level cumulative risk assessment of the chloroacetanilide pesticides developed based on the common carcinogenic mechanism observed between alachlor, acetochlor and butachlor. While the document itself was published in 2006, the references to alachlor ESA are not based on new data or a new degradate-specific assessment of relative toxicity. As such, none of the data gaps referenced by DHFS in developing an uncertainty factor have been reduced, and no corresponding modification to the DHFS recommendation is warranted.

**H. *The proposed standard for alachlor-ESA was developed as required by the applicable statute, and serves to ensure the protection of the health of farm families.***

DHFS acknowledges and appreciates the support expressed in this comment.

Attachment #3

**SCIENTIFIC SUPPORT DOCUMENTATION  
FOR GROUNDWATER ENFORCEMENT STANDARD AND  
PREVENTIVE ACTION LIMIT RECOMMENDATIONS  
FOR ETHANE SULFONIC ACID METABOLITE OF ALACHLOR  
(ALACHLOR-ESA)**

**Prepared by:**

**Mark Werner, Ph.D., Toxicologist  
Henry Anderson, MD, Chief Medical Officer**

**Wisconsin Department of Health and Family Services  
Division of Public Health**

**June 2007**

## ETHANE SULFONIC ACID METABOLITE OF ALACHLOR (ALACHLOR-ESA)

### Introduction

Alachlor-ESA is a metabolite of the herbicide alachlor. Alachlor is a broadleaf preemergent acetanilide herbicide used widely on corn and soybeans in Wisconsin.

### Chemical Profile

Chemical Name: Alachlor, ethane sulfonic acid metabolite  
Molecular Formula:  $C_{13}H_{20}SNO_5$   
Molecular Weight: 302.37  
Synonyms: MON 5775  
2',6'-diethyl-N-methoxymethyl-2-sulfoacetanilide, sodium salt  
2-[2,6-diethylphenyl (methoxymethyl) amino]-2-oxoethane sulfonic acid, sodium salt

### Occurrence

Alachlor-ESA has been detected in groundwater and surface waters in Wisconsin and elsewhere in the Midwest. In a 1994 study of acetochlor and related herbicides in 12 Midwestern states, alachlor-ESA was found in each of 104 surface water samples at median concentrations of 0.80  $\mu\text{g/L}$  (pre-application) and 5.2  $\mu\text{g/L}$  (post-application).<sup>1</sup> Alachlor-ESA was detected in 65.8% of groundwater samples at a median concentration of 0.28  $\mu\text{g/L}$ .

### Human Exposure

In a 1994 Wisconsin survey of private wells considered at risk for contamination, alachlor-ESA was detected in 206 of 293 samples. Observed concentrations ranged from 1.1 to 26.7  $\mu\text{g/L}$  (average = 4.9  $\mu\text{g/L}$ ).<sup>2</sup> Alachlor was detected in only 12 of these 293 samples.

In 2000, the Wisconsin Department of Agriculture, Trade and Consumer Protection (DATCP) conducted a survey of chloroacetanilide herbicides and their degradates in monitoring wells, private drinking water wells and municipal wells considered at risk for herbicide contamination.<sup>3</sup> The survey yielded the following results:

Well Type	Wells Sampled	Wells with Detects	Percent w/Detects	Average Detect ( $\mu\text{g/L}$ )	Highest Detect ( $\mu\text{g/L}$ )
Monitoring Wells	27	22	81	4.7	33
Private DW Wells	22	20	91	3.5	9.0
Municipal Wells	23	11	48	1.9	4.4

In a separate Wisconsin survey, 336 private water supplies selected in a random, stratified fashion were sampled for atrazine, alachlor and other herbicides as well as their degradates. Alachlor-ESA was detected in 27.8% of surveyed wells, and was detected in a higher percentage of wells than any other contaminant. The mean observed concentration of alachlor-ESA was 1.0  $\mu\text{g/L}$ , with the highest concentration observed at 14.8  $\mu\text{g/L}$ .<sup>4</sup>

### Toxicity

#### **Acute**

An acute oral  $LD_{50}$  of greater than 6000 mg/kg was observed for alachlor-ESA in rats.<sup>5</sup>

## **Subchronic**

Two oral subchronic rat studies have been conducted on the toxicity ofalachlor-ESA.

In a 91-day study,alachlor-ESA was administered to male and female Fischer F-344 rats (10 per sex per dose level) in drinking water at doses of 0, 20, 182 or 1002 mg/kg/day.<sup>6,7</sup> Effects observed in the study included changes in physical appearance of test animals, decreased body weight, ophthalmic effects and alterations in clinical chemistry and hematological measures.

- **Physical appearance.** Increased incidence was reported versus controls for the following endpoints at all dose levels: decreased activity, rapid/shallow breathing, few feces, feces small in size, dehydration, urine staining, emaciation, hunched posture, rough coat, unkempt appearance, dark material/stain on pads of forelimb, around eyes, mouth and nose, clear and red ocular discharge, and hair loss around eyes.
- **Decreased body weight.** Female rats in the lowest dose group showed a statistically significant decrease in body weight relative to controls on days 22 through 85 of the study, although food and water intakes were similar. Similarly, body weights in the high-dose group were significantly lower on days 8 through 91. Body weights for mid-dose females were lower as well. Two-sample t tests conducted by the Wisconsin Department of Health and Social Services (now DHFS) showed significant differences between the body weights of controls and animals in each of the three dose groups ( $p = 0.016, 0.044$  &  $<0.001$ , respectively).<sup>8</sup>
- **Ophthalmic changes.** Both dacryoadenitis (inflammation of the lacrimal gland) and chorioretinopathy (lesions on the retina and/or chorion) were observed with increased frequency in exposed animals versus controls. In laboratory studies assessing the toxicity ofalachlor, ocular lesions and molting of retinal pigmentation (described as *uveal degeneration syndrome*) have been seen in Long-Evans rats.<sup>5</sup> Because the Fischer 344 rat has an unpigmented eye, the full range ofalachlor-related ocular effects could not be assessed in this experiment.
- **Clinical chemistry indices.** Low-dose females had a statistically significant decrease in levels of aspartate aminotransferase relative to controls ( $p < 0.01$ ). Low- and mid-dose females also had significantly lower levels of potassium ( $p < 0.05$ ) and calcium ( $p < 0.01$ ). Effects were not consistent at higher dose levels.
- **Hematological effects.** Male rats in the middle dose group had a statistically significant decrease in erythrocyte counts ( $p < 0.05$ ). This finding was more pronounced ( $p < 0.01$ ) in test animals at the highest dose. Hematocrit values and hemoglobin levels, both of which were significantly lower at the high dose vs. controls ( $p < 0.05$ ), were moderately lower than controls at the mid-dose, consistent with a dose-response relationship. Bilibubin, a by-product of the breakdown of hemoglobin, was increased at statistically-significant levels in both mid-dose and high-dose animals.

In a more recent 90-day study,alachlor-ESA was administered to three groups of Cr1:CD(SD)IGS BR rats in the diet at dosage levels of 3000, 6000 and 12,000 ppm (209, 422 and 857 mg/kg/day, respectively).<sup>9</sup> Observed effects included changes in sensory observations, testis weight, serum chemistry and hematological effects.

- **Sensory observations.** Unresponsiveness to touch response was measured in control and test animals. The mean number of times animals had no reaction to the touch response was increased in males in the high-dose group ( $p < 0.05$ ). No dose-related change was observed in other sensory observations such as tail pinch response, startle response and approach response.
- **Organ weights.** Relative testis weight was found to be increased in low-dose males ( $p < 0.05$ ). No corresponding increase was seen in mid-dose and high-dose males, and no increase in absolute testis weight was observed.

- **Serum chemistry.** Mean triglyceride levels were significantly lower in high-dose males when compared to controls ( $p < 0.05$ ). There were no significant changes in triglyceride levels among the low-dose and mid-dose groups.
- **Hematological effects.** Mean absolute and relative reticulocyte counts were elevated in both mid-dose and high-dose males ( $p < 0.05$ ). These values were also elevated in low-dose males, but the increase at this dose level was not statistically significant.

### **Chronic**

No data on the chronic toxicity of alachlor-ESA are available.

### **Carcinogenicity**

No data from long-term carcinogenicity studies are available for alachlor-ESA.

In oral feeding studies, alachlor has been shown to cause tumors in nasal epithelium, stomach and thyroid. Among the primary metabolites of alachlor of concern for nasal tumors is 2-chloro-*N*-(2,6-diethylphenyl)acetamide (CDEPA), which can be metabolized to 2,6-diethylaniline (DEA). DEA can be oxidized to form a diethylbenzoquinone imine (DEBQI), which binds to cellular protein, leading to cell death. Ensuing regenerative cell proliferation has been hypothesized by EPA to lead to neoplasia through fixation of spontaneous mutations.<sup>5</sup> The mechanism by which rats and humans form the DEBQI metabolite is similar.<sup>10</sup>

Alachlor-ESA has been demonstrated to show less affinity for accumulation in nasal turbinates than alachlor.<sup>11</sup> A 91-day study failed to show nasal cell proliferation following administration of alachlor-ESA at a dose level of 157 mg/kg/day.<sup>12</sup> A separate 91-day study showed no apparent fundic mucosal atrophy upon exposure to alachlor-ESA, an effect which precedes cell proliferation and stomach tumors upon alachlor exposure.<sup>13</sup> Cell proliferation in the stomach resulting from alachlor-ESA exposure was described by the investigators as minimal.

### **Mutagenicity**

Chromosomal effects of alachlor-ESA were evaluated in the mouse micronucleus test. Single oral doses of 500, 1000 or 2000 mg/kg alachlor-ESA were administered to five male CD-1 mice by gavage.<sup>5,7</sup> Animals were sacrificed at 24 or 48 hours after administration. Bone marrow cells were harvested and examined for the presence of micronucleated polychromatic erythrocytes. No treatment-related increase was observed in the frequency of polychromatic erythrocytes with micronuclei. A range of other tests have failed to demonstrate any substantive mutagenic potential for alachlor-ESA.<sup>14,15</sup>

### **Reproductive and Developmental Toxicity**

Single doses of alachlor-ESA in doses of 0, 150, 400 and 1000 mg/kg/day in corn oil were administered by gavage to bred female rats (25 at each dose level) on gestational days 6 through 15.<sup>5,7</sup> Animals were euthanized on gestational day 20 and examined for uterine and ovarian abnormalities. Fetuses were sexed, weighed and examined for gross developmental abnormalities. Rales were observed in some dams at the highest dose, and body weight of mid-dose pups was decreased relative to controls ( $p < 0.05$ ). No treatment-related changes were observed between test and control animals in food consumption or organ weight among dams or fetuses, and no increase in external, visceral or skeletal variations or malformations were seen in fetuses.

### **Interactive Effects**

No data on interactive effects of alachlor-ESA are available.

## Environmental Fate

### **Atmospheric**

The vapor pressure of alachlor-ESA has not been determined. Given its chemical similarity to alachlor (vapor pressure =  $2.2 \times 10^{-5}$  mm Hg), the volatility of alachlor-ESA is likely to be relatively low.

### **Terrestrial**

In a study of the behavior of alachlor and metolachlor and their metabolites in soil following a single application, alachlor-ESA was found to penetrate more deeply in soil than its parent compound. In the upper 15 cm of soil, alachlor-ESA concentrations reached peak levels at 9 to 10 weeks after application at 60% of parent concentration. Conversely, alachlor-ESA concentrations were more than 10 times greater than alachlor at depths of 60 to 75 cm after six weeks.<sup>16</sup>

### **Aquatic**

Alachlor-ESA was found to be very mobile in studies conducted with Sable silty clay loam soils and Sarpy sandy loam soils mixed and equilibrated with calcium chloride.<sup>5</sup> Alachlor-ESA is highly persistent in surface water, with long-term declines in surface water concentration attributed more directly to dilution than degradation.<sup>17</sup>

## Analytical Methods

Alachlor-ESA can be quantified in water samples by high-performance liquid chromatography / mass spectrometry. This method yields detection limits as low as 0.10  $\mu$ g/L.<sup>18</sup>

## U.S. EPA Regulatory Position

	<u>Alachlor-ESA</u>	<u>Alachlor</u>
EPA MCL & MCLG:	None	2 $\mu$ g/L (MCL), 0 $\mu$ g/L (MCLG)
EPA Reference Dose:	None	0.01 mg/kg/day
EPA Reference Concentration:	None	None
EPA Lifetime Health Advisory:	None	None
EPA Carcinogenicity Classification:	No classification	B2, probable human carcinogen <sup>19</sup>

## **EPA Office of Pesticide Program (OPP) Reviews**

In its 1998 Reregistration Eligibility Document (RED) for alachlor, the hematological effects observed at the middle and high doses in the 91-day subchronic oral study for alachlor-ESA were acknowledged to be of statistical significance, but were described as "minor, mostly not dose related and...not considered to be biologically relevant, especially in the absence of any organ or tissue pathology".<sup>5</sup> In addressing the development of a reference dose for alachlor-ESA, two alternative methods with default assumptions were offered: (1) the use of the RfD for alachlor of 0.01 mg/kg/day, which is based on observations of hemolytic anemia and hemosiderosis at various organ sites in a one-year study in dogs, and (2) a value based on the agency's NOEL and an uncertainty factor of 1000 to account for "interspecies extrapolation, intraspecies variability and a lack of a complete database". In the RED, alachlor is described as "likely to be a human carcinogen at high doses but not likely at low doses". No quantitative benchmark is provided to distinguish between 'high doses' and 'low doses'. Alachlor-ESA is described in the RED as "unlikely to be carcinogenic".

In 2006, OPP published a screening-level cumulative risk assessment for chloroacetanilide pesticides.<sup>20</sup> The document sought to characterize risks from exposure to acetochlor and alachlor in food and water based on their designation by OPP as a "common mechanism group." This designation was based on

their common mode of action for the production of tumors of the nasal olfactory epithelium in rats. In the document, OPP declined to include alachlor-ESA or other degradates of alachlor and acetochlor in its risk assessment, stating that the ethane sulfonic acid and oxanilic acid degradates of alachlor and acetochlor show a different toxicological profile than their parent compounds and do not contribute to the nasal epithelial tumors on which the designation of a common mechanism group was based.

#### Recommendations and Conclusions for Alachlor-ESA

Ch. 160 Stats. defines a "no-observable-effect-level" (NOEL) as "that level of intake of a substance which, when administered to a group of humans or experimental animals, does not produce any of the effects observed or measured at any higher level of intake and produces no significant difference between the test groups and an unexposed control group of humans or animals maintained under identical conditions". In reviewing the available data on alachlor-ESA, the two subchronic studies represent the best available data on which to identify a NOEL. The results from these studies show a marked difference in observed toxicity, which may be due to differences in the route of exposure. Test compound was administered in drinking water in the 1993 study, was administered with food in the 2003 study. Given that the route of exposure in the older study matches that of concern for a groundwater enforcement standard and the sharp difference in observed toxicity between the two studies, it is appropriate to give deference to the 1993 study as a better representation of the toxicity of alachlor-ESA in drinking water than the more recent subchronic. Therefore, based on Ch. 160 Stats. and our analysis of data from studies of the subchronic toxicity of alachlor-ESA, the hematological findings in the study by Siglin *et al* at the dose of 182 mg/kg/day constitute the lowest level at which effects are observed, thereby establishing a no-observed-effect-level (NOEL) of 20 mg/kg/day.

In establishing an uncertainty factor, DHFS is directed in Ch. 160 Stats. to consider a range of factors, including the quality and quantity of available data, potential interactions with environmental chemicals and known chronic or subchronic effects of exposure to similar or related compounds. In the case of alachlor-ESA, the lack of data on chronic or carcinogenic effects and the frequency with which alachlor-ESA is found in drinking water with alachlor, metolachlor and acetochlor and other degradates of these chloroacetanilide herbicides, require special consideration.

Based on these considerations, an uncertainty factor of 10,000\* (10 for interspecies variability, 10 for intraspecies variability, 10 for use of a subchronic study and 10 for data gaps, including lack of a carcinogenicity study for the metabolite of a potentially carcinogenic parent compound) is applied.

$$\frac{(20 \text{ mg/kg/day}) (10 \text{ kg})}{(1 \text{ L/day}) (10,000)} = 0.02 \text{ mg/L} (20 \text{ } \mu\text{g/L})$$

In accordance with Chapter 160 of Wis. Stats., the Department of Health and Family Services recommends adoption of a groundwater enforcement standard and preventive action limit for alachlor-ESA as follows:

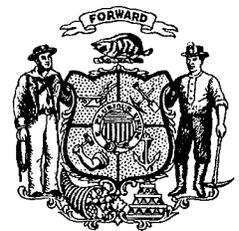
Recommended enforcement standard:	20 $\mu$ g/L**
Recommended preventive action limit factor:	20%
Recommended preventive action limit:	4 $\mu$ g/L

\*Uncertainty factors of 10,000 have been previously used in developing groundwater enforcement standards for methyl-tert-butyl ether and n-hexane; they have also been used by EPA in establishing the MCLs for lindane and styrene that were adopted as Wisconsin groundwater enforcement standards.

\*\*Corresponds to an acceptable daily intake value of 20  $\mu$ g/day.

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160.001



**160.001 Legislative intent.** The legislature recognizes that prior to May 11, 1984, most groundwater regulatory programs were not based on numerical standards. The legislature intends, by the creation of this chapter, to minimize the concentration of polluting substances in groundwater through the use of numerical standards in all groundwater regulatory programs. The numerical standards, upon adoption, will become criteria for the protection of public health and welfare, to be achieved in groundwater regulatory programs concerning the substances for which standards are adopted. To this end, the legislature intends that:

160.001(1)



(1) This chapter will establish an administrative process which will produce numerical standards, comprised of enforcement standards and preventive action limits, for substances in groundwater. As more specifically provided in this chapter, administrative procedures also provide for minimizing the concentration of substances in groundwater.

160.001(2)



(2) The enforcement standards and preventive action limits will be adopted under the authority of this chapter, independent of any regulatory programs concerning the substances for which enforcement standards and preventive action limits are adopted.

160.001(3)



(3) This chapter supplements the regulatory authority elsewhere in the statutes, whether the regulatory programs exist under current statutes on May 11, 1984, or are created after that date. Regulatory agencies will continue to exercise the powers and duties in those regulatory programs, consistent with the enforcement standards and preventive action limits for substances in groundwater under this chapter. This chapter provides guidelines and procedures for the exercise of regulatory authority which is established elsewhere in the statutes, and does not create independent regulatory authority.

160.001(4)



(4) In order to comply with this chapter, a regulatory agency is not required to adopt a particular type of regulation; regulatory agencies are free to establish any type of regulation which assures that regulated facilities and activities will not cause the concentration of a substance in groundwater affected by the facilities or activities to exceed the enforcement standards and preventive action limits under this chapter at a point of standards application. A regulatory agency may adopt regulations which establish specific design and management criteria for regulated facilities and activities, if the regulations will ensure that the regulated facilities and activities will not cause the concentration of a substance in groundwater affected by the facilities or activities to exceed the enforcement standards and preventive action limits under this chapter at a point of standards application.

160.001(5)



(5) The enforcement standards and preventive action limits adopted under this chapter provide adequate safeguards for public health and welfare. However, this chapter does not prevent regulatory agencies from adopting regulations under regulatory authority elsewhere in the statutes based on the best currently available technology for regulated activities and practices which ensure a greater degree of groundwater protection.

160.001(6)



(6) Where necessary to comply with federal statutes or regulations, the department of natural resources may

adopt rules in regulatory programs administered by it which are more stringent than the enforcement standards and preventive action limits adopted under this chapter.

160.001(7)



(7) A regulatory agency may take any actions within the context of regulatory programs established in statutes outside of this chapter, if those actions are necessary to protect public health and welfare or prevent a significant damaging effect on groundwater or surface water quality for present or future consumptive or nonconsumptive uses, whether or not an enforcement standard and preventive action limit for a substance has been adopted under this chapter. Nothing in this chapter requires the department of health and family services or the department of natural resources to establish an enforcement standard for a substance if a federal number or state drinking water standard has not been adopted for the substance and if there is not sufficient scientific information to establish the standard.

160.001(8)



(8) Preventive action limits shall serve as a means to inform regulatory agencies of potential groundwater contamination problems, to establish the level of groundwater contamination at which regulatory agencies are required to commence efforts to control the contamination and to provide a basis for design and management practice criteria in administrative rules. A preventive action limit is not intended to be an absolute standard at which remedial action is always required.

160.001 - ANNOT.



**History:** 1983 a. 410; 1995 a. 27 s. 9126 (19).

160.001 - ANNOT.



**Cross Reference:** See also ch. Comm 46, Wis. adm. code.

160.001 - ANNOT.



*The promulgation of rules that prescribe the use of risk-based methodologies to respond to petroleum contamination in soil and groundwater would violate ch. 160. OAG 3-99.*

160.01



**160.01 Definitions.** As used in this chapter, unless the context requires otherwise:

160.01(1)



(1) "Department", when used without qualification, means the department of natural resources.

160.01(2)



(2) "Enforcement standard" means a numerical value expressing the concentration of a substance in groundwater which is adopted under ss. 160.07 and 160.09.

160.01(3)



(3) "Federal number" means a numerical expression of the concentration of a substance in water, established as:

160.01(3)(a)



(a) A drinking water standard or maximum contaminant level, by the federal environmental protection agency;

160.01(3)(b)

(b) A suggested no-adverse-response level, by the federal environmental protection agency; or



160.01(3)(c)

(c) For oncogenic substances, a concentration based on a risk level determination by the federal environmental protection agency or a concentration based on a probability of risk model determined by the national academy of sciences.



160.01(4)

(4) "Groundwater" means any of the waters of the state, as defined in s. 281.01 (18), occurring in a saturated subsurface geological formation of rock or soil.



160.01(5)

(5) "Point of standards application" means the specific location, depth or distance from a facility, activity or practice at which the concentration of a substance in groundwater is measured for purposes of determining whether a preventive action limit or an enforcement standard has been attained or exceeded.



160.01(6)

(6) "Preventive action limit" means a numerical value expressing the concentration of a substance in groundwater which is adopted under s. 160.15.



160.01(6m)

(6m) "Property boundary" means the boundary of the total contiguous parcel of land owned by a common owner, regardless of whether public or private roads run through the parcel.



160.01(7)

(7) "Regulatory agency" means the department of agriculture, trade and consumer protection, the department of commerce, the department of transportation, the department of natural resources and other state agencies which regulate activities, facilities or practices which are related to substances which have been detected in or have a reasonable probability of entering the groundwater resources of the state.



160.01(8)

(8) "Substance" means any solid, liquid, semisolid, dissolved solid or gaseous material, naturally occurring or man-made chemical, parameter for measurement of water quality or biological organism which, in its original form, or as a metabolite or a degradation or waste product, may decrease the quality of groundwater.



160.01 - ANNOT.

**History:** 1983 a. 410; 1995 a. 27 ss. 4441, 9116 (5); 1995 a. 227.



160.03

**160.03 Duties of department.** The department shall exercise both the responsibilities assigned specifically to it under this chapter as well as those assigned generally to the department as a regulatory agency.



160.03 - ANNOT.

**History:** 1983 a. 410.



160.03 - ANNOT.

**Cross Reference:** *See also chs. NR 140 and 746 and Comm 46, Wis. adm. code.*



160.05



**160.05 Identification of groundwater contamination; categories.**

160.05(1)



**(1) Identification.** Each regulatory agency shall submit to the department a list of those substances which are related to facilities, activities and practices within its authority to regulate and which are detected in or have a reasonable probability of entering the groundwater resources of the state.

160.05(2)



**(2) Petition.**

160.05(2)(a)



(a) Any person may petition a regulatory agency to add a substance to or delete a substance from the list submitted to the department under sub. (1). The petition shall clearly and concisely state all of the following:

160.05(2)(a)1.



1. The name of the substance which is proposed to be added or removed from the list.

160.05(2)(a)2.



2. The regulatory authority of the regulatory agency over the facility, activity or practice which is the source of the substance.

160.05(2)(a)3.



3. The reasons for believing the substance exists in or has a reasonable probability of entering the groundwater or the reasons for believing the substance should be removed from the list.

160.05(2)(b)



(b) Within a reasonable period of time after the receipt of a petition a regulatory agency shall either deny the petition in writing or submit the name of the substance to the department under sub. (1). If the regulatory agency denies the petition, it shall give notice of the denial promptly to the person who filed the petition, including a statement of its reasons for the denial.

160.05(3)



**(3) Establish categories.** Within 60 days following receipt of a name of a substance under sub. (1), the department shall place the substance into one of the following categories:

160.05(3)(a)



(a) Category 1, if the substance is detected in groundwater in concentrations in excess of a federal number for that substance.

160.05(3)(b)



(b) Category 2, if the substance is detected in groundwater and is of public health or welfare concern but:

160.05(3)(b)1.



1. Is not detected in concentrations in excess of a federal number; or

160.05(3)(b)2.



2. For which there is no federal number.

160.05(3)(c)



(c) Category 3, if the substance has a reasonable probability of being detected in groundwater and is of public health or welfare concern.

160.05(4)



**(4) Ranking within categories.** The department shall rank each substance within its category. The department shall give highest rankings to those substances which pose the greatest risks to the health or welfare of persons in the state, taking into consideration, among other things, the following characteristics:

160.05(4)(a)



(a) Carcinogenicity.

160.05(4)(b)



(b) Teratogenicity.

160.05(4)(c)



(c) Mutagenicity.

160.05(4)(d)



(d) Interactive effects.

160.05(5)



**(5) Revision of substance lists.** The department shall revise, as necessary, the ranking of substances within categories to include additional substances as they are reported, to reflect a change in the status of a substance which requires that it be placed in a different category or to remove from the list substances which are not shown to involve public health or welfare concerns or which do not have a reasonable probability of entering the groundwater.

160.05(6)



**(6) Public health concerns.**

160.05(6)(a)



(a) The department shall designate which of the substances in each category are of public health concern and which are of public welfare concern.

160.05(6)(b)



(b) In determining whether a substance is of public health concern, the department shall take into account the degree to which the substance may:

160.05(6)(b)1.



1. Cause or contribute to an increase in mortality;

160.05(6)(b)2.



2. Cause or contribute to an increase in illness or incapacity, whether chronic or acute;

160.05(6)(b)3.



3. Pose a substantial present or potential hazard to human health because of its physical, chemical or infectious characteristics; or

160.05(6)(b)4.



4. Cause or contribute to other adverse human health effects or changes of a chronic or subchronic nature even if not associated with illness or incapacity.

160.05(6)(c)



(c) In determining whether a substance is of public health concern, the department may consider other effects not specified under par. (b) if those effects are reasonably related to public health.

160.05(6)(d)



(d) In determining whether a substance is of public welfare concern, the department shall take into account whether the substance may:

160.05(6)(d)1.



1. Influence the aesthetic suitability of water for human use;

160.05(6)(d)2.



2. Influence the suitability of water for uses other than human drinking water; or

160.05(6)(d)3.



3. Have a substantial adverse effect on plant life or animal life.

160.05(6)(e)



(e) In determining whether a substance is of public welfare concern, the department may consider additional characteristics not specified under par. (d) if those characteristics are reasonably related to public welfare.

160.05 - ANNOT.



**History:** 1983 a. 410.

160.07



**160.07 Establishment of enforcement standards; substances of public health concern.**

160.07(1)



(1) The department of health and family services and the department shall enter into a memorandum of understanding setting forth the procedures and responsibilities of each agency in establishing enforcement standards under this section. The memorandum shall include those standards to be used by the department in making the designation required under s. 160.05 (6).

160.07(2)



(2) Within 10 days after placing the name of a new substance within a category or changing the category of a substance under s. 160.05, the department shall submit the current list of categories and rankings of substances to the department of health and family services.

160.07(3)



(3) The department of health and family services shall recommend to the department an enforcement

standard for each substance submitted to it under sub. (2) which is designated as of public health concern, in the order of rankings within each category under s. 160.05 (4).

160.07(4)



**(4)** The department of health and family services shall develop recommendations for enforcement standards for substances of public health concern as follows:

160.07(4)(a)



(a) If a single federal number exists for a substance, the federal number shall be the enforcement standard.

160.07(4)(b)



(b) If more than one federal number exists for a substance, the most recently established federal number representing the most current data shall be the enforcement standard.

160.07(4)(c)



(c) If no federal number exists for a substance, but there is a state drinking water standard, the state drinking water standard shall be the enforcement standard.

160.07(4)(d)



(d) If neither a federal number nor a state drinking water standard exists for a substance, the department of health and family services shall develop a recommended enforcement standard using the methodology under s. 160.13.

160.07(4)(e)



(e) Notwithstanding pars. (a) and (b), the department of health and family services may recommend an enforcement standard different than the federal number if there is significant technical information which is scientifically valid and which was not considered when the federal number was established, upon which the department of health and family services concludes, utilizing the methodology under s. 160.13 and with a reasonable scientific certainty, that such a standard is justified. The department of health and family services may recommend a change in an enforcement standard previously adopted by utilization of a federal number. In evaluating the evidence for establishing an enforcement standard different than a federal number, the department of health and family services shall consider the extent to which the evidence was developed in accordance with scientifically valid analytical protocols and may consider whether the evidence was subjected to peer review, resulted from more than one study and is consistent with other credible medical or toxicological evidence.

160.07(5)



**(5)** Within 9 months after transmitting the name of a substance to the department of health and family services under sub. (2), the department of natural resources shall propose rules establishing the recommendation of the department of health and family services as the enforcement standard for that substance and publish the notice required under s. 227.16 (2) (e), 227.17 or 227.24 (3).

160.07(6)



**(6)** If a federal number is established or changed for a substance after an enforcement standard is recommended by the department of health and family services and if any person or regulatory agency submits a request, the department of natural resources shall determine whether the enforcement standard needs revision based on recommendations under sub. (4).

s. 160.05, the department shall submit the current list of categories and rankings of substances to the department of health and family services.

(3) The department of health and family services shall recommend to the department an enforcement standard for each substance submitted to it under sub. (2) which is designated as of public health concern, in the order of rankings within each category under s. 160.05 (4).

(4) The department of health and family services shall develop recommendations for enforcement standards for substances of public health concern as follows:

(a) If a single federal number exists for a substance, the federal number shall be the enforcement standard.

(b) If more than one federal number exists for a substance, the most recently established federal number representing the most current data shall be the enforcement standard.

(c) If no federal number exists for a substance, but there is a state drinking water standard, the state drinking water standard shall be the enforcement standard.

(d) If neither a federal number nor a state drinking water standard exists for a substance, the department of health and family services shall develop a recommended enforcement standard using the methodology under s. 160.13.

(e) Notwithstanding pars. (a) and (b), the department of health and family services may recommend an enforcement standard different than the federal number if there is significant technical information which is scientifically valid and which was not considered when the federal number was established, upon which the department of health and family services concludes, utilizing the methodology under s. 160.13 and with a reasonable scientific certainty, that such a standard is justified. The department of health and family services may recommend a change in an enforcement standard previously adopted by utilization of a federal number. In evaluating the evidence for establishing an enforcement standard different than a federal number, the department of health and family services shall consider the extent to which the evidence was developed in accordance with scientifically valid analytical protocols and may consider whether the evidence was subjected to peer review, resulted from more than one study and is consistent with other credible medical or toxicological evidence.

(5) Within 9 months after transmitting the name of a substance to the department of health and family services under sub. (2), the department of natural resources shall propose rules establishing the recommendation of the department of health and family services as the enforcement standard for that substance and publish the notice required under s. 227.16 (2) (e), 227.17 or 227.24 (3).

(6) If a federal number is established or changed for a substance after an enforcement standard is recommended by the department of health and family services and if any person or regulatory agency submits a request, the department of natural resources shall determine whether the enforcement standard needs revision based on recommendations under sub. (4).

History: 1983 a. 410; 1985 a. 182 s. 57; 1995 a. 27 s. 9126 (19).

**160.09 Establishment of enforcement standards; substances of public welfare concern.** (1) Notwithstanding the authority of the department under ss. 280.11, 281.15 and 281.17 (8) to establish standards for pure drinking water, the department shall establish enforcement standards for substances of public welfare concern as follows:

(a) If a single federal number exists for a substance, the federal number shall be the enforcement standard.

(b) If more than one federal number exists for a substance, the most recently established federal number representing the most current data shall be the enforcement standard.

(c) If no federal number exists for a substance, but there is a state drinking water standard, the state drinking water standard shall be the enforcement standard.

(d) If neither a federal number nor a state drinking water standard exists for a substance, the department shall establish an enforcement standard using all relevant and scientifically valid information available in technical literature concerning the substance and, if necessary, by comparison to similar compounds or classes of compounds.

(e) Notwithstanding pars. (a) and (b), the department may establish an enforcement standard different than the federal number if there is significant technical information which is scientifically valid and which was not considered when the federal number was established, upon which the department concludes, with a reasonable scientific certainty, that such a standard is justified. The department may change an enforcement standard previously adopted by utilization of a federal number. In evaluating the evidence for establishing an enforcement standard different than a federal number, the department shall consider the extent to which the evidence was developed in accordance with scientifically valid analytical protocols and may consider whether the evidence was subjected to peer review, resulted from more than one study and is consistent with other credible medical or toxicological evidence.

(2) The department shall establish an enforcement standard for each substance of public welfare concern in the order of rankings within each category under s. 160.05 (4).

(3) The department shall establish enforcement standards by rule. The department shall prepare proposed rules establishing enforcement standards and shall provide the notice under s. 227.16 (2) (e), 227.17 or 227.24 (3) within 9 months after the name of a substance is received under s. 160.05.

(4) If a federal number is changed or newly established for a given substance after an enforcement standard is established by the department and if a request is submitted to the department by any person or regulatory agency, the department shall determine whether the enforcement standard needs to be revised based on sub. (1).

History: 1983 a. 410; 1985 a. 135; 1985 a. 182 s. 57; 1995 a. 227.

**160.11 Public information.** In promulgating any enforcement standards as rules under ss. 160.07 and 160.09, the department, with the assistance of the department of health and family services, shall prepare a document describing the information and methodology used and the conclusions reached in establishing each proposed enforcement standard. The department shall make the document available when the notice is provided under s. 227.16 (2) (e), 227.17 or 227.24 (3). Any person may submit written questions on the document to the department at any time after the notice is provided under s. 227.16 (2) (e), 227.17 or 227.24 (3) and before any public hearing on the proposed rule is held. The department, with the assistance of the department of health and family services, shall respond at the public hearing to all questions previously submitted in writing.

History: 1983 a. 410; 1985 a. 182 s. 57; 1995 a. 27 s. 9126 (19).

**160.13 Methodology to establish enforcement standard.** (1) DEFINITIONS. In this section:

(a) "Acceptable daily intake" means the dose of a substance which, if ingested daily over an entire human lifetime, appears to be without appreciable risk on the basis of all known facts at the time it is established. Acceptable daily intake is expressed in units of milligrams of the substance per kilogram of body weight.

(b) "Department" means the department of health and family services.

(c) "No-observable-effect level" means that level of intake of a substance which, when administered to a group of humans or experimental animals, does not produce any of the effects observed or measured at any higher level of intake and produces no significant difference between the test group and an unexposed control group of humans or animals maintained under identical conditions.

**160.13 GROUNDWATER PROTECTION STANDARDS**

(2) **METHODOLOGY.** (a) The department shall establish a recommended enforcement standard for a substance by first determining the acceptable daily intake for the substance under par. (b) and then basing the recommended enforcement standard on that acceptable daily intake under par. (c). In complying with pars. (b) and (c), the department shall utilize, where available, relevant and scientifically valid information from the office of pesticide programs and the office of drinking water in the federal environmental protection agency.

(b) The department shall determine the acceptable daily intake for the substance as follows:

1. If an 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, that federal value shall be the acceptable daily intake.

2. Notwithstanding subd. 1., the department may determine an acceptable daily intake value different than the federal value established by the office of pesticide programs or office of drinking water in the federal environmental protection agency, if there is significant technical information which is scientifically valid and which was not considered when the federal value was established, upon which the department concludes, with a reasonable scientific certainty, that such a value is justified. In evaluating the evidence for establishing an acceptable daily intake value different than a federal value, the department shall consider the extent to which the evidence was developed in accordance with scientifically valid analytical protocols and may consider whether the evidence was subjected to peer review, resulted from more than one study and is consistent with other credible medical or toxicological evidence.

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. In establishing a suitable uncertainty factor, the department shall consider all of the following, utilizing, where available, information from the office of pesticide programs and the office of drinking water in the federal environmental protection agency:

a. The quality and quantity of data relevant to establishing an acceptable daily intake.

b. The relative importance to full health of the most sensitive target organs or body systems affected by the substance.

c. The amount of interspecies and intraspecies variations in the effects of the substance.

d. The dose-response curve and the time-concentration relationships for the substance.

e. The nature and degree of severity of injury incurred at the intake level at which the effect of exposure to the substance ceases to be reversible.

f. The potential interactions of the substance within the body with other environmental chemicals or therapeutic drugs.

g. The known potential cumulative effects of repeated exposure to the substance.

h. The known chronic or subchronic effects of exposure to similar or related compounds.

i. The identification of physiologic or pathologic states and functional abnormalities among the potentially exposed population which would constitute a health hazard in the event of exposure to the substance.

j. The possibility of chronic health effects from repeated, acute short-term exposure to the substance.

4. If no acceptable daily intake or equivalent value for an oncogen is established by the federal environmental protection agency or if an acceptable daily intake is established but oncogenic potential at the established acceptable daily intake presents an unacceptable probability of risk, the department shall provide

the department of natural resources with an evaluation of the oncogenic potential of the substance. This evaluation of oncogenic potential shall indicate an acceptable daily intake for the substance which, if ingested daily over an entire human lifetime, appears to present an acceptable probability of risk which is presumed to be a risk level equal to a ratio of one to 1,000,000. A risk level equal to a ratio of one to 1,000,000 is the expectation that no more than one excess death will occur in a population of 1,000,000 over a 70-year period. The department shall base the evaluation of oncogenic potential on a review of the most recent and scientifically valid information available.

(c) The department shall base the recommended enforcement standard for the substance on the intake of one liter of water per day by a person weighing 10 kilograms, where that water is the only source of the substance for the person. The department shall establish the recommended enforcement standard so that the acceptable daily intake of the substance is not exceeded for this type of person under these conditions.

**History:** 1983 a. 410; 1995 a. 27 s. 9126 (19).

**160.15 Establishment of preventive action limits.**

(1) The department shall establish by rule a preventive action limit for each substance for which an enforcement standard is established, as follows:

(a) For any substance of public welfare concern, the preventive action limit shall be 50% of the concentration established as the enforcement standard.

(b) For any substance of public health concern, the preventive action limit shall be 20% of the concentration established as the enforcement standard.

(c) Notwithstanding par. (b), for any substance that has carcinogenic, mutagenic or teratogenic properties or interactive effects, the preventive action limit shall be 10% of the concentration established as the enforcement standard.

(2) The department may establish a preventive action limit for a substance which is lower than the level specified under sub. (1) if the department concludes, to a reasonable degree of scientific certainty, based on significant technical information which is scientifically valid, that a more stringent level is necessary to protect public health or welfare from the interactive effects of the substance. In evaluating whether the evidence provides a sufficient basis for a more stringent level, the department shall consider the extent to which the evidence was developed in accordance with generally accepted analytical protocols and may consider whether the evidence was subjected to peer review, resulted from more than one study and is consistent with other credible medical or toxicological evidence.

(3) Notwithstanding sub. (1), the department may establish by rule preventive action limits for indicator parameters used in monitoring waste storage, treatment or disposal facilities regulated by the department such as biochemical or chemical oxygen demand, alkalinity, hardness, conductivity and pH, if enforcement standards are not established under s. 160.07 or 160.09 for the indicator parameters. In establishing preventive action limits for indicator parameters, the department shall consider the background water quality and the potential for the indicator parameters to show that preventive action limits under sub. (1) may be exceeded.

**History:** 1983 a. 410.

**160.17 Collection of information.** Concurrently with the identification of substances under s. 160.05 (1), the regulatory agency shall conduct a literature search and shall request, where appropriate, the manufacturer of each substance and other knowledgeable sources to provide relevant data, information on the environmental fate of the substance and recommendations on measures which may be implemented to minimize the concentration of the substance in the groundwater.

**History:** 1983 a. 410.

**160.19 Regulatory agency; review of existing regulations; design and management criteria.** (1) When an enforcement standard or a preventive action limit is established by rule for a substance, each regulatory agency shall review its rules and commence promulgation of any rules or amendments of its rules necessary to ensure that the activities, practices and facilities regulated by the regulatory agency will comply with this chapter.

(2) (a) Each regulatory agency shall promulgate rules which define design and management practice criteria for facilities, activities and practices affecting groundwater which are designed, to the extent technically and economically feasible, to minimize the level of substances in groundwater and to maintain compliance by these facilities, activities and practices with preventive action limits, unless compliance with the preventive action limits is not technically and economically feasible.

(b) If a regulatory agency proposes a rule under par. (a) which is not designed to maintain compliance with preventive action limits, the proposed rule and the notice required under s. 227.16 (2) (e), 227.17 or 227.24 (3) shall include a statement to that effect, and a summary of the rationale for the proposed rule. If a regulatory agency determines not to amend the substance of an existing rule which contains design or management practice criteria that do not maintain compliance with preventive action limits, it shall nonetheless amend the rule to include a notice that the rule does not maintain preventive action limits. A summary of the rationale for not amending the substance of the rule shall be included in the notice required under s. 227.16 (2) (e), 227.17 or 227.24 (3).

(3) A regulatory agency may not promulgate rules defining design and management practice criteria which permit an enforcement standard to be attained or exceeded at the point of standards application.

(4) Notwithstanding previous regulatory agency action to review and amend existing rules or to promulgate new rules:

(a) If a rule is designed to maintain compliance with a preventive action limit under sub. (2) (a) and if a preventive action limit is attained or exceeded at a point of standards application, the regulatory agency shall review its rules and, if necessary, revise the rules to maintain or achieve the objectives of subs. (2) and (3).

(b) If an enforcement standard is attained or exceeded at a point of standards application, the regulatory agency shall review its rules and, if necessary, revise the rules to ensure that the enforcement standard is not attained or exceeded at a point of standards application at other locations in the future.

(5) In conducting any review under sub. (4), the regulatory agency's analysis shall include an examination of the performance of other comparable activities in the state to determine if the noncompliance at a single site suggests an isolated problem or a problem which is likely to recur.

(6) The department shall promulgate by rule a scientifically valid procedure for determining if a preventive action limit or enforcement standard is, in fact, attained or exceeded or if a change in concentration of a substance has, in fact, occurred. This procedure shall be used for all regulatory and enforcement purposes under this chapter.

(7) Notwithstanding subs. (2) and (4) (a), modifications to rules and changes in the manner of their administration are not required under this section solely because the background concentration of nitrate or a substance of public welfare concern at individual locations is equal to or greater than the preventive action limit.

(8) Notwithstanding subs. (2) to (4), the department may allow a facility which is regulated under chs. 283 or 289 to 292 to be constructed, after May 11, 1984, in an area where the background concentration of nitrate or a substance of public welfare concern attains or exceeds the preventive action limit or the enforcement standard if the facility is designed to achieve the lowest possible concentration for that substance which is technically and economically feasible and the anticipated increase in the con-

centration of the substance does not present a threat to public health or welfare.

(9) Notwithstanding subs. (2) to (4), the department may allow a facility which is regulated under chs. 283 or 289 to 292 to be constructed, after May 11, 1984, in an area where the background concentration of a substance of public health concern, other than nitrate, attains or exceeds a preventive action limit for that substance:

(a) If the facility will not cause the further release of that substance into the environment;

(b) If the background concentration of the substance does not exceed the enforcement standard for that substance, the facility will not cause the concentration of the substance to exceed the enforcement standard for that substance and the facility is designed to achieve the lowest possible concentration of that substance which is technically and economically feasible; or

(c) If the background concentration of the substance equals or exceeds the enforcement standard for that substance, the facility is designed to achieve the lowest possible concentration of that substance which is technically and economically feasible, the anticipated increase in the concentration of the substance will not cause an increased threat to public health or welfare and the anticipated incremental increase in the concentration of the substance, by itself, will not exceed the preventive action limit. The department shall take action under s. 160.25 if it determines that the increase in the substance causes an increased threat to public health or welfare or it determines that the incremental increase in the concentration of the substance, by itself, exceeds the preventive action limit.

(10) If the department allows a facility to be constructed under sub. (9) (b) or (c), the department shall specify in the initial approval of or the initial or modified permit for the facility the terms and conditions under which the department may seek remedial action for the specific site under ss. 160.23 and 160.25, relating to the substance.

(11) Regulatory agencies shall enforce rules promulgated under this section with respect to specific sites in accordance with ss. 160.23 and 160.25.

(12) The requirements in this section shall not apply to rules governing an activity regulated under ch. 293, or to a solid waste facility regulated under subch. III of ch. 289 which is part of an activity regulated under ch. 293, except that the department may promulgate new rules or amend rules governing this type of activity, practice or facility if the department determines that the amendment or promulgation of rules is necessary to protect public health, safety or welfare.

History: 1983 a. 410; 1985 a. 182 s. 57; 1995 a. 227.

**160.21 Adoption of rules for regulatory responses for groundwater contamination.** (1) For each substance for which an enforcement standard or a preventive action limit is adopted by the department, each regulatory agency shall promulgate rules which set forth the range of responses which the regulatory agency may take or which it may require the person controlling a facility, activity or practice which is a source of the substance to take if:

(a) The preventive action limit is attained or exceeded at the point of standards application; or

(b) The enforcement standard is attained or exceeded at the point of standards application.

(2) Each regulatory agency shall determine by rule the point of standards application for each facility, activity or practice which is the source of a substance for which an enforcement standard or a preventive action limit is established, as follows:

(a) If monitoring is required under existing rules for a facility, activity or practice:

1. The regulatory agency shall establish a point of standards application at any location where groundwater is monitored for