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STATE OF ILLINOIS
Pollution Control Board

BEFORE THE ILLINOIS POLLUTION CONTROL BOARD
OF THE STATE OF ILLINOIS

IN THE MATTER OF:	)	
	)	
PROPOSED MTBE GROUNDWATER	)	R01-14
QUALITY STANDARDS AMENDMENTS:	)	(Rulemaking - Water)
35 ILL. ADM. CODE 620	)	

P.C. #2

NOTICE OF FILING

TO Dorothy M. Gunn, Clerk
Clerk of the Board
Illinois Pollution Control Board
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Chicago, Illinois 60601
(VIA EXPRESS MAIL)

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PLEASE TAKE NOTICE that I have filed today with the Clerk of the Illinois Pollution Control Board a copy of the AGENCY'S POST-HEARING COMMENTS. A copy of this document is herewith served upon each person on the attached service list.

Respectfully submitted,
ILLINOS ENVIRONMENTAL
PROTECTION AGENCY

by: Stephen C. Ewart

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Deputy Counsel
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DATE: May 30, 2001

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IN THE MATTER OF:	)	
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PROPOSED MTBE GROUNDEWATER	)	R01-14
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AGENCY'S POST-HEARING COMMENTS

The Illinois Environmental Protection Agency ("Agency") respectfully submits its post-hearing comments in the above-referenced proceeding to the Illinois Pollution Control Board ("Board") pursuant to 35 Ill. Adm. Code 102.108 and at the direction of the Hearing Officer. During the April 5, 2001 hearing, the Hearing Officer set the deadline for public comment to be May 18, 2001. On May 17, 2001, the Agency filed a motion to extend the public comment to provide additional time for comment on Methyl tertiary Butyl Ether ("MTBE") issues raised by the Board. On May 17, 2001, the Hearing Officer granted the motion and extended the public comment deadline until June 1, 2001. The mailbox rule does not apply.

I. OVERVIEW

Two hearings have been held on the Agency's proposal for the amendment of 35 Ill. Adm. Code 620. The hearings were held on March 1, 2001, in Springfield, Illinois, and on April 5, 2001, in Chicago, Illinois. During the course of these hearings, approximately 129 pages of testimony and thirteen exhibits were admitted to the record.

During the hearings, the Agency presented evidence in support of adopting amendments to the existing Groundwater Quality Regulations, 35 Ill. Adm. Code 620, to include the MTBE level of 0.020 milligram per liter ("mg/l) as an amendment to the preventive response level, 35 Ill. Adm. Code 620.310(a)(3)(A)(i); and the MTBE standard of 0.070 mg/l for Class I: Potable Resource Groundwater Standard, 35 Ill. Adm. Code 620.410(b), and for Class II: General Resource Groundwater Standard, 35 Ill. Adm. Code 620.420(b).

In addition, the Agency provided support for amendments to 35 Ill. Adm. Code 620.505 which address certain deficiencies in compliance point determination conditions and criteria, and the Agency has proposed to incorporate the definitions of "Licensed Professional Engineer" and Licensed Professional Geologist" into the "Definitions" Section of the Groundwater Quality Regulations at 35 Ill. Adm. Code 620.110.

During the April 5, 2001 hearing, the Board introduced into the record two MTBE studies from California and New Hampshire for Agency technical review and comment. In response to this request, the Agency has included the review of Thomas C. Hornshaw, Ph.D. in these post-hearing comments.

II. ISSUES RAISED BY AGENCY'S PROPOSALS

A. "Licensed Professional Engineer" and "Licensed Professional Geologist"

As proposed amendments to the definitions of the Groundwater Quality regulations, 35 Ill. Adm. Code 620.110, the Agency developed and proposed definitions for the "Licensed Professional Engineer" and "Licensed Professional Geologist," which were different from those definitions currently under consideration by the Board in other regulatory proceedings, 35 Ill. Adm. Code 732 (R01-26) and 35 Ill. Adm. Code 740 (R01-27 and R01-29). Accordingly, the Agency has reviewed these proceedings and the definitions for "Licensed Professional Engineer" and "Licensed Professional Geologist," and hereby modifies the proposed definitions for 35 Ill. Adm. Code 620.110 as follows:

> "Licensed Professional Engineer" or "LPE" means a person, corporation or partnership licensed under the laws of this State to practice professional engineering. ~~[225 ILCS 745]~~
>
> "Licensed Professional Geologist" or "LPG" means an individual who is licensed under the Professional Geologist Licensing Act ~~[the laws of the State of Illinois]~~ to engage in the practice of professional geology in Illinois ~~personal registered under~~. (Professional Geologist Licensing Act [225 ILCS 745/15])

B. Agency's Technical Review of MTBE Studies

In response to the Board's request during the April 5, 2001 hearing regarding the Proposed MTBE Groundwater Quality Standards Amendments, 35 Ill. Adm. Code 620, ("R01-14"), Thomas C. Hornshaw, Ph.D., Manager of the Toxicity Unit of the Agency has reviewed the *Public Health Goals for Methyl Tertiary-Butyl Ether ("MTBE") in Drinking Water* (March 1999), prepared by the Office of Environmental Health Assessment, California Environmental Protection Agency ("Exhibit No. 12"), and the *Draft Final Technical Support Document: Derivation of Proposed Primary and Secondary Drinking Water Standards for Methyl* tert-*Butyl Ether in NH Drinking Water Supplies* (February, 2000) prepared by the New Hampshire Department of Health & Human Services, Office of Community and Public Health ("Exhibit No. 13"). Dr. Hornshaw has also discussed the status of groundwater and drinking water standards for MTBE in New York with Nancy Kim, Ph.D., of the New York State Department of Health. Dr. Hornshaw's comments on the standards from the three states are stated below.

General – The standards for all three States are based on cancer risk, as Dr. Hornshaw stated at the April 5, 2001 hearing in this proceeding (T.2. pp. 38-39). Each state has evaluated evidence of the cancer-causing potential of MTBE, as reported in articles from the scientific literature, and determined that MTBE has the potential to cause cancer in humans. These determinations have been made by the State toxicologists independently of USEPA scientists, using procedures specified in their state regulations to arrive at the conclusion that MTBE may cause cancer in humans. As Dr. Hornshaw also stated at the April 5, 2001 hearing, the determination of cancer-causing potential for the purposes of establishing groundwater standards in Illinois is deferred to U.S. Environmental Protection Agency's ("USEPA") cancer ranking system (T.2. pp. 39-45). The cancer risk ranking has been incorporated into the Groundwater Quality Regulations, 35 Ill. Adm. Code 620, as part of the definition of "Carcinogen," which states:

> "Carcinogen" means a chemical, or complex mixture of closely related chemicals, which has been listed or classified in the Integrated Risk Information System or as specified in a final rule adopted by USEPA in accordance with USEPA Guidelines for Carcinogenic Risk Assessment, incorporated by reference at Section 620.125, to be a group A, B_1, or B_2 carcinogen.
>
> 35 Ill. Adm. Code 620.110

California – The California document, Exhibit No. 12, contains a wealth of information on MTBE, including an in-depth review of noncancer and cancer endpoints. Regarding noncancer endpoints, the toxicologists reviewed studies on acute, subacute, and subchronic effects on various organs and organ systems, including reproductive/developmental, immune system, endocrine system, nervous system, and genetic effects. The document also reviewed the results of the few chronic studies published, which reported effects on the kidney, liver, and nervous system. Regarding cancer endpoints, the toxicologists reviewed the results of six assays: male and female rats of two strains, Sprague/Dawley and Fischer 344, by the oral and inhalation routes, respectively, and male and female mice by inhalation.

After reviewing these studies, the toxicologists developed potential drinking water criteria based on both cancer and noncancer endpoints. The following is a description of how the cancer and the noncancer endpoints were derived.

Regarding noncancer effects, the toxicologists determined that the effects on the kidney reported in the *Robinson et al., 1990* study ("Exhibit No. 1, Ex. 3 and 4") were the most relevant toxicological endpoint for calculation of a drinking water criterion. The *Robinson* study was also the study selected by the Agency to develop its 0.070 mg/l draft MTBE Health Advisory, which was published in the *Environmental Register, No. 484, July, 1994* ("Exhibit No. 1, Ex. 4"). It is important to note that the toxicologists reviewed a number of MTBE studies, including several published after the Agency developed the draft Health Advisory, which provided evidence for and against the possibility that the kidney effects seen in male rats were effects unique to male rats. (Effects, including cancer, on the kidneys of only male rats by some chemicals are well-recognized phenomena, arising from damage caused when the chemical triggers overproduction of the $alpha_{2u}$-globulin protein by the kidney.)

As a result of this review, the toxicologists determined that the kidney effects reported in MTBE studies were likely not the result of this mechanism, and that the kidney effects seen in the *Robinson* study were relevant to the evaluation of human health risks. In contrast, at the time the draft Health Advisory was developed, the Agency was unwilling to conclude that these kidney effects were not unique to male rats, preferring to defer this determination to USEPA. Since the

kidney effects were seen at all doses in the *Robinson* study, the toxicologists concluded that the lowest dose tested, 100 milligrams per kilogram per day ("mg/kg/d"), was a Lowest Observable Adverse Effect Level ("LOAEL"), and determined that an Uncertainty Factor ("UF") of 10,000 was appropriate in the calculation of the drinking water criterion. Using a formula equivalent to the formula specified for the calculation of Health Advisories in Subpart F of the Groundwater Quality Regulations (35 Ill. Adm. Code 620.Subpart F), and a water intake equivalent to 3 liters per day ("l/d"), the toxicologists derived a criterion for noncancer effects of 0.047 mg/l. For comparison purposes, the draft Health Advisory developed by the Agency also determined from the *Robinson* study that 100 mg/kg/d was a LOAEL (for diarrhea and elevated cholesterol instead of kidney effects) and that a UF of 10,000 was appropriate, and used the value for water intake of 2 l/d specified in Subpart F to derive the 0.070 mg/l draft MTBE Health Advisory. Thus, the basic difference between the California value for noncancer effects and the draft Health Advisory for Illinois is the use of 3 l/d versus 2 l/d as the water intake rate.

Regarding cancer effects, because the toxicologists had determined that MTBE's effects on the kidney were not unique to male rats, it followed that the kidney tumors reported in the inhalation study with male Fischer 344 rats were relevant to human cancer risk. The toxicologists also determined that the excess tumor incidence found in four of the other five cancer assays (liver tumors in male and female mice, testicular tumors in male rats, and leukemia/lymphoma in female rats) were relevant to human cancer risk (only the inhalation study with female Fischer 344 rats did not produce an excess tumor incidence). Thus, the toxicologists concluded that since MTBE caused tumors in both sexes of two species by two routes of exposure, and that there was consistency in the results as demonstrated by the excess numbers of testicular tumors in rats by both routes of exposure, therefore MTBE should be considered an animal carcinogen and a possible human carcinogen.

The toxicologists then calculated a cancer slope factor ("CSF") for each of the tumor types found to have an excess incidence in the five assays. All CSFs were expressed in units of risk per mg/kg/d, which required conversion of the inhaled doses to oral equivalents using physiologically-based pharmacokinetic modeling. The CSFs ranged from 1.55E-03 (for testicular tumors in rats by

the oral route) to 8.7E-03 (for testicular tumors in rats by the inhalation route), a fairly narrow six-fold range. Because the range of CSFs was so narrow and no clear mechanistic reason to prefer one of the studies was apparent, the toxicologists decided to use the geometric mean of the CSFs, 1.8E-03 per mg/kg/d, for the final CSF. This CSF was then used to calculate a drinking water concentration that corresponded to an excess cancer risk of 1 in 1,000,000, assuming that a person consumes the equivalent of 3 l/d for a lifetime. This value is 0.013 mg/l for cancer effects. Because the value for cancer effects is lower than the value for noncancer effects, the final drinking water standard was 0.013 mg/l.

It should be noted that the approach used by the California toxicologists is consistent with the guidelines published by USEPA for cancer risk assessment, and in instances where scientific judgment was required, there is a full discussion of the various options and why a particular option was chosen. It should also be noted that if the value of 2 l/d specified as the drinking water intake rate in Subpart F of the Groundwater Quality Regulations (35 Ill. Adm. Code 620.Subpart F) is used instead of the 3 l/d used by California, a drinking water criterion of 0.019 mg/l would be calculated.

New Hampshire – The New Hampshire document, Exhibit No. 13, does not contain the same depth of review as the California document, citing to other recent reviews (including the California document) as the main source of its information. As in the California document, this document finds that for noncancer endpoints the kidney effects reported in the *Robinson* study are the most relevant for developing a drinking water criterion, although the lowest dose of 100 mg/kg/d was determined to be a No Observable Adverse Effect Level ("NOAEL") instead of a LOAEL as determined in the California document. Using the 2 l/d drinking water intake rate specified by their regulations and a Relative Source Contribution ("RSC") value of 15 percent instead of the value of 20 percent used by the California toxicologists (and used also in the development of the Illinois draft Health Advisory), the New Hampshire toxicologists calculated a criterion for noncancer effects of 0.050 mg/l.

For cancer effects, the New Hampshire toxicologists concurred with the conclusion of the California toxicologists that MTBE is an animal carcinogen, and determined that based on the

USEPA cancer guidelines MTBE falls on a continuum between a possible and a probable human carcinogen. In a manner similar to California's decision, the New Hampshire toxicologists decided to use the geometric mean of the CSFs calculated from each tumor type, but they determined that an adjustment was necessary for certain results to correct for less than lifetime exposure and also decided to discount the importance of the liver tumors found in male and female mice. Thus, the final CSF of 2.83E-03 was calculated from three assay results (instead of the five used by California), ranging from 2.45E-03 (for kidney tumors in male rats by the inhalation route) to 3.24E-03 (for testicular tumors in rats by the oral route). Using the 2 l/d intake rate, this CSF results in a drinking water criterion of 0.013 mg/l for protection against an excess cancer risk of 1 in 1,000,000. Because this value is lower than the value for noncancer effects, this became the final drinking water standard.

New York – As of May 2, 2001, the date of Dr. Hornshaw's discussion of the drinking and groundwater standards for New York with Dr. Nancy Kim, these standards had not been formally issued by the Governor's Office, so the details of the development of the standards are not publicly available. Therefore, the Agency is providing only a brief summary of the derivation of these standards. Dr. Kim stated that New York regulations specify that for any organic chemical found in drinking water or groundwater that does not have an existing standard, the initial standard is 0.05 mg/l. This standard remains in effect until a replacement value is derived from appropriate studies of the chemical's toxicity. For MTBE, the toxicologists determined, as did the California toxicologists, that MTBE is an animal carcinogen and a possible human carcinogen. Dr. Kim did not specify further details of the calculation of the CSF or the final standards, other than to say that the final value was rounded to one significant digit, or 0.01 mg/l.

III. AGENCY PROPOSAL and CONCLUSION

The Agency has presented testimony and comment which it believes supports the adoption of amendments to the existing Groundwater Quality Regulations, 35 Ill. Adm. Code 620, to include the MTBE level of 0.020 mg/l as the amendment to the preventive response level of 35 Ill. Adm. Code 620.310(a)(3)(A)(i); and the MTBE standard of 0.070 mg/l for Class I: Potable Resource

Groundwater Standard, 35 Ill. Adm. Code 620.410(b), and Class II: General Resource Groundwater Standard, 35 Ill. Adm. Code 620.420(b).

In addition, the Agency has provided support for amendments to 35 Ill. Adm. Code 620.505 to address deficiencies in compliance point determination conditions and criteria and for the inclusion of definitions of "Licensed Professional Engineer" and Licensed Professional Geologist" to the definitions of 35 Ill. Adm. Code 620.110.

The Agency urges the Board to adopt for First Notice these Agency proposals.

Respectfully submitted,
ILLINOIS ENVIRONMENTAL
PROTECTION AGENCY

By: Stephen C. Ewart

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Deputy Counsel

Date: May 30, 2001

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