BEFORE THE POLLUTION CONTROL BOARD OF THE STATE OF ILLINOIS

RECEIVED CLERK'S OFFICE

OCT 1 1 2001

STATE OF ILLINOIS Pollution Control Board

IN THE MATTER OF:

PROPOSED AMENDMENTS TO TIERED APPROACH TO CORRECTIVE ACTION OBJECTIVES (TACO)(MTBE): 35 ILL. ADM. CODE 742

R00-19(C) (Rulemaking-Land)

P.e. #1

NOTICE OF FILING

Dorothy M. Gunn, Clerk Illinois Pollution Control Board James R. Thompson Center 100 West Randolph Street, Suite 11-500 Chicago, Illinois 60601

Robert Lawley, Chief Legal Counsel Dept. of Natural Resources 524 South Second Street Springfield, Illinois 62701-1787

See Attached Service List

Matthew J. Dunn, Chief Environmental Bureau Office of the Attorney General 188 W. Randolph, 20th Floor Chicago, Illinois 60601

Amy Jackson, Hearing Officer Illinois Pollution Control Board 500 South Second Street Springfield, Illinois 62706

NOTICE OF FILING

PLEASE TAKE NOTICE that I have filed today with the Illinois Pollution Control Board the <u>Supplemental</u> <u>Comments and Exhibits of the ENVIRONMENTAL PROTECTION AGENCY</u>, a copy of which is herewith served upon you.

ENVIRONMENTAL PROTECTION AGENCY OF THE STATE OF ILLINOIS

Kimberly A. Geving Assistant Counsel Division of Legal Counsel

Dated: October 8, 2001

Illinois Environmental Protection Agency 1021 N. Grand Ave. E. P.O. Box 19276 Springfield, Illinois 62794-9276 (217/782-5544)

RECEIVED

CLERK'S OFFICE

OCT 1 1 2001

BEFORE THE ILLINOIS POLLUTION CONTROL BOAR TATE OF ILLINOIS Pollution Control Board

IN THE MATTER OF:

PROPOSED AMENDMENTS TO TIERED APPROACH TO CORRECTIVE ACTION OBJECTIVES (TACO)(MTBE): 35 ILL. ADM. CODE 742 ROO-19(C) (Rulemaking-Land)

SUPPLEMENTAL COMMENTS

The Illinois Environmental Protection Agency ("Illinois EPA"), by its attorney, Kimberly Geving, and at the request of the Illinois Pollution Control Board ("Board") in its September 6, 2001 First Notice Opinion and Order in the above-captioned matter, respectfully submits these Supplemental Comments to the Board.

In its discussion of the Proposed Amendments regarding MTBE that were sent to First Notice via the September 6th Opinion and Order, the Board stated that "While the Agency has provided the Board with information supporting the proposed standards, the record is lacking a detailed explanation of the calculations employed by the Agency in reaching the proposed numbers." (Proposed Rule. First Notice Opinion and Order dated September 6, 2001 at pages 4-5). Page 5 of the Board's Opinion and Order specifically requested the Illinois EPA to provide supplementation for its MTBE proposal during the first notice period.

The Illinois EPA maintains that its proposal was technically substantiated on the record. However, in the interest of establishing a more complete, technically sound record, the Illinois EPA offers two attachments that we believe further explain how the objectives were established. The first attachment (Exhibit 1)¹ provides a very detailed description of the Health Advisory that was proposed by

1

¹ Exhibit 1 was also submitted to the Board this year during the Part 620 regulatory proceedings. In that proceeding, it was labeled as Exhibit V to the Illinois EPA's Statement of Reasons in R01-14.

the Illinois EPA in 1994 for MTBE and the scientific justification for the advisory. The Health Advisory served as a base for determining remediation objectives for groundwater in this proceeding. Exhibit 1 explains in detail how the numbers for MTBE were derived. Additionally, Exhibit 1 includes Illinois EPA responses to significant comments that were received regarding the health advisory proposal for MTBE, further substantiating its scientific basis. Exhibit 2 provides supplementation for how the Illinois EPA calculated the soil remediation objectives for MTBE in Part 742.

The Illinois EPA maintains that its proposed remediation objectives for MTBE in both soil and groundwater have been scientifically justified. The Illinois EPA hopes that these Supplemental Comments and attachments further clarify for the Board how the calculations were performed.

WHEREFORE, the Illinois EPA submits these Supplemental Comments to the Board for its consideration and respectfully requests the Board to adopt the objectives proposed by the Illinois EPA in their entirety.

ILLINOIS ENVIRONMENTAL PROTECTION AGENCY

Mg Bv: ving

Assistant Coursel

Dated: October 5, 2001

1021 North Grand Ave. East P.O. Box 19276 Springfield, Illinois 62794-9276 (217) 782-5544

THIS FILING SUBMITTED ON RECYCLED PAPER

2

NOTICE OF HEALTH ADVISORY FOR METHYL TERTIARY-BUTYL ETHER (MTBE)

Prepared by Office of Chemical Safety Illinois EPA June 9, 1994



REASON FOR ACTION

As a result of routine monitoring of public water supply systems, the gasoline additive Methyl Tertiary-Butyl Ether (MTBE) has been detected at least in two public water supplies. Therefore, the Illinois Environmental Protection Agency (Agency) is announcing its intention to issue a health advisory, pursuant to 35 Illinois Administrative Code Part 620 Subpart F: Health Advisories, for Methyl Tertiary-Butyl Ether. According to Section 620.605 of Subpart F, the Agency shall issue a health advisory for a chemical substance if all of the following conditions are met:

1) A community water supply well is sampled and a substance is detected and confirmed by resampling;

- 2) There is no standard under Section 620.410 for such chemical substance; and
- The chemical substance is toxic or harmful to human health according to the procedures of Appendix A, B, or C.

The Agency has determined that all three conditions have been met, prompting the issuance of this draft proposal for a health advisory. By this issuance, the Agency is opening a 30-day public comment period, <u>until August 22, 1994</u>, regarding this health advisory draft. Upon closing the public comment period, the Agency will consider all comments received and amend the health advisory if warranted. The final health advisory will then be published in the Environmental Register (the Illinois Pollution Control Board News) with responses to comments received. An abbreviated version of the final health advisory will also be published in local newspapers which serve communities in whose public water supply systems MTBE has been detected.

PROPOSED GUIDANCE LEVELS

Section 620.605 of Subpart F prescribes the methods for developing health advisories for carcinogens and noncarcinogens. Since the Agency has determined that there is insufficient evidence of the carcinogenicity of MTBE at this time (discussed in the attachment to this notice), the method for developing a health advisory for noncarcinogens was used. Briefly, this method specifies that the USEPA's maximum contaminant level goal (MCLG) is the guidance level, if available, or the human threshold toxicant advisory concentration (HTTAC) must be determined using the procedures contained in Appendix A of Section 620. USEPA has not published an MCLG for MTBE, therefore the Agency used the Appendix A procedures to calculate the HTTAC.

Appendix A specifies in prescribed order the toxicological data to be used in developing the HTTAC, ranging from a verified Reference Dose developed by USEPA to a laboratory animal study of subchronic duration in which only a lowest observable adverse effect level (LOAEL) has been determined. This preferred order reflects increasing uncertainty in the toxicological database regarding a chemical's potential to cause adverse health effects in humans, and is manifested in increasingly large safety factors which are applied to the data to calculate the HTTAC (maximum 10,000-fold safety factor).

In the case of MTBE, the Agency has selected the only study available in which the test animals were exposed by the oral route of exposure as the basis for the HTTAC. Among other findings, this 90-day subchronic study reported increases in structure tasks of the language of Subpart F specifies the application of safety factors totalling to 10,000 to the animal data, resulting in the HTTAC guidance level of 0.07 mg/l, or 70 parts per billion (ppb). The details of the derivation of the HTTAC are presented in the attachment to this notice.

At this point it is necessary to discuss an aspect of the evolving science of risk assessment which has a bearing on this notice. The Agency has been informed verbally by USEPA personnel that in most cases USEPA no longer favors the

Environmental Register No. 484

July, 1994/Page 19

calculation of acceptable exposure values for humans by using laboratory animal data divided by uncertainty factors totalling to 10,000. This preference will be included in a chapter in the book <u>Essential Elements</u> (in press; ILSI Press, 1994). Instead, USEPA now prefers to utilize uncertainty factors totalling to no more than 3,000. The Agency agrees with this approach in general, except in cases where the overall toxicity database for a chemical is very weak. In the case of MTBE, the database contains enough laboratory animal data to determine that there are not major toxicity gaps which would warrant the use of a 10,000-fold uncertainty factor. The Agency is therefore also using an overall uncertainty factor, of 3,000 to calculate a guidance level for MTBE. Use of a 3,000-fold safety factor with the same laboratory animal data described above results in a <u>HTTAC guidance level of 0.23 mg/l, or 230 ppb</u>. The details of the derivation of this HTTAC are also presented in the attachment to this notice.

Since there is no provision in the language of Subpart F for the use of a 3,000-fold uncertainty factor in the derivation of the HTTAC, the Agency is proposing to utilize HTTACs derived by both a 3,000-fold and a 10,000-fold uncertainty factor in the health advisory for MTBE. It is proposed that the HTTAC derived using the 10,000-fold uncertainty factor (70 ppb) be a precautionary health advisory concentration and the HTTAC derived using the 3,000-fold uncertainty factor (230 ppb) be the final health advisory concentration. The precautionary health advisory would be a level in a public water supply below which no action would be necessary and above which caution should be exercised by the public water supply (such as increased sampling of the water and identification of the potential source(s)), while the final health advisory would be a level above which the public water supply should begin actions to decrease the concentration or utilize an alternate water supply. The Agency is requesting comment on the use of this approach when a total uncertainty factor of 10,000-fold is utilized to calculate a health advisory.

SUPPLEMENTARY INFORMATION

Section 620.605 also specifies that the health advisory must contain a general description of the characteristics of the chemical substance and its potential adverse health effects.

General Description of MTBE

MTBE (Chemical Abstracts Service Number 1634-04-4), also known as 2-methoxy-2-methylpropane, is a colorless liquid with a disagreeable taste and odor. Its taste in water can be recognized at approximately 0.7 mg/ ℓ (700 ppb) (Connecticut DEP), although recent research suggests that some people may be able to detect its presence in the range of 0.25 mg/ ℓ and possibly as low as 0.04 mg/ ℓ (API, 1993). It has a high solubility in water, approximately 48,000 mg/ ℓ (von Burg, 1992). Because of this high solubility, it has a high propensity to move through soil with infiltrating rainwater and snowmelt and to potentially reach groundwater.

Its main use is as an octane booster in unleaded gasoline; it also has minor uses as an intermediate in the production of other chemicals, especially isobutene, and as a treatment to dissolve gallstones. Its use has been increasing recently due to requirements under the Clean Air Act Amendments of 1990 for metropolitan areas which are not in compliance with carbon monoxide standards to increase the percentage of oxygenated fuel in gasolines, especially in the wintertime. As a result, it has been estimated that approximately 20% of the gasoline sold in the United States contains MTBE, at levels ranging from 2% to 15% in the gasolines (Costantini, 1993).

Potential Adverse Health Effects of MTBE

Relatively few reports of adverse effects of MTBE on humans exist, and testing for the full range of possible health effects in laboratory animals has not yet been completed. Summaries of the acute, reproductive and developmental, and chronic toxicity data for MTBE are presented.

<u>Acute Toxicity</u> - Other than a single report in the medical literature of acute kidney failure due to leakage of MTBE during gallstone treatment (Ponchon. 1988), there is no information regarding the effects of short-term, high level exposure to MIDE in numans. The data from laboratory animal studies indicate that this enemical is not very toxic during brief exposures, with lethal doses in the range of 3,000-4,000 ppm by oral exposure (about one pint for an adult human) and 24,000-40,000 ppm (in air) by inhalation exposure (this would be within the explosive range in air) (Reese and Kimbrough, 1993; von Burg, 1992; USEPA, 1993). The toxic effect in both exposure types was central nervous system depression. MTBE does not appear to cause skin irritation except in cases of previously damaged skin, and eye irritation and opacity of the cornea has been reported (von Burg, 1992).

<u>Reproductive and Developmental Toxicity</u> - The reproductive effects of MTBE have been reported in three studies, and reproductive and developmental toxicity has been assessed in a fourth, using rats, mice, and/or rabbits. No significant effects were reported in two of the reproductive studies (Biles <u>et al.</u>, 1987; Conaway <u>et al.</u>, 1985), and the third reported effects on offspring (reduced body weight and reduced weight gain in rat pups, and slightly reduced pup survival) only at doses which were also toxic to the parents (Neeper-Bradley, 1991). Similarly, the reproductive and developmental study also reported offspring effects (reduced numbers of viable implantations and/or live births, reduced body weight, decreased ossification, and increased incidence of cleft palate in mouse pups) only at doses toxic to the adults (Tyl and Neeper-Bradley, 1989). This makes it difficult to say whether the effects on reproductive performance were truly an effect of MTBE on the offspring, or whether these effects resulted from the toxicity to the parents. Since the doses which showed these toxic effects were high (3,000-4,000 ppm), the potential for human reproductive effects at the much lower anticipated environmental exposure levels is extremely small.

<u>Chronic Toxicity</u> - There are no studies of the effects on humans exposed to MTBE for long periods, although anecdotal reports of increased complaints of headache, nausea, vomiting, eye irritation, and respiratory problems have surfaced recently in certain areas in conjunction with wintertime MTBE increases in gasoline. These complaints are the subject of on-going research.

There is only one 90-day subchronic study in laboratory <u>animals</u> exposed by the oral route, which was the study finally selected to derive the HTTAC by the Agency after following the procedures of Appendix A. This study is evaluated in depth in the attachment to this notice. There are several animal subchronic and chronic studies using the inhalation route of exposure, primarily evaluating the neurotoxic effects of MTBE. In one study (Greenough <u>et al.</u>, 1980) in which the maximum dose tested was 1,000 ppm for 6 hrs/day, 5 days/wk, for 13 weeks, no significant effects (other than anesthesia following dosing at high concentrations) were reported. In another study (Dodd and Kintigh, 1989), in which the maximum dose tested was 8,000 ppm (same dosing regimen), slight changes in blood chemistry, increased serum cortisone levels in both sexes, reduced weight gain, increased kidney, liver, and adrenal gland weights, and sporadic neurotoxic effects were seen at doses of 4,000 and/or 8,000 ppm. There is also a recently completed lifetime cancer bioassay in mice and rats (Burleigh-Flayer <u>et al.</u>, unpublished; Chun <u>et al.</u>, unpublished), the details of which are evaluated in the attachment to this notice.

FOR FURTHER INFORMATION, COMMENTS

Persons who wish to receive further information about this notice or who wish to provide comment on its contents are requested to contact:

Illinois Environmental Protection Agency Office of Chemical Safety P. O. Box 19276 2200 Churchill Road Springfield, Illinois 62794-9276 217/785-0830

ATTACHMENT TO NOTICE OF HEALTH ADVISORY FOR METHYL TERTLARY-BUTYL ETHER (MTBE)

OVERVIEW OF THE KEY STUDIES

In the only oral study (Robinson et al., 1990), rats were given 0, 100, 300, 900, or 1,200 mg/kg (ppm) by gavage. Rats given 1,200 ppm exhibited profound anesthesia after dosing throughout the study, but recovered after the dose within two hours and suffered no aftereffects. Body weight decreased with increasing dose, with the difference between treated and control rats being statistically significant at 1,200 ppm. Other measurements showing statistical significance included: decreased blood urea nitrogen (BUN) and serum creatinine (measures of kidney function) at all doses; increased serum cholesterol at all doses; increased kidney weight at 300 ppm and above; increases in several other organ weights at 900 ppm, and above; and changes in blood parameters at 1,200 ppm. Microscopic examinations revealed effects only at 1,200 ppm, where degenerative changes in the kidneys of the male rats were noted. Finally, loose stools and diarrhea were seen at all doses throughout the study.

Viewing the results of this study, it would appear that the kidney is the target organ of MTBE. However, these results must be interpreted carefully. The <u>decreases</u> in BUN and serum creatinine probably have no adverse effect on the animals (decreased kidney function is often signaled by <u>increases</u> in these parameters), and may even indicate an increase in kidney function. The increased kidney weights seen at 300 ppm and above are not in themselves an adverse effect, only an indication of a possible adverse effect at even higher doses or longer exposure times. Finally, the microscopic changes seen at 1,200 ppm in males are often seen in male rats (and only male rats) exposed to certain organic chemicals, due to overproduction of a unique protein in the male rat kidney. Thus, it is not clear at this time whether MTBE is toxic to the kidney.

It would appear that a no observed adverse effect level (NOAEL) has not been determined by this study, since increased serum cholesterol and diarrhea were observed at all doses. Thus, the 100 ppm dose would be considered to be the lowest observable adverse effect level (LOAEL) for MTBE. The procedure for calculating a health advisory for drinking water in the groundwater quality standards (35 III. Adm. Code 620, Subpart F) gives preference to oral studies which determine a NOAEL or LOAEL, and this study may be considered to develop the health advisory for MTBE.

A lifetime inhalation cancer bioassay has recently been completed with mice and rats, but the results have not been published (Burleigh-Flayer et al.; Chun et al.). The Agency has been given summaries of the studies submitted to USEPA by the USEPA contact for MTBE. These results are briefly summarized, but since the studies are still undergoing review it must be realized that this information is preliminary.

Both species were exposed to 0, 400, 3,000, or 8,000 ppm in air. As in the oral study above, the male rats experienced an increased incidence of kidney degeneration. This became the leading cause of death_in male rats, and resulted in early termination of the 3,000 and 8,000 ppm male groups. The other main cause of death in male rats was leukemia, seen in both the control and 400 ppm group. (In fact, the incidence in the control group was higher, 33/50, than in the 400 ppm group, 22/50.) Non-cancer effects of MTBE included symptoms of central nervous system depression in both sexes of rats at 3,000 and 8,000 ppm, but not at 400 ppm, and an increased incidence of kidney degeneration in male rats at 400 ppm. The only tumors which were related to MTBE exposure were tumors in the kidneys of male rats in the 3,000 and 8,000 ppm groups. These tumor types are also thought to be related to the overproduction of the male rat protein, and the significance of these results for humans is questionable.

In the mouse study, symptoms of central nervous system depression similar to those seen in rats were observed at 3,000 and 8,000 ppm. Increases in liver and kidney weights were also seen at these doses, and an increase in the number of liver cells (noncancerous), an indication of toxic effects on the liver, was reported at 8,000 ppm. The only tumors found in excess of controls were liver tumors in females in the 8,000 ppm group. However, the significance of this finding for humans is also questionable, since this tumor type is common in the strain of mouse used in this study, and is known to occur in controls at a tetatively digit rate.

In reviewing the results of these studies, it is difficult to say whether MTBE presents a carcinogenic hazard to humans. However, the noncancer effects may be relevant for determining a health advisory level for MTBE. In this regard, the rat study has produced a LOAEL of 400 ppm based on kidney effects in male rats (this dose may be a NOAEL given the questionable significance of this effect for humans), while the mouse study has produced a NOAEL of 400 ppm. The mouse

Page 22/ July, 1994

18. A.T

-95

portion of this study may be considered to develop the health advisory for MTBE, once it has finished USEPA's review process.

DERIVATION OF THE HEALTH ADVISORY FOR MTBE

The first step in the derivation of a health advisory is to determine whether the chemical presents a carcinogenic hazard to humans. To date, there have been no investigations whether there is an increased incidence of cancer in humans associated with exposure to MTBE. As discussed above, there is some evidence that MTBE causes tumors in laboratory animals, but the types of tumors found in the rat and mouse cancer bioassays may not provide good evidence of a carcinogenic hazard to humans since these tumors may be species-specific responses with little or no relevance to humans. Furthermore, these studies are still undergoing review by USEPA and a final determination of the usability of the results for determining the carcinogenic hazard to humans has not been made. Therefore, the Agency has determined at this time that the derivation of the health advisory for MTBE will be based on the non-cancer effects of this chemical. This derivation may be changed in the future, depending on the USEPA's determinations, once the cancer bioassay data have been published and the weight-of-evidence for human carcinogenic potential has been determined.

In deriving a health advisory to protect against a health effect for which there is a threshold dose below which no damage occurs (i.e., noncarcinogenic effects), Section 620.605 specifies that USEPA's maximum contaminant level goal (MCLG), if available, is the health advisory concentration. USEPA has not published a MCLG for MTBE, therefore, the Agency must calculate the human threshold toxicant advisory concentration (HTTAC) as the health advisory concentration, using the procedures specified in Appendix A of Section 620.

Appendix A specifies in subsection (a) that the HTTAC is calculated as follows:

 $HTTAC = \frac{RSC \times ADE}{T}$

Where:

HTTAC = Human threshold toxicant advisory concentration in milligrams per liter (mg/l);

RSC =

Relative source contribution, the relative contribution of the amount of the exposure to a chemical via drinking water when compared to the total exposure to that chemical from all sources. Valid chemical-specific data shall be used if available. If valid chemical-specific data are not available, a value of 20% (=0.20) must be used;

ADE = Acceptable daily exposure of substance in milligrams per day (mg/d) as determined pursuant to subsection (b); and

W = Per capita daily water consumption equal to 2 liters per day (L/d).

Subsection (b) of Appendix A specifies that the ADE be calculated using, in specified order: USEPA's Verified Oral Reference Dose (an estimate of a daily exposure to a chemical which is expected to be without adverse effect for humans, including sensitive subgroups, for a lifetime of exposure); a NOAEL which has been identified as a result of human exposures; a LOAEL which has been identified as a result of human exposures; a NOAEL which has been determined from studies with laboratory animals; and a LOAEL which has been determined from studies with laboratory animals.

There is no Verified Reference Dose currently available from USEPA. As mentioned above, there is a paucity of studies on the adverse effects in humans exposed to MTBE. Thus, the Agency has determined that a NOAEL or LOAEL based on numeric exposures is not available at this time. Interclore, the ADE must be calculated from incoracily attime. On the studies reviewed by the Agency, the 90-day rat subchronic study and the cancer bioassay (noncarcinogenic effects) are the most appropriate animal studies for calculation of the ADE. It is then necessary to determine which study is the most valid for purposes of calculating the ADE.

Subsection (c) of Appendix A specifies criteria for establishing the validity of data from animal studies, leading to determinations of high, medium, or low validity. High validity studies are those using the oral route of exposure and which

meet specified criteria depending on the type of study, and are to be used preferentially if available. The rat 90-day subchronic study was conducted using the oral route, while the cancer bioassay was an inhalation study. Therefore, only the subchronic study could be a high validity study. However, the requirements for a high validity subchronic study include, among other things, a study using two species and determining a well-defined NOAEL. The 90-day rat subchronic study used only one species and only determined a LOAEL, as discussed above. Having no high validity study, the Agency must determine which of the two studies is most appropriate for calculating the ADE.

Subsection (c) goes on to specify that in order for a subchronic study in which a LOAEL is determined to be deemed a medium validity study, the study must satisfy all other standards for a high validity study. This is not the case for the 90day rat subchronic study, since there was only one species tested. Similarly, in order for a study other than an oral exposure study to be deemed a medium validity study, the study must satisfy all other standards for a high validity study and use appropriate correction factors for conversion to the oral route. However, the requirements for a high validity cancer bioassay include, among other things, at least 25% survival at 18 months in mice and 24 months in rats. This was not the case in the cancer bioassay, since the male rats in the 3,000 and 8,000 ppm groups were terminated early due to excessive mortality. Thus, both candidate studies are defined as low validity studies, and the 90-day rat subchronic study is selected because exposure was by the oral route.

The determination of the ADE from the subchronic study is made using the language of subsections (b)(5) and (b)(6). Subsection (b)(6) specifies that for substances for which a NOAEL is not available, one-tenth of the LOAEL is substituted for the NOAEL in subsection (b)(5). Subsection (b)(5) specifies that if studies of low validity must be used, the ADE must be calculated using 1/1000 of the NOAEL. The overall result of the procedures in these two subsections is that the ADE is 1/10,000 of the LOAEL, times the average weight of an adult human, 70 kg:

$ADE = \frac{100mg/kg/d \times 70kg}{10,000kg/d} = 0.7mg/d$

At this point, the calculation of the HTTAC would proceed according to the formula listed above. However, the Agency has been informed by USEPA personnel that in most cases USEPA now prefers to calculate acceptable exposure values for humans by using laboratory animal data divided by no more than a 3,000-fold uncertainty factor; a 10,000-fold uncertainty factor would be used only where the overall toxicity database is very weak for a chemical. The Agency agrees with this emerging USEPA approach. Since the MTBE database contains enough laboratory animal research to indicate that there are not major toxicity data gaps which would warrant the use of a 10,000-fold uncertainty factor, the Agency is also calculating the ADE using a 3,000-fold uncertainty factor:

$$ADE = \frac{100 mg/kg/d \times 70 kg}{3,000} = 2.3 mg/d$$

Finally, the determination of the HTTAC is straight-forward, since there are no chemical-specific data available for the RSC term:

$$HTTAC = \frac{0.20 \times 0.7 mg/d}{2.0 \ell/d} = 0.07 mg/\ell$$

Or:

$$HTTAC = \frac{0.20 \times 2.3 mg/d}{2.0 \ell/d} = 0.23 mg/\ell$$

The final step in determining the health advisory is to compare the HTTAC value calculated from the Appendix A procedures to the chemical's Practical Quantitation Limit (PQL). In the case of MTBE, no USEPA SW-846 analytical method specifies a PQL for this chemical. However, the Agency's Division of Laboratories has determined that a detection limit of 0.005 mg/t is appropriate for water samples. Therefore, the HTTAC value is above the detection limit.

Page 24/ July, 1994

an sin Si Min

Environmental Register No. 484

The Agency has decided to issue a two-part health advisory. The precautionary health advisory concentration for Methyl Tertiary-Butyl Ether (MTBE) is 0.07 mg/l or 70 parts per billion in drinking water. People can be exposed to this concentration of MTBE in drinking water over a 70 year lifetime. Above this concentration, appropriate caution should be exercised by the Public Water Supply, such as increased frequency of sampling and identification of the MTBE source(s). The final health advisory concentration is 0.23 mg/l or 230 parts per billion in drinking water. Above this concentration, the Public Water Supply should begin actions to decrease the amount of MTBE in the system.

REFERENCES

API, American Petroleum Institute. 1993. Odor Threshold Studies Performed with Gasoline and Gasoline Combined with MTBE, ETBE, and TAME. API Publication Number 4592.

Biles, R. W., Schroeder, R. E., and Holdsworth, C. E. 1987. Methyl Tertiary Butyl Ether Inhalation in Rats: A Single Generation Reproductive Study. Toxicol. Ind. Health 3: 519-534.

Burleigh-Flayer, H. D., Chun, J. S., and Kintigh, W. J. (unpublished). Methyl Tertiary Butyl Ether: Vapor Inhalation Oncogenicity Study in CD-1 Mice. Submitted to USEPA, Docket No.: OPTS-42098.

Chun, J. S., Burleigh-Flayer, H. D., and Kintigh, W. J. (unpublished). Methyl Tertiary Butyl Ether: Vapor Inhalation Oncogenicity Study in Fischer 344 Rats. Submitted to USEPA, Docket No: OPTS-42098.

Conaway, C. C., Schroeder, R. E., and Snyder, N. K. 1985. Teratology Evaluation of Methyl Tertiary-butyl Ether in Rats and Mice. J. Toxicol. Environ. Health 16: 797-809.

Connecticut Dept. of Environmental Protection. (undated). Action Level for Methyl Tertiary Butyl Ether (MTBE) in Drinking Water. Prepared by H. V. Rao, C. J. Dupuy, and D. R. Brown, Connecticut Dept. of Health Services.

Costantini, M. G. 1993. Health Effects of Oxygenated Fuels. Environ. Health Perspectives Suppl. 101 (Suppl. 6): 151-160.

Dodd, D. E. and Kintigh, W. J. 1989. Methyl Tertiary Butyl Ether (MTBE): Repeated (13-Week) Vapor Inhalation Study in Rats with Neurotoxicity Evaluation (unpublished study). Union Carbide, Bushy Run Research Center for MTBE Committee. TSCATS 403189. EPA/OTS # FY1-OTS-0889-0689. Cited in Revised and Updated Drinking Water Quantification of Toxicological Effects for Methyl Tert-Butyl Ether (MTBE), Final Draft. USEPA; ECAO-CIN-D023, July, 1993.

Essential Elements (in press). ILSI Press, Washington, D.C. 1994.

Greenough, R. J., McDonald, P., Robinson, P., et al. 1980. Methyl Tertiary-Butyl Ether (Driveron) Three Month Inhalation Toxicity in Rats. Project No. 413038. Unpublished report submitted to Chemische Werke Höls AG, Marl, West Germany. 230 p. Cited in Revised and Updated Drinking Water Quantification of Toxicological Effects for Methyl Tert-Butyl Ether (MTBE), Final Draft. USEPA; ECAO-CIN-D023, July, 1993.

Neeper-Bradley, T. L. 1991. Two-Generation Reproduction Study of Inhaled Methyl tert-Butyl Ether in CD Sprague-Dawley Rats (unpublished study). Union Carbide, Bushy Run Research Center. Cited in Revised and Updated Drinking Water Quantification of Toxicological Effects for Methyl Tert-Butyl Ether (MTBE), Final Draft. USEPA; ECAO-CIN-D023, July, 1993.

Ponchon, T., Baroud, J., Pujol, B., Valette, P. J., and Perrot, D. 1988. Renal Failure during Dissolution of Gallstone by Methyl Terr Daryl Educet 2. 276-277.

Reese, E., and Kimbrough, R. D. 1993. Acute Toxicity of Gasoline and Some Additives. Environ. Health Perspectives Suppl. 101 (Suppl. 6): 115-131.

Robinson, M., Bruner, R.H., and Olson, G.R. 1990. Fourteen and Ninety-Day Oral Toxicity Studies of Methyl Tertiary-Butyl Ether in Sprague-Dawley Rats. Journal of the American College of Toxicology 9(5): 525-540.

Environmental Register No. 484

Tyl, R. W., and Neeper-Bradley, T. L. 1989. Developmental Toxicity Study of Inhaled Methyl Tertiary Butyl Ether in "D-1 Mice. Project Report 52-526. Prepared by Bushy Run Research Center, Union Carbide Corporation for the Methyl Tertiary Butyl Ether Committee, Washington, D.C. Microfiche No. OTS0000689-1. Cited in Revised and Updated Drinking Water Quantification of Toxicological Effects for Methyl Tert-Butyl Ether (MTBE), Final Draft. USEPA; ECAO-CIN-D023, July, 1993.

USEPA. 1993. Revised and Updated Drinking Water Quantification of Toxicological Effects for Methyl Tert-Butyl Ether (MTBE), Final Draft. USEPA; ECAO-CIN-D023, July, 1993.

von Burg, R. 1992. Toxicology Update. Methyl Tert-Butyl Ether. J. Appl. Toxicol. 12: 73-74.

State of Illinois ENVIRONMENTAL PROTECTION AGENCY

Mary A. Gade, Director

2200 Churchill Road, Springfield, IL 62794-9276

217/785-0830

November 4, 1994

G.A. Van Gelder, DVM, Ph.D., ABVT Manager, Toxicology Health, Safety and Environment Shell Oil Company One Shell Plaza P.O. Box 4320 Houston, TX 77210

Dear Dr. Van Gelder:

This letter confirms the meeting to evaluate comments received regarding the Illinois Environmental Protection Agency's proposed Health Advisory for MTBE which we discussed over the telephone. The meeting is scheduled for November 14, 1994, beginning at 12:30. The room is available until 5:00 PM, if necessary. The meeting will be held in Room 031 on Floor 8, James R. Thompson Center, 100 W. Randolph, Chicago, Illinois, 60601.

I have enclosed an agenda for the meeting, a copy of the Health Advisory Section of the Illinois Groundwater Quality Standards, and a summary of the Agency's opinions on two key issues which have emerged from the comments.

I'm looking forward to a productive meeting. Please call (217/785-0830) if you have any further comments or questions.

Sincerely,

Tow Howshaw

Thomas C. Hornshaw, Ph. D. Manager, Toxicity Assessment Unit Office of Chemical Safety

f:\psf\epa8566\mtbe.mtg

Attachment

MTBE Meeting Agenda

12:30 - 12:45	Introductions and Background
12:45 - 1:45	Key Issues (LOAEL vs. NOAEL, RSC)
1:45 - 2:00	Break
2:00 - 3:15	Other Issues (Tase/Odor Threshold, Uncertainty Factors, 2-Tier Vs. Single Advisory, Edits
3:15 - 3:30	Wrap-up

RESPONSES TO SIGNIFICANT COMMENTS REGARDING PROPOSAL FOR HEALTH ADVISORY FOR METHYL TERTIARY-BUTYL ETHER

The Illinois Environmental Protection Agency (Agency) has received three comments in response to the Notice of Health Advisory for Methyl Tertiary-Butyl Ether (MTBE), published in the Illinois Environmental Register No. 484, July, 1994. The comments were received from the American Petroleum Institute (API), the Methyl Tertiary Butyl Ether Task Force (Task Force), and Shell Oil Company (Shell). The comments cover several technical and typographical subjects, the most significant of which address the Agency's determination of a Lowest Observable Adverse Effect Level (LOAEL) versus a No Observable Adverse Effect Level (NOAEL) and the uncertainty factors which result from this determination, and the Agency's use of the default value of 20% as the Relative Source Contribution (RSC) term versus the use of an RSC derived from chemical-specific data in the calculation of the Health Advisory. The Agency's responses to these key issues are presented in this paper.

LOAEL vs. NOAEL

API and Shell disagree with the Agency's characterization of the diarrhea and elevated serum cholesterol reported at the 100 mg/kg dose in the Robinson et al. (1990) study as a LOAEL. In reviewing the results of this study, the Agency determined that the authors' reports that "treated rats in all dose groups also displayed diarrhea throughout the exposure period" and their findings that "females exposed to all dose levels exhibited significant increases in serum cholesterol" indicated that the study had not identified a No Observed Adverse Effect Level. This determination is an outcome of the evaluation of the validity of the candidate studies required by the Groundwater Quality Standards regulation when animal studies must be used to develop a Health Advisory. This evaluation was discussed briefly in the July, 1994 Notice, and will be expanded for explanation of the Agency's rationale.

Section 620. Appendix A(c)(1)(A)(iii), which identifies the elements necessary for High Validity Studies, requires:

Data from animal subchronic studies with a minimum of 3 dose levels and control, 2 species, both sexes, 4 animals per dose per sex for non-rodent species or 10 animals per dose per sex for rodent species, a duration of at least 5% of the test species' lifespan, and a well-defined NOAEL (emphasis added).

The Agency determined that the reports of diarrhea in all animals and elevated serum cholesterol in females in all dose groups could not be called a "well-defined NOAEL" for purposes of establishing High Validity for this study. Thus, the lowest dose tested, 100 mg/kg, was determined to be a LCAEL.

API and Shell have commented that the results of the study should not be interpreted in this manner. Both claim that the occurrence of diarrhea in treated animals is not well-documented

or described in the Robinson study, that diarrhea is a common observation in rats dosed with - corn oil, and it is a questionable endpoint for extrapolation to low-dose lifetime health effects. Both also claim that the modest increases in serum cholesterol in the female rats are not indicative of a meaningful health effect, arguing that the authors' statistical evaluation incorrectly attributes a significant difference for the 300 mg/kg dose, that there is no compelling evidence for a dose response, that only the 900 mg/kg dose in males achieved values significantly different from controls, and that the increases are near the range of normal variability. Finally, API argues that the diarrhea and elevated serum cholesterol are not significant results, citing the authors' conclusions that the study indicated that dose levels below those which induce anesthesia (1200 mg/kg) do not result in significant pathophysiological changes.

The Agency remains unconvinced that the Robinson et al. study has identified a well-defined Regarding the occurrence of diarrhea, we have interpreted the authors' reports of NOAEL. diarrhea in "treated rats in all dose groups" to mean all groups receiving doses of MTBE, but not those receiving the vehicle control (corn oil). Thus, we believe that the diarrhea is likely to be treatment -related, at least in females; this belief is supported by the findings of the 14-day study also reported in this paper, in which "by the third day of dosing, all treated animals displayed loose stools which continued throughout the remainder of the exposure period." We have reviewed the National Toxicology Program's report on the lifetime cancer bioassays of gavage vehicles in male Fisher rats, which included corn oil, and find no mention of diarrhea as an effect of corn oil (NTP, 1994). Finally, we have relied on the experience of one of the Agency's Office of Chemical Safety toxicologists, who reports that, in over 8 1/2 years of experience in an industrial toxicology laboratory, the occurrence of diarrhea in rats in conjunction with corn oil vehicles was very infrequent (Morrow, 1994). While we cannot rule out the possibility that the diarrhea reported by Robinson et al. was vehicle-related, we continue to believe that this effect was a result of the MTBE exposure.

Regarding the elevated serum cholesterol findings, the Agency acknowledges that the statistical significance of the 300 mg/kg dose in female rats is questionable and possibly incorrectly reported, and that there is no obvious dose-response relationship among the female treatment groups even though all but the 300 mg/kg group is significantly greater than controls. However, we maintain that these results are potentially indicative of a real effect in the rats; it is possible (although unlikely) that the effect may plateau relatively quickly, such that the dose-response relationship is defined at doses below those tested in this study. Further, we again note that the results of the 14-day study reported in this paper also include elevated serum cholesterol in females of most treatment groups.

Regarding the biological significance of the diarrhea and elevated serum cholesterol and whether these endpoints are relevant for extrapolating to human health risks, the Agency maintains that such effects are relevant for use in developing the Health Advisory. While neither endpoint is relatively serious, diarrhea can be deleterious to the organism over time by contributing to dehydration, electrolyte imbalance, and/or poor nutritional status, and elevated cholesterol, while not in itself a oloiogically serious effect, is a caution for more serious effects over time. While the authors' concluded that dose levels below those which induce anesthesia do not result in significant pathophysiological changes, the Agency would be very uncomfortable using a dose which does not induce anesthesia as the basis for developing a Health Advisory. We continue or described in the Robinson study, that diarrhea is a common observation in rats dosed with corn oil, and it is a questionable endpoint for extrapolation to low-dose lifetime health effects. Both also claim that the modest increases in serum cholesterol in the female rats are not indicative of a meaningful health effect, arguing that the authors' statistical evaluation incorrectly attributes a significant difference for the 300 mg/kg dose, that there is no compelling evidence for a dose response, that only the 900 mg/kg dose in males achieved values significantly different from controls, and that the increases are near the range of normal variability. Finally, API argues that the diarrhea and elevated serum cholesterol are not significant results, citing the authors' conclusions that the study indicated that dose levels below those which induce anesthesia (1200 mg/kg) do not result in significant pathophysiological changes.

The Agency remains unconvinced that the Robinson et al. study has identified a well-defined Regarding the occurrence of diarrhea, we have interpreted the authors' reports of NOAEL. diarrhea in "treated rats in all dose groups" to mean all groups receiving doses of MTBE, but not those receiving the vehicle control (corn oil). Thus, we believe that the diarrhea is likely to be treatment -related, at least in females; this belief is supported by the findings of the 14-day study also reported in this paper, in which "by the third day of dosing, all treated animals displayed loose stools which continued throughout the remainder of the exposure period." We have reviewed the National Toxicology Program's report on the lifetime cancer bioassays of gavage vehicles in male Fisher rats, which included corn oil, and find no mention of diarrhea as an effect of corn oil (NTP, 1994). Finally, we have relied on the experience of one of the Agency's Office of Chemical Safety toxicologists, who reports that, in over 8 1/2 years of experience in an industrial toxicology laboratory, the occurrence of diarrhea in rats in conjunction with corn oil vehicles was very infrequent (Morrow, 1994). While we cannot rule out the possibility that the diarrhea reported by Robinson et al. was vehicle-related, we continue to believe that this effect was a result of the MTBE exposure.

Regarding the elevated serum cholesterol findings, the Agency acknowledges that the statistical significance of the 300 mg/kg dose in female rats is questionable and possibly incorrectly reported, and that there is no obvious dose-response relationship among the female treatment groups even though all but the 300 mg/kg group is significantly greater than controls. However, we maintain that these results are potentially indicative of a real effect in the rats; it is possible (although unlikely) that the effect may plateau relatively quickly, such that the dose-response relationship is defined at doses below those tested in this study. Further, we again note that the results of the 14-day study reported in this paper also include elevated serum cholesterol in females of most treatment groups.

Regarding the biological significance of the diarrhea and elevated serum cholesterol and whether these endpoints are relevant for extrapolating to human health risks, the Agency maintains that such effects are relevant for use in developing the Health Advisory. While neither endpoint is relatively serious, diarrhea can be deleterious overtime to the organism by contributing to dehydration, electrolyte imbalance, and/or poor nutritional status, and elevated cholesterol, while not in itself a biologically serious effect, is a caution for more serious effects over time. While the authors' concluded that dose levels below those which induce anesthesia do not result in significant pathophysiological changes, the Agency would be very uncomfortable using a dose which does not induce anesthesia as the basis for developing a Health Advisory. We continue to believe that the 100 mg/kg dose, as a LOAEL, is the most relevant value to use in the development of the Health Advisory. This reasoning, plus the relative paucity of data regarding the ingestion of MTBE, argues for the continued use of the 3000-fold uncertainty factor as the most appropriate value for the final Health Advisory.

MTBE RELATIVE SOURCE CONTRIBUTION TERM

The comments of both API and the Task Force addressed the Agency's use of the default value of 20% as the Relative Source Contribution (RSC) term, which is specified in Section 620. Appendix A(a). (This is also a standard USEPA default assumption, used in risk assessments to account for all other exposures to a chemical other than direct ingestion in drinking water, such as through the diet, ambient air, the workplace, and volatilization from the household water supply).

Both comments cite a USEPA study (USEPA, 1993) which estimates the amount of MTBE exposure experienced by the general public during activities other than drinking water, such as working, outdoor exercise, refueling, driving, etc. This study is proposed to be used as chemical-specific data instead of the default value to account for exposures to MTBE other than via direct ingestion of drinking water. If this study is used to define the RSC term, the range of weighted annual MTBE ambient air concentrations of $0.04 - 0.07 \text{ mg/m}^3$ would result in a RSC term of approximately 45% - 70% for drinking water exposures. Depending on the final determination of the RSC term, the Health Advisory (HA) for MTBE would then be in the range of 0.52 - 0.80 mg/l, instead of the proposed 0.23 mg/l using a 20% RSC term.

While the Agency agrees with the data presented in the USEPA study, it cannot agree that these data fully account for all other sources of MTBE contributing to a person's daily exposure. Use of only this study to account for inhalation exposures does not consider inhalation exposures which will occur in the home as a result of volatilization of MTBE from the household water supply during uses of the supply for purposes other than drinking. Since the Agency is not aware of studies evaluating such exposures, an evaluation of the indoor inhalation pathway was undertaken using data reported for trichloroethylene (TCE).

The transfer of volatile organic chemicals (VOCs), including TCE, from water to air has been studied by several investigators (Andelman, 1985; McKone, 1987; McKone and Knezovich, 1991). Of particular interest for this analysis are studies which measure the transfer of VOCs during showering since this activity is likely to be the greatest contributor to indoor VOC exposure due to the temperature, amount of water used, turbulent flow, and the relatively small volume of air in the bathroom. Therefore, the McKone and Knezovich study, which measures the evolution of TCE into a bathroom's air during operation of the shower was selected for development of the transfer rate of MTPE to the air during showering. This study evaluated the effects of shower temperature and duration on the transfer efficiency of TCE from water to air, concluding that the transfer efficiency is $61 \pm$ 9% and that inhalation exposures in the shower could be equivalent to an ingestion exposure of from 1-4 liters per day.

Assuming that the transfer efficiency of any VOC for which transfer efficiency has not been measured is directly proportional to that of another VOC having a measured transfer efficiency, the transfer efficiency of MTBE from water to air can be estimated from the TCE data by comparing the overall mass transfer coefficients from water to air (K_{LA}) for both chemicals. McKone (1987) has shown that K_{LA} can be approximated by:

- $K_{LA} \approx \left[\frac{2.5}{D_{BL}^{2/3}} + \frac{RT}{HD_{BA}^{2/3}}\right]^{-1}$, where
- D_{BL} = diffusion coefficient in water (m²/s), D_{BA} = diffusion coefficient in air (m²/s), R = universal gas constant, 0.0624 torr-m³/mol-K, T = temperature, 303K (air temperature in hot shower), and H = Henry's law constant (torr-m³/mol).

The diffusion coefficients of TCE and MTBE were calculated according to methods recommended in Lyman (1982), assuming a water temperature of 37°C and an air temperature of 30°C to be representative of hot shower conditions. The calculated values for TCE and MTBE for D_{BL} are 1.094E-09 m²/s and 9.870E-10 m²/s, respectively, and for D_{BA} are 9.40E-06 m²/s and 9.28E-06 m²/s, respectively.

Substituting the calculated D_{BL} and D_{BA} values and Henry's law constants of 6.916 torr-m³/mol for TCE and 4.484 torr-m³/mol for MTBE into the overall mass transfer coefficient equation, values for K_{LA} were calculated to be 4.236E-07 m²/s and 3.950E-07 m²/s for TCE and MTBE, respectively. The ratio of the two K_{LA} values of 0.9325, when compared to the measured TCE transfer efficiency of 61%, suggests an MTBE transfer efficiency of approximately 56.89%.

Once the transfer efficiency has been determined, an estimate of a resident's cumulative daily intake from showering (CDI_s) can be calculated for any VOC water concentration (C_w) using reasonable estimates of water use during showering and the volume of the shower, plus standard USEPA assumptions for body weight (BW, 70 kg) and breathing rate (BR, 20 m³/d = 0.014 m³/min). For this exercise, it is assumed that the resident's shower duration (SD) is 10 min/d, the shower flow rate (FR) is 10 1/min, and the volume (V) of the shower is 2.3 m³. The CDI_s for any C_w is calculated from:

$$CDI_{s} = \begin{bmatrix} (FR \times SD \times Transfer \ Efficiency) \times BR \times SD \\ V \times BW \end{bmatrix} \times C_{w}.$$

After substituting, the CDI_s for any C_w becomes:

$$CDI_{s} = (0.049 \text{ J/kg/d}) \times C_{w}.$$

This shower inhalation intake can be compared directly with the daily ingestion intake (CDI_{l}) of the VOC from drinking water for the same C_{w} by again employing standard USEPA.

assumptions for BW (as above) and daily water intake (WI, 2.0 l/d). The CDI_I is calculated from:

$$CDI_{I} = \frac{WI}{BW} \times C_{w},$$

which becomes after substitution:

 $CDI_{t} = (0.029 \ l/kg/d) \ x \ C_{w}.$

These two CDIs are now directly comparable for any water concentration of MTBE. The ratio of CDI_s to CDI₁ is 1.69, suggesting that the resident's daily showering contributes approximately 169% of the daily exposure to MTBE compared to the exposure due to ingestion alone. This is equivalent to an additional ingestion intake of (169% x 2.0 1/d), or 3.38 1/d.

An evaluation of other non-ingestion household water uses (cooking, toilet use, washing dishes and clothes, humidifier, etc.) is not as straightforward as the evaluation of shower exposures due to greater variability in the frequencies of the activities/uses. McKone (1987) estimates that the ratio of the indoor inhalation dose to the drinking water ingestion dose for VOCs ranges from 1.5 - 6.0 (includes showering and all other inhalation exposures). As estimated above, the ratio for showering alone is 1.69 for MTBE, which suggests that the ratio for all indoor inhalation exposures must be greater than 1.69. Assuming that the other indoor inhalation exposures are at least one-sixth to one-fifth the magnitude of the shower exposure, it can be assumed that these exposures' ratio to the drinking water ingestion exposure is at least 0.31, or 31% of the ingestion exposure. Thus, these exposures contribute at least the equivalent of 0.62 l/d of direct ingestion, and the total adjusted intake due to in-home water use for purposes of a chemicalspecific RSC should be at least (3.38 l/d + 0.62 l/d + 2.0 l/d), or 6.0 l/d.

The data from USEPA (1993) can now be used to calculate the remainder of the resident's daily exposure to MTBE. This exposure is the result of ambient air exposures plus indoor air exposures which are <u>not</u> due to an MTBE-contaminated water supply (i.e., exposure to MTBE which originated from the ambient air and is then inhaled in the residence, workplace, and other buildings). These calculations have been completed using the USEPA data for a 6-month oxyfuel season, which predicts 0.04 mg/m³ and 0.07 mg/m³ as the Low and High annual average MTBE air concentration, and the standard USEPA assumption for breathing rate as above. The CDI (in mg/d) resulting from ambient air exposures (CDI_A) can be calculated from:

 $CDI_A = BR \times Annual Average Concentration,$

which results in estimates of 0.8 mg/d and 1.4 mg/d for the Low and High annual averages, respectively.

The final step in the development of a chemical-specific RSC is to apportion the contributions of the Acceptable Daily Exposure (ADE) of 2.3 mg/d of MTBE between ambient air and the home water supply. As calculated from the USEPA data, the ambient air exposures contribute between 0.8 mg/d and 1.4 mg/d of the 2.3 mg/d ADE. This leaves between (2.3 mg/d - 1.4

mg/d or 2.3 - 0.8 mg/d), or 0.9 mg/d to 1.5 mg/d to be contributed by the home water supply. As calculated above, the equivalent exposure intake value for the water supply is at least 6.0 l/d. Distributing the 0.9 mg/d to 1.5 mg/d portion of the ADE for home and water use into the adjusted exposure value of at least 6.0 l/d, the Health Advisory concentration for MTBE using chemical-specific RSC data can be no more than 0.15 mg/l to 0.25 mg/l. Since the value for the Health Advisory originally proposed by the Agency, 0.23 mg/l, falls within this range, the Agency proposes to adopt the Health Advisory as originally proposed.

REFERENCES

- Andelman, J.B. 1985. Inhalation exposure in the home to volatile organic contaminants of drinking water. Sci. Total Environ. 47:443.
- Lyman, W.J. 1982. Handbook of Chemical Property Estimation Methods. W.J. Lyman, W.F. Reehl, and D.H. Rosenblatt, Eds. (McGraw-Hill Book Co., NY).
- McKone, T.E. 1987. Human exposure to volatile organic compounds in household tap water: the indoor inhalation pathway. Environ. Sci. Technology. 21:1194.
- McKone, T.E. and Knezovich, J.P. 1991. The transfer of trichloroethylene (TCE) from a shower to indoor air: experimental measurements and their implications. J. Air Waste Manage. Assoc. 40:282.

Morrow, Leslie D. 1994. Personal communication.

- NTP. 1994. Comparative Toxicology Studies of Corn Oil, Safflower Oil, and Tricaprylin in Male F344/N Rats as Vehicles for Gavage. National Toxicology Program, Technical Report Series, No. 426. U.S. Dept. of Health and Human Services, Public Health Service, National Institutes of Health. April, 1994.
- Robinson, M., Bruner, R. H., and Olson, G. R. 1990. Fourteen- and ninety-day oral toxicity studies of Methyl Tertiary-Butyl Ether in Sprague-Dawley rats. J. Amer. Coll. Toxicol. 9:525.
- USEPA. 1993. Assessment of Potential Health Risks of Gasoline Oxygenated with Methyl Tertiary Butyl Ether (MTBE). EPA/600/R-93/206. Office of Research and Development. November, 1993.

F:\psf\epa8566\MTBEHA

Illinois Environmental Protection Agency



1021 NORTH GRAND AVENUE EAST, P.O. BOX 19276, Springfield, Illinois 62794-9276

Renee Cipriano, Director

DATE: October 2, 2001

TO:

FROM: Tom Hornshaw

TAC-ON File

SUBJECT: Soil Remediation Objective Recommendation

Methyl tert-butyl ether

	EXHIBIT	
TABLES.	2	
-		

(CAS #1634-40-4)

CONFIDENTIAL

The Toxicity Assessment Unit (TAU) has been asked to recommend cleanup objectives for methyl tertbutyl ether (MTBE). Groundwater objectives have previously been established as presented in the Notice of Health Advisory for Methyl tertiary-butyl ether, developed using methodology prescribed in 35 IAC 620.Subpart F, and published in the *Environmental Register*, No. 484, pages 18-24, July, 1994. Because soil remediation objectives for MTBE are not listed in 35 IAC Part 742 (TACO), the determination of the soil cleanup objectives recommendation was also referred to the TAU.

Calculation of the soil remediation objectives was accomplished through use of the risk-based soil screening level (SSL) equations from 742. Appendix C, Table A of TACO. Default exposure durations and contact rates from 742. Appendix C, Table B of TACO were used in these calculations. The results are presented in the following table.

	Residentia S	l Values for oil	Industrial/ Value:	Commercial s for Soil	Constructi Values	on Worker for Soil	Soil Comp Groundwat Ro	onent of the er Ingestion ute	
Chemicál Name	Ingestion (mg/kg)	Inhalation (mg/kg)	Ingestion (mg/kg)	Inhalation (mg/kg)	Ingestion (mg/kg)	Inhalation (mg/kg)	Class I (mg/kg)	Class II (mg/kg)	ADL
Methyl tert-butyl ether	780*	8,800*	20,000*	8,800 ⁶	2,000ª	140ª	0.32*	0.32	* .

a = Calculated value corresponds to a target hazard quotient of 1.0.

b = Soil saturation concentration (Csat).

* = Indicates that the ADL is less than or equal to the specified remediation objective.

TACO equation S1 was used to calculate the soil ingestion exposure route cleanup objectives. The inhalation exposure route remediation objectives were calculated using equation S4 for the residential and industrial/commercial scenarios and equation S5 was used for the construction worker. Equations S17 and S18 were used to calculate the soil component of the groundwater ingestion exposure route objectives. The saturation limit (Csat) for MTBE was calculated using equation S29. Csat may be substituted for the inhalation objective, if lower, due to MTBE's melting point of -109 degrees C. The critical data inputs into the calculations and their sources are summarized below.

CRITICAL DATA SUMMARY						
parameter	value	source				
Chemical/Physical Properties for Methyl tert-butyl ether						
boiling point (°C)	55.2	CHEMFATE Database (June 4, 1998).				
Henry's Law Constant (atm- m ³ /mole)	5.87E-04	CHEMFATE, ibid.				
dimensionless Henry's Law Constant (unitless)	2.41E-02	derived by "Henry's Law Constant * 41".				
logP(oct)	1.24	CHEMFATE, ibid.				
Koc (L/kg)	11.5	derived from logP(oct).				
melting point (°C)	-109	CHEMFATE, ibid.				
molecular weight	83.1	USEPA. CHEMDAT8. Version 1.0. Office of Air Quality Planning and Standards. Research Triangle Park, NC.				
solubility (mg/L)	51,000	CHEMFATE, ibid.				
diffusivity in air (cm²/s)	0.1024	CHEMDAT8, ibid.				
diffusivity in water (cm ² /s)	1.1E-05	CHEMDAT8, ibid.				
vapor pressure (mm Hg)	249	CHEMFATE, ibid.				
Toxicology Values for Methyl tert-butyl ether						
Class I groundwater objective (mg/L)	0.07	calculated using the 35 IAC 620.Subpart F evaluation methods.				
Class II groundwater objective (mg/L)	0.07	Class I groundwater objective with no adjustment for treatability.				

CRITICAL DATA SUMMARY						
parameter	value	source				
RfD _{chronic} (mg/kg-day)	1.0E-02	Developed by the Toxicity Assessment Unit (TAU) using procedures specified in 35 IAC 620 Subpart F.				
RfD _{chronic} target	increased cholesterol and diarrhea	TAU, ibid.				
RfD _{subchronic} (mg/kg-day)	1.0E-02	RfD _{chronic} adopted as the RfD _{subchronic} .				
RfD _{subchronic} target	increased cholesterol and diarrhea	same as RfD _{chronic} .				
RfC _{chronic} (mg/m3)	3.0	Integrated Risk Information System (IRIS), National Center for Environmental Assessment, USEPA, Accessed via Internet 6/22/98.				
RfC _{chronic} target	liver and kidney effects, prostration, and eye irritation	IRIS, ibid.				
RfC _{subchronic} (mg/m3)	3.0	RfC _{chronic} adopted as the RfC _{subchronic} .				
RfC _{subchronic} target	liver and kidney effects, prostration, and eye irritation	same as RfC _{chronic} .				

TH/mtbetac.wpd

STATE OF ILLINOIS

COUNTY OF SANGAMON

PROOF OF SERVICE

I, the undersigned, on oath state that I have served the attached Supplemental Comments and Exhibits upon the

person to whom it is directed, by placing a copy in an envelope addressed to:

Dorothy M. Gunn, Clerk IL. Pollution Control Board James R. Thompson Center 100 W. Randolph, Ste 11-500 Chicago, Illinois 60601

Robert Lawley, Chief Legal Counsel Dept. of Natural Resources 524 South Second Street Springfield, Illinois 62701-1787

See Attached Service List

and mailing it from Springfield, Illinois on $\frac{10-9-01}{10}$

with sufficient postage affixed.

Matthew J. Dunn, Chief

Office of the Attorney General 188 W. Randolph, 20th Floor

Amy Jackson, Hearing Officer

Illinois Pollution Control Board

Environmental Bureau

Chicago, Illinois 60601

500 South Second Street

Springfield, Illinois 62706

Hancy JD Lamport

SUBSCRIBED AND SWORN TO BEFORE ME

day of OCTOR

Notary Public

official seal **BRENDA BOEHNER** NOTARY PUBLIC, STATE OF ILLINOIS MY COMMISSION EXPIRES 11-14-2001

THIS FILING IS SUBMITTED ON RECYCLED PAPER

R00-19 SERVICE LIST PROPOSED AMENDMENTS TO TIERED APPROACH TO CORRECTIVE ACTION OBJECTIVES May 21, 2001

loame	fname	company	Address	citysiate	zip
Anderson	Joan G.	Joan G. Anderson, Ltd.	PMB #202 4700 Gilbert Road, Suite 47	Western Springs, 1L	60558
Anderson	Steve	Admiral Environmental Services, Inc.	2025 S. Arlington Heights Road, Suite 103	Arlington Heights, IL	60005-4141
Bianco	Chris	CICI	9801 Higgins Road, Suite 515	Rosemont, IL	60018
Curley	Erin	Environmental Dept. Manager	4243 West 166th Street	Oak Forest, IL	60452
	•	Midwest Engineering Services	• • • •	·	
Dickett	William G.	Sidley, Austin, Brown & Wood	Bank One Plaza 10 South Dearborn Street	Chicago, lL	60603
Dunn	Matihew J.	Chief, Environmental Bureau Office of the Attorney General	188 W. Randolph Street, 20th Floor	Chicago, IL	60601
Geving	Kimberly A.	IEPA, Division of Legal Counsel	1021 N. Grand Avenue East P.O. Box 19276	Springfield, IL	62794-9276
Gobelman	Steven	IDOT	2300 South Dirksen Parkway	Springfield, IL	62764
•		Design & Environment	· •		•
Gunn	Dorothy	Clerk of the Board . Illinois Pollution Control Board	100 W. Randolph St., Suite 11-500	Chicago, IL	60601
Hambley	Douglas F.	Graeis, Anlialy, Schloemer & Associates, Inc.	8501 W. Higgins Road, Suite 280	Chicago, IL	60631-2801
Heyde, Esq.	John M.	Sidley, Austin, Brown & Wood	Bank One Plaza 10 South Dearborn Street	Chicago, IL	60603
Hodge, Esq.	Katherine D.	Hodge, Dwyer & Zeman	3150 Roland Avenue P.O. Box 5776	Springfield, IL	62705-5776
Jackson	Amy	Illinois Pollution Control Board	600 South Second Street, Suite 402	Springfield, IL	62704
Jacobs	Richard	Thompson Coburn	One Firststar Plaza	St. Louis, MO	63101
Jamison	George	Hanson Engineers	3971 Bison Trail	Rochester, IL	62563
Keefer	Don	Illinois State Geological Survey	615 East Peabody Drive	Champaign, IL	61820
Larson	Jeffrey	Missman, Stanley & Associates	333 East Stale Street P.O. Box 4327	Rockford, IL	61110-0827
Lawley	Robert T.	Chief Legal Counsel Department of Natural Resources	524 South Second Street	Springfield, IL	62701
Mankowski	Bob	EPI	16650 South Canal Street	South Holland, IL	60473
Marszalek	Mark	Andrews Environmental Engineering	3535 Mayflower Blvd.	Springfield, IL	62707
				1	

DCT-09-2001 10:15 0ct-09-01 10:10am From-ILLINIOS POLLUTION CONTROL BOARD

P.02/03 F-040

1

R00-19 SERVICE LIST PROPOSED AMENDMENTS TO TIERED APPROACH TO CORRECTIVE ACTION OBJECTIVES May 21, 2001

Nienkerk	Monte	Clayton Group Services	3140 Finley Road	Downers Grove, IL	60515
Peterson	Brooke	IERG	215 East Adams	Springfield, IL	62701
Penti	Raymond T.	lenner & Block	One IBM Plaza, 39th Floor	Chicago, IL	60611
Richardson	Diane H.	Commonwealth Edison Environmental Services Department	10 South Dearborn	Chicago, IL	60603
Diecon	David 1	Ross & Harries	150 North Michigan, Suite 2500	Chicago, IL	60601
Rieser	Layld L. Mort D	Mauck Bellande & Cheely	19 South LaSalle Street, Suite 1203	Chicago, IL	60603
Sargis	BRIE K.	IDOT	2300 South Dirksen Parkway	Springfield, IL	62764
Soutter Steinhour Trivedi	Douglas G. Elizabeth Chetan Bick	Legal Department Conestoga-Rovers & Associates Weaver, Boos & Gordoo Trivedi Associates, Inc. DAI Environmental, Inc.	8615 West Bryn Mawr 2021 Timberbrook Lane 2055 Steeplebrook Court 5 Revere Drive, Suite 310	Chicago, IL Springfiekl, IL Naperville, IL Northbrook, IL	60631 62702 60565 60062
Vlahos	Georgia	Office of Counsel Naval Training Center	2601 A Paul Jones St.	Great Lakes, IL	60088
Vogel Walton Yonkauski Zolyak	Museite H. Harry Stan Gary	The Stolar Partnership Site-Remediation Advisory Comm. Department of Natural Resources Department of Defense Regional	911 Washington Avenue, 7th Floor 2520 Brooks Drive 524 South Second Street 5179 Hoadley Road, Bldg. E-4460	St. Louis, MO Decatur, IL Springfield, IL Aberdeen, MD	63101 62521 62701 21010-5401

P.03/03

T-043

2

TOTAL P.03