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October 30, 2001



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NOV 1 - 2001

STATE OF ILLINOIS Pollution Control Board

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

P.C. #3

RE: Docket R-00-19(c)

Dear Ms. Gunn:

Enclosed are comments submitted for the record by the Illinois Petroleum Council in regard to Docket R-00-19(c) which adds MTBE as a constituent to be tested for during a site remediation under part 742 of the Board's land regulations.

Attached is a summary of actions taken by a number of governmental agencies that have chosen not to classify MTBE as a carcinogen. We would urge the Board to consider a similar ruling.

Sincerely,

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BEFORE THE ILLINOIS POLLUTION CONTROL BOARD STATE OF ILLINOIS Pollution Control Board

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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)

COMMENTS OF THE ILLINOIS PETROLEUM COUNCIL

The Illinois Petroleum Council ("IPC") files these comments in response to the Board's First Notice Order of September 6, 2001. The IPC supports the Board's action in adopting the Illinois Environmental Protection Agency's proposed MTBE standards. As the Agency indicated in its comments on First Notice, the record compiled before the Board included a comprehensive discussion of the scientific information available regarding MTBE and supports the proposed standards. The Agency's process of arriving at the proposed standards reflected their procedures for proposing other TACO values and groundwater protection standards which have been adopted by the Board. No one testified in opposition to the proposed standard during the hearing or submitted comments prior to the close of the record during the Subdocket B proceedings. In light of this complete record in support of the proposal, the Board should adopt the MTBE values proposed by the Agency.

In its First Notice opinion, however, the Board questioned both the current status of determinations of the possibility of human carcinogenicity of MTBE and its authority to evaluate such determinations outside of the statutory framework of the Illinois Environmental Protection Act. Section 58.2 (415 ILCS 5/58.2) of the Act specifically defines "carcinogen" in terms of the determinations of four respected agencies in order to ensure that the Board set TACO standards on

the basis of the best science available. The listed organizations have the resources and expertise to fully evaluate the myriad studies performed on different chemicals and to make decisions based on a complete record subject to peer review. The determinations of these agencies should, in any event, be given great weight by the Board and the Act simply confirms that the Board is bound to respect their findings.

Per the Board's suggestion, the IPC has gathered the most recent evaluations of MTBE by the main independent health organizations. The findings of these evaluations are listed in the attached document. These findings indicate that MTBE has not been determined to be a human carcinogen and does not fall into the categories required by the Act for the Board to determine that it should be treated as a carcinogen.

The Board should adopt the proposed standard for its final rule. The complete record before the Board supports the adoption of this standard and there is no contrary information in the record which would support the adoption of any other standard. As always, the IPC appreciates the opportunity to submit these comments.

ILLINOIS PETROLEUM COUNCIL

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Executive Director

Date: October 30, 2001

SUMMARY of RECENT HEALTH EFFECTS EVALUATIONS of MTBE

(BJB Revision, 5-17-00)

Note: In the last 24 months, several independent organizations have conducted extensive reviews of MTBE's health effects. Each of these organizations reviewed the collective body of health research on MTBE – they did not perform any new technical studies.

- 1) IARC: International Agency for Research on Cancer
- 2) NTP: National Toxicology Program
- 3) CalEPA OEHHA (Office of Environmental Health Hazard Assessment)
- 4) WHO: World Health Organization
- 5) European Union MTBE Risk Assessment

1) IARC: International Agency for Research on Cancer (http://www.iarc.fr)

Evaluated MTBE in its recent Monograph (October, 1999), "Volume 73: Some Chemicals that Cause Tumours of the Kidney or Urinary Bladder in Rodents, and Some Other Substances" http://193.51.164.11/htdocs/Indexes/Vol73Index.html; 674 pages, ISBN 92 832 1273 8 (1999) See METHYL tert-BUTYL ETHER (p. 339) <u>http://193.51.164.11/htdocs/monographs/Vol73/73-13.html</u>

MTBE was evaluated for evidence of being an animal or human carcinogen. They can classify the carcinogenicity of a compound into one of several Groups (1-3). They found that 1) there are no data directly showing cancer in humans (like Group 1 compounds), and 2) limited evidence of MTBE being an animal carcinogen (like Group 2 compounds). Their overall assessment was that **MTBE is "not classifiable as to its carcinogenicity to humans".** (Also see table at http://193.51.164.11/past&future/OCT98.html)

Officially, IARC classified MTBE as a "Group 3" chemical agent. According to IARC's classification system, a Group 3 chemical agent is defined as "not classifiable as to its carcinogenicity to humans." This category is used most commonly for agents, mixtures and exposure circumstances for which the evidence of carcinogenicity is inadequate in humans and inadequate or limited in experimental animals. Other agents officially classified as "Group 3" compounds include such common household products as caffeine, tea, rubbing alcohol, talc, and fluorescent lighting.

The International Agency for Research on Cancer (IARC) was established in 1965 by the World Health Organization. IARC's mission is to coordinate and conduct research on the causes of human cancer, and to develop scientific strategies for cancer control. The Agency is involved in both epidemiological and laboratory research, and disseminates scientific information through meetings, publications, courses and fellowships.

2) NTP: National Toxicology Program (http://ntp-server.niehs.nih.gov/)

The 9th Report on Carcinogens (RoC) was formally published in May 2000. <u>http://ehis.niehs.nih.gov/roc/toc9.html</u> Of the 14 substances reviewed for possible inclusion, **MTBE** was the only one the NTP decided <u>not</u> to include in the 9th RoC, citing that the existing rodent cancer data are not sufficient to justify listing. The other 13 substances were listed in the report as either: 1) known to be human carcinogens; or

2) may reasonably be anticipated to be human carcinogens.

Compounds not meeting the criteria for inclusion in either category are not listed.

Note: There were three NTP groups that sequentially conducted reviews of MTBE for the 9th edition. The first two groups split – 1 voted 4-3 to list MTBE as 'reasonably anticipated . . ' and the second voted 3-4 against listing. At its Dec. 1-2, 1998 meeting to evaluate MTBE and 13 other chemicals, the NTP Report on Carcinogens Subcommittee voted <u>against</u> listing MTBE. Specifically the vote to list MTBE as 'reasonably anticipated to be a human carcinogen' was <u>defeated</u> - 5 in favor, 6 opposed, with 1 abstention.

The National Toxicology Program (NTP) is administered by the Dept. of Health and Human Services to coordinate toxicology research and testing activities within the Department, to provide information about potentially toxic chemicals to regulatory and research agencies and the public, and to strengthen the science base in toxicology. In its seventeen years, the NTP has become the world's leader in designing, conducting, and interpreting animal assays for toxicity/ carcinogenicity.

3) CalEPA OEHHA (Office of Environmental Health Hazard Assessment) <u>http://www.oehha.org</u> 1997 legislation required OEHHA to evaluate listing MTBE as a 'Proposition 65'' chemical. Two OEHHA committees (Developmental and Reproductive Toxicology Committee, Cancer Identification Committee) decided in Dec. 1998 that data **was not sufficient** to list MTBE as either 1) a cancer causing compound (vote was 4-2 against listing) or 2) a reproductive toxin (vote was 5-0 against listing). See CalEPA press release at http://www.calepa.ca.gov/publications/press/1998/C2898.htm

A quote from the press release about the Cancer Identification Committee: "That Committee found insufficient support for the proposition that MTBE is a carcinogen and that there was not a demonstrable majority in favor of listing within that Committee."

Background Prop 65 documents available at <u>http://www.oehha.org/prop65/CRNR_notices/getDmtbe.html</u> **Note:** This was a little surprising, as the threshold for meeting Prop 65 criteria is considerably lower than either for the IARC or NTP evaluations.

Also note that OEHHA has recently published documents related to their assessment of the cancer potency of MTBE related to CalEPA's Air Toxics program, and related to the California 'Public Health Goal' for MTBE. Those reports are accessible at http://www.oehha.org/air/mtbe/MTBECRNR.html#download

4) World Health Organization (WHO) report (May, 1999)

International Programme On Chemical Safety (IPCS) "Environmental Health Criteria 206: Methyl *tertiary*-butyl ether" <u>http://www.who.int/pcs/docs/ehc_206.htm</u> Here is an excerpt from the WHO report:

9. Evaluation of human health risks and effects on the environment

Based on collective evidence, it appears unlikely that MTBE alone induces adverse acute health effects in the general population under common exposure conditions.

In studies on animals, MTBE is "moderately" acutely toxic and induces mild skin and eye irritation but not sensitization. Repeated exposure affects primarily the kidney of rats and the liver of mice, with lowest reported adverse effect levels of 440 mg/kg body weight per day in rats following ingestion and 1440 mg/m³ (400 ppm) following inhalation. MTBE has not induced adverse reproductive or developmental effects at concentrations less than those that were toxic to the parents.

MTBE is not genotoxic but has induced tumours in rodents primarily at high concentrations that also induce other adverse effects. These data are considered currently inadequate for use in human carcinogenic risk assessment. The Task Group concluded that, in order to provide quantitative guidance on relevant limits of exposure and to estimate risk, acquisition of additional data in several areas is necessary.

It does not appear that the concentrations of MTBE in ambient water are toxic to aquatic organisms except during spills. Although there are no data on the terrestrial toxicity of MTBE, this appears not to be of concern since concentrations in ambient air are low and its half-life is relatively short.

5) European Union MTBE Risk Assessment (EINECS-No.:216-653-1)

There is a European Union draft review (Feb., 2000) of MTBE health effects prepared by the Finnish Environment Institute and the Finnish Institute of Occupational Health concerning the human health. It is a chapter in a larger volume of that is an overall risk assessment for MTBE. That draft document does not yet contain any conclusions.

Keep in mind that none of the above are 'final' assessments. MTBE can be reconsidered by any of the above groups pending publication of new data. It is possible that other animal studies or metabolic studies are in progress, e.g., in Europe, and not known to us. However, it seems unlikely that the above assessments would change at any time in the near future, and then only if new data is published that would justify a revision of current classifications.