



Western States Petroleum Association
Credible Solutions • Responsive Service • Since 1907

Michael D. Wang

Senior Advisor, Legal, Excise Tax and Environmental Issues

Via Email: Coshita@oehha.ca.gov

July 13, 2009

Ms. Cynthia Oshita
Office of Environmental Health Hazard Assessment
P.O. Box 4010, MS-19B
Sacramento, California 95812-4010

RE: Prop 65 Listing by Labor Code Mechanism

Dear Ms. Oshita:

The Western States Petroleum Association (WSPA) is a trade association representing twenty-eight companies that explore for, produce, refine, transport and market petroleum, petroleum products, natural gas and other energy products in six western states – California, Arizona, Nevada, Oregon, Washington and Hawaii.

WSPA member companies own and operate various types of facilities (e.g., oil and gas production properties, refineries, marketing terminals, retail gasoline outlets, etc.) that would be impacted by the recent proposal from OEHHA. WSPA is pleased to provide our comments in response to the Request for Comments on Chemicals Proposed for Listing by the Labor Code Mechanism (06/25/09).

We also urge your agency to consider the important comments prepared by the California Chamber of Commerce. While our comments center on the scientific and technical basis for the proposed action by OEHHA, OEHHA should not understand by our comments that WSPA accepts that the Labor Code reference mechanism as a proper methodology for adding substances to the List.

Informed Mechanism for Listing

We strongly believe that OEHHA should consider using a more informed and deliberative process for three chemicals it proposes to add to the Proposition 65 (Prop 65) List, “diesel fuel, marine”, tert-amyl methyl ether (TAME) and ethyl tert-butyl ether (ETBE) based upon their unique toxicological data Rather than simply including them through the Labor Code mechanism.

Review by the Carcinogen Identification Committee (CIC) and the Developmental and Reproductive Toxicant (DART) Identification Committee is warranted for these three chemicals. The review would assess whether sufficient documentation exists, gained through scientifically valid testing according to generally accepted principles, to determine if they cause cancer or reproductive or developmental toxicity and listing as a Proposition 65 (Prop 65) compound.

Accurate Risk Communication

The primary function of Prop 65 is to provide risk communication through warnings. The objective of the warning is to provide clear and accurate information to enable informed decision-making by the warning recipient to avoid a specific risk. If the information is unclear or inaccurate, this objective is frustrated. Warnings that are inaccurate or misunderstood can also put the recipient at greater risk.

Comprehensive review by the CIC or DART to determine if these three chemicals should be added to the Prop 65 List will better serve Prop 65's primary objective of accurate risk communication to potentially exposed persons. If the toxicology data for any proposed chemical is insufficient to justify adding it to the list, adding it to the list will lead to unnecessary warnings to the public, mislead warning recipients, and dilute the impact of Prop65 warnings.

"Characterization of Diesel Fuel, Marine"

The data does not support inclusion of diesel fuel, marine as a Prop 65 compound.

OEHHA has identified "diesel fuel, marine" as a chemical it proposes to add to the Prop 65 List as a carcinogen based upon findings by IARC in its "Monographs on the Evaluation of Carcinogenic Risks to Humans, Occupational Exposures in Petroleum Refining: Crude Oil and Major Petroleum Fuels", Volume 45, 1989 (IARC, 1989). Other than IARC generally equating "marine diesel fuel" with residual fuels, the characterization and identity of "marine diesel fuel" is vague.

Moreover, the 1986 NTP study relied upon by IARC was determined by its peer reviewers to have flaws making interpretation of the results difficult and leading to contradictory conclusions by the reviewers. Specifically, IARC Volume 45 evaluated occupational exposures to petroleum refining and various petroleum streams, including diesel fuels and fuel oils. IARC classified "marine diesel fuel" as "possibly carcinogenic to humans (Group 2B)" based on the findings of a single study in which a substance identified as "marine diesel fuel" was administered to the skin of mice over a two year period.¹ The test material produced severe skin ulceration and chronic

¹ IARC, 1989. See pages 231-232 and 235-236 citing National Toxicology (NTP) Program (1986) Toxicology and Carcinogenesis Studies of Marine Diesel Fuel and JP-5 Navy Fuel (CAS No. 8008-20-6) in B6C3F1 Mice (Dermal Studies) (Technical Report Series No. 310), Research Triangle Park, NC, US Department of Health and Human Services.

dermatitis. A slight increased incidence of squamous cell papillomas or carcinomas (combined) was observed.

The peer reviewers of the NTP study were concerned with the validity of the study and considered it to be flawed in two areas. First, the severe skin ulceration made the interpretation of the results difficult while the study design limited the ability to determine whether the test material was a direct acting carcinogen or merely a promoter. The other flaw was the lack of characterization of the test material. The peer reviewers found the “marine diesel fuel” was “poorly defined chemically” and, therefore, “difficult to evaluate because the materials evaluated may not be representative”.² Due to the lack of characterization of the test material, the peer reviewers found it “unclear which component caused the toxic response.”³

IARC’s sister agency, the International Programme on Chemical Safety (IPCS), also acknowledged the apparent lack of genotoxicity associated with the 1986 NTP study. In summarizing the carcinogenic potential of diesel fuels in animal studies, IPCS found that these “studies of dermal carcinogenicity in animals demonstrated that diesel fuels have weak carcinogenic potency in mice. As no clear genotoxicity is seen, cancer may be induced by nongenotoxic mechanisms, such as chronic dermal irritation characterized by repeated cycles of skin lesions and epidermal hyperplasia.”⁴

Regarding chemical characterization of “marine diesel fuel”, IARC did not identify a unique characteristic or component. Instead IARC equated “marine diesel fuel” with historical diesel fuel No. 4. IARC characterized historical No.4 as a residual fuel normally containing up to 15% residual oil components.⁵ The NTP study described the test material as “marine diesel fuel” obtained in one lot from Wright Patterson Air Force Base and it was reported to be composed of a mixture of hydrocarbons containing 12.7% paraffins, 43.7% naphthalenes, and 43.6% aromatic compounds. Analytical data indicated that there were more than 200 components in the study material. The date of manufacture was not identified.⁶ In fact, the National Cancer Institute specifically nominated this fuel for this study because of the potential exposure of armed forces personnel.⁷ The study did not indicate if the test material was representative of commercial diesel fuel used in non-military marine applications. Based on the limited information in IARC and the 1986 NTP study, the “marine diesel fuel” tested and classified as possibly carcinogenic in humans (Group 2B) was a residual fuel comparable to historical diesel No. 4 that may have only been available to the military.

In the same volume, IARC evaluated other petroleum streams and concluded there was inadequate evidence of carcinogenicity in humans of diesel fuels. Specifically, it decided that distillate (light) diesel fuels were not classifiable as to their carcinogenicity to humans (Group

² NTP, 1986 at p. 14.

³ *Id.*

⁴ United Nations, Environment Programme International Labour Organisation, World Health Organization International Programme on Chemical Safety, Environmental Health Criteria 171, Diesel Fuel and Exhaust Emissions, 1996, at p. 87.

⁵ NTP, 1986 at p.34 and 220.

⁶ *Id.* at p.22.

⁷ *Id.* at p.18.

3).⁸ IARC generally equated distillate (light) diesel fuel with diesel fuels No. 1 and No. 2. IARC did not identify a specific methodology to identify a substance as being “marine diesel fuel.” Instead IARC focused on the manufacturing process to characterize the substances evaluated. For both diesel fuels and fuel oils evaluated in the Volume 45, IARC generally classified residual fuel streams as possibly carcinogenic (Group 2B) and distillates as not classifiable (Group 3).⁹

Current diesel fuel used for marine applications in California is low sulfur distillate diesel fuel, referred to as marine diesel oil (MDO) or marine gas oil (MGO).¹⁰ MDO is composed of diesel marine B (DMB), while MGO is composed of either diesel marine A (DMA) or diesel marine X (DMX).¹¹ In vessels subject to the California Air Resources Board (CARB) fuel regulations set forth at 8 CCR § 2299.2, only distillate fuels may be used within California waters.

Furthermore, diesel fuel No. 4 is not commercially marketed in California and is sold only to the military which is specifically excluded from Proposition 65 under H&S Code § 25249.11(b). And, as shown below in Table 1, the distillate fuels used in marine applications in California today have different properties than diesel fuel No. 4, a residual fuel.

Table 1. Diesel Fuel Properties

Fuel Characteristic and Grade (Standard)	Diesel No. 4 (ASTM D975)	DMA (ISO 8217)	DMB (ISO 8217)	DMX (ISO 8217)
Kinematic Viscosity	5.5 to 24	1.5 to 6.0	No more than 11.0	1.4 to 5.5
Flashpoint (deg C)	55	60	60	43
Cetane index	30	40	35	45
Ash	0.1	0.01	0.01	0.01

“Marine diesel fuel” is an anachronistic term that may have been applied in a general manner to various grades of diesel fuels used in marine applications in the past. The terminology for diesel fuel used in marine applications has changed since the time the NTP study was conducted and IARC evaluated “marine diesel fuel”. From a general technical basis, the term “marine diesel

⁸ IARC at p.235 -236.

⁹ *Id.* at p.236 and 264.

¹⁰ 13 California Code of Regulations (CCR) § 2299.2

¹¹ See 13 CCR § 2299.2(d)(18), (19), “‘Marine Diesel Oil (MDO)’ means any fuel that meets all the specifications for DMB grades as defined in Table I of International Standard ISO 8217, as revised in 2005, which is incorporated herein by reference”; and “‘Marine Gas Oil (MGO)’ means any fuel that meets all the specifications for DMX or DMA grades as defined in Table I of International Standard ISO 8217, as revised in 2005, which is incorporated herein by reference.” International Standard ISO 8217:2005E Table I identifies DMA, DMB, and DMX as marine distillate fuels.

fuel” is obsolete and unused. From a toxicological basis, “marine diesel fuel” is vague and undefined.

Moreover, the limited data do not indicate that the “marine diesel fuel” tested in the 1986 NTP study is representative of DMA, DMB or DMX used in California or elsewhere today. To the extent the findings in IARC Volume 45 are to be considered in classifying current marine distillate fuels DMA, DMB and DMX, they are comparable to the category of fuels identified as “distillate (light) diesel fuels” classified by IARC as Group 3 - not classifiable as to their carcinogenicity to humans.

Current marine distillate fuels used in California are different from historical diesel No. 4 and the “marine diesel fuel” used in the 1986 NTP study. OEHHA has provided no data demonstrating the appropriateness of extrapolating the 1986 NTP study results to current marine distillate fuels or assuming they are Group 2B carcinogens. The current fuels are distillates, and therefore, comparable to the category of fuels identified as “distillate (light) diesel fuels” by IARC and determined to be not classifiable as to their carcinogenicity to humans (Group 3).

Adding “diesel fuel, marine” to the Prop 65 List would likely result in warnings that DMA, DMB, and DMX are known to the State to be carcinogenic despite the fact that IARC concluded that distillate fuels are not known or possible human carcinogens. Such warnings are inherently misleading. Compounding this problem is the difficulty of assessing compliance as no unique characteristics of the listed material or specific analytical method to detect its presence are identified by IARC.

For these reasons, OEHHA should not list “diesel fuel, marine” via the Labor Code mechanism or otherwise. Instead, if OEHHA remains convinced after considering these comments that “diesel fuel, marine” should still be considered for listing, we recommend the CIC review the available data to determine if it should be added to the Prop 65 List as well as to clarify the characteristics of the “chemical”, to improve risk communication and compliance. If such a review were conducted, the CIC and OEHHA could take advantage of research on dermal effects of hydrocarbons that has been conducted in the 20 years since this IARC monograph was published.

Tert-Amyl Methyl Ether (TAME) and Methyl Tertiary Butyl Ether

The listing of TAME would also benefit from additional review of the relevant data by the DART. OEHHA proposes to add tert-amyl methyl ether (TAME) to the Prop 65 List as a reproductive toxicant because the 2009 ACGIH recommended TLV of 20 ppm is reportedly based on a developmental endpoint.

The documentation of the ACGIH TLV for TAME¹² states that the TLV of 20 ppm was derived using the “so-called ‘preferred value’ approach” considering no-observed-adverse effect levels (NOAELs) of 250 ppm for “chronic effects, such as neurologic and reproductive toxicity” in

¹² Documentation of the TLV for tert-Amyl Methyl Ether, ACGIH, 2002 available at <http://www.acgih.org/Products/>.

several inhalation studies by Welsch et al.¹³ The “so-called preferred value approach” is not described further nor is there any citation provided as a reference. It is unclear how the proposed value of 20 ppm was derived.

In these studies maternal toxicity, including mortality, was observed at all dose levels developmental effects were observed making it unclear if the developmental effects observed were a direct effect of TAME or a secondary response associated with maternal toxicity. The authors suggested that it was a secondary response. They pointed out maternal exposure to high concentrations of MTBE produced anesthetic qualities as well as associated maternal stress resulting in elevated endogenous corticosteroid levels, which cause cleft palate in the developing offspring in mice. Based on this information, the authors opined that TAME acts in an analogous manner as MTBE to induce maternal stress. The authors also found the increased incidence of enlarged lateral ventricles of the fetal cerebrum at 3500 ppm to be consistent with developmental delay because the fetuses in this dose group had body weights that were approximately 40% less than the controls.

It should be noted that DART unanimously decided not to list MTBE because the data did not clearly demonstrate through scientifically valid testing according to generally accepted principles that it caused developmental or reproductive toxicity.¹⁴ It seems likely that DART would reach a similar conclusion for TAME based on its similarities to MTBE in structure and toxicology.

No technical evaluation has been performed by any scientific body to determine if the data for TAME clearly demonstrates through scientifically valid testing according to generally accepted principles that it causes developmental or reproductive toxicity. Moreover, it is inappropriate for OEHHA to rely upon a single study purportedly used by the ACGIH to derive a TLV as the sole basis to conclude TAME has been shown to clearly demonstrate through scientifically valid testing according to generally accepted principles to cause developmental or reproductive toxicity.

Consequently, it is inappropriate for OEHHA to add TAME to the Prop 65 List in light of the findings for MTBE; rather if OEHHA remains convinced after considering these comments that TAME should still be considered for listing, OEHHA should recommend that the DART review the relevant data to determine if TAME should be added to the Prop 65 List as a developmental toxicant.

Ethyl Tert-Butyl Ether (ETBE)

¹³ *Id.* at p. 1 and 3; see Welsch F; Tyl RW; Marr MC; et al.: Evaluation of the Developmental Toxicity of Inhaled Tertiary Amyl Methyl Ether in Mice and Rats. *Toxicologist* 36(1 Part 2):338 (1997); Welsch F; Tyl RW: Developmental Toxicity Evaluation of Inhaled TAME in CD-1 Mice. American Petroleum Institute/ Chemical Industry Institute of Toxicology Study 95061. API, Washington, DC (February 25, 1997); and Welsch F; Tyl RW: Developmental Toxicity Evaluation of Inhaled TAME in CD (Sprague--Dawley) Rats. American Petroleum Institute/Chemical Industry Institute of Toxicology Study 95060. API, Washington, DC (February 20, 1997).

¹⁴ Cal-EPA News Release (C-28-98), *Scientific Review Panels Conclude MTBE Is Neither a Reproductive or Developmental Toxicant nor a Carcinogen*, November 10, 1998 at <http://www.calepa.ca.gov/PressRoom/Releases/1998/C2898.htm>.

OEHHA proposes to add ethyl tert-butyl ether (ETBE) to the P65 List as a reproductive toxicant because the 2009 ACGIH recommended TLV of 5 ppm is purportedly based on the endpoint of male reproductive toxicity. Three endpoints were jointly identified in developing the TLV's as well as the toxicity data for MTBE.¹⁵

On page 1 of the ETBE TLV documentation it states:

“A TLV-TWA of 5 ppm (21 mg/m³) is recommended for occupational exposure to ethyl tert-butyl ether (ETBE). This value is based on a no observed-adverse-effect level (NOAEL) of 500 ppm for neurotoxic effects and testicular lesions in ETBE exposed rats; a NOAEL of 5 ppm for light but statistically significant decreases in pulmonary function measurement in male volunteers exposed to ETBE at 25 and 50 ppm; and by analogy with the toxicity data for methyl tert-butyl ether (MTBE) (see the current TLV Documentation for MTBE).” (emphasis added)

While on page 4 of the ETBE TLV documentation it states:

“There exists little relevant, published, toxicologic information on ETBE in either animals or humans at this time, and there is no previous TLV for this compound. In a 4-week inhalation study, White et al.¹⁶ found an NOAEL of 500 ppm for neurotoxic effects in rats. In the 90-day inhalation study by Bond et al.¹⁷, the NOAEL of ETBE for male rats was 500 ppm, based on testicular lesions. When Nihlen et al.¹⁸ exposed eight healthy male volunteers to ETBE for 2 hours at 50 ppm or less, there were nonsignificant tendencies towards elevated ratings for a variety of complaints and, more importantly, slight but significant (p <0.05) decreases in objective pulmonary function measures (VC DLco, FEV1) after ETBE exposure at 25 and 50 ppm. Based on a safety factor from the rodent NOAELs taken in light of the significant results from the brief (2-hour) controlled trials in human volunteers with a NOAEL of 5 ppm, as well as analogy to MTBE and its much larger database, the recommended TLV TWA for ETBE is 5 ppm.” (emphasis added)

The recommended TLV is the same value as the NOAEL in the human study. The animal data was used solely as a point of reference for assuring that the recommended TLV was sufficiently conservative considering an unspecified “safety factor”. The recommended TLV value appears to be based solely on the human NOAEL while the rat NOAELs were used solely as a point of reference to assure the TLV is adequately protective of workers.

¹⁵ Documentation of the TLV for Ethyl tert-Butyl Ether, ACGIH, 2001 available at <http://www.acgih.org/Products/>. See p. 1 and 4.

¹⁶ White, R.D.; Daughtrey, W.C.; Wells, M.S.: Health Effects of Inhaled Tertiary Amyl Methyl Ether and Ethyl Tertiary Butyl Ether. *Toxicol. Lett.* 82/83: 719-724 (1995).

¹⁷ Bond, J.A.; Medinsky, M.A.; Wolf, D.C.; et al.: ETBE: 90-Day Vapor Inhalation Toxicity Study with Neurotoxicity Evaluation in F344 rats. Report No. 95029. Chemical Industry Institute of Toxicology, Research Triangle Park, NC (1996).

¹⁸ Nihlen, A.; Johanson, G.; Lof, A.: Acute Effects of Ethyl t-Butyl Ether in Male Volunteers. *Fund. Appl. Toxicol.* 36(1, Pt 2):339 (1997).

Like TAME, the TLV also considered the toxicity data available for MTBE, which DART unanimously determined should not be added to the Prop 65 List as a reproductive toxicant. ¹⁹ It seems likely that DART would reached a similar conclusion for ETBE based on its similarities to MTBE.

No technical evaluation has been performed by any scientific body to determine if the data for ETBE clearly demonstrates through scientifically valid testing according to generally accepted principles that ETBE causes developmental or reproductive toxicity. It is inappropriate for OEHHA to add ETBE to the Prop 65 List because the TLV is not based on male reproductive toxicity and in light of the DART's decisions not to list MTBE; rather if OEHHA remains convinced after considering these comments that ETBE should still be considered for listing, OEHHA should recommend that DART review the relevant data to determine if ETBE should be added to the Prop 65 List as male reproductive toxicant.

For these reasons, we feel that adding these compounds to the Prop 65 List via the Labor Code mechanism without further technical review is inappropriate.

Thank you for consideration of our comments. We appreciate this opportunity to provide the comments to OEHHA regarding this matter. Should you have comments, please feel free to contact me 626-590-4905. If OEHHA is interested in discussing these comments in detail, we will be happy to make Dr. Michael Lakin (Ensign) who was the primary contributor to this letter, available to you and your staff.

Regards,



Michael Wang

Cc: Catherine Reheis-Boyd, WSPA

¹⁹ Cal-EPA News Release (C-28-98), *Scientific Review Panels Conclude MTBE Is Neither a Reproductive or Developmental Toxicant nor a Carcinogen*, November 10, 1998 at <http://www.calepa.ca.gov/PressRoom/Releases/1998/C2898.htm>.