

Final Statement of Reasons
Secondary Maximum Contaminant Level for Methyl tert-Butyl
Ether and Revisions to the Unregulated Chemical Monitoring
List
Title 22, California Code of Regulations

All suppliers of domestic water to the public are subject to regulations adopted by the U.S. Environmental Protection Agency (EPA) under the Safe Drinking Water Act (42 U.S.C. 300f et seq.) as well as by the California Department of Health Services (Department) under the California Safe Drinking Act (Sections 4040.1 and 116300-116750, Health and Safety Code). California has been granted “primacy” for the enforcement of the Federal Act. In order to receive and maintain primacy, states must promulgate regulations that are no less stringent than the federal regulations.

In accordance with federal regulations, California requires public water systems to sample their sources and have the samples analyzed for inorganic and organic substances in order to determine compliance with drinking water standards, also known as maximum contaminant levels (MCLs). Primary MCLs are based on health protection, technical feasibility, and costs. Secondary MCLs are based on consumer acceptance, using parameters such as odor, taste, and appearance as measures of acceptability. The water supplier must notify the Department and the public when a primary or secondary MCL has been violated and take appropriate action. Public water systems must also sample for a number of “unregulated” chemicals, as set forth in regulation.

The Department proposes the following amendments to Chapter 15, Title 22 of the California Code of Regulations:

- To amend Section 64449, Article 16, to add the chemical methyl tertiary-butyl ether (MTBE) with a secondary maximum contaminant level (MCL) to Table 64449-A.
- To amend Section 64450, Article 17, to add ethyl tert-butyl ether (ETBE) and tert-amyl methyl ether (TAME) to Table 64450-B, limit MTBE unregulated chemical monitoring to nontransient-noncommunity water systems, and add Table 64450-D with perchlorate.
- To amend Section 64450.1, Article 17, to require monitoring at five-year intervals in conformance with federal regulations; eliminate obsolete deadlines; establish an appropriate date to use as criteria for grandfathered data for ETBE, TAME and perchlorate monitoring requirements; and make editorial corrections for text clarification.

The net effect is that:

- Community water systems would be required to monitor for MTBE to determine compliance with a secondary MCL, but would no longer be required to monitor MTBE as an unregulated chemical.
- Nontransient-noncommunity water systems would continue to monitor for MTBE as an unregulated chemical to determine if any contamination were present.
- Community and nontransient-noncommunity water system sources would be monitored for unregulated chemicals at five-year intervals.
- Vulnerable community and nontransient-noncommunity water system sources would be monitored for ETBE, TAME, and/or perchlorate to determine if any contamination were present.
- Water systems would be able to use ETBE, TAME and perchlorate data collected subsequent to January 1, 1993 toward initial monitoring requirement compliance.

The amendment, which would require unregulated chemical monitoring at five-year intervals, does affect California's primacy status in that it is a federal requirement and must be adopted into California's regulations. The other proposed amendments, with the exception of text clarification, would make the state's regulation more stringent than the federal, which is allowed. Therefore, these changes would not affect California's primacy status.

In addition to the above amendments, the Health and Safety Code citations in the authority/reference NOTES for sections 64449 and 64450.1 have been amended for consistency with the authority/reference NOTE updates. Further, section 64449(h) has been amended to use the technically correct reference to a subsection.

The following paragraphs describe and explain the proposed amendments.

Article 16. Secondary Drinking Water Standards
64449. Secondary Maximum Contaminant Levels

The purpose of this section is to list the chemicals for which secondary maximum contaminant levels (MCLs) have been established to protect the taste, odor and/or appearance of drinking water. Methyl tert-butyl ether (MTBE) would be added to this list with a secondary MCL of 0.005 mg/L.

MTBE is a colorless, liquid hydrocarbon that has been used as an octane booster in gasoline since the 1970s. Highly mobile in soils through which it rapidly migrates to groundwater, very soluble in water, and extremely slow to biodegrade (or possibly non-biodegradable), MTBE has been found in shallow groundwater throughout the U.S. Due to concerns regarding possible MTBE contamination of drinking water supplies in California, the Department added MTBE to the list of unregulated chemicals (22 CCR Section 64450) for which community and nontransient-noncommunity water systems are required to monitor in order to collect solid occurrence data for MTBE in drinking water sources. Data collected prior to and since the effective date of the requirements (February 13, 1997) by regional water quality control boards and drinking water utilities indicates there is some groundwater and surface water contamination in California. As of June 13, 1997, MTBE had been detected in 14 of the 388 systems that had monitored (26 sources). The Department is continuing to collect occurrence data and, at the same time, intends to establish appropriate drinking water standards for MTBE.

The Department has two concerns regarding MTBE from a public health standpoint: Risks to human health, and consumer acceptance of drinking water containing MTBE in terms of odor and taste. To address public health issues, the Department currently uses an action level of 35 micrograms per liter (ug/L), based on the non-carcinogenic effects seen in animal studies. This level was established in 1991 by the Pesticide and Environmental Toxicology Section which was then in the Department, but is now in Cal/EPA's Office of Environmental Health Hazard Assessment (OEHHA). At that time, there was very little known about the occurrence of MTBE in drinking water supplies. The action level provides non-regulatory guidance to the Department's Drinking Water Program, County Health Departments, utilities and the public about the significance of findings in drinking water of chemicals without drinking water standards.

In December 1996, EPA released a draft health advisory of 70 ug/L, based on kidney and liver effects observed in laboratory animal experiments for MTBE ("Methyl-t-Butyl Ether [MTBE] Drinking Water Health Advisory, Health and Ecological Criteria Division, Office of Science and Technology, Office of Water US EPA, Washington D.C. 20460).

OEHHA is reviewing the available health effects data on MTBE in order to establish a protective public health level; subsequently, the Department will propose a primary drinking water standard.

Due to its chemical properties, MTBE can be both smelled and tasted by many people at levels below both the federal and state health advisory levels discussed above. Therefore, to address the potential adverse effect of MTBE on the aesthetic quality of water, the Department has determined that a secondary MCL should be established. Under California regulations, violations of secondary MCLs require public notification and treatment. Under certain

circumstances, a water utility may be able to qualify for a waiver, but to date, waivers have only been granted for existing water systems with iron and manganese problems. Adoption of a secondary MCL for MTBE would ensure that consumers are not exposed to drinking water with objectionable taste and odor related to MTBE contamination and would also ensure that MTBE levels are below current, and presumably future, health-based advisory levels.

Only two MTBE taste and odor studies have been conducted. A Great Britain study evaluated the taste and odor of a number of drinking water contaminants including MTBE ("Taste and Odor Threshold Concentrations of Potential Potable Water Contaminants", by W.F. Young, H. North, R. Crance, T. Ogden, and M. Arnott, Water Research, Volume 30, Number 2, 1996, pages 331-340). In this study, a panel of 9 specially selected and trained odor and taste assessors (females between ages 25 and 55) were used to evaluate known concentrations of MTBE dissolved in water. MTBE was prepared in different concentrations, diluted 2.5- to 3-fold between concentrations. Concentrations of chemicals in this study were over a 2000-fold range.

Results were presented in terms of the threshold concentration, that is, the lowest concentration in water for which an assessor detected an odor or taste. Rather than a simple average, the authors used the geometric, "because of the geometric interval between dilutions of concentrations and, as the best estimate, it assumes a normal distribution of sensitivities to give 50-50 divisions of a population." The lowest concentration detected by panelists was also presented. For odor detection, the average (geometric mean) threshold MTBE concentration was 34 ug/L (7 of 9 panelists; 78 percent) and the lowest concentration was 15 ug/L (3 of 9 panelists; 33 percent). For taste detection, the average (geometric mean) threshold MTBE concentration was 48 ug/L (5 of 9 panelists; 56 percent) and the lowest was 40 ug/L (4 of 9 panelists; 44 percent).

In summary, the thresholds for odor and taste of 15 and 40 ug/L, respectively, were detected by a sizable proportion of the assessment panel (33 and 44 percent). The methods of the study and the reported findings indicate that at the next lower concentration, estimated at 5 and 12.5 ug/L for odor and taste, respectively, no MTBE was detected by the assessors.

The Orange County Water District in California also performed a study on threshold odor concentrations of MTBE. The results of the study, "Threshold Odor Concentrations of MTBE and Other Fuel Oxygenates" by Y.F. Shen, L.J.Y. Yo, S.R Fitzsimmons, and M.K. Yamamoto, was presented at a national meeting of the American Chemical Society in San Francisco in April 1997. They found geometric means of 13.5 to 43.5 ug/L, indicating that half of the panelists detected MTBE at those levels. The geometric means odor thresholds were of the same magnitude, regardless of water type (odor-free water, chloraminated tap water, or water containing free chlorine) or temperature (room temperature, 40°C, or 60°C).

The lowest MTBE concentrations in water at which odor was detected among the various test runs were 2.5, 5, and 15 ug/L. The lowest threshold of 2.5 ug/L occurred in 7 (44 percent) of 16 test runs combining water types and temperatures. A lowest odor threshold of 5 ug/L was reported in 4 tests (2.5 percent) and 15 ug/L was reported in 5 tests (31 percent). The 2.5-ug/L odor threshold was reported in: (a) 2 of 4 runs in odor free water at room temperature, and 1 of 2 at 60°C; (b) 2 of 2 runs in tap water at room temperature, and 1 of 1 run at 60°C; and community 0 of 2 in water with free chlorine at room temperature, and 1 of 1 at 40°C.

In summary, the Shen et al study shows that MTBE odor may be detected at levels as low as 2.5 ug/L. No lower concentration was tested. Hence, the highest concentration that would not be detected under conditions of this study is unknown, but less than 2.5 ug/L.

Shen, et al., also investigated MTBE in the laboratory to check for cross contamination of laboratory samples, which is of concern since MTBE is used as a common laboratory extraction solvent. They found "background" concentrations of MTBE ranging from 0.07 to 3.12 ug/L (average 0.93 ug/L) in 40 vials containing deionized water that had been placed throughout the laboratory for an unspecified period of time. This suggests that detecting very low levels of MTBE in water may be confounded by MTBE in the laboratory, which is why the Department established a detection level for the purposes of reporting (DLR) of 5 ug/L at the time that it adopted the MTBE unregulated chemical monitoring requirement.

Since MTBE's odor is detected at a lower concentration than its taste, odor is the appropriate endpoint for establishing the secondary MCL. The Department believes the study by Young et al. is the most appropriate for establishing the secondary MCL because it was a large study of a number of chemicals which would hopefully preclude any unintended bias that could be associated with a study focused on fuel additives conducted in a highly politicized situation. Therefore, the Department proposes a secondary MCL of 5 ug/L (0.005 mg/L) for MTBE. In addition, because of the possibility of MTBE cross-contamination in analytical laboratories, the Department believes an MCL of 5 ug/L would provide adequate protection of consumers from adverse odors (and, therefore, taste) while sparing drinking water systems from MCL violations based on spurious laboratory results resulting from laboratory contamination.

Although, as noted above, MTBE has been detected in some California drinking water supplies, at this time, there do not appear to be any active drinking water sources that would be out of compliance with the proposed MTBE secondary MCL.

The Department proposes to correct a typographical error in subsection 64449(i). The published text shows an underline (“_”) preceding “pH”; the space immediately preceding should be blank.

Article 17. Special Monitoring Requirement for Unregulated Organic Chemicals

64450. Unregulated Chemicals

The purpose of this section is to list those chemicals for which monitoring must be conducted to determine their occurrence in drinking water supplies. The proposed regulation would amend this section in several ways: Add ethyl tert-butyl ether (ETBE) and tert-amyl methyl ether (TAME) to Table 64450-B, limit unregulated chemical monitoring for MTBE to nontransient-noncommunity water systems, and add Table 64450-D for inorganic chemicals with perchlorate listed.

Due to the concerns related to oxygenates used in reformulating gasoline, the Department is proposing to add ETBE and TAME to the unregulated monitoring section in order to collect occurrence data in California. These oxygenates, particularly ETBE which is not known to be in current use in California, are much less likely to be found in water than MTBE. However, there is still some potential for occurrence and this risk might increase in the future due to the many issues that have been raised related to MTBE that might result in its use being curtailed. TAME is known to be in current use by one refinery in some of its reformulated gasoline at 2 percent TAME to 9 percent MTBE. When used, ETBE and TAME are used in small percentages along with a larger proportion of MTBE. Hence, vulnerability to ETBE and/or TAME would be determined on the basis of whether a source had an MTBE detection. Very little is known about the possible adverse health effects associated with either of these chemicals.

The proposed regulation would limit MTBE monitoring as an unregulated chemical to nontransient-noncommunity water systems because under this proposed regulation, community water systems would be conducting their monitoring under the secondary MCL requirements. Hence, only the nontransient-noncommunity water systems need to continue monitoring under this section.

Due to the recent findings of perchlorate in drinking water supplies in northern California (primarily eastern Sacramento County) and southern California (Los Angeles, San Bernardino, and Riverside Counties) by the Department through its Drinking Water Program, and the concern related to overall occurrence, the Department is proposing to add perchlorate to the list of unregulated chemicals for monitoring in order to better assess occurrence in California.

Perchlorate is an anion resulting from the chemical dissociation of industrial chemicals such as ammonium perchlorate, potassium perchlorate, and sodium

perchlorate which have been in use for several decades in the manufacture of solid rocket fuel, munitions, and fireworks. Though little is known about perchlorate's behavior in the environment, it appears to be mobile in soils through which it migrates to groundwater, soluble in water, and extremely slow to biodegrade (or possibly not biodegradable). In February 1977, the Department initiated testing of highly vulnerable wells near suspect facilities and provided the supporting laboratory services; as of July 7, 1997, 232 wells from 48 systems had been sampled with perchlorate detected in 69 at levels greater than 4 ug/L, the detection limit for reporting purposes. It has also been found at low levels in the Colorado River as the result of the contamination of Lake Mead in Nevada.

The Department established a health-based action level for perchlorate of 18 ug/L in early 1997, based on its effects on the thyroid gland in a human study of non-carcinogenic effects.

The Department proposes to correct an editorial error in table 64450-B: the synonym for 1,2,3-Trichlorobenzene should read "vis-Trichlorobenzene" instead of "vic- Trichlorobenzene". The latter is a typo and is not correct.

64450.1. Monitoring - Unregulated Chemicals

The purpose of this section is to establish the monitoring requirements and criteria for monitoring waivers and exemptions for unregulated chemicals. The Department is proposing to amend this section as follows:

Subsection (a) would be amended to incorporate the requirement that monitoring be repeated at five-year intervals for conformance with federal regulations (40 CFR Section 141.40(1), Federal Register 52, 25715, July 8, 1987). Subsection (a) would also be amended for clarification to incorporate monitoring frequency and the specification regarding using the same sites unless Department approval is obtained from subsection (b). Specifically, paragraph (a)(1) would specify the tables of chemicals for which monitoring frequency differs according to type of source and would incorporate the requirements from the existing paragraph (a)(1) and (a)(2). The proposed paragraph (a)(2) would incorporate the existing monitoring requirement from subsection (b) for Table 64450-C and establish that monitoring frequency for perchlorate as well. The Department believes that quarterly monitoring rather than a single sample is more appropriate for perchlorate data collection because the data collected since February 1977 has demonstrated that results at a single source can vary considerably. Subsection (3) would be amended to establish an appropriate grandfathered data date for ETBE, TAME, and perchlorate data. 1993 would provide for data up to five years old to be used with repeat monitoring five years from the date of that data. The word "initial" would be added for clarification. The caveat that there should have been no detections in order to grandfather data is not actually applicable since unregulated chemical monitoring does not specify follow-up procedures for

positive findings. Paragraph (a)(4) is a requirement from subsection (b), placed here for continuity.

Subsection (b) would be amended to delete the obsolete deadline for sampling and the redundant (to subsection (a) requirement for “representative samples”. The phrase “by the Department” would be added to clarify how a water system is determined to be nonvulnerable and the proposed table 64450-D would be added.

Appendix 1

List of Commentators

Public Comment Period Ending September 8, 1998

R-44-97

Reference #	Commentator Name and Representation
1	John Kneiss, Director, Health Sciences and Product Stewardship Oxygenated Fuels Association
2	Gene Livingston and S. Craig Hunter Livingston & Mattesich Law Corp. Attorneys for the Oxygenated Fuels Association
3	Jeff Sickenger, Environmental Issues Coordinator Western States Petroleum Association (WSPA)
4	Michael J. McGuire, Ph.D. McGuire Environmental Consultants, Inc.
5	John McKnight, Director of Environmental and Safety Compliance National Marine Manufacturers Association
6	Margaret H. Nellor, Head Monitoring Section County Sanitation Districts of Los Angeles County
7	Mark Buehler, Director of Water Quality Metropolitan Water District of Southern California
8	Andrew DeGraca, P.E., Water Quality Bureau Manager Public Utilities Commission, City and County of San Francisco
9	Nira Yamachika, Director of Water Quality Orange County Water District
10	Dan Smith, Manager of Regulatory Affairs Association of California Water Agencies (ACWA)
11	Gilbert M. Borbos, Jr., P.E., Utilities Manager City of Santa Monica Utilities Division

Final Statement of Reasons

Secondary MCL and Unregulated Chemical Regulations

Page 9

Response to Public Comments on R-44-97

No request for a public hearing pursuant to Government Code 11346.8 was received in a timely manner.

The following responses to public comments on R-44-97 are organized as follows: “Appropriate Threshold Level” includes comments/responses related to the appropriate level to use to establish the MCL (lowest level of detection in a study vs geometric mean of the levels detected in the study); “Appropriate Criteria” addresses comments/responses related to consumer acceptance criteria; “Good Science” includes comments/responses related to the scientific basis for the proposed MCL; “Cost” includes any comments related to the cost of the regulation; and “Miscellaneous” includes comments not fitting in any of the above categories.

Appropriate Threshold Level

Commentator 1 stated that the Department inaccurately defined the threshold concentration as the lowest concentration detected by an assessor. Specific points were that the Young study included results expressed not only as the lowest concentrations detected, but also as geometric means; that the ASTM method E-679 defines detection threshold differently from the Department; and that the “Standard Methods for the Examination of Water and Wastewater states that the Threshold Odor Number (TON) is the concentration of an odorant where three dilutions will produce no perceptible odor.” The Department would like to note that the definition ascribed to Standard Methods is incorrectly stated, by the commentator; the definition is, “The ‘threshold odor number,’ designated by the abbreviation TON, is the greatest dilution of sample with odor-free water yielding a definitely perceptible odor.” (Standard Methods, 19th edition, p. 2-13) Further, the Department would like to cite the dictionary’s definition for “threshold”: “The point at which a stimulus, as of a nerve or muscle, just produces a response.” (Funk and Wagnalls, 1968) The Department is using the term “threshold for odor and taste” in the sense defined in the dictionary, i.e., as the lowest concentration at which a sensory response of smell or taste occurs.

Commentators 1 and 4 stated that the Department should use the geometric mean to establish the MCL, citing the ASTM Standard. Commentator 1 also referenced the opinion of the Expert Advisory Panel that it had used for the Malcolm Pirnie, Inc., study (1998): “... using the geometric mean to support a secondary MCL is a scientifically justifiable approach”. However, the commentator has not demonstrated why a geometric mean is more scientifically justifiable than the lowest level detected. Although, the studies that investigated MTBE odor and taste present their results in terms of geometric means of the study panel, as well as lowest levels detected, the geometric mean simply indicates that the “average” person would sense MTBE at that level, based on

that study's results in which half the panel reported sensing MTBE in drinking water at that level and half did not.

The Department believes that in setting a drinking water standard, it should strive to meet a higher goal for public welfare protection than only half the population. Clearly, Health & Safety Code § 116275 (d) indicates the application of a secondary MCL to any contaminant in drinking water that "may cause a substantial number of persons served by the public water system to discontinue its use," and directs the Department to a lower level than the geometric mean for sensation of MTBE's odor or taste. Setting the standard at 5 ppb enables the water supply to remain wholesome, and protects a larger proportion of the population from the taste and odor of MTBE. Since only a small change in the proportion of the population can account for many millions of people when applied to California, it is important that such a standard be set as low as is reasonable. The Department would not be acting in the best interests of the public if it were to set a standard that could result in half the population being at risk of smelling MTBE in their drinking water. Neither would such an approach be consistent with the public welfare policy of providing protection for the entire population to the extent that that is feasible.

Commentator 1 suggested that the 7 detections at 2.5 ppb in the Orange County Water District study were likely to have been made by the same tester and that since the tester did not always detect down to this level, this reinforced the Young study statement regarding variation in sensitivity of individuals. Following this line of reasoning, the commentator then concluded that it was inappropriate to base the threshold on a single individual. The commentator has no way of knowing whether all these detections were by the same panelist, because this information was not provided in the study report. Further, a subsequent study (Shen et al., 1997) found detections down to 2.5 ppb and not all by the same tester. Hence, the Department did not base the MCL on a single individual's sensitivity to MTBE in water.

Commentator 1 stated that the Young study does not support a secondary MCL of 5 ppb, because no panelist could detect MTBE at 5 ppb. Commentator 4 stated that the proposed MCL was below the lowest detectable level for a compound in a panel test. Both of these commentators appear to not be aware of the studies in which panelists detected levels less than 5 ppb. Although no panelists in the Young study detected at 5 ppb, the 1997 study by Shen et al. showed MTBE odor detected by individual panelists at levels as low as 2.5 ug/L. The lowest concentrations of MTBE in water at which odor was detected among the 24 test runs in the 1998 Orange County Water District study were: 2.5 ppb (6/24, 25 percent), 5 ppb (4/24, 17 percent), 10 ppb (7/24, 29 percent), 20 ppb (2/24, 8 percent), or 30 ppb (1/24, 4 percent). No concentration lower than 2.5 ppb was tested in either study. Hence, the highest concentration that would not be detected by an individual under conditions of these studies is unknown (but

less than 2.5 ug/L.). Subsequently, the Malcolm Pirnie study results showed 10 of the 57 panelists able to sense MTBE odor down to 2 ppb.

The Department would like to note that under the secondary MCL regulations (22 CCR Section 64449), a water utility may obtain a waiver for the MTBE secondary MCL if it were able to document that the community being served by the water utility “accepted” the odor and/or taste of MTBE in preference to paying to remove it. This would address issues related to local sensitivities, water quality, and economic considerations.

Appropriate Criteria

Several commentators addressed the criteria used to determine an acceptable level for the MCL related to consumer acceptance and objectionable odors. In addition, commentator 3 stated that the Department should establish objective secondary standard setting criteria. Commentator 7 urged the Department to set a standard that protects consumers from objectionable water and stated that reliable threshold data and a determination of an objectionable concentration level are critical in establishing the MCL. Commentator 10 stated that it believed that the studies available support a conservative standard and that it supports the use of good science in rulemaking. The Department agrees with these comments and believes that they have been addressed during the standard setting process, as well as below.

Commentator 1 stated that the Department did not discuss “consumer acceptability” in the documentation, yet stated a goal of ensuring that consumers were not exposed to objectionable taste and odor related to MTBE in their drinking water. The commentator went on to note that common descriptor words used for MTBE in taste and odor tests were “estery,” “vanilla,” “sweet,” “bitter” and “sweet solvent” and, hence, the taste or odor “is likely not objectionable, and would not, therefore, affect consumer acceptability of drinking water.” The Department believes that its “goal” reflects the appropriate public health agency policy position and, therefore, did not discuss whether such tastes or odors would be “acceptable” to the consumer. The commentator implies that because testers selected the words “vanilla” and “sweet” and “sweet solvent” to describe the tastes and odors they were detecting, that they would not object to drinking such waters from their home taps. From the Department’s experience, any indication in a drinking water that a contaminant is present is generally highly objectionable to the consumer, even if reassured that no health risk is posed. In addressing the effect of a contaminant on odor or taste, the Department would not give deference to a pleasant tasting contaminant over one that is less pleasant, nor to a level of a specific contaminant that is pleasant tasting over a level that is not. Furthermore, the public will find objectionable any odor and taste that it has learned to identify with MTBE or any other chemical. In addition, existing regulations allow water systems the option of requesting a waiver from

compliance with a secondary MCL if their costumers accept drinking water exceeding the MCL.

Commentator 2 stated that studies conclude that odors at levels greater than 5 ppb are not objectionable. The commentator does not specify to which studies he refers. It may be that he is referring to the above descriptors used by panelists and has concluded that they would not object to having the test waters coming from their home taps; there are no data to substantiate this conclusion.

Commentator 2 stated that the Department exceeded the scope of Health and Safety Code sections 116275(d) and 116610(d), both of which provide criteria for establishing a secondary MCL for MTBE. The first section mandates that the Department set secondary MCLs to protect public welfare for any contaminant that adversely affects the odor or appearance, causes a substantial number of persons to discontinue use or otherwise adversely affects public welfare.” The second section mandates that the MTBE secondary MCL be set at a level that does not exceed the consumer acceptance level. The Department believes that it has acted consistently with these mandates: Based on the studies available, MTBE does adversely affect the odor (as well as taste) of water, could cause a substantial number of persons to discontinue use, and, by its presence, could adversely affect public welfare. Based on its role as a public health agency, the Department believes that establishing an MCL for MTBE of 5 ppb will ensure that the consumer acceptance level of the large majority of the population is addressed. As previously noted, the MCL can be waived if consumers accept drinking water in excess of the MCL.

Commentator 2 stated that the Department should look for guidance to the ‘counterpart federal scheme, and to the interpretations thereof...” because the California statutes were passed to carry out the federal mandates. Commentator 3 stated that the Department should look to other federal, state and local agency programs. When appropriate, the Department does refer to federal guidance. However, California is not precluded from adopting more stringent standards than those recommended at the federal level. In fact, California has adopted several MCLs that are more stringent than the federal counterpart. In the case of MTBE, the Department believes that an MCL which is more stringent than the federal guidance is necessary to ensure public acceptance and protect against adverse effects to the public welfare

Good Science

Commentators 7 and 10 stated that the Department should use “good science” in establishing the MCL. Commentators 1, 2 and 3 noted that the Department mentioned only two MTBE taste and odor studies; the first commentator listed four others. Commentator 3 stated that the Department did not take into account the Malcolm Pirnie study. Although the Department did not mention the Arco and API studies, it had reviewed the findings of both and gave less weight to them

because the lower levels of sensation detection were established by statistical projection as opposed to the Shen, et al., 1997 study and the Young, et al. study. The Shen and Young studies exposed panelists to lower concentrations of MTBE. The Malcolm Pirnie study was not completed and was not available at the time the regulation package was developed. However, the Malcolm Pirnie study was submitted during the comment period and was reviewed. The Department believes that the Malcolm Pirnie study supports establishing an MCL of 5 ppb.

Commentator 2 stated that the Department has failed to establish a scientific necessity for an MCL that is so restrictive and that “has relied on a single, fatally flawed taste and odor test”, and that it has “cherry-picked” the Young study findings, ignoring those portions that compel a higher standard. This commentator also stated that the Malcolm Pirnie study should be the basis of a 15 ppb standard since its testers consisted of untrained California residents. Commentator 3 noted the lack of documentation of consumer complaints for MTBE in drinking water and that the available taste and odor studies did not use naturally occurring substances common to California groundwater supplies which can mask MTBE. These comments are addressed in the paragraphs below.

Commentator 1 provided a copy of the Malcolm Pirnie study that if funded. A number of commentators (1, 2, 3, 4, and 6) recommended that the Department base the MCL on this study. Commentator 1 made the following statements regarding the study. That it is the only one conducted on consumer panelists with a large statistical population, that study results should be more representative of the general California population than those of other studies, that the results fall within the same range as those from other studies with one exception, that the commentator’s Expert Advisory Panel agreed that this was the best study, and that the study’s geometric mean should be used as the basis for the MCL instead of the lowest level detected. The Department has reviewed the Malcolm Pirnie study, which used a panel of 57 subjects, roughly half male and half female, from 18 to 65 years of age. Panelists were exposed to MTBE at concentrations in water from 2 to 100 ppb

Based on the data from this study (Table 3.2), the lowest concentration detected by individual panelists was 2 ppb MTBE, and this was sensed by 10 of 57 panelists (18 percent). The percentage of panelists indicating they sensed MTBE increased with increasing MTBE concentration, as follows: 6 ppb (18/57, 32 percent), 10 ppb (22/57, 39 percent), 18 ppb (31/57, 54 percent), 30 ppb (38/57, 67 percent), 60 ppb (44/57, 77 percent), and 100 ppb (49/57, 86 percent). The geometric mean of the data was 14.5 ppb.

These data clearly indicate that using the geometric mean as the basis for the MCL would potentially result in a much higher percentage of consumers detecting MTBE than at the proposed MCL of 5 ppb. Therefore, the Department

does not believe that using the geometric mean would ensure consumer acceptance or avoid adversely affecting the public welfare.

Commentator 1 stated that a statistical analysis of the Malcolm Pirnie data by Dr. Richard Berk of UCLA showed that any correct detection below 22 ppb was the result of either guessing or identification by the most sensitive 5% of the population. It is not clear how Dr. Berk drew this conclusion. When it received the report by Malcolm Pirnie in July 1998, the Department requested information on the methods used by the consultant to estimate guessing, since, as Dr. Beck suggested in the Malcolm Pirnie report, the basic method used in the study (ASTM Method E679-91) appears to already account for guessing. No additional information was received by the Department prior to the close of the comment period.

The ASTM approach to guessing would not consider a positive sensation of MTBE to be “positive” if a “negative” occurred at a higher concentration. For example, if a panelist reported MTBE at 2 ppb, but not at 3.5 ppb, and then at 5, 10, and higher concentrations, that panelist’s “threshold” would be 5 ppb, not 2 ppb. Making these adjustments (using the information presented in Table 3.2 of the Malcolm Pirnie report), the number of panelists sensing various levels of MTBE becomes: 2 ppb (10/57, or 18 percent, 3.5 ppb (10+0 [panelists sensing MTBE at this concentration plus those at lower concentrations]=10/57, 18 percent) 6 ppb (10+0+8=18/57, 32 percent) 10 ppb (10+0+8+4=22/57, 39 percent), 18 ppb (10+0+8+4+9=31/57, 54 percent), 30 ppb (10+0+8+4+9+7=38/57, 67 percent), 60 ppb (10+0+8+4+9+7+6=44/57, 77 percent), and 100 ppb (10+0+8+4+9+7+6+5=49/57, 86 percent).

The Malcolm Pirnie study treated 8 of the 57 panelists as not having identified MTBE as being present at even 100 ppb, and assigned them a value of 132.3 as an individual threshold. However, these eight panelists also indicated MTBE as being present in one or more tests lower than 100 ppb. Specifically, the eight panelists gave a positive response in the following number of tests (out of eight different MTBE concentrations): 3, 2, 4, 5, 3, 1, 3, and 3. Two of the eight identified MTBE at 2 ppb, and the rest at higher concentrations, though all were assigned the 132.3-value.

In summary, the study by Malcolm Pirnie found a geometric mean of 14.5 ppb for MTBE odor sensation, while a significant fraction of the 57-member panel indicated that MTBE could be sensed at levels as low as 2 ppb. These results were not inconsistent with other studies reviewed and, therefore, they suggest that even if some of the other studies had limitations, their results were within a reasonable range and definitely not inapplicable to California waters and consumers. Hence, the Department has concluded that the Malcolm Pirnie study further supports the proposed MCL of 5 ppb.

Clearly, the primary point of difference between the commentators and the Department relates to whether the standard should be set to protect half the population or a larger portion of the population. As stated above under “Appropriate Level”, the Department, as a public health agency, must act to protect the greatest portion of the consumer population as is feasible, and therefore, the Department believes establishing the secondary MCL at 5 ppb is appropriate.

Commentator 1 stated that USEPA “urged water utilities” in 1989 to use the 3 TON standard as a criteria for odor in finished drinking water, i.e., a concentration of odorant 3 times greater than the maximum level of no perception, but the Department has used a 1 TON standard which is “needlessly conservative”. The commentator also stated that the Department is establishing a dangerous precedent of setting chemical-specific standards based on criteria that is not accepted by any scientific body; both ASTM and Standard Methods specify a taste and odor result that is greater than the lowest perceived concentration detectable by a single panel member; and the Department should use a rigorous scientific method. The context for the statement attributed to USEPA is not provided, so the Department is unable to adequately address this comment. The commentator’s comment regarding establishing a dangerous precedent implies that ASTM and Standard Methods provide criteria for setting a secondary standard, which they do not. These methods simply address procedures for determining odor threshold in water samples. For example, the TON is conducted by water treatment operators who have developed expertise by repetitively conducting the same test on the same water to identify a known sensation.

When it began the process of establishing a secondary MCL, the Department initially considered the study by Young et al., 1996, to be the most appropriate for establishing a concentration at which no odor would be detected. The 1997 study by Shen et al., suggested that MTBE could be sensed at lower levels, less than 2.5 ppb, but the Department felt that given the attention focused on MTBE and problems of local ground water contamination, there might have been some unintentional bias that entered into the California study, compared to the British study that investigated MTBE along with many other substances. In addition, the Department also felt that intralaboratory contamination issues should be addressed; within that context, a secondary standard lower than 2 ppb would be too restrictive. The Department believed that an MCL of 2 ppb would bring with it a potential for false positives and a need for drinking water systems to investigate contamination where there might be none.

However, with the additional studies by Dale et al., (1997), Shen et al., (1998), and Malcolm Pirnie the Department recognizes that certain individuals, and in some cases a fairly high proportion of them, are able to sense MTBE at levels as low as 2 ppb.

Consequently, based on a need to protect the public welfare, to protect against the odor and taste of MTBE, and to assure that a substantial number of persons served by the public water system would not discontinue their use of drinking water from public water systems, and considering the totality of information from MTBE odor and taste studies, the Department believes that it could justify a level of MTBE lower than the proposed 5 ppb. Commentator 4 claimed he could design studies to include sensitive people able to detect very low levels of MTBE and wanted to know how the Department would proceed if it had such data. In this case, the Department did consider revising the proposed secondary MCL downward to 1 ppb, based on the more recent studies, in order to protect a larger portion of the population than would be protected by 5 ppb. However, the Department decided not to do so, because the lower level would raise the potential for false positives and consequently unnecessary investigations of contaminant sources. Hence, more data at lower levels does not necessarily lead to a lower standard since there are other considerations; however, given the Department's policy related to protecting the largest percentage of the population as is feasible, the additional studies providing data at low levels further substantiates the need to set the MCL no higher than 5 ppb.

Cost

Commentator 3 stated that the Department did not consider the cost to public water systems to upgrade their facilities in order to comply with the proposed secondary MCL. At the time that the regulation package was developed, there were no active drinking water sources that would have been out of compliance with the proposed standard. Since the costs of a regulation are generally developed within the context of known parameters, not hypothetical, the Department did not address this issue. Further, based on data collected to date and the actions taken by the few utilities with MTBE-contaminated sources, the Department does not anticipate that many drinking water sources will actually require treatment.

Commentator 3 stated that the Department did not address whether the proposed MCL would impose a mandate of a local agency to provide a new or increased level of service and that it should have done so since improved water quality could constitute an increased level of service. The Department did address this issue in the "Local Mandate Determination" and determined that any costs that might result would not be due to a "new program or higher level of service" within the meaning of Article XIII B, Section 1k6 of the California Constitution because they apply generally to all individuals and entities that operate public water systems in California and do not impose unique requirements on local governments.

Commentator 3 stated that the Department ignored costs associated with anticipated widespread application of the proposed MCL as a default cleanup level by regional and local water agencies. The Commentator further stated that

the Department was required to determine the cost to private businesses to remediate MTBE impacted sites and attached a cost analysis comparing the cost increase at leaking underground storage tank remediation sites at the proposed 5 ppb MCL and the Malcolm Pirnie recommended MCL of 15 ppb. Commentator 6 stated that the Department failed to address the impact on wastewater or reclaimed water sources. Since the proposed MCL regulation is directly applicable to only public drinking water systems, the Department is not required to address any other costs than those resulting from that application. Furthermore, to do so is speculative and becomes more so as the effect ripples out from the regulated community. There would be no end to such an analysis.

Commentator 3 stated that the Department did not determine the fiscal impact on California businesses, then added that the Department concluded that no jobs would be eliminated. The Department refers the commentator to the “Fiscal Impact” statement in which it addressed the fiscal impact on the businesses directly impacted by the regulation (i.e., private drinking water systems) and the “Business Impact” statement in the proposed regulation package. The conclusion that no jobs would be eliminated is accurate in terms of those to which this regulation directly applies. As noted above, the Department is only required to estimate the fiscal impact to those businesses to which the regulation directly applies.

Commentator 3 did not agree with the Department that this regulation would not result in the creation or elimination of water systems. The Department’s experience with previously adopted MCL regulations is that water systems are not eliminated as a result, but rather, approaches to compliance are worked out since the community needing the water supply continues to exist.

Commentator 3 stated that the waiver procedures for secondary standards would have no practical application if the economic impact considerations were limited to incremental monitoring costs. The commentator apparently does not understand that the waiver considerations address only the cost of treatment, not monitoring costs.

Commentator 3 stated that the Department provided no guidance on determining what level of incremental cost is appropriate to meet the secondary MTBE MCL. The Department assumes that the commentator is suggesting that the Department should have “appropriate level of cost” criteria for compliance with a secondary MCL such as the criteria that EPA has developed for primary MCL treatment costs to consider the impact on smaller water systems. The Department does not feel that such an analysis is necessary since existing regulations allow for waivers to secondary MCLS. One of the factors considered by the customers in determining whether to have the water system seek a waiver is the cost to meet the secondary standard.

Commentator 3 stated that the Department did not analyze any alternatives to the proposed standard, nor analyze the economic impact of potential alternatives. As noted above, the Department approached the standard-setting process from a public welfare perspective related to the provision of a water supply that is pure, wholesome and potable. Analysis of available data indicated that the appropriate standard to meet that objective was 5 ppb. The Department did consider other alternative levels but determined that no other alternative level would feasibly meet that public welfare objective.

Commentator 3 stated that the Department's "implicit goal of protecting 100% of the population is inconsistent with statutory requirements, unnecessarily conservative and unreasonable from an economic impact perspective." The Department goal is to achieve protection for the greatest portion of the population that is feasible. The Department believes that the proposed MCL achieves that goal. The commentator's concern related to economic impact is primarily associated with the potential impact on dischargers if the MCL is utilized as criteria by the Regional Boards and other agencies. The Department's responsibility is to ensure that drinking water quality is protected, not try to anticipate if, how, when, or where the drinking water standards may be applied beyond the public drinking water systems that are addressed in the regulation.

Commentator 5 stated that a stringent standard would have serious economic consequences for small California recreational marine dealers, far exceeding the fiscal impacts noted in the regulation package. The Department is aware that secondary and tertiary impacts may occur although these impacts are not addressed in the analysis since marine dealers are not directly affected by this regulation, i.e., the regulation does not contain any requirements with which the marine dealers must comply.

Commentator 8 stated that the Department did not address the cost of ETBE, perchlorate, and TAME analyses in the business impact section. The Department definitely addressed this cost in the business impact section; specifically mentioning anticipated percentages of systems expected to monitor, the monitoring cost, etc.

Commentator 8 stated that the fiscal impact section's overall governmental estimates appear to be low, but provided no specific comments. The Department followed normal procedures for developing these costs which are basically a function of the number of water systems operating under government agencies. As far as the Department knows, the cost estimates represent a reasonable estimate.

Miscellaneous Comments

Commentator 1 noted that the Department stated that the Young study methods and reported findings indicate that at the next lower concentration, estimated at 5

and 12.5 ppb for odor and taste, no MTBE was detected by the assessors; the commentator believes that the second level should be 15, based on the dilutions. The Department agrees that this could be possible, but it is not possible to conclude that based on the data available.

Commentator 1 noted that the Department incorrectly stated that Orange County Water District found geometric means of 13.5 to 43.5 ppb and that the second mean was actually 45.4 ppb. The Department agrees.

Commentator 9 asked the Department to specify detection limits for purposes of reporting (DLRs) for MTBE, TAME, ETBE, and perchlorate. The Department has incorporated DLRs for these chemicals in its laboratory data reporting process. However, the Department does not put DLRs in regulation until a primary MCL is adopted. It is anticipated that a DLR of 3 ppb will be proposed when the primary MCL for MTBE is proposed.

Commentator 9 asked the Department for dates to initiate or complete MTBE, TAME, ETBE, and perchlorate monitoring. MTBE monitoring should be coordinated with other secondary MCL monitoring done by a system. TAME, ETBE and perchlorate are required only for vulnerable sources; monitoring for TAME and ETBE can be coordinated with any other volatile organic chemical monitoring being conducted by the system, while perchlorate requires a unique method and, if required to monitor, a system should move to do so as directed by the Department. Guidance on these matters will be provided.

Commentator 9 suggested that if MTBE is detected, repeat monitoring should be required to track MTBE migration and requested repeat monitoring guidance. Secondary MCL monitoring does not include repeat monitoring because it is a non-health issue. A water system may conduct this type of monitoring if it wishes.

Commentator 11 expressed support for the proposed MCL of 5 ppb and monitoring for TAME, ETBE, and perchlorate.

Commentator 6 recommended that the Department create a policy for reclaimed water dischargers for compliance or exempt reclaimed water from the secondary drinking water provisions unless direct potable reuse is planned. The Department reminds the commentator that this regulation does not require compliance from reclaimed water dischargers.

Commentator 6 stated that the Department needs to address reclaimed water issues related to the proposed MCL, as well as revisit older MCLs. Since this regulation applies directly to only public drinking water systems, addressing reclaimed water issues within this context would not be appropriate. However, when the Department proposes regulations for reclaimed water, under separate

statutory authority, the commentator should make a point of bringing up these issues.

Commentator 8 stated that he supports the use of grandfathered data; the Department appreciates this information.

Commentator 8 is not clear whether one year of quarterly samples per site is required every five years or one year of quarterly samples per site initially and then only one sample per site every five years thereafter (reference section 64450.1). Initial and repeat monitoring at five-year intervals follow the same sampling scenario in terms of number of samples. The Department believes that the regulation text is clear on this point.

Commentator 5 requested that the Department hold a public hearing to provide an opportunity for further comment. Unfortunately, this request was not received until the close of the comment period on September 8, 1998. In order to have been considered, pursuant to Government Code 11346.8, the request would have had to have been received by the Office of Regulations no later than 15 days prior to the close of the comment period. This deadline was noted in the notice for this regulation package.

Commentators 2 and 5 recommended that the Department utilize the USEPA nationwide drinking water advisory recommending a limit value range of 20 to 40 ppb. In 1997, USEPA published this consumer acceptance advisory, "...recognizing that some people may detect the chemical below this range." The Department believes that the concentration of MTBE at the EPA advisory level is too high to protect customers from the undesirable odor and taste effects of MTBE in drinking water, particularly in view of the 1998 studies by Shen et al, and Malcolm Pirnie, Inc., cited above.

Commentator 4 stated that the Department "opens itself to concerns that can be raised due to bias" since the Young study used to derive the MCL had an all-female panel. Except for this commentator, no one has made any reference to the all-female panel. The Young study was a scientific study using a panel of trained testers who happened to be all-female. The Department is not aware of any information that indicates females are more or less sensitive to MTBE than males. Therefore, the Department does not believe that there is any issue here.

Commentator 3 recommended that the Department give flexibility to water utilities by establishing a range of concentrations as a function of geographic and other circumstances that may affect water quality rather than a fixed standard. The Department does not believe that such an approach would be appropriate for a chemical contaminant affecting the odor of a drinking water supply. The commentator suggested that an appropriate concentration within the range could be selected depending on the specific circumstances of the water supply, but did not elaborate as to what those might be or how such a standard could be

implemented. As noted previously, existing regulations provide for flexibility by allowing waivers from secondary MCLS based on consumer acceptance and cost of compliance.

Commentator 3 recommended that the Department subject the proposed secondary MCL to a formal peer review process prior to adoption. The Department has found that the public comment period for proposed regulations for both primary and secondary MCLs is quite adequate as a review process.

Commentator 3 stated that the Department should establish implementation guidelines for drinking water well treatment and site remediation and preferably include them in the regulations. When the Department proposes a primary MCL for MTBE, it will also propose a best available technology (BAT); at this time, air stripping is the only technology that meets the statutory criteria for BAT in California. The Department is responsible for drinking water treatment, not site remediation; hence, it would be inappropriate to address site remediation in regulations promulgated by the Department.