Maine Center for Disease Control and Prevention
Maximum Exposure Guidelines for Drinking Water

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CONTENTS

1.0 Overview

The Maine Center for Disease Control and Prevention (MECDC) Environmental and Occupational Health Program (EOHP) develops Maximum Exposure Guidelines (MEGs) to assist risk managers, homeowners and others in making decisions regarding the suitability for human consumption of drinking water contaminated by chemicals.

MEGs are not promulgated by rule making and therefore are not issued as legally enforceable drinking water "standards." Rather, MEGs represent the MECDC's most recent recommendations for concentrations of chemical contaminants in drinking water below which there is minimal risk of a deleterious health effect resulting from long-term ingestion of contaminated water.

The MEGs are intended to be solely health-based guidelines, and do not take into account analytical methods, treatment technology, or economic impacts. This is in contrast to the legally enforceable drinking water standards called Maximum Contaminant Levels (MCLs). MCLs are promulgated under the Safe Drinking Water Act for the purpose of regulating public drinking water supplies, and allow for consideration of the technical and economic feasibility of attaining a standard. Most MCLs are promulgated as national standards by the U.S. Environmental Protection Agency (USEPA).[1] MEGs tend to have closer agreement with USEPA Lifetime Health Advisories (HA) for chemical contaminants in drinking water, as these guidelines are primarily health based.

The first list of MEGs was issued in 1984 as one of several criteria to be used by the Department of Human Services to determine eligibility for the waving of laboratory fees incurred with the testing of private residential water supplies for potentially hazardous contaminants.[2] The MECDC periodically updates the MEGs, revising existing MEGs based on new toxicological data and adding MEGs for additional compounds.

The MEGs have been derived following standard risk assessment practices and in general accordance with USEPA guidelines on development of drinking water health advisories and standards (USEPA, 1990). This methodology is summarized below. MEGs are posted on the website for the MECDC's EOHP (http://www.maine.gov/dhhs/eohp/wells/index.htm). The February 4, 2011 MEG list is intended to replace all previously released MEG lists.

2.0 Procedures for Deriving Maximum Exposure Guidelines

The MECDC generally uses a risk-based approach for developing MEGs. The risk assessment methods used are in general accordance with procedures described by USEPA (1990). MEGs are set to be protective of both carcinogenic effects and noncarcinogenic effects. The calculation of different MEGs for noncarcinogenic and carcinogenic effects is intended to provide the MECDC with the necessary information for recommending an MEG for a given chemical that is

[1] The MCL for MTBE of 35 µg/L is an example of a MCL derived by the State of Maine.
[2] Rules Relating to Testing of Private Water Systems for Potentially Hazardous Contaminants, 10-144A CMR 233

protective of both cancer and noncancer effects. In general, when two MEGs are calculated for a given chemical using the methods described in Section 2.1 for noncarcinogenic effects and Section 2.2 for carcinogenic effects, the lower of the two values is selected as the basis for the MEG and is considered protective of both cancer and noncancer effects.

2.1 Derivation of Maximum Exposure Guidelines for Noncarcinogenic Effects

MEGs based on noncarcinogenic toxicological effects are set at a level believed to represent a minimal risk of a deleterious effect from lifetime exposure even for sensitive subpopulations. It is assumed that noncarcinogenic effects have a threshold response (i.e., there is a dose below which toxic effects will not occur). An attempt is made to set MEGs such that total exposure will result in a daily dose below the threshold. This is believed to be accomplished through use of a *reference dose* and an allowance for *relative source contribution* of less than 100 percent.

The *reference dose* (**RfD**) is defined by the USEPA as an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure level (mg/kg-day) for the human population, including sensitive subpopulations, that is likely to be without an appreciable risk of deleterious effects during a lifetime. The RfD is most often derived from studies of laboratory animals by application of one or more uncertainty factors for extrapolating from animal bioassay data to humans. Uncertainty factors may be applied in performing one or more of the following extrapolations: a) from a lowest-observable-adverse-effect level (LOAEL) to a no-observable-adverse-effect-level (NOAEL)[3]; b) from an acute or subchronic exposure to chronic exposure[4]; c) from responses in laboratory animals to responses expected for the average human; d) from responses for the average human to possible sensitive sub-populations; and e) for limitations in the database. These uncertainty factors typically range from 3 to 10 and are combined multiplicatively. In this way, it is not unusual for RfDs to be set 100 to 1000-times lower than the daily dose found not to cause any observable adverse effect in an animal bioassay. The value of the RfD is chemical-specific. The lower the value of the RfD, the more toxic the substance.

The *relative source contribution* (**RSC**) is the fraction of the chemical intake allowed to come from a drinking water source. Following EPA (1990) guidance, in the absence of data to estimate exposure to the chemical from other water-related routes of exposure or other sources (e.g., food), the default relative source contribution is 20%. That is, the MEG is set to allow only 20 percent of the RfD to result from ingestion of up to 2 liters of contaminated water per day. When sufficient data are available to assess the contribution of other sources of exposure, a chemical-specific RSC may be derived.[5] In accordance with EPA (1990) guidance, 80 percent is the ceiling for the RSC.[6]

Two key inputs to deriving MEGs are *water consumption rate* and *body weight*. The water consumption rate (**WCR**) is the assumed total amount of tapwater consumed daily by an

[3] Applied when the key toxicological study does not determine a NOAEL, only a LOAEL.
[4] Applied when the key toxicological study is not of chronic duration (e.g., a lifetime rodent study), but rather something shorter.
[5] MTBE, a gasoline additive, is an example of a chemical where MECDC performed microenvironmental modeling that indicated the need for a RSC of 10%.
[6] See also: Federal Register / Vol. 58, No. 20 / Wednesday, January 30, 1991 / Rules and Regulations / p. 3535.

individual. For adults (male and female), the WCR is assumed to be 2 liters per day (EPA, 1997). A 2 liter per day water intake rate is believed to represent the upper 84th percentile of intake rates among the adult population (USEPA, 1997). The estimated body weight (**BW**) of the exposed individual is required in the MEG calculation since the RfD is expressed on a "per kilogram body weight" basis. The average BW for adult males and females combined is assumed to be 70 kilograms (kg). This value is slightly less than the mean general population BW estimated at 71.8 kg for adults 18-74 years old (USEPA, 1997). For adult females, the average BW is assumed to be 60 kg. This is the mean BW for adult women 18-25 years old (USEPA, 1997). The 70-kg adult general population BW is used for all MEG calculations except for chemicals in which the RfD is based on reproductive or development effects. The 60-kg adult female BW is used for calculating MEGs for reproductive and developmental toxicants. The latest version of the Exposure Factors Handbook (USEPA, 1997) recommends 2.35 liters per day for total tapwater ingestion by adults as a reasonable upper limit (90th percentile value) and a general population BW of 71.8 kg (USEPA, 1997). Use of these values would result in about a 13% reduction in noncarcinogenic MEGs calculated using a WCR of 2 liters per day and BW of 70 kg. A similar reduction is expected for carcinogens, though here it is necessary to also check for effects on carcinogenic potency that may have been derived using a body weight of 70 kg. While a BW of 71.8 kg and WCR of 2.35 liters per day are reasonable upper limits recommended in the USEPA Exposure Factors Handbook, a BW of 70 kg and a WCR of 2 liters per day remain standard values used in risk assessments conducted in Maine and by USEPA. Therefore, to maintain consistency with Maine's risk assessment methodology and USEPA approaches, these values (2 liters per day and 70 kg) will continue to be used in the MEG calculations.

MEGs for noncarcinogenic effects are calculated algebraically as follows:

$$MEG = \frac{RfD \times BW}{WCR} \times RSC \qquad (eq.1)$$

RfDs were selected based on the toxicity hierarchy described in the "Guidance for Human Health Risk Assessments for Hazardous Substances Site in Maine" (July 2009). Possible sources of RfDs, listed in the order in which they are discussed in the hierarchy, include the *IRIS* (Integrated Risk Information System) database, California's Office of Environmental Health Hazard Assessment (CA-OEHHA) Toxicity Criteria database, ATSDR's (Agency for Toxic Substances and Disease Registry) Minimal Risk Levels, USEPA Provisional Peer-Reviewed Toxicity Values (PPRTVs) available through the Risk Assessment Information System (RAIS) database, USEPA's Health Effects Assessment Summary Tables (HEAST), and the International Toxicity Estimates for Risk (ITER) database which contains toxicity information from international sources (e.g., Health Canada). USEPA's Office of Pesticide Programs (OPP) also maintains a database for RfDs and other toxicological data for pesticides. An OPP RfD was used if an RfD was not available from any of the above-referenced source. RfDs developed by the Massachusetts Department of Environmental Protection for the petroleum hydrocarbon fractions (i.e,. C5-C8 aliphatics, C9-C12 aliphatics, C9-C18 aliphatics, C19-C36 aliphatics, C9-C10 aromatics and C11-C22 aromatics). Absent toxicological data from any of the above-listed

sources, the MECDC derives RfDs directly from the primary toxicity data following standard risk assessment methods.

In deriving the February 4, 2011 MEGs, the MECDC has relied upon the information presented in the online databases as of May 1, 2010, and the most current version of hard copy information for HEAST (1997).

2.2 Derivation of Maximum Exposure Guidelines for Carcinogenic Effects

For chemicals classified by USEPA as *known* (also called group "A") or *probable* (group "B") human carcinogens, MEGs are derived from a quantitative estimate of the chemical's carcinogenic potency (called the *cancer slope factor*) and are set at a *incremental lifetime cancer risk* of 1 additional cancer per 100,000 population exposed.

The cancer slope factor (**CSF**) is derived by the USEPA, usually but not always, as the 95th percent upper confidence limit of the low-dose linear slope of the dose response curve and is expressed in units of $(mg/kg\text{-}day)^{-1}$. The CSF is most often derived from studies of laboratory animals, traditionally by application of dose-response models that assume no threshold for carcinogenic effects (i.e., any dose, no matter how small, will result in some risk) and allow for linearity in response at low dose. The value of the CSF is chemical-specific. The greater the value of the CSF, the greater the carcinogenic potency of the substance.

The incremental lifetime cancer risk (**ILCR**) is the allowable level of increased lifetime cancer risk over background rates of cancer risk. Under the assumption of a non-threshold mode of action for carcinogens, there is some increased cancer risk with any amount of exposure. Historically, federal and state standards and guidelines to limit exposure to chemical carcinogens present in environmental media and food have tended to be set at ILCR levels ranging from one in ten thousand (1×10^{-4}) to one in one million (1×10^{-6}). The ILCR associated with those chemicals for which there are federal MCLs for regulated drinking water supplies range from two in a thousand (2×10^{-3}) to less than one in a million (1×10^{-6}). As a general policy, the MECDC has used an ILCR of one in a hundred thousand (1×10^{-5}) as a reference in the derivation of action levels.[7] MEGs derived by MECDC that are based on carcinogenic effects are established at an ILCR level of one in a hundred thousand (1×10^{-5}). Note that to obtain a MEG at either an ILCR level of one in ten thousand (1×10^{-4}) or one in a million (1×10^{-6}), simply multiply or divide, respectively, the current MEGs by 10.

The algebraic equation for deriving MEGs based on carcinogen effects is:

$$MEG = \frac{\frac{ILCR}{CSF} \times BW}{WCR} \qquad (eq.\,2)$$

[7] Policy for Identifying and Assessing the Health Risks of Toxic Substances, Maine Department of Human Services, Bureau of Health, February 1988; see page 5.3.

As discussed above in Section 2.1, the default values for *water consumption rate* (WCR) and *body weight* (BW) are 2 liters per day and 70 kilograms, respectively.

USEPA (1990) guidance on developing drinking water regulations and health advisories sets out a different approach for chemicals classified as *possible* (group "C") human carcinogens. For these chemicals, USEPA derives health-based drinking water limits following the approach described above for noncarcinogenic effects, but dividing by an additional uncertainty factor (**UF**) ranging from 1 to 10 to account for potential carcinogenicity.

$$MEG = \frac{RfD \times BW}{WCR \times UF} \times RSC \qquad (eq.\ 3)$$

The MECDC departs somewhat from this policy. If a cancer slope factor is available for a chemical classified as a *possible* (Group C) human carcinogen, the MECDC will use it in equation (2) to derive a MEG for carcinogenic effects. This MEG based on carcinogenic effects will then be compared to the MEG for noncarcinogenic effects calculated using equation (1) (i.e., without the added 10-fold uncertainty factor for a possible carcinogen). The lower of the two values will be used as the basis for the listed MEG. If a cancer slope factor is only available from the HEAST or OPP databases and the resulting MEG based on carcinogenic effects is substantially lower than the MEG calculated using equation (3), MECDC will consider on a case-by-case basis using the MEG for carcinogenic effects as the listed MEG. If a cancer slope factor available from HEAST or OPP results in a MEG for carcinogenic effects substantially greater than the MEG based on equation (3), MECDC will consider on a case-by-case basis using an UF of less than 10. Otherwise, and in the absence of a CSF, MECDC will use equation (3) applying an UF of 10 in deriving MEGs for *possible* human carcinogens.

The toxicity hierarchy described for the selection of RfDs has also been used to select cancer slope factors. In deriving the February 4, 2011 MEGs, the MECDC has relied upon the information presented in the online databases as of May 1, 2010, and the most current version of hard copy information for HEAST (1997).

3.0 Departures from Standard Methods

For some chemicals, it becomes necessary or otherwise appropriate to depart from the standard methods described above. In the February 4, 2011 revisions, departures from standard methods fall into two general categories: a) chemicals with 1992 MEGs, but for which toxicity data from available databases are no longer (or were never) available; and b) special cases.

3.1 Chemicals with 1992 MEGs but lacking toxicity data

The MECDC has derived MEGs since 1984. For some of these previously issued MEGs, toxicity data are no longer (or never were) available from available databases. In some cases,

these MEGs were based on USEPA HAs for chemicals that have since had either an RfD of CSF withdrawn from IRIS. Rather than drop these chemicals from the MEG list, MECDC will continue to list the compounds either: 1) defaulting to a USEPA HA or USEPA Drinking Water Exposure Limit (DWEL) adjusted by the RSC term, or 2) defaulting to a Bureau of Health 1992 MEG in absence of either a USEPA HA or DWEL. The following chemicals fall under this grouping of departures from the standard methods:

Ammonia	Bromochloromethane
Chloramine	Chloromethane
Chlorate	p-Nitrophenol
Chromium (total)	Resorcinol
Iodide	1,3,5-Trichlorobenzene
Nitrate	Trinitroglycerol
Nitrite	2,4,6-Trinitrophenol
Sodium	TRIS

It is the intent of the MECDC to eventually conduct reviews of each of these chemicals. Work will be prioritized according to the frequency with which the chemical is encountered as a contaminant in Maine drinking water.

3.2 Special Cases

Special cases include two groups of chemicals: a) those for which new MEGs had to be derived in the absence of available toxicity data and consequently toxicity data were derived from either other sources or from the primary literature by MECDC toxicologists; and b) chemicals for which MECDC believes departures from standard methods are otherwise appropriate. All special case MEGs have a technical report describing their derivation. These technical reports can be obtained by contacting the MECDC EOHP. The following chemicals fall under this grouping of departures from the standard methods:

Arsenic	Methyl tert-Butyl Ether
4-Isopropyltoluene	Radon
Lead	Tetrahydrofuran
Manganese	

4.0 Designation of Status of MEGs and Future Updates

MEGs were previously designated as either *Final* or *Interim*. A chemical was designated as *Final* if toxicity data are obtained from IRIS or otherwise derived by the MECDC and subject to scientific peer review and comment.[8] Otherwise, chemicals were listed as *Interim* MEGs. The purpose of these designations was to communicate the MECDC's confidence in the toxicity data used in deriving the MEG. As part of this update, the *Final* and *Interim* designations have been

[8] MTBE is an example of a chemical with a MEG (and State MCL) derived by the MECDC that received outside scientific review and public comment.

removed. Instead, a "Basis" column has been added to identify the source of the toxicity value used to calculate each MEG (e.g., IRIS, CA-OEHHA, ATSDR, etc.). This change provides information that can be used to judge the confidence in toxicity data used to derive the MEG.

Special attention is called to those chemicals where either RfDs or CSFs have been obtained from the USEPA HEAST (1997) database. A review of these chemicals for HEAST updates from the USEPA Superfund Program Office is planned. Individuals evaluating data on the presence of any of the chemicals listed below may wish to contact the MECDC about recent HEAST updates. Chemicals based on toxicity data from the HEAST (1997) database are:

Diallate	Methyl isobutyl ketone	Terbufos
Cyanazine	4-Methylphenol	1,2,3-Trichloropropane
N,N-Dimethylformamide	Parathion	Vinyl acetate
n-Hexane	Phorate	Vanadium

It is the MECDC's intent that MEGs will be updated at least biennially. In between biennial updates, MEGs may be added at any time for chemicals without current MEGs. These chemicals will be designated as new values on the website of the MECDC's EOHP. During the biennial reviews, all chemicals will be checked for updates on toxicity databases.

5.0 References

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