HUMAN HEALTH-BASED WATER QUALITY CRITERIA AND STANDARDS WATER QUALITY CONTROL COMMISSION POLICY 96-2

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Water Quality Control Commission Policy Statement

regarding

Human Health-Based Water Quality Criteria and Standards

I. <u>Introduction</u>

This policy addresses the Water Quality Control Commission's methodology and rationale for establishing human health-based water quality criteria and standards for Colorado surface and ground waters. Colorado's current human health-based water quality criteria and standards have evolved through a series of rulemaking actions that have occurred since the Commission was established. The Commission believes that it is appropriate to adopt this policy statement due to the importance of these criteria and standards to the citizens of Colorado. This policy is intended as a general informational guide of the Commission's established approach to the adoption of these criteria and standards.

The contents of this document have no regulatory effect, but rather describe the cumulative result of regulatory actions historically taken by the Commission. Moreover, this policy is not intended and should not be interpreted to limit any options that may be considered, or adopted, by the Commission in future rulemaking proceedings. Therefore, this policy statement can, and will, be modified over time as warranted by future rulemaking proceedings.

This policy addresses chronic human health criteria and standards for manmade organic chemicals and toxic metals in both surface and ground waters. This policy does not address human health criteria and standards for other parameters (e.g. microbial pathogens, nitrate and nitrite), or those associated with household drinking water that is supplied by a public water system.

II. Background

The Commission's Basic Standards and Methodologies for Surface Water, Regulation #31 (5 CCR 1002-31), and Basic Standards for Ground Water, Regulation #41 (5 CCR 1002-41)--which embody the framework for Colorado's water quality classification and standards system--contain both (1) water quality criteria (more commonly referred to as "table values") and (2) statewide water quality standards. **Table values** are criteria that have been determined by the Commission to be generally protective of identified beneficial uses of water (such as drinking water). The table values in these two regulations are not enforceable standards, but rather are used by the Commission as a guide in setting appropriate site-specific water quality standards. In contrast, **water quality standards**--either statewide or site-specificare legally enforceable limits on ambient surface or ground water quality.

In the first version of the Basic Standards and Methodologies for Surface Water, adopted in 1979, the Commission established sets of table values to protect a "domestic water supply" beneficial use in order to protect human health from potential contaminants in streams used as a drinking water source. Table values were established for metals, other inorganic pollutants, and for a limited list of man-made organic chemicals (mainly pesticides). These table values were based on the EPA criteria documents and/or the federal drinking water standards available at that time. No statewide numerical human health-based standards were adopted in 1979, except for a limited suite of radioactive constituents. Since then, metals and other inorganic pollutants have continued to be addressed by the establishment of table value criteria in the Basic Standards regulations, which are then considered in adopting site-specific water quality standards. However, the approach to the establishment of standards for organic chemicals has evolved substantially over time.

In the early 1980's, the organic chemical table values included in the Basic Standards regulation were adopted as basin-wide standards in several individual river basin standard-setting hearings. In a 1984 revision of the Basic Standards and Methodologies for Surface Waters, these table values were adopted

as water quality standards applicable to all surface waters of the State. The Statement of Basis and Purpose (31.18) for adopting these statewide organic chemical standards states:

"The organic parameters in the table are not substances that form a naturally occurring background. They are toxic [sic] controlled at the point of sale or use. They are not ambient and subject to the same treatment as are other naturally occurring parameters. The Commission found it inappropriate to regulate these organic constituents in the same manner as are those that can be ambient or uncontrollable background parameters."

1. 1989 Hearing

In 1989, the Commission adopted the first major revisions to these organic chemical standards. A substantially expanded list of organic chemicals, for both surface water and ground water were adopted as statewide standards. Water quality standards to protect human health from drinking water contaminants were adopted, for both carcinogens (Table A) and non-carcinogens (Table B), as Domestic Water Supply standards in both of the Basic Standards Regulations. A carcinogen is a chemical with the ability to produce a cancer in animals or humans; a non-carcinogen is a chemical that produces other recognized adverse health effects. The Statement of Basis and Purpose for this rulemaking, 31.22, states:

"These standards are being adopted in part in response to new requirements in the 1987 amendments to the federal Clean Water Act (CWA) to adopt water quality standards for toxic pollutants, 'the discharge or presence of which in the affected waters could reasonably be expected to interfere with' classified beneficial uses. CWA, section 303(c)(2)(B). Although toxic organic pollutants generally are not a major problem in Colorado surface waters at present, the Commission believes that the best policy option is to adopt numerical standards now, to help assure that these pollutants do not become a problem."

2. 1991 Hearing

In 1991, these organic chemical standards were revised and consolidated into one table. In addition to the water supply standards, a new set of "Water+Fish" standards were adopted to protect human health from the combined exposures from drinking water and ingesting fish. These Water+Fish standards for the first time addressed the issue of bioaccumulation of pollutants in fish. The Commission also modified its approach to the use of maximum contaminant levels (MCLs) established under the federal Safe Drinking Water Act in setting domestic water supply standards during this hearing.

In the 1991 rulemaking hearing, the Commission made a policy decision that all statewide standards for domestic water supply would presumptively be based solely on health-based values, with MCLs only being used when information was not available to calculate the health-based standard. This decision is addressed in the Statement of Basis and Purpose, 31.26, as follows:

"The vast majority of the standards adopted in 1989 were already set equal to health-based criteria. MCLs generally are more lenient than health-based criteria, and have been developed taking into account laboratory detection limits and the economic ability of water suppliers to treat for removal of these constituents. For most dischargers, the availability of low flow dilution credits in calculating effluent limitations has resulted in a second level of relaxation--i.e. movement away from underlying health-based-levels--when applying non-health-based MCL standards. The Commission already has attempted to temper the application of stringent health-based standards for non-MCL organic pollutants by providing for the application of the practical quantitation limit (PQL) concept in determining compliance with the standards. Use of low flow dilution credits in calculating effluent limitations provides for a further tempering of these very stringent standards in application. Therefore, the Commission has determined that it is a more appropriate policy to base these water quality standards on health-based criteria, rather than MCLs."

3. 2000 Hearing

In 2000, the organic chemical standards were revised in light of new information about these compounds and newly published federal 304(a) criteria. In addition, a new set of "Fish Ingestion" criteria were adopted to protect human health from the exposure due to consuming fish. These Fish Ingestion standards are applied to all segments with class 1 aquatic life use designation which do not also have a water supply designation, and for class 2 aquatic life segments on a case-by-case basis. The application of "Water+Fish" criteria was modified so that they are applied only where both aquatic life class 1 (or 2 on a case-by-case basis) and water supply uses are designated.

4. 2004 Hearing

In the 2004 hearing, the Water+Fish and Fish Ingestion standards were again updated to account for new information published by the US Dept of Agriculture, and adopted by US EPA, that increased the national average per capita fish consumption from 6.5 to 17.5 grams-per-day. Comprehensive Colorado specific fish consumption rates were unavailable, so the Commission elected to use this national average fish consumption rate until such data was available. During this hearing the Commission also decided to modify the manner in which standards for certain Group C compounds are derived. For Group C compounds that have both carcinogenic (cancer slope) and toxic (reference dose) data the Commission decided, in accordance with their past practice, to base the standards for these compounds on the reference dose approach, but to adjust the resulting standard with an uncertainty factor of 10 to account for any unknown carcinogenic effects. The Commission also decided that for these compounds, in order to remain consistent with the reference dose approach, relative source contributions (RSC) should be included, when available, in the derivation of the associated standard.

Since the 1989 hearing, there has been debate about whether standards for compounds with MCLs should be based on the MCLs or purely health-based numbers (MCLGs). For surface water this debate centered on whether it is reasonable to require in-stream standards, and potentially wastewater treatment, to a level cleaner than allowed for drinking water. For groundwater the arguments for MCLs focused on whether it is reasonable to require ground water remediation to a level below that required for drinking water. The arguments for health-based standards focused on maximizing human-health protection, putting the clean-up burden on pollution sources, and protection of State waters as a resource. At the 2004 hearing, the Commission adopted a hybrid Maximum Contaminant Level Goal / Maximum Contaminant Level (MCLG/MCL) standard that provides much of the benefits advocated for each of these options. This hybrid MCLG/MCL standard utilizes the MCL for effluent limits and historical groundwater contamination, but the MCLG as an in-stream standard and for control of groundwater contamination occurring in the future.

5. 2005 Hearing

During the June of 2005 Basic Standards Hearing the Commission elected to utilize the methodology developed in EPA Region 6 to derive the associated W+F and FI standards for arsenic. The Region 6 methodology included two differences that the Commission believed more appropriately represented conditions found in Colorado. First, Region 6 excluded salt-water species from the derivation of bioconcentration factor for arsenic. Secondly, since arsenic in fish tissue occurs in both the inorganic as well as less toxic organic forms, the resulting standards were adjusted to account for these different forms. The inorganic/Organic Fraction ("I/O Frac") consideration was added to equation 2-2 and 3-2. This process resulted in standards less stringent than the national criteria yet are scientifically sound and appropriately reflect Colorado's unique water quality conditions.

In the 1989 hearing, the Commission decided that, as a matter of policy, the acceptable risk to human health should be 1x10⁻⁶. Since that time, the Commission has reaffirmed this policy decision at multiple standard setting hearings. At the recent rulemaking hearing regarding 1,4-dioxane the acceptable level of risk was thoroughly discussed and the Commission again decided that 10⁻⁶ represents an appropriate level of risk.

III. Policy

For those pollutants identified as priority toxic pollutants under Section 307(a) of the federal Clean Water Act, or any other pollutants that may present a risk to human health, it is the policy of the Commission to establish water quality criteria and standards for both surface and ground water that provide a reasonable certainty of protecting the public from adverse risks to their health. This policy is implemented through adoption of statewide water quality standards for manmade organic chemicals and table value criteria for naturally occurring toxic pollutants. Water quality standards for naturally occurring toxic pollutants are established on a site-specific basis. The statewide standards and table value criteria apply to waters of the state to protect human health for domestic water supply (drinking water only), Water+Fish (drinking water and consuming fish), and Fish Ingestion only exposure pathways.^a

All human health-based statewide water quality standards and most of the table value criteria are based on lifetime exposure, and are intended to protect against chronic exposures to the pollutants in question. The lifetime exposure standards for both carcinogens and non-carcinogens are applied as "chronic standards" in Colorado's surface water quality standards system, with compliance assessed based on an average of all samples collected in a 30-day period.

- 1. Statewide Standards and Table Value Criteria for Domestic Water Supply
 - a. For non-carcinogens, the table value criteria and statewide standards for domestic water supply (which consider exposure solely through the drinking water pathway) are based upon published toxicological data. In the absence of any published toxicological data, the National Primary Drinking Water Regulations' maximum contaminant level goals (MCLGs) are used as the corresponding standard. A MCLG is defined by EPA under the federal Safe Drinking Water Act as the concentration of a contaminant in water at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety. MCLGs are calculated by the following equation that is specified in the National Primary Drinking Water Regulations (40 CFR Part 141):

Equation 1-1: DWS/MCLG,
$$\mu$$
g/I = $\frac{\text{RfD} \times 70 \times 1000 \ \mu\text{g/mg} \times \text{RSC}}{2 \times \text{UF}}$

where:

RfD^b = verified reference dose for non-carcinogens,

mg/kg-day

70 = weight of an average adult, kg

The statewide domestic water supply standards apply to all ground waters and to surface waters for which a "water supply" use classification has been adopted. The appropriate Water+Fish and fish ingestion standards apply to all Class 1 aquatic life segments which also have a water supply classification or Class 2 aquatic life segments which also have a water supply classification designated by the Commission after rulemaking hearing. These Class 2 segments will generally be those where fish of a catchable size and which are normally consumed are present, and where there is evidence that fishing takes place on a recurring basis. The Commission may also consider additional evidence that may be relevant to a determination whether the conditions applicable to a particular segment are similar enough to the assumptions underlying the Water+Fish ingestion criteria to warrant the adoption of Water+Fish ingestion standards for the segment in question.

RfD is an estimate of the daily exposure to humans, including sensitive subpopulations, which are likely to be without an appreciable risk of deleterious effect during a lifetime; derived from the "no observed adverse effect level" or "lowest observed adverse effect level."

2 = daily drinking water consumption, liters/day
RSC° = relative source contribution (0.2 is default value)
UF = Uncertainty Factor (1.0 for most chemicals, 10 for certain Group C chemicals)

b. For carcinogens^d, a 10⁻⁶ incremental lifetime cancer risk level^e is used in calculating table value criteria and statewide standards for domestic water supply. The concentration corresponding to a 10⁻⁶ cancer risk from drinking water, as contained in the Integrated Risk Information System (IRIS) and/or EPA health advisories, is used as the basis for the table value criteria and statewide standards. The Commission has opted not to adopt table value criteria and statewide standards for carcinogens that, due to EPA policy, have been assigned a MCLG equal to zero, and for these compounds the standard is set to the MCL.

Equation 1-2: DWS/MCLG,
$$\mu$$
g/I = ILCR x 70 x 1000 μ g/mg 2 x q1*

where:

ILCR^e = incremental lifetime cancer risk factor
70 = weight of an average adult, kg
2 = daily drinking water consumption, liters/day
q1*^f = cancer slope factor

A 10⁻⁶ incremental lifetime cancer risk factor is used in the derivation of the table value or statewide basic standard.

c. In addition to the procedures described in subsections a. and b. above, domestic water supply statewide standards or table value criteria may be based on maximum contaminant levels (MCLs)⁹ established in the National Primary Drinking Water Regulations or less restrictive risk levels in two circumstances: (1) where information necessary to calculate a standard based solely on health protection is unavailable or (2) where information is provided which shows that the chemical is pervasive statewide and

RSC is the percentage of the total daily exposure to the contaminant contributed by drinking water. A value other than the default value may be used when relevant information is available.

d Carcinogens are considered to be those pollutants classified by EPA as Group A, known human carcinogens, or Group B, probable human carcinogens. The Commission has not adopted carcinogenicity-based criteria and standards for pollutants classified as Group C, possible human carcinogens, due to the inadequacy of the available data for this category of pollutants.

^e Incremental lifetime cancer risk (ILCR) means the increased probability of cancer occurring beyond that experienced by an individual or population not exposed to the water in question; i.e., increased risk beyond background incidence.

The cancer slope factor is an estimate of carcinogenic potency derived from animal studies or epidemiological data of human exposure. It is based on extrapolating high-dose levels over short periods of time to low-dose levels and a lifetime exposure period through the use of a linear model.

^g An MCL is defined by EPA as the maximum permissible level of a contaminant in water, which is delivered to any user of a public water system. An MCL is established as close to the MCLG as is feasible with the use of the best technology, treatment techniques, and other means that EPA finds are available, taking into account field efficacy and costs.

that costs associated with treatment required to meet concentrations based solely on the protection of public health outweigh the incremental improvements to the health of the general population. In no case, however, are domestic water supply statewide standards or table value criteria adopted by the Commission less stringent than the current MCL.

d. In cases where the DWS/MCLG standard derived using either equation 1-1 or 1-2 is less (more restrictive) than the Federally promulgated MCL, then a range in standards is adopted as the hybrid MCLG/MCL approach. The intent of this hybrid MCLG/MCL range is so that future control requirements for the associated chemical are implemented to attain a level of ambient water quality that is equal to or better than the MCLG, while the MCL is applicable to effluent limits and historical groundwater contamination.

For illustrative purposes, a flowchart representing the procedure that the Commission has historically used for determining the applicable domestic water supply standards and table values is presented in Figure 1.

2. Statewide Standards and Table Value Criteria for Water+Fish (Drinking Water and Consuming Fish)

Statewide standards and table value criteria for Water+Fish are developed in accordance with procedures specified by EPA criteria guidance promulgated under Section 304(a) of the federal Clean Water Act.

a. For non-carcinogens,

Equation 2-1: W+F,
$$\mu$$
g/I =
$$\frac{\text{RfD x 70 x 1000 } \mu\text{g/mg x RSC}}{(2 + (\text{DFC x BCF})) \text{ x UF}}$$

where:

RfD verified reference dose for non-carcinogens

70 weight of an adult, kg =

daily drinking water consumption, liters/day 2 =

DFC daily fish consumption, kg/day

(0.0175 is the default value)

BCF^h bioconcentration factor, liters/kg

RSC relative source contribution

UF Uncertainty Factor (1.0 for most chemicals, 10

for certain Group C chemicals)

b. For carcinogens,

> Equation 2-2: W+F, μg/I ILCR x 70 x 1000 μg/mg

 $q1*[2 + (DFC \times BCF \times I/O Frac)]$

where:

ILCR incremental lifetime cancer risk factor

DFC = daily fish consumption, kg/day

(0.0175 is the default value)

cancer slope factor, kg-day/mg q1*

BCF is the ratio of a substance's concentration in tissue versus its concentration in water, in situations where the food chain is not exposed or contaminated.

BCF = bioconcentration factor, liters/kg

I/O Frac = Fraction that is inorganic. For use where only

the inorganic fraction is of concern. For arsenic I/O Frac = 0.30, other substances, I/O Frac = 1.0.

A 10⁻⁶ incremental lifetime cancer risk factor is used in the derivation of the table value or statewide basic standard.

- c. When a calculated Water+Fish table value or statewide standard for a compound is greater (i.e. less stringent) than the analogous domestic water supply value from Section 1, the Water+Fish table value or statewide standard is set equal to the domestic water supply table value or statewide standard for the parameter, as there is no reason that the additional exposure to potentially contaminated fish should lessen the level of protection provided for the drinking water use alone.
- d. Where an established table value to protect aquatic life from long-term (chronic) exposure to a pollutant is more stringent than the calculated Water+Fish table value criteria or statewide standard to protect human health, no Water+Fish table value criteria or statewide standard will be adopted. Because the Water+Fish table values or standards apply only where fish are present, in all such cases human health will be protected by the more restrictive table values or standards established to protect the aquatic life use.

For illustrative purposes, a flowchart representing the procedure that the Commission has historically used for determining the applicable Water+Fish standards and table values is presented in Figure 2.

3. Statewide Standards and Table Value Criteria for Fish Ingestion (Eating Fish)

Statewide standards and table value criteria for Fish Ingestion are developed in accordance with procedures specified by EPA criteria guidance promulgated under Section 304(a) of the Clean Water Act.

a. For non-carcinogens,

Equation 3-1: FI,
$$\mu$$
g/I = $\frac{\text{RfD x 70 x 1000 } \mu$ g/mg x RSC (DFC x BCF) x UF

where:

RfD = verified reference dose for non-carcinogens

70 = weight of an adult, kg

DFC = daily fish consumption, kg/day

(0.0175 is the default value)

BCF = bioconcentration factor, liters/kg

RSC = relative source contribution

UF = Uncertainty Factor (1.0 for most chemicals, 10

for certain Group C chemicals)

b. For carcinogens,

Equation 3-2: FI, μ g/I = $\frac{\text{ILCR x 70 x 1000 } \mu$ g/mg}{q1*[DFC x BCF x I/O Frac]}

where:

ILCR = incremental lifetime cancer risk factor DFC = daily fish consumption, kg/day

(0.0175 is the default value)

q1* = cancer slope factor, kg-day/mg BCF = bioconcentration factor, liters/kg

I/O Frac = Fraction that is inorganic. For use where only

the inorganic fraction is of concern. For arsenic I/O Frac = 0.30, other substances, I/O Frac = 1.0.

A 10⁻⁶ incremental lifetime cancer risk factor is used in the derivation of the table value or statewide basic standard.

c. Where an established table value to protect aquatic life from long-term (chronic) exposure to a pollutant is more stringent than the calculated Fish Ingestion table value criteria or statewide standard to protect human health, no Fish Ingestion table value criteria or statewide standard will be adopted. Because the Fish Ingestion table values or standards apply only where fish are present, in all such cases human health will be protected by the more restrictive table values or standards established to protect the aquatic life use.

4. Site-Specific Standards

- a. Naturally occurring toxics. Site-specific surface or ground water quality standards will be based on the table value criteria unless the 85th percentile of ambient water data for a pollutant exceeds the table value, or site-specific information (e.g., economic impacts of compliance, site-specific risk analysis) warrants the adoption of different standards in accordance with section 31.7(1)(b)(ii) of the Basic Standards and Methodologies for Surface Water and 41.4(A) of the Basic Standards for Ground Water.
- Non-naturally occurring toxics. Site-specific surface or ground water quality standards for non-naturally occurring toxics will be the statewide standard unless site-specific information (e.g., economic impacts of compliance, site-specific risk analysisⁱ) demonstrates that different standards are warranted.

IV. Rationale

Overall, the Commission has chosen to apply a conservative and protective approach to the establishment of statewide water quality standards and table value criteria, to assure adequate protection of human health in Colorado. If, in particular circumstances, it can be demonstrated that less stringent water quality standards result in adequate protection of human health, potentially with the associated benefit of reduced economic impacts on the regulated community, those circumstances can, and should, be addressed in site-specific standard-setting hearings. The current Basic Standards regulations provide for this option. For example, section 31.11(4) of the Basic Standards and Methodologies for Surface Water clarifies the Commission's ability to adopt site-specific standards to apply in lieu of the statewide basic standards for organic chemicals where appropriate. In addition, section 31.7 delineates the procedures for deviating from table values by setting ambient quality-based or other site-specific standards. Similar provisions are contained in section 41.4 of the Basic Standards for Ground Water.

Site-specific standards may be more stringent or less stringent than statewide standards where warranted by evidence brought forth in a rulemaking hearing. Note that a less stringent site-specific standard may not imply a lesser degree of risk protection where it is based on a detailed, site-specific risk assessment, supported by defensible scientific data and field observations, that results in refined exposure assumptions.

Two major issues have been discussed and debated at length as the Commission's approach to adopting human health-based water quality criteria and standards has evolved over the years. First, there has been considerable discussion about the appropriate risk level to utilize in establishing criteria and standards for carcinogens. As indicated above, the Commission has chosen to use a 10⁻⁶ incremental cancer risk level. This decision was first made in a 1989 rulemaking hearing. In the Statement of Basis and Purpose for that hearing, 31.25, the Commission states:

"Recognizing that there is no scientifically 'correct' risk level, the Commission has selected this level as a matter of policy, because it believes this is an appropriately conservative and protective level for human health risks."

The second major issue that has received considerable attention is whether to base statewide standards and table value criteria on (1) solely health-based values such as MCLGs and a conservative and protective risk level for carcinogens, or (2) MCLs that have been established under the federal Safe Drinking Water Act for the regulation of public water supplies. In the 1989 rulemaking hearing, the Commission based statewide standards for organic chemicals on MCLs whenever they were available. For pollutants for which MCLs were not available, standards were based on the 10⁻⁶ risk level for carcinogens and on EPA drinking water health advisories or reference dose information from IRIS for non-carcinogens. This adoption of MCLs was modified in the 1991 rulemaking hearing when the Commission made a policy decision that all statewide standards for domestic water supply uses would presumptively be based solely on health-based criteria. In 2004 the Commission again considered the MCL issue and adopted the hybrid MCLG/MCL approach that incorporates both of these concepts.

In several cases, the associated statewide human-health standards for some organic chemicals have been established below the limit at which current analytical laboratory methodologies can detect the compound. In these cases, the Practical Quantitation Limit (PQL) is used as the default standard for regulating specific activities. Appropriate PQLs for those compounds that have standards below the current limit achievable by analytical laboratories are set forth in a Water Quality Control Division PQL guidance document, or determined on a case-by-case basis.