

Once EPA decides to regulate a contaminant, how does the Agency develop a regulation?

(excerpted from: <https://www.epa.gov/dwregdev/how-epa-regulates-drinking-water-contaminants#develop>)

After reviewing health effects data, EPA sets a maximum contaminant level goal (MCLG). The MCLG is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety.

MCLGs are non-enforceable public health goals. MCLGs consider only public health and not the limits of detection and treatment technology effectiveness. Therefore, they sometimes are set at levels which water systems cannot meet because of technological limitations.

When determining an MCLG, EPA considers the adverse health risk to sensitive subpopulations:

- Infants
- Children
- The elderly
- Those with compromised immune systems and chronic diseases

The way EPA determines MCLGs depends on the type of contaminant targeted for regulation:

For **microbial contaminants** that may present public health risk, EPA sets the MCLG at zero. This is because ingesting one protozoan, virus, or bacterium may cause adverse health effects.

For **chemical contaminants that are carcinogens**, EPA sets the MCLG at zero if both of these are the case:

- there is evidence that a chemical may cause cancer
- there is no dose below which the chemical is considered safe.

If a chemical is carcinogenic and a safe dose can be determined, EPA sets the MCLG at a level above zero that is safe.

For **chemical contaminants that are non-carcinogens but that can cause adverse non-cancer health effects** (for example, reproductive effects), the MCLG is based on the reference dose. A **reference dose (RfD)** is an estimate of the amount of a chemical that a person can be exposed to on a daily basis that is not anticipated to cause adverse health effects over a lifetime.

- To determine the RfD, the concentration for the non-carcinogenic effects from an epidemiology or toxicology study is divided by uncertainty factors (for example, for sensitive subpopulations). This provides a margin of safety for consumers of drinking water.
- The RfD is multiplied by body weight and divided by daily water consumption to provide a Drinking Water Equivalent Level (DWEL).
- The DWEL is multiplied by the relative source contribution. The relative source contribution is the percentage of total drinking water exposure for the general population, after considering other exposure routes (for example, food, inhalation).

Once the MCLG is determined, EPA sets an enforceable standard. In most cases, the standard is a maximum contaminant level (MCL). The MCL is the maximum level allowed of a contaminant in water which is delivered to any user of a public water system.

When there is no reliable method that is economically and technically feasible to measure a contaminant at concentrations to indicate there is not a public health concern, EPA sets a "treatment technique" rather than an MCL. A treatment technique is an enforceable procedure or level of technological performance which public water systems must follow to ensure control of a contaminant.

Treatment technique rules also list:

- The best available technology for meeting the standard
- Compliance technologies available and affordable for small systems

Examples of treatment technique rules are the:

- Surface Water Treatment Rule (disinfection and filtration)

- Lead and Copper Rule (optimized corrosion control)
- Acrylamide and Epichlorohydrin Rules (purity of treatment chemicals)

The MCL is set as close to the MCLG as feasible. Taking cost into consideration, EPA must determine the feasible MCL or treatment technique. This is defined by the SDWA as the level that may be achieved with:

- use of the best available technology or treatment approaches
- other means which EPA finds are available (after examination for efficiency under field conditions, not solely under laboratory conditions)

As a part of the rule analysis, the SDWA also requires EPA to prepare a health risk reduction and cost analysis (HRRCA) in support of any NPDWR. EPA must analyze the quantifiable and non-quantifiable benefits that are likely to occur as the result of compliance with the proposed standard. EPA must also analyze certain increased costs that will result from the proposed drinking water standard.

In addition, EPA must consider:

- Incremental costs and benefits associated with the proposed and alternative MCL values
- The contaminant's adverse health effects on the general population and sensitive subpopulations
- Any increased health risk to the general population that may occur as a result of the new MCL
- Other relevant factors such as data quality and the nature of the risks

Where the benefits of a new MCL do not justify the costs, EPA may adjust the MCL for a particular class or group of systems to a level that "maximizes health risk reduction benefits at a cost that is justified by the benefits."