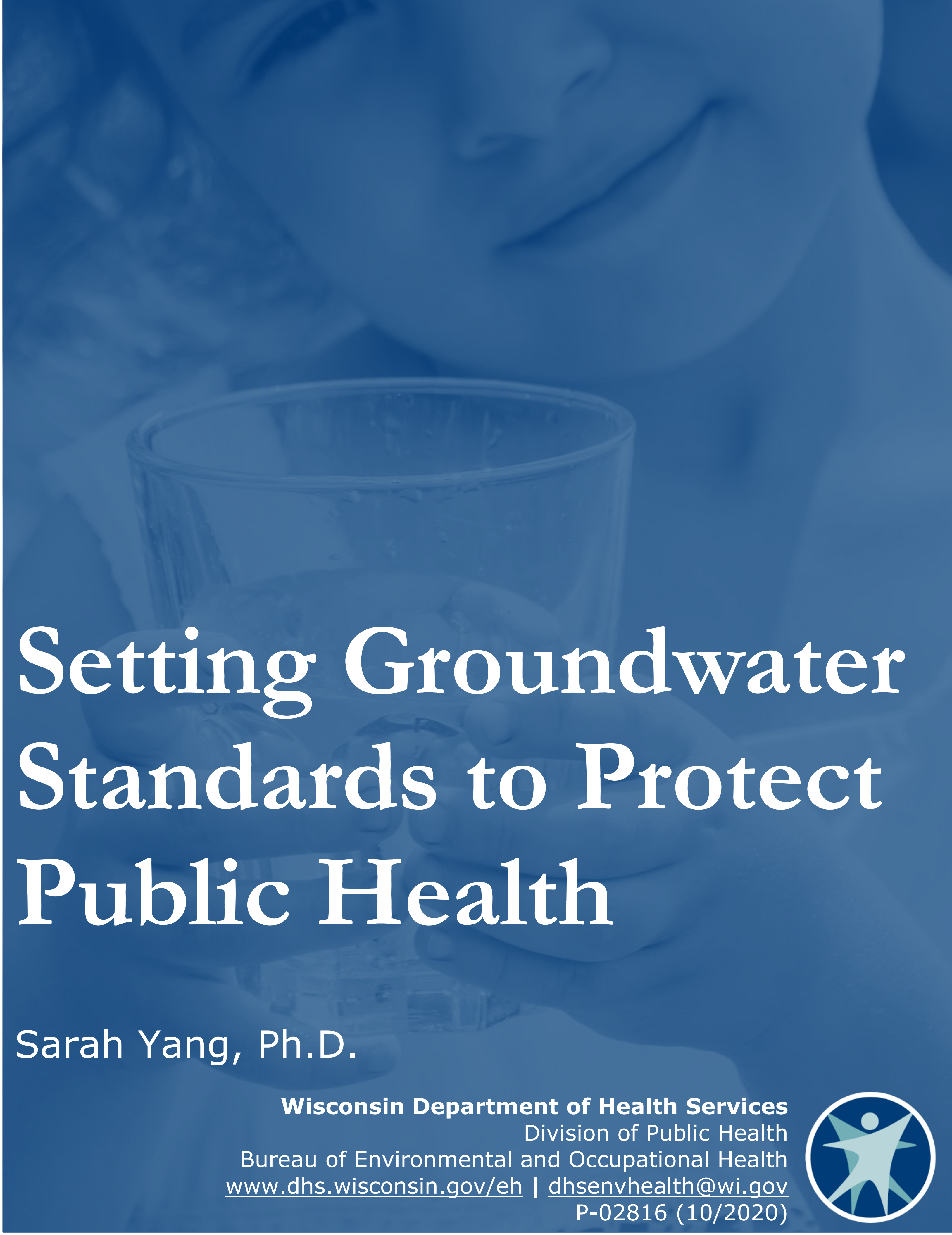

# Setting Groundwater Standards to Protect Public Health

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# Contents

**Groundwater standards protect public health.** ................................ **3**
Wisconsin's Groundwater Standards Process ........................................ 3
**DHS reviews the available scientific information.** ............................ **5**
Federal numbers ........................................................................ 5
State Drinking Water Standard ........................................................ 5
Acceptable Daily Intake ................................................................ 6
Technical Information .................................................................. 6
**DHS identifies the appropriate standard.** ........................................ **9**
Enforcement Standard .................................................................. 9
Preventive Action Limit ................................................................ 12
**Once the review is complete, DHS documents and shares the findings.** ...... **13**
Scientific Support Documents ......................................................... 13
Sharing Findings ........................................................................ 13
**References** ............................................................................ **14**
**Additional Information** ............................................................... **16**
Glossary .................................................................................. 16
Types of Federal Numbers ............................................................. 18
Dose-response analyses ............................................................... 22
Uncertainty Factor Selection Process ............................................... 24
Enforcement Standard Selection Process ........................................... 26

# Groundwater standards protect public health.

More than two-thirds of people in Wisconsin use groundwater as their drinking water source. Groundwater standards protect the quality of this water by limiting the amount of contaminants that can be discharged to Wisconsin's groundwater.[1]

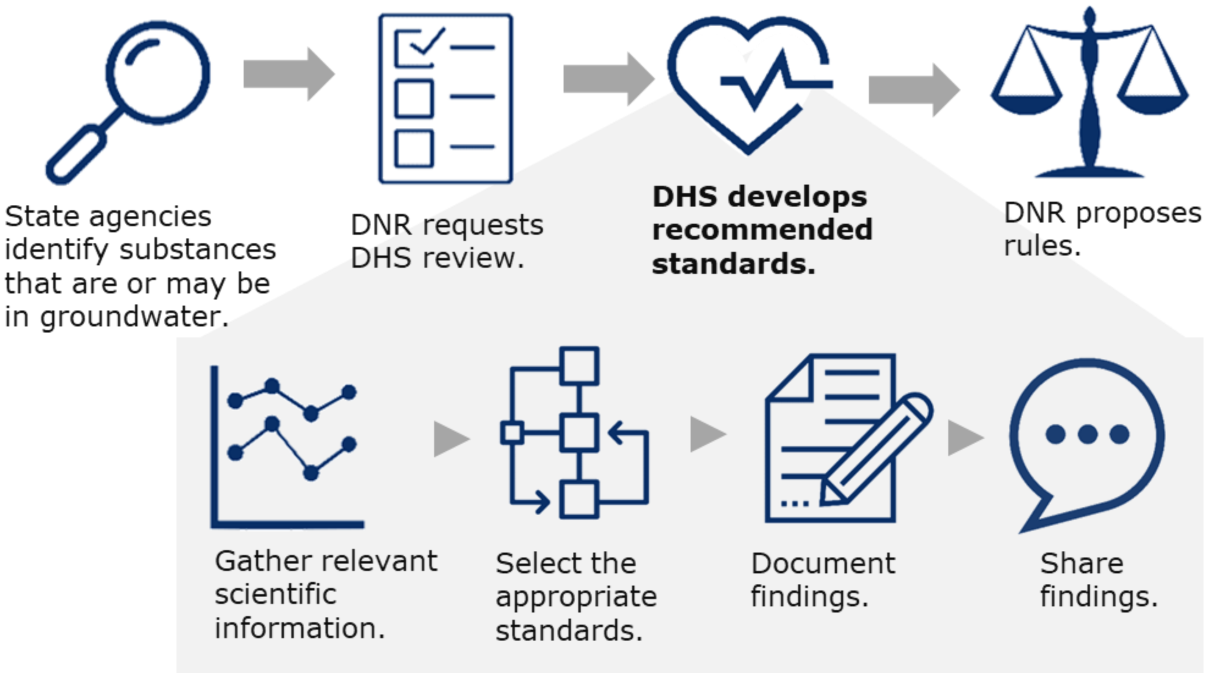
- **Public health standards** protect groundwater from substances that increase the risk of illness, disease, or death; pose a hazard to human health; or increase the risk or severity of a long-term disease.
- **Public welfare standards** protect groundwater from substances that influence the color, taste, or smell of the water; impact plant or animal life; or influence the use of the water for other purposes.

Groundwater standards consist of an enforcement standard and a preventive action limit.

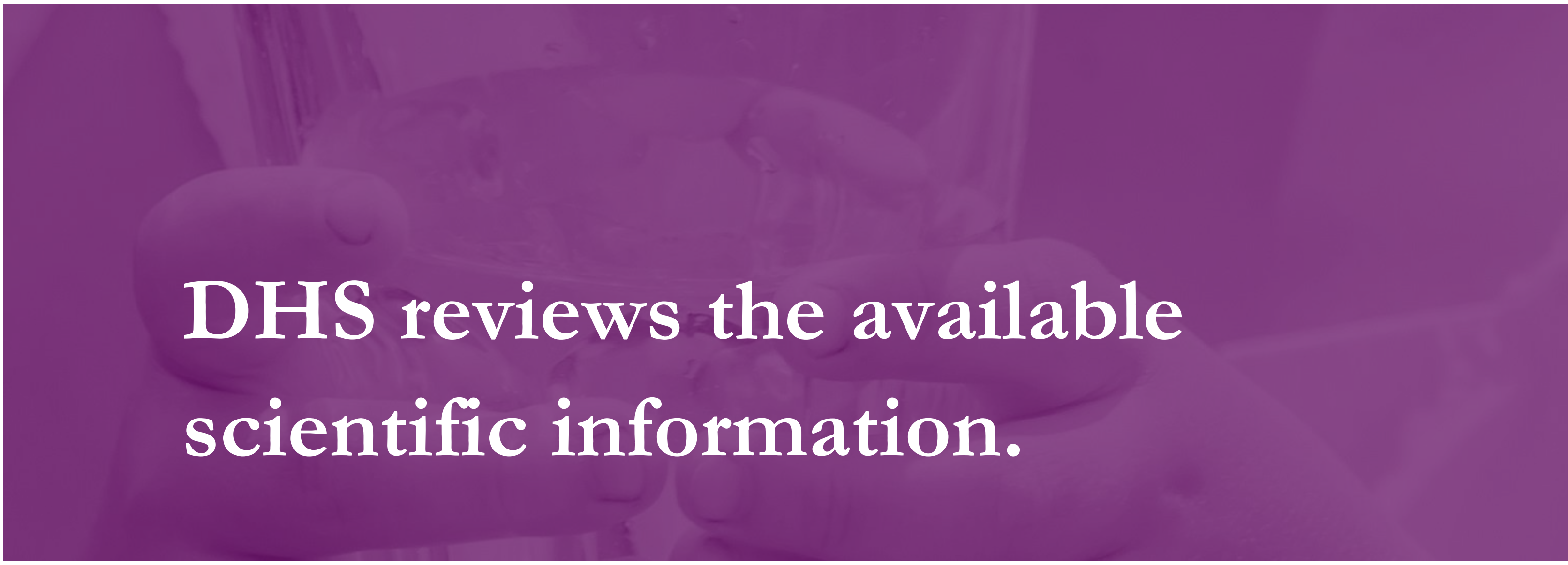
- The **enforcement standard** is the level used to establish limits for discharge to groundwater.
- The **preventive action limit** is used to trigger actions to prevent additional contamination.

## Wisconsin's Groundwater Standards Process

The process for developing groundwater standards is specified in state statute. This process includes identification of groundwater contaminants, establishment of enforcement standards and preventive action limits, and rule-making.[2]




While the Wisconsin Department of Natural Resources (DNR) is responsible for implementing the majority of the steps in the groundwater standards process, the Wisconsin Department of Health Services (DHS) is responsible for developing recommended standards for substances of public health concern. DHS follows a three-step process in which we collect the available scientific information about the substance, select the appropriate standard, and develop a scientific support document describing the findings of our review and basis for the recommendation.



# DHS reviews the available scientific information.

Wis. Stat. ch. 160 specifies the type of information that can be used to establish public health groundwater standards. This includes federal numbers, state drinking water standards, and acceptable daily intake values from the United States Environmental Protection Agency (EPA) or research studies.

## Federal numbers

Federal numbers are concentrations of a substance in drinking water below which adverse health effects are not expected or for which cancer risk is considered acceptable. Examples of federal numbers include:

- Maximum contaminant level,
- Action level,
- Health advisory, and
- Drinking water concentration at a specified cancer risk level.

The *Additional Information* section has more details on each of these values.

## State Drinking Water Standard

Wis. stat. ch. 160 requires that DHS use a state drinking water standard if there are no federal numbers and a state drinking water standard is available. State drinking water standards are established by the DNR as maximum contaminant levels in Wis. Admin. Code ch. NR 809. Typically, state drinking water standards are based on MCLs established by EPA.

# Acceptable Daily Intake

Wis. Stat. ch. 160 defines acceptable daily intake as the dose of a substance which, if ingested daily over an entire human lifetime, appears to be without appreciable risk on the basis of all known facts at the time it is established. The EPA provides these values, termed oral reference doses, as part of a health advisory, human health risk assessment for pesticides, or assessment by the EPA IRIS program.

EPA defines an **oral reference dose** as an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

EPA calculates oral reference doses from a toxicity value taking into consideration the uncertainty in the available data. The *Acceptable Daily Intake* calculation section has more details on how these values are determined.

# Technical Information

Wis. stat. ch. 160 allows DHS to recommend a value other than a federal number or acceptable daily intake from the EPA if there is significant technical information that was not considered when the value was established and indicates a different value is more appropriate. To ensure the recommended groundwater standards are based on the most appropriate scientific information, we search for relevant health-based guidance values from national and international agencies and for relevant data from the scientific literature.

## Guidance values

DHS conducts a search for guidance values established by national and international agencies. Some example values include oral minimum risk levels from the Agency for Toxic Substances and Disease Registry (ATSDR), drinking water guidance values from the World Health Organization (WHO), and acceptable daily intakes from WHO and the Joint Meeting on Pesticide Residues.

## Literature search

DHS conducts a literature search for recent peer-reviewed publications related to the substance's toxicity or effects on a disease state using scientific databases (like PubMed and Clarivate Web of Science). We first identify key studies for additional review. Key studies are those that use *in vivo* (live animal) models; describe and document the study design, methods, study population, data, and results; and use appropriate analytical and statistical methods to test a hypothesis.

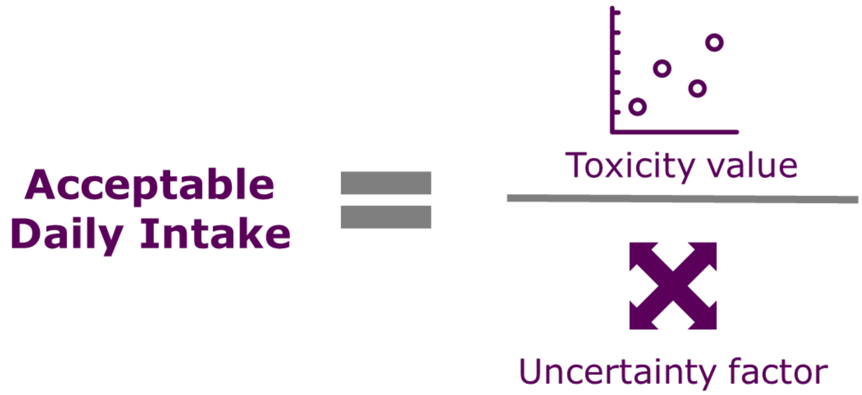
## Critical study identification

Next, we determine if any of these key studies can be classified as a critical study and used to establish a candidate acceptable daily intake. To be considered a critical toxicity study, the study should provide data for multiple doses over an exposure duration proportional to the lifetime of humans; demonstrate results that are biologically-plausible in humans and consistent with or confirmatory of other studies; and have an identifiable toxicity value. The *Additional Information* section has more details on how toxicity values are identified.

## Acceptable daily intake calculation

Wis. stat. ch. 160 states that DHS can calculate an acceptable daily intake by dividing the substance's no observable effect level (NOEL) by a suitable uncertainty factor. However, NOEL values are rarely reported or distinguishable due to current testing and reporting procedures. Furthermore, advances in scientific technology allow us to view effects at the protein and gene scale. However, the direct link of these effects to human health impacts are often unclear. As such, these effects are typically not considered adverse and generally not used as the basis for health-based values from EPA and other national and international health agencies.

Benchmark dose modeling is considered the state of the science for establishing health-based values like an acceptable daily intake.[11-13] Benchmark dose modeling takes into account all of the data for a particular effect from a particular experiment, allows for increased consistency, and can better account for statistical uncertainties. As such, DHS uses this value when available and appropriate. If appropriate, DHS will also use a no observable adverse effect level (NOAEL) or a lowest observable adverse effect level (LOAEL) with an uncertainty factor to account for this limitation in the data.




- The **toxicity value** is obtained from available dose response information and can be the no observed adverse effect level (NOAEL), lowest observed adverse effect level (LOAEL), or benchmark dose (BMD).
- The **uncertainty factor** is used to account for scientific uncertainty that is inherent in the type of data used to establish human health standard.

When selecting uncertainty factors, DHS considers a number of factors including variations between research animals and people, variations among people, the dose-response relationship, potential effects of repeated exposure, and the quality and quantity of data.[2] The *Additional Information* section contains a full list of the factors considered when selecting uncertainty factors and the process that DHS follows to identify values.

To ensure appropriate human health protection, we do not use studies that have significant scientific uncertainty (total uncertainty factor > 3000) as the basis for the recommended enforcement standards. This approach is consistent with that taken by EPA when they establish an oral reference dose.[14]

# DHS identifies the appropriate standard.

If data are available, DHS recommends a public health enforcement standard and preventive action limit.

## Enforcement Standard

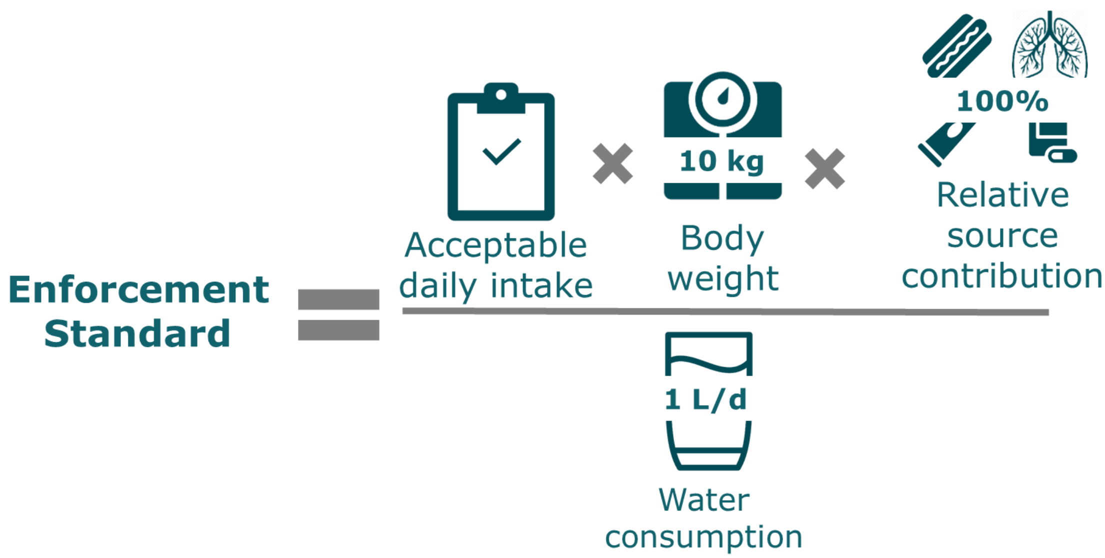
Wis. stat. ch. 160 specifies the process that DHS must use to determine the recommended enforcement standard. DHS is required to use the most recent federal number unless one does not exist or there is significant technical information that indicates a different number should be used. If there are no federal numbers but there is a state drinking water standard, DHS must recommend that number as the standard. If a federal number and a state drinking water standard are not available, DHS must use an acceptable daily intake from the EPA to develop the recommendation unless one does not exist or there is significant technical information that indicates a different number should be used. The *Additional Information* section has more details on how these steps.

If there is significant technical information available that indicates a number different than one established by the EPA is appropriate, DHS uses this information to calculate an acceptable daily intake. DHS toxicologists use best professional judgment when determining if significant technical information is available. DHS toxicologists use a weight of evidence approach in which they consider the available information (that is, peer-reviewed publications, acceptable daily intakes from national and/or international health agencies other than EPA) in context of toxicity and human health research to determine what standard is most appropriate for protecting human health.

Because federal numbers and state drinking water standards represent how much of the chemical can be in drinking water without causing unnecessary harm, DHS uses them directly as the recommended enforcement standard when appropriate. When DHS determines that an acceptable daily intake or cancer slope factor should be used instead, these values are used to derive a drinking water concentration.

## Non-Cancer Equation

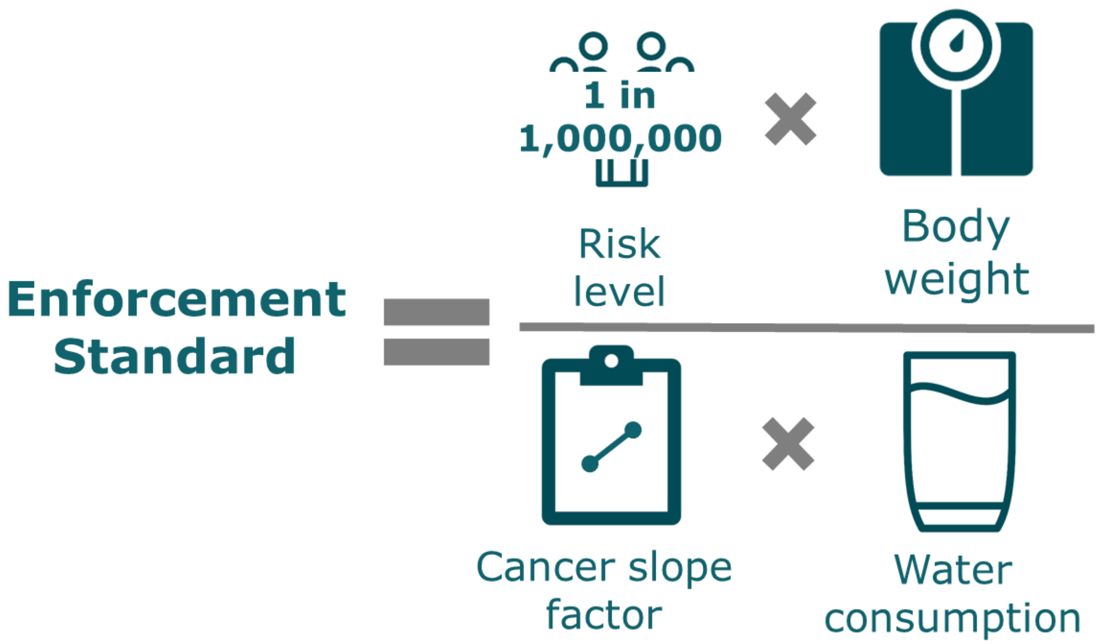
The non-cancer equation is used when there is an acceptable daily intake from EPA, another health agency, or the available scientific information. The enforcement standard for non-cancer effects is established to protect young children, which are assumed to be the most sensitive population.




- The **acceptable daily intake (ADI)** is established for the substance based on the available health information.
- Wis. Stat. ch. 160 specifies that DHS use a **body weight** of 10 kilograms (kg) to protect a young child.
- The **relative source contribution** is percent of daily exposure that is attributed to drinking water. Wis. Stat. ch. 160 specifies that DHS assume that all exposure comes from drinking water meaning that the relative source contribution equals 100%.
- Wis. Stat. ch. 160 specifies that DHS use a **daily water consumption rate** of 1 liter per day to protect a young child.

## Cancer Equation

Wis. stat. ch. 160 requires that DHS evaluate the cancer potential of a substance when establishing the groundwater standard. For carcinogenic substances for which there is no federal number or acceptable daily intake from the EPA, DHS must set the standard at a level that would result in a cancer risk equivalent to 1 in 1,000,000. DHS must also set the standard at this level if the EPA has an acceptable daily intake, but an enforcement standard based on this would result in a cancer risk that is greater than 1 in 1,000,000.




- Wis. Stat. ch. 160 specifies that DHS use a **risk level** of 1 case in 1,000,000 people.
- DHS uses a **body weight** of an average adult male to be protective of a lifetime of exposure. Body weight is not specified in Wis. Stat. ch. 160 so DHS uses the value most recently recommend by the EPA (80 kg).[13]
- The **cancer slope factor** is an estimate of the increased cancer risk from oral exposure to a substance. Often times, EPA establishes cancer slope factors as part of its IRIS and Office of Pesticide Programs. The *Additional Information* section has more details on how cancer slope factors are determined.

- DHS uses a **drinking water consumption rate** of an average adult male to be protective of a lifetime of exposure. This rate is not specified in Wis. Stat. ch. 160 so DHS uses the value most recently recommend by the EPA (2.4 L/d).[13]

If a substance has both cancer and non-cancer effects, DHS calculates possible enforcement standards using both equations and selects the more protective value as the recommended groundwater standard.

# Preventive Action Limit

Wis. stat. ch. 160 requires that DHS recommend a preventive action limit for each substance for which an enforcement standard is recommended. The preventive action limit is used to ensure that levels of a substance in groundwater do not exceed the health-based enforcement standard. When a preventive action limit is exceeded, the regulating agency (e.g., DNR, DATCP) is required to assess the cause of the increased concentration, determine any known or suspected contributors in the area, and evaluate the significance of the concentration.

**Key Health Effects for Selecting the Preventive Action Limit**

Carcinogenic = produces or incites cancer.

Mutagenic = alters or damages DNA.

Teratogenic = causes structural developmental defects.

Interactive = increases the toxicity of other substances or substance's toxicity is increased by the presence of other substances.

The preventive action limit is set at 10% of the enforcement standard when a substance has been shown to cause carcinogenic, mutagenic, teratogenic, or interactive effects in people, research animals, or cell cultures. The preventive action limit is set at 20% of the enforcement standard for all other substances. Wis. stat. ch. 160 allows DHS to set a lower preventive action limit if it is determined that a more stringent level is necessary to protect public health from the interactive effects of the substance.

# Once the review is complete, DHS documents and shares the findings.

## Scientific Support Documents

DHS details the recommended enforcement standard and preventive action limit for each substance under review in a scientific support document. This document includes an overview of the health effects associated with exposure to the chemical and known exposure routes and a detailed summary of the results of our scientific research and the basis for the recommendations.

## Sharing Findings

Once the recommendations are complete, DHS shares these recommendations with partner agencies including the DNR and Department of Agriculture, Trade, and Consumer Protection.

When the recommendations are complete, DNR proposes rules to update or create new standards based on these recommendations. Rulemaking is an extensive process and there are many internal steps that DNR and the Natural Resources Board must follow during a rulemaking effort.[15] There are several opportunities for the public to participate in the rulemaking process.

Throughout the rule-making effort, DHS supports DNR by describing the recommendations at public meetings and responding to relevant public comments.

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# Additional Information

## Glossary

**Acceptable daily intake:** the dose of a substance, which if ingested daily over an entire human lifetime, appears to be without appreciable risk on the basis of all known facts at the time it was established[*]

**Acceptable probability of (cancer) risk:** level equal to a ratio of one to 1,000,000.[*]

**Cancer slope factor**: an upper bound, approximating a 95% confidence limit, on the increased cancer risk from a lifetime exposure to an agent.

**Carcinogen**: chemical that has the potential to cause cancer; also called an oncogen.

**Confidence interval:** the range of values defined such that that there is a specified probability that the value of a parameter lies within it.

**Federal number:** a numerical expression of the concentration of a substance in water based on a drinking water standard or maximum contaminant level; a suggested no-adverse-response level; or for oncogenic substances, a concertation based on a risk level determination or a concentration based on a probability of risk model.[*]

**Maximum contaminant level (MCL):** the maximum permissible level of a contaminant in water which is delivered to any user of a public water system

**Maximum contaminant level goal (MCLG)**: amount of a contaminant that can be in drinking water below which there is no known or expected risk to health.

**No observable effect level:** level of intake of a substance which, when administered to a group of humans or experimental animals, does not produce any of the effects observed or measured at any higher level of intake and produces no significant difference between the test group and an unexposed control group of humans or animals maintained under identical conditions.[*]

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[*] This term is specifically defined in Wis. Stat. ch. 160

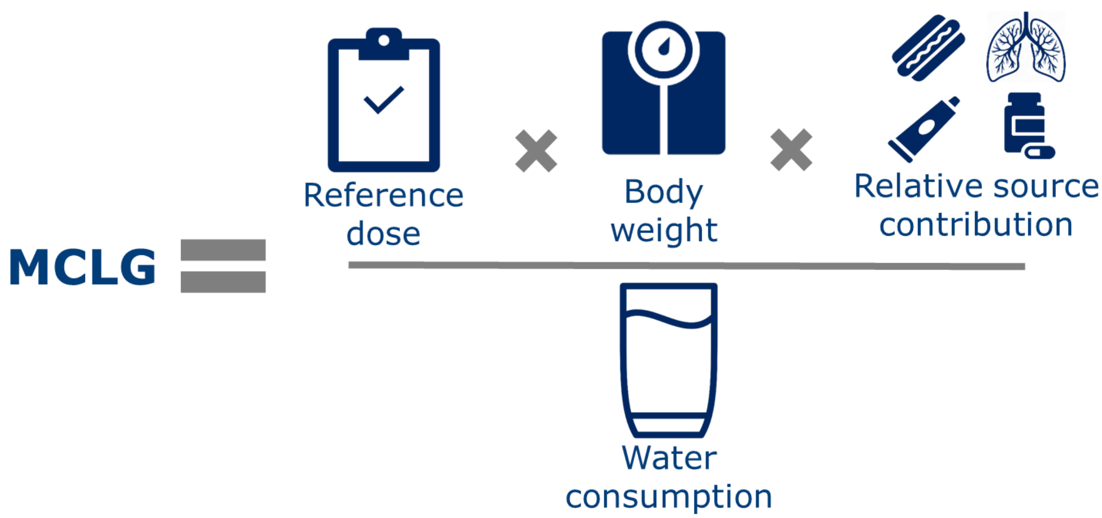
**Relative Source Contribution**: proportion a chemical's daily exposure that is attributed to drinking water.

# Types of Federal Numbers

## Maximum Contaminant Level

The Safe Drinking Water Act (SDWA) requires EPA to set national standards for drinking water to protect against health effects from exposure to naturally occurring and man-made contaminants. The SDWA also requires EPA to review the existing standards once every six years and revise them if necessary.

Before setting a maximum contaminant level (MCL), EPA establishes a maximum contaminant level goal (MCLG). The MCLG is the amount of a contaminant that can be in drinking water at which there is no known or expected risk to health. These goals typically allow for a margin of safety and are non-enforceable public health goals. However, the MCLG is set at zero for carcinogens (substances that have the potential to cause cancer).




- The **oral reference dose** is an estimated amount of the contaminant that a person can be exposed to orally every day over their lifetime and not experience negative health impacts (mg/kg-d)
- The **body weight** is the assumed weight of an adult (kg)
- The **daily water intake** is the assumed water intake of an adult (L/d)

Because MCLGs consider only public health, they are sometimes set at a level which water systems cannot meet because of technological limitations. Therefore, the MCL is set as close to the MCLG as feasible in terms of technological capabilities and cost.

## Action Level

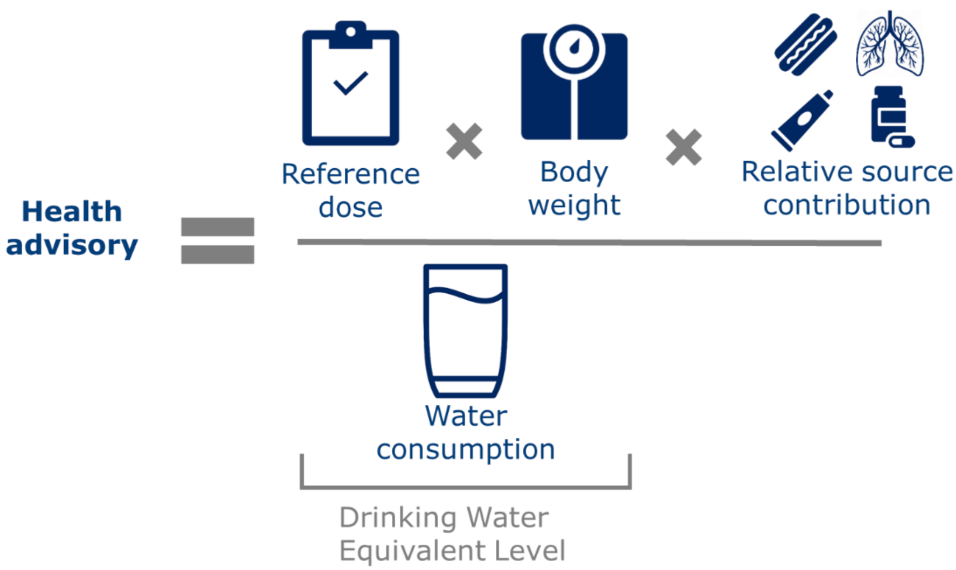
In 1991, the EPA established action levels for copper and lead as part of the Lead and Copper Rule.[16] Action levels are established as part of a treatment technique. The treatment technique requires systems to monitor for lead and copper at customer taps. If concentrations exceed the action level in more than 10% of sampled taps, the system must take action to control corrosion.

EPA uses this approach for lead and copper because these contaminants typically occur as a result of the corrosive action of the water in contact with plumbing materials and are typically not found in high concentrations in source water. As such, the traditional approach of treating the water prior to distribution would have little effect lead and copper levels at the tap.

## Health Advisories

Health advisories are established by the EPA to provide technical information on health effects, analytical methodologies, and treatment technologies associated with drinking water contamination.

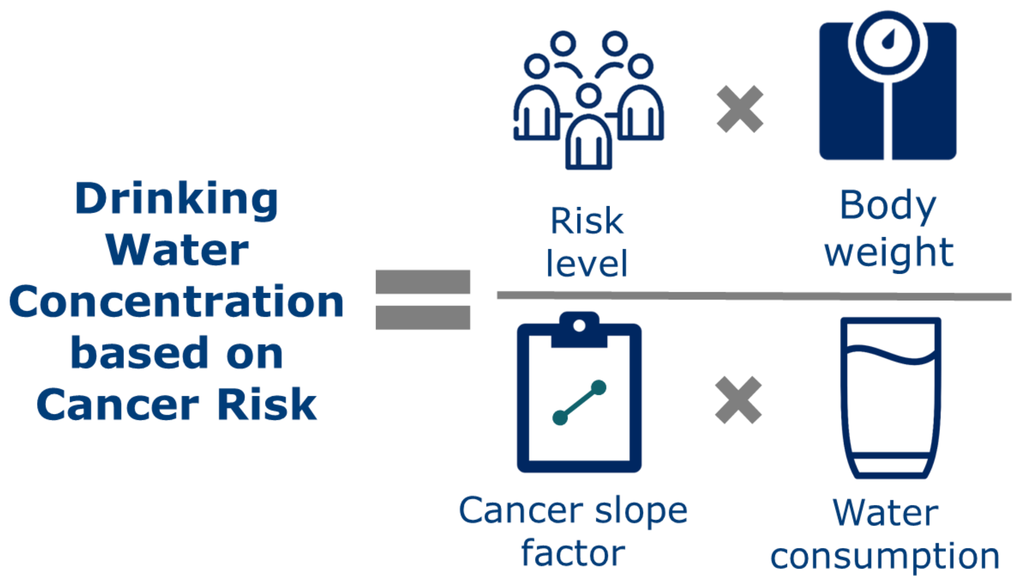
EPA develops short-term, longer-term, and lifetime health advisories. Typically, the life-time health advisory is the most protective. Lifetime health advisories cover an exposure period of 70 years, which is the average lifespan of a human. Lifetime health advisories are calculated as follows:




- The **reference dose** is an estimated amount of the contaminant that a person can be exposed to orally every day over their lifetime and not experience negative health impacts (mg/kg-d)
- The **body weight** is the assumed weight of a child or adult (kg)
- The **relative source contribution** is the proportion a chemical’s daily exposure that is attributed to drinking water
- The **daily water intake** is the assumed water intake of child or adult (L/d)

## Drinking Water Concentration Based on Cancer Risk Level

EPA's Integrated Risk Information System (IRIS) program evaluates cancer risk as part of their systemic toxicity reviews.[17] When data are available, the IRIS program establishes an oral cancer slope factor and uses this to establish drinking water concentrations based on cancer risk level. The drinking water concentration protects from a lifetime of exposure to the substance.

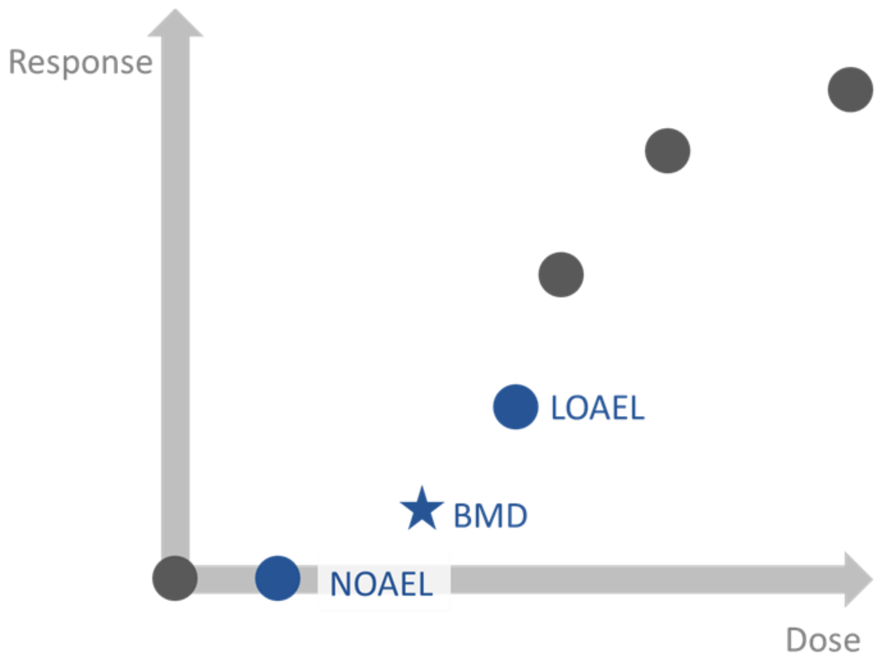



- The target **risk level** is the threshold of acceptable cancer risk. EPA generally considers cancer risk between 1 case in 10,000 people and 1 case in 1,000,000 people to be as acceptable.[18]
- EPA has historically used 70 kg as the average **body weight** of an adult but currently recommends 80 kg.[17,18]
- The **cancer slope factor** is an estimate of the increased cancer risk from oral exposure to a substance.
- EPA has historically used 2 L/d as the **daily water intake** of an adult but currently recommends 2.4 L/d.[17,18]

# Dose Response Analyses

Scientists use dose-response experiments to evaluate the effect (response) of a substance after exposure to various amounts (doses) of a substance. Example of responses include death, reproduction changes, behavioral changes, cancer rates, and genetic changes. These data are often graphed in a dose-response curve.

## For non-cancer effects, several toxicity values can be obtained from these experiments.

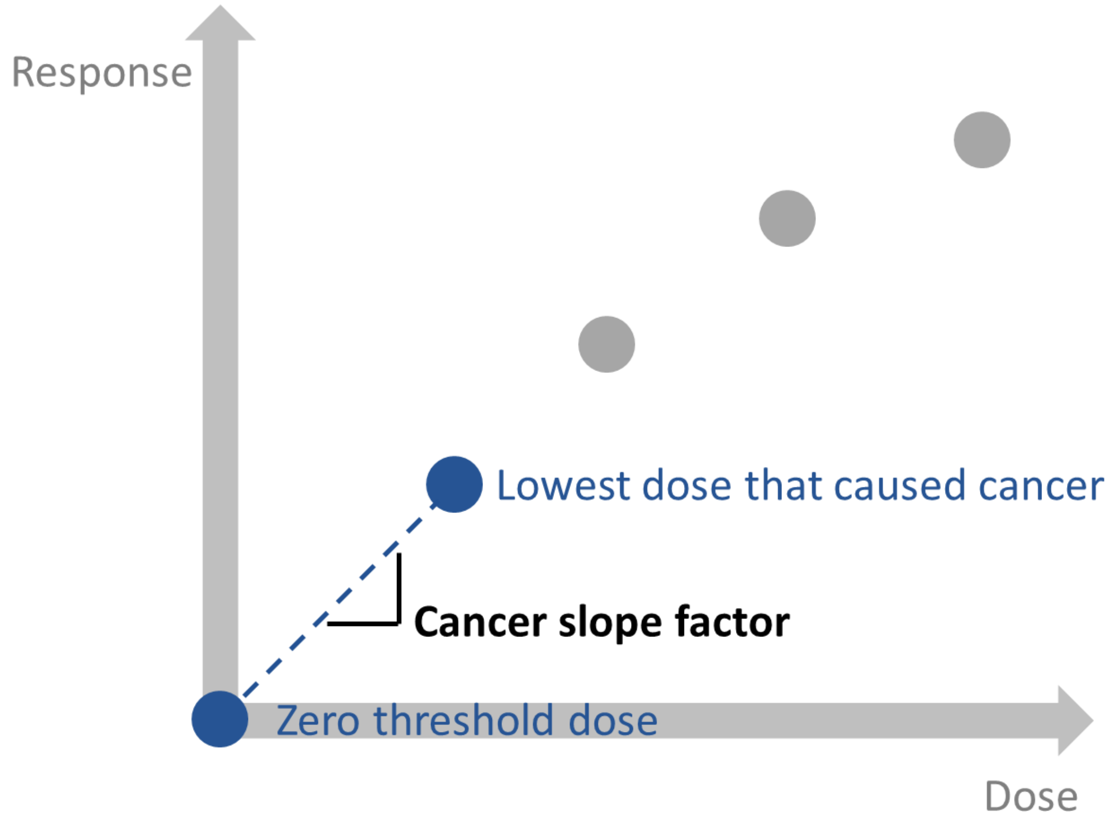



The **no observable adverse effect level (NOAEL)** is the highest tested dose at which no adverse health effects were observed.

The **lowest observable adverse effect level (LOAEL)** is the lowest tested dose at which adverse health effects were observed.

The **benchmark dose (BMD)** is an estimate of the dose that would result in a specific level of the effect (typically 20%).

## For cancer effects, a cancer slope factor is used to evaluate toxicity.




A mathematical model is used to estimate the slope from the lowest dose that caused cancer in a human or animal study to a zero threshold dose.

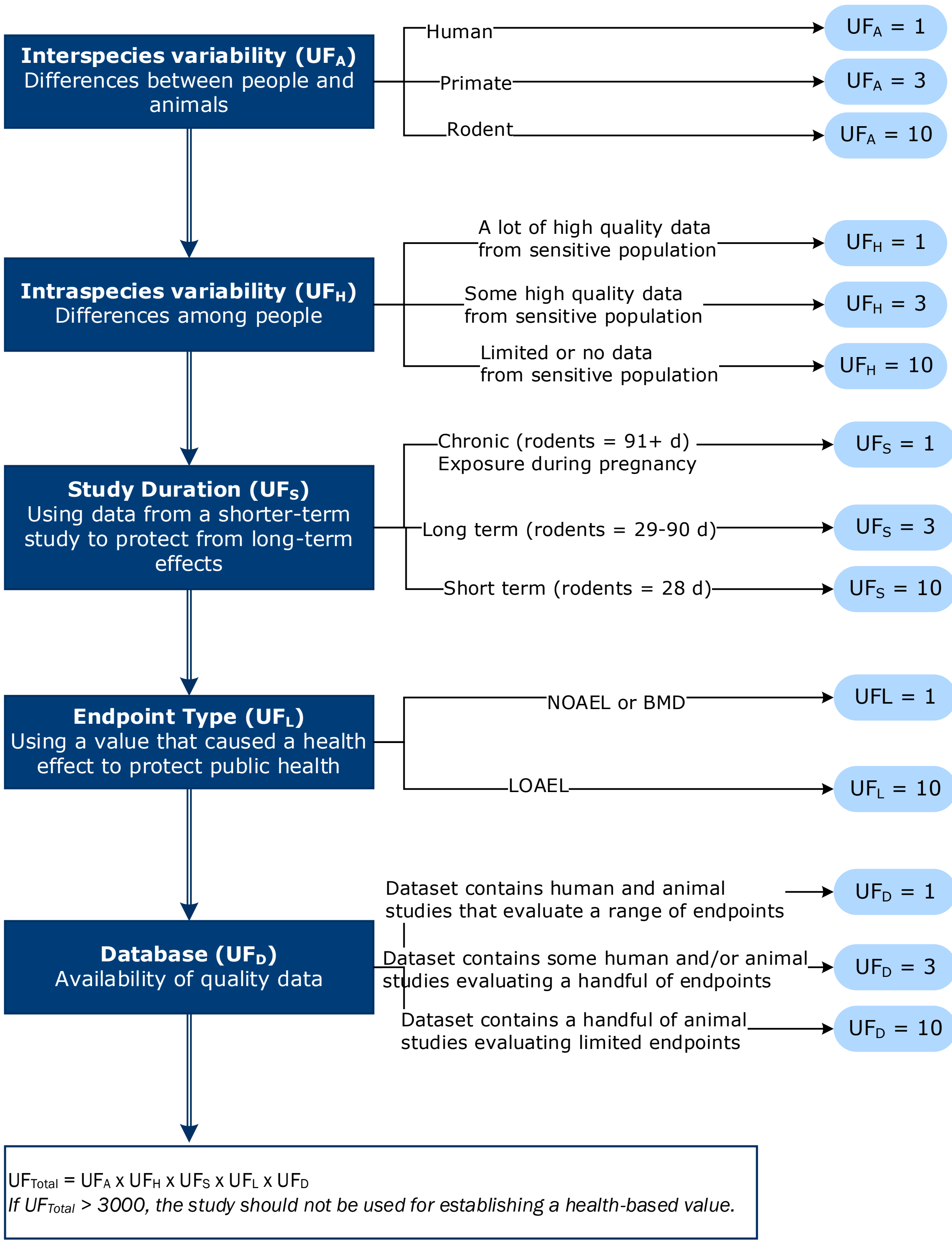
The **cancer slope factor** can then be used to determine a level of the chemical that corresponds to an acceptable level of cancer risk.

# Uncertainty Factor Selection Process

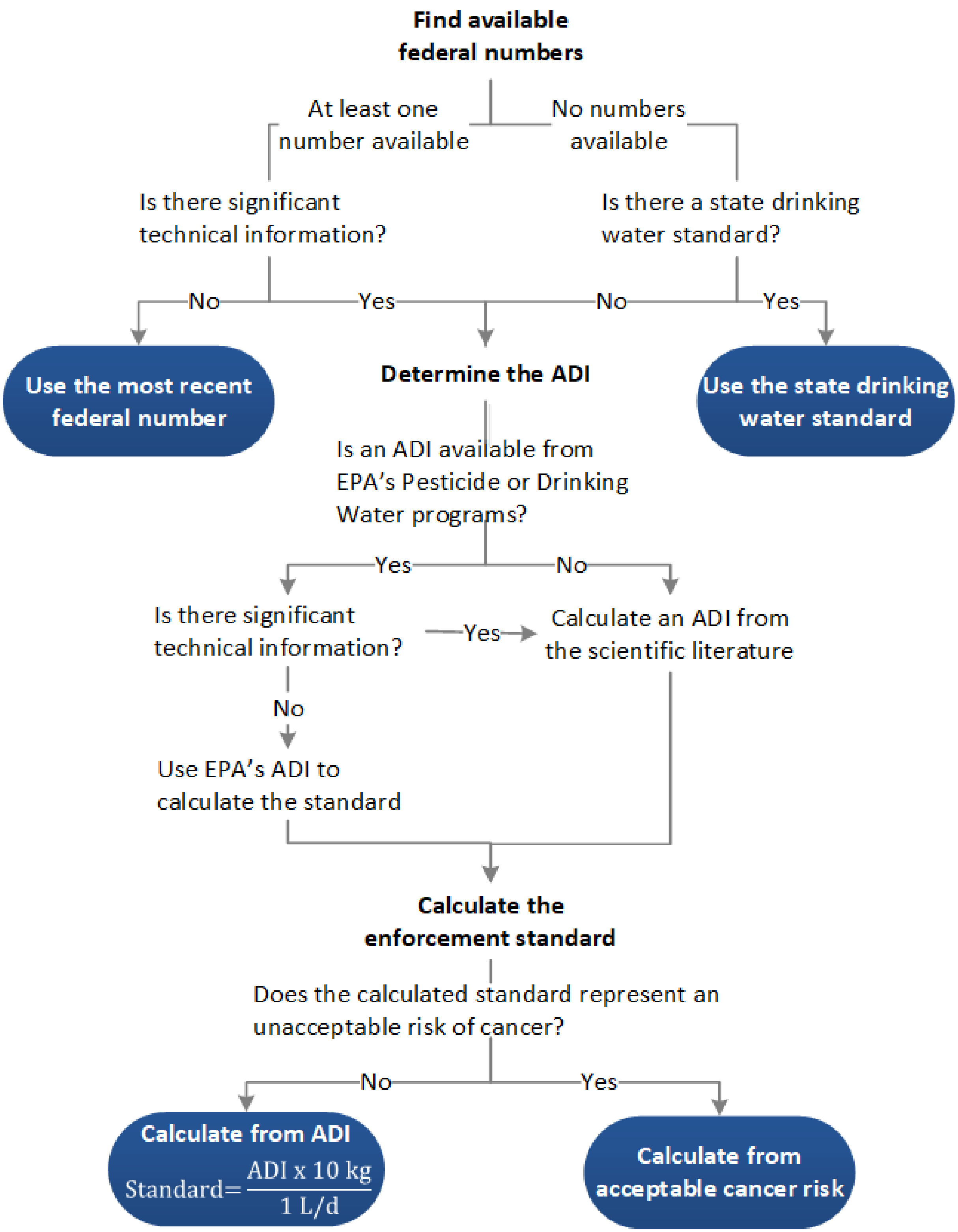
Wis. Stat. ch. 160, specifies the variables that DHS must consider when selecting uncertainty factors to calculate an acceptable daily intake. These variables include:

- The quality and quantity of data relevant to establishing an acceptable daily intake.
- The relative importance to full health of the most sensitive target organs or body systems affected by the substance.
- The amount of interspecies and intraspecies variations in the effects of the substance.
- The dose−response curve and the time−concentration relationships for the substance.
- The nature and degree of severity of injury incurred at the intake level at which the effect of exposure to the substance ceases to be reversible.
- The potential interactions of the substance within the body with other environmental chemicals or therapeutic drugs.
- The known potential cumulative effects of repeated exposure to the substance.
- The known chronic or subchronic effects of exposure to similar or related compounds.
- The identification of physiologic or pathologic states and functional abnormalities among the potentially exposed population which would constitute a health hazard in the event of exposure to the substance.
- The possibility of chronic health effects from repeated, acute short−term exposure to the substance.

## DHS follows a procedure based on that used by EPA to select uncertainty factors



# Enforcement Standard Selection Process




ADI = Acceptable Daily Intake