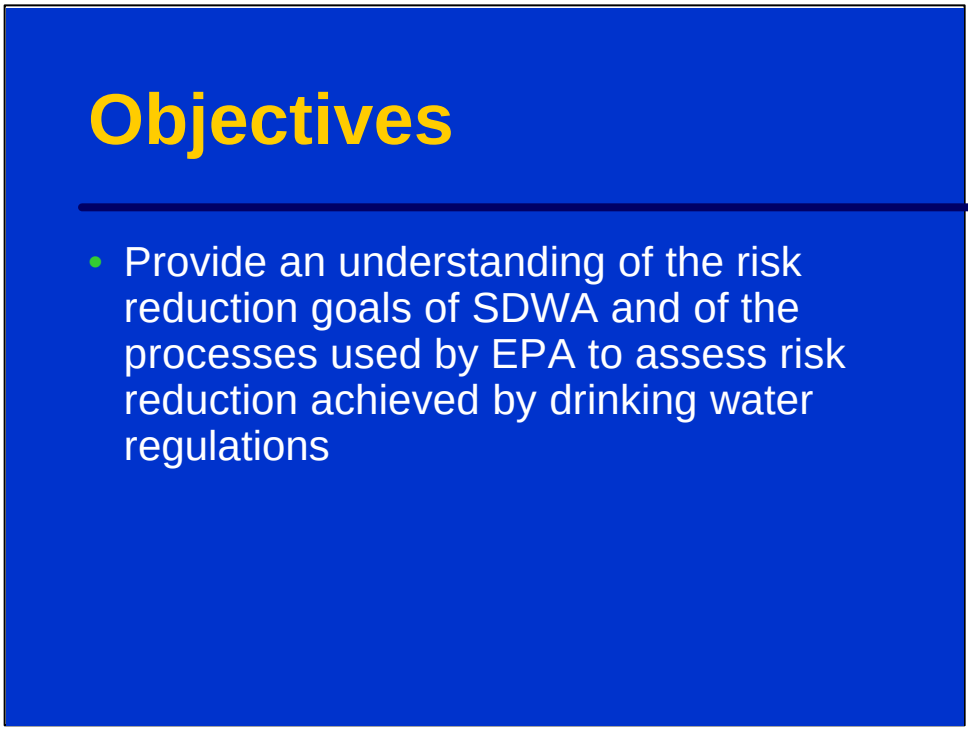
From Risk to Rule: How EPA Develops Risk-Based Drinking Water Regulations

Introduction



- The primary objective of the "From Risk to Rule" course is to provide training on how EPA assesses risk and uses risk information to develop drinking water regulations under the Safe Drinking Water Act (SDWA).
- The purpose of this course is to provide people who are primarily involved in implementing the regulations with a better understanding of the scientific and other considerations – specifically, those related to public health risk assessment – that support EPA's rulemaking activities under SDWA.
- By the end of this module, it is hoped that students will better understand:
  - The types of adverse health effects – hazards – that have been associated with contaminants in drinking water;
  - How those health hazards are identified and assessed;
  - How the risk of those health hazards occurring is quantified from exposure and dose-response information; and
  - How risk reduction from drinking water regulatory options is estimated and considered in the regulatory decision-making process.

Objectives

- Describe the two aspects of SDWA regulations involving health risk assessments:
  - Establishing public health protection goals
  - Estimating and comparing the benefits of risk reduction for regulatory options

- In this course we will discuss how EPA considers health risks in:
  - Establishing a Maximum Contaminant Level Goal (MCLG), and
  - Establishing a Maximum Contaminant Levels (MCLs) or a Treatment Technique (TT) to reduce health risks in the exposed population
- With respect to the health benefits, we will discuss how they are measured, valued, and compared with costs of regulatory options.

Objectives

- Discuss specific health hazard and risk assessment issues of contaminants that have been regulated under SDWA
- Review current and upcoming regulatory efforts aimed at further reducing health risks from drinking water

- We will review the information that was used to develop the health goals and regulations of several specific drinking water contaminants that are currently regulated under SDWA.
- We will discuss the procedures established under SDWA to identify and assess the hazards and risks of other currently unregulated drinking water contaminants.

"Take Home" Items

- A better understanding of the health risk assessment and benefits analysis procedures used in developing national drinking water regulations
- An enhanced familiarity with the terminology, concepts, and methods used in this process
- A greater ability to use information on drinking water health risk assessments and benefit analyses in your specific job

- This course is not intended to train students to perform these assessments, but rather to provide them with a better understanding of how they are done to better communicate about these topics in the context of each participant's own activities with respect to SDWA implementation.

What is Risk?

- EPA definition (from Integrated Risk Information System)
  - Probability of injury, disease or death from exposure to a chemical agent or a mixture of chemicals

- In defining risk, the emphasis is on the ***probability*** of the adverse effect or event occurring not the nature of the effect itself.

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Lesson 1: Historical Overview

Earliest Records of Drinking Water Treatment

- Earliest record of methods to improve the taste and odor of drinking water date to ~4000 BC
- Alum used by Egyptians for clarifying water ~ 1500 BC
- Hippocrates advised people to boil and strain water ~ 400 BC

- Ancient Sanskrit and Greek writings recommended the use of charcoal, boiling, exposing to sunlight, and straining to remove suspended particles from water.
- Egyptians used alum as a coagulant as early as 1500 BC to clarify water.
- In the 4th century B.C., Hippocrates advised citizens to ***boil and strain water*** before drinking it to prevent hoarseness.
- For the most part, however, water treatment prior to the late 1800s focused on aesthetic quality and not health concerns.
- There was little understanding of the link between water quality and health until the late 1800s and early 1900s.

Earliest Association of Diseases with Drinking Water

- Dr. John Snow demonstrated in 1854 that cholera in London was spread through drinking water
- In the 1890s, studies in Lawrence, Massachusetts, demonstrated a reduction in typhoid fever incidence with drinking water filtration

- In 1854, Dr. John Snow proved cholera as a waterborne disease. A London drinking water well contaminated with human sewage was blamed for 616 cholera deaths.
- In the late 1880s and early 1890s, experiments on water filtration were being performed in Lawrence, Massachusetts. An epidemic of typhoid fever broke out particularly affecting parts of the city using unfiltered water. Subsequent use of filtration was associated with a marked decrease in typhoid incidence.
- In the 1880s Louis Pasteur first postulated the germ theory of disease. The theory was proven by Robert Koch in Europe in the late 1800s. It was not until the germ theory of disease was broadly accepted in the early 1900s, however, that treatment of water to mitigate disease spread through untreated water began on a significant level.

Early Water Treatment Milestones in U.S.

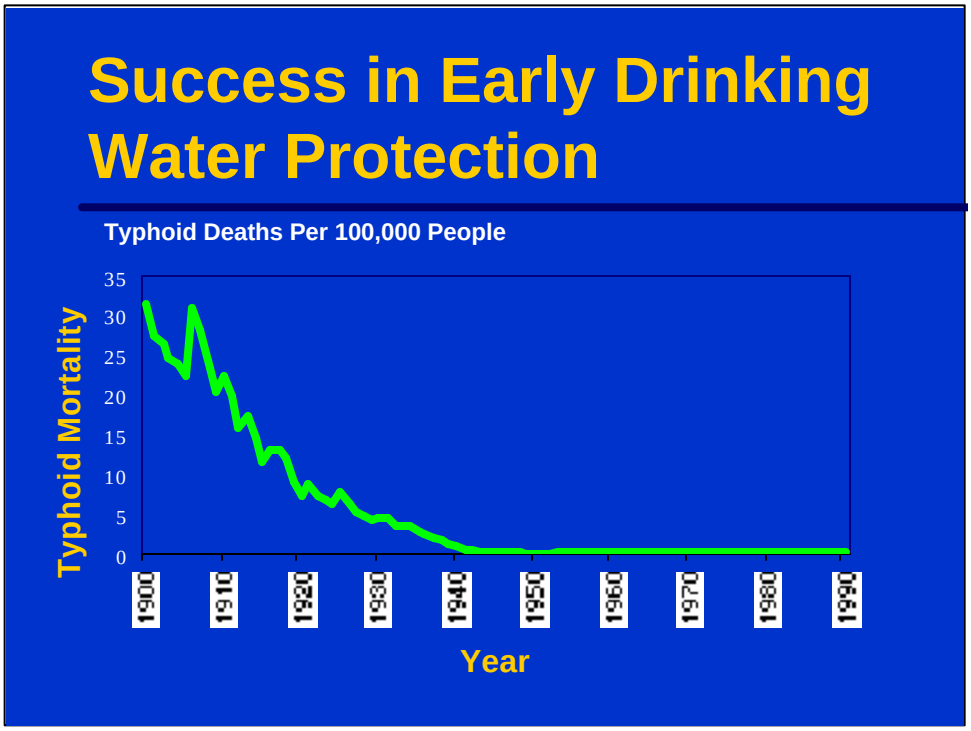
1871:	First slow sand filter in U.S.
1896:	First rapid sand filter in U.S.
1908:	First use of chlorine as a primary disinfectant
1920s:	Filtration and chlorination used widely in large cities

- In the 1800s and early 1900s, States, water systems, and local governments began establishing programs to ensure safe supplies of drinking water. Early efforts focused on ***microbiological contaminants,*** such as protozoan, bacteriological, or viral contaminants. Efforts were made to prevent raw sewage from entering water bodies used as sources of drinking water and to treat water taken from lakes, rivers, and reservoirs.
- Studies in Providence (1893-94) and Louisville (1985-97) demonstrated that the use of coagulants in a mechanical filtration system could remove bacteria.
- Slow sand filtration was conducted in large beds of fine sand that had relatively slow filtration rates. The removal of pathogens is accomplished by the trapping by the sand filter and by the scavenging of predatory organisms as water filters slowly through the sand.
- Rapid sand filtration has largely replace slow sand filtration. In this process, smaller filter beds (carefully sieved sand on top of graded gravel) with more rapid filtration rates are used.
- In 1908, Jersey City, New Jersey, began treating its water supply with chlorine. Within a few years, many other cities adopted chlorination of water supplies.
- Large scale treatment of drinking water began in cities with above-average numbers of typhoid outbreaks, such as Philadelphia and Chicago. The earliest treatment provided disinfection and sometimes filtration of surface water sources. Chicago, for example, began chlorinating its entire water supply in 1916.

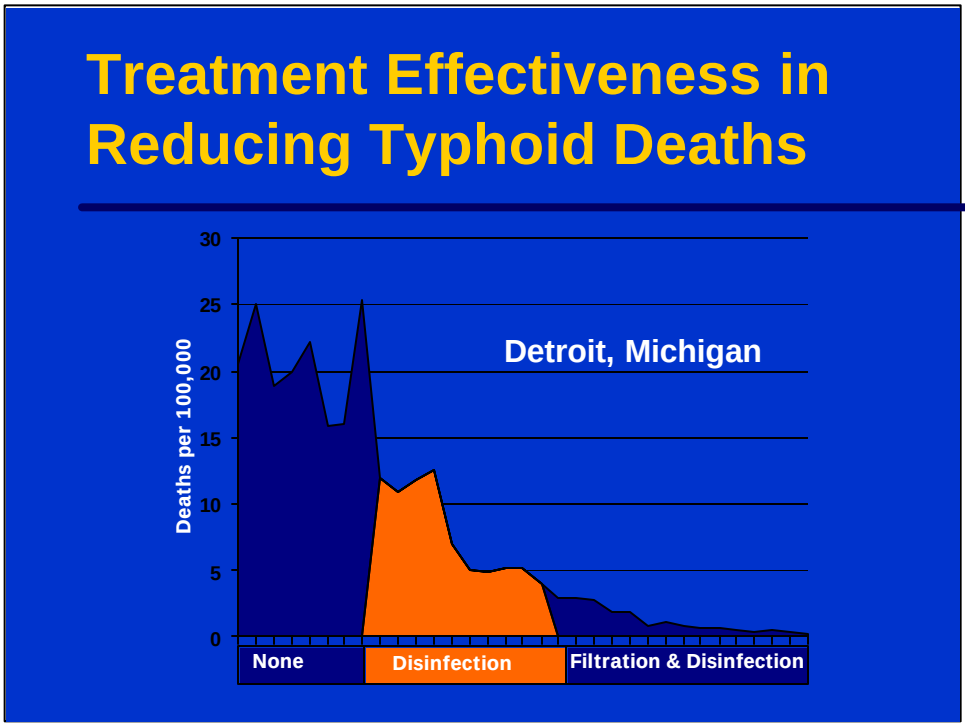
More Recent Water Treatment Milestones in U.S.

1940s:	Treatment for inorganic contaminants
1970s:	Treatment for organic contaminants
1980s:	Advanced water treatment methods employed

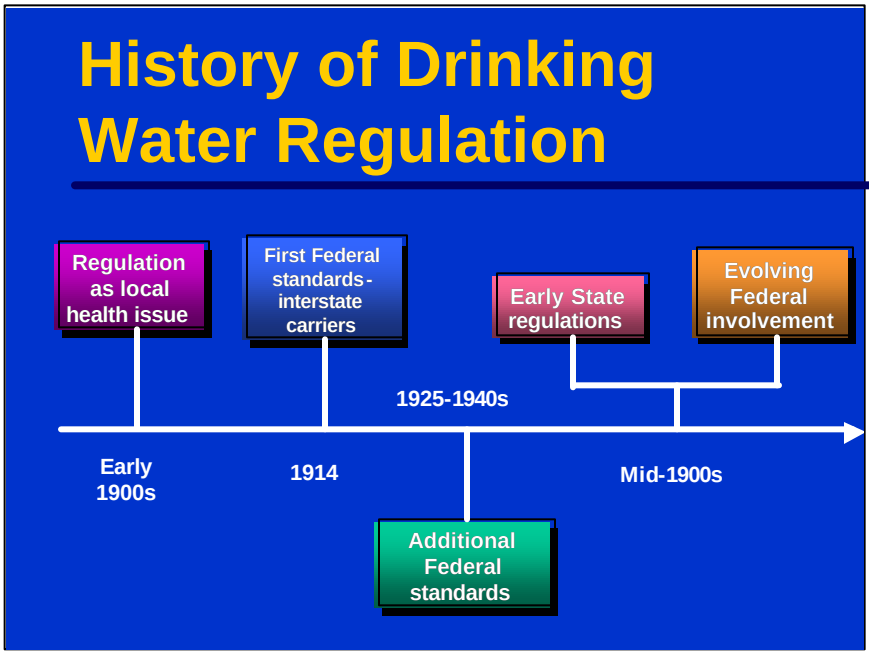
- Attention to some inorganics (metals) in 1940s.
- Attention to a wide variety of organic contaminants in 1970s and 1980s
- Increasing usage of advanced treatments (granulated activated carbon (GAC), membranes, ozonation) in 1980s and 1990s.



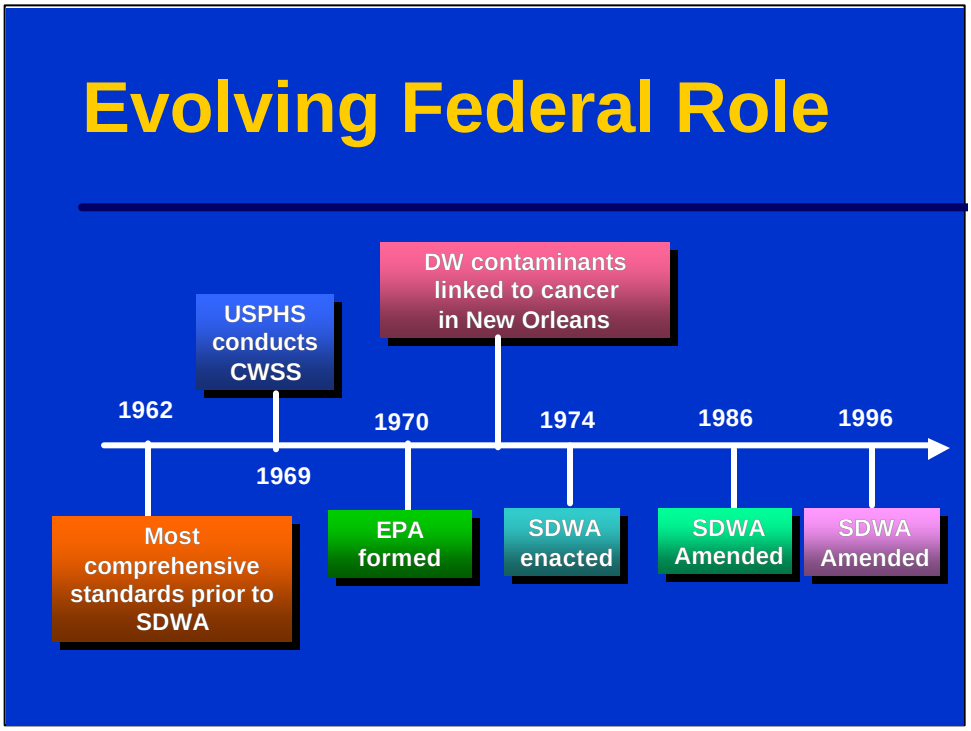
- Typhoid deaths dropped rapidly with the advent of widespread water quality and drinking water programs at the state and local levels in the early 1900s. In particular, chlorination and slow and rapid sand filtration contributed significantly to such a rapid reduction.
- For example, in Albany, New York, prior to filtration of the public water supply in 1899, the typhoid death rate was 110 per 100,000. From 1900 to 1910 filtration was used and the typhoid death rate dropped to 20 per 100,000. In 1910, chlorination was introduced and the typhoid death rate between 1924 and 1929 dropped to zero.
- On a national scale, the percentage of individuals who died from typhoid fever in 1910 is similar to the percentage of people who die in car accidents today (i.e., about 16 per 100,000 per year).
- For comparison, the annual risk of death associated with cancer (all types) is 129 per 100,000 per year.



- The design of most drinking water treatment systems built in the U.S. during the early 1900s was driven by the need to reduce turbidity, thereby removing microbial contaminants which were linked to typhoid, dysentery, and cholera epidemics. By 1911, about 20 percent of the U.S. urban population was using filtered water.
- While filtration was a fairly effective treatment method for reducing turbidity, it was disinfectants like chlorine that played the largest role in reducing the number of waterborne disease outbreaks in the early 1900s.
- The graphic above demonstrates the role that disinfection and later filtration played in reducing typhoid deaths in Detroit, Michigan. Nationwide, the death rate from typhoid fell from 31.3 per 100,000 in 1900 to 22.5 in 1910 and to 7.6 in 1920.



- The ***first Federal drinking water standards*** were adopted in 1914 by the U.S. Public Health Service (PHS). The standards were only required for interstate carriers, but many States voluntarily adopted them. The standards included a limit for total bacterial plate count and stipulated sampling standards for *E. coli*. The 1914 standards only addressed the bacteriological quality of water because the commission that drafted the standards could not agree on specific physical and chemical requirements. In 1925, PHS established standards for some physical and chemical (lead, copper, zinc, excessive soluble mineral substances) constituents.
- By 1925, large cities were using filtration and chlorination. It is likely that filtration and chlorination in combination have saved more lives than any other public health effort.
- By the mid-1900s, State public health departments were well-established regulatory agencies. The primary contaminants of concern were still those, such as pathogens and nitrate, that cause immediate or acute health problems.
- During the mid-twentieth century, the Federal government gradually increased its emphasis on programs to increase the public's access to safe and adequate drinking water. PHS ***established standards in the 1940s*** that addressed the chemical quality of water.



- In 1962, mandatory limits (for interstate carriers) for health-related chemical and biological impurities and recommended limits for impurities affecting appearance, taste, and odor were established for 28 constituents. All 50 States accepted these standards, with minor modifications, either as regulations or as guidelines.
- In 1969, PHS conducted the ***Community Water Supply Survey (CWSS)***. The survey indicated that several million people were being supplied inadequate quality water and that 360,000 people were being supplied potentially dangerous drinkin g water.
- In 1970, the ***Environmental Protection Agency (EPA)*** was established, and the Federal drinking water program moved from PHS to EPA. The newly-formed EPA faced growing public concerns about the safety of drinking water.
    - Data from the CWSS and other surveys conducted by EPA in the early 1970s showed that drinking water was widely contaminated on a national scale, particularly with synthetic organic chemicals.
    - In addition, in ***New Orleans in 1974***, high incidences of bladder cancer were associated with contaminants in drinking water.
- In response to these developments, Congress enacted the ***Safe Drinking Water Act*** in 1974. The SDWA gave EPA the authority to establish national drinking water standards, to be enforced by the states.
- SDWA was amended significantly in 1986 requiring EPA to regulate a set of 83 contaminants.
- SDWA was amended significantly again in 1996 with increased emphasis on risk-based standard setting.

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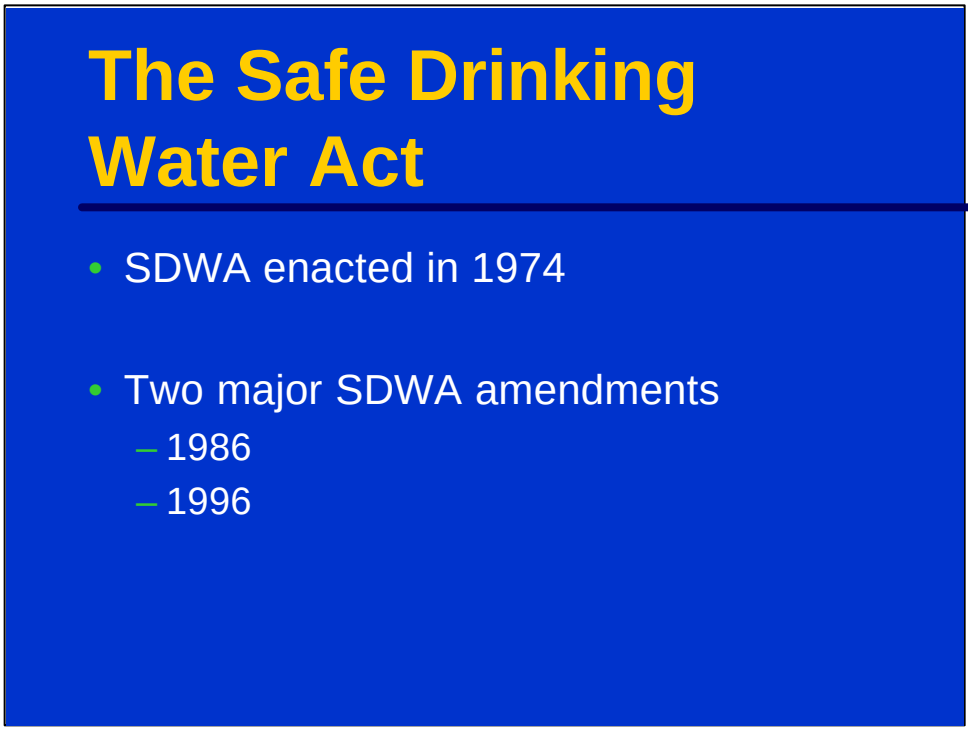
Lesson 2: SDWA Provisions

- The purpose of Lesson 2 is to summarize the important provisions of SDWA with respect to consideration of risk in developing regulations.



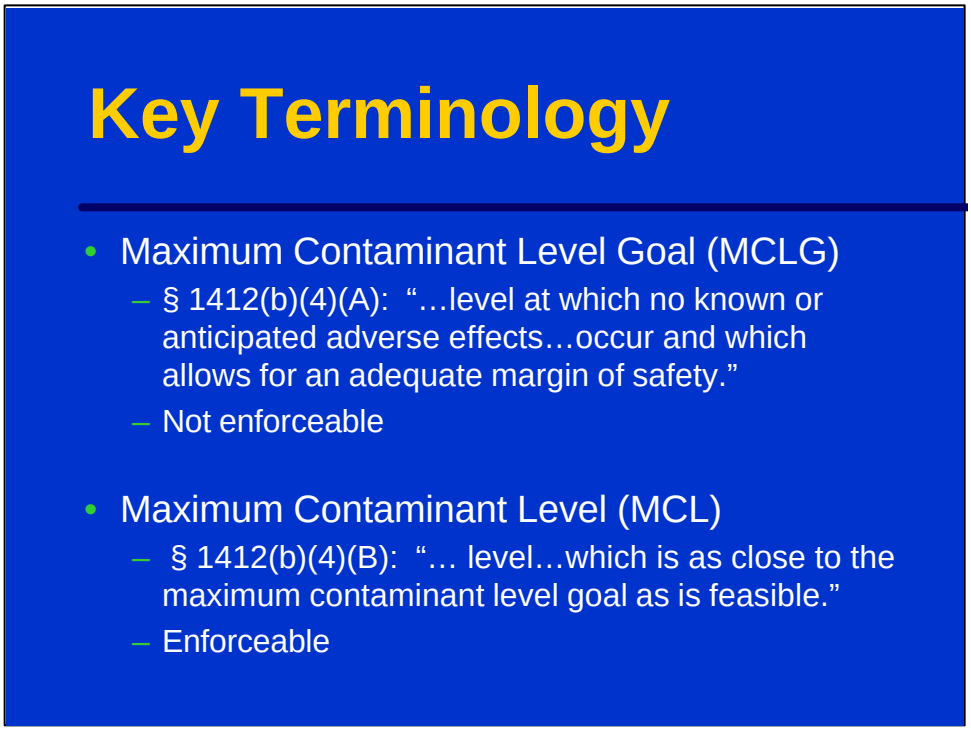
- The original SDWA gave EPA authority to publish national drinking water standards.
- The 1986 Amendments required EPA to regulate 83 specific contaminants and 25 additional contaminants every three years.
- The 1996 Amendments focused the regulatory program on risk-based priority setting. They also added benefit-cost analysis requirements to setting standards.

The Safe Drinking Water Act

- Key regulatory provisions of SDWA:
  - Definitions (§1401)
  - Coverage (§1411)
  - National Primary Drinking Water Regulations (NPDWRs) (§1412)

- Major provisions of section 1412:
  - §1412(b)(1) – Identification of Contaminants for Listing
  - §1412(b)(2) – Schedules and Deadlines
  - §1412(b)(3) – Risk Assessment, Management and Communication
  - §1412(b)(4) – Goals and Standards
  - §1412(b)(5) – Additional Health Risk Considerations
  - §1412(b)(6) – Additional Health Risk Reduction and Cost Considerations
  - §1412(b)(7) – Treatment techniques
  - §1412(b)(8) – Disinfection
  - §1412(b)(9) – Review and Revision
  - §1412(b)(10) – Effective Date
  - §1412(b)(11) – Prohibition on additives for preventive health care
  - §1412(b)(12)-(14) – Specific requirements for arsenic, sulfate, radon, and recycling of filter backwash
  - §1412(b)(15) – Variance Technologies

- There are two categories of drinking water regulations:
  - ***National Primary Drinking Water Regulations*** (NPDWRs or primary standards) are legally enforceable standards that apply to public water systems. Primary standards protect drinking water quality by limiting the levels of specific contaminants that can adversely affect public health and are known or anticipated to occur in water. They take the form of Maximum Contaminant Levels (MCLs) or Treatment Techniques (TTs).
  - ***National Secondary Drinking Water Regulations*** (NSDWRs or secondary standards) are nonenforceable guidelines regarding contaminants that may cause cosmetic effects (such as skin or tooth discoloration) or have aesthetic effects (such as affecting the taste, odor, or color of drinking water). EPA recommends secondary standards to water systems but does not require systems to comply. However, States may choose to adopt them as enforceable standards. NSDWRs are intended to protect "public welfare."

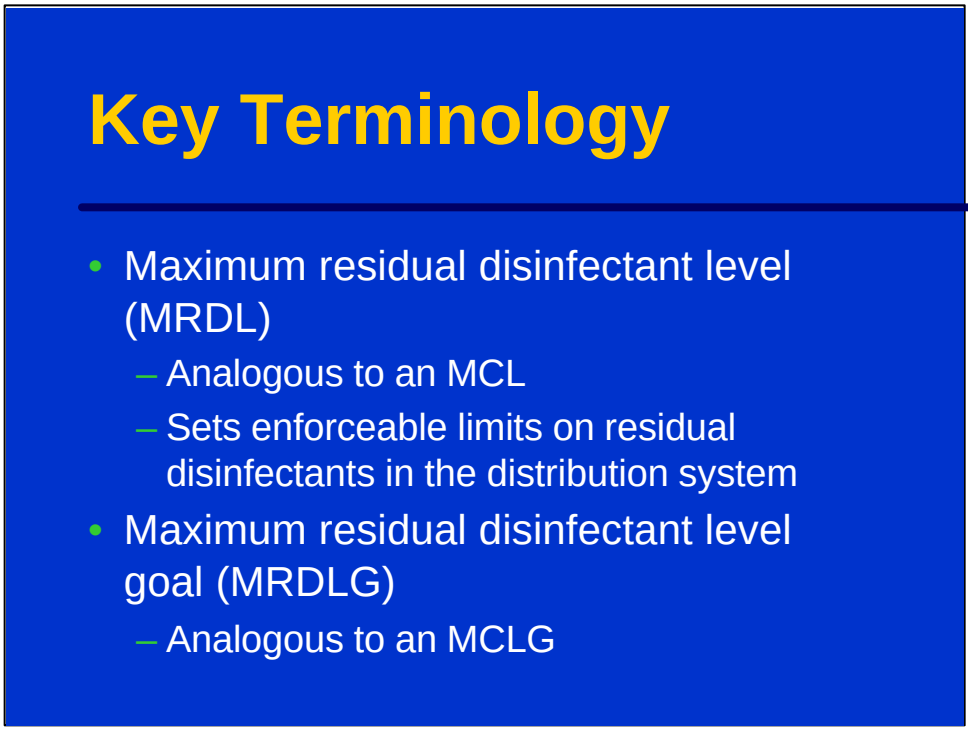


- Once EPA has selected a contaminant for regulation, it examines the contaminant's health effects and sets a ***maximum contaminant level goal*** (MCLG). This is the maximum level of a contaminant in drinking water at which no known or anticipated adverse health effects would occur, and which allows an adequate margin of safety. MCLGs do not take cost and technologies into consideration.
- MCLGs are nonenforceable public health goals. Since MCLGs consider only public health and not the limits of detection and treatment technology, they are sometimes set at a level that water systems cannot meet. For most carcinogens (contaminants that cause cancer) and microbiological contaminants, MCLGs are set at zero because a safe level often cannot be determined.
- EPA also establishes ***maximum contaminant levels (MCLs)***, which are enforceable limits that finished drinking water must meet. MCLs are set as close to the MCLG as feasible. SDWA defines "feasible" as the level that may be achieved with the use of the best available technology (BAT), treatment technique, or other means specified by EPA, after examination for efficacy under field conditions (that is, not solely under laboratory conditions) and taking cost into consideration.

Key Terminology

- Treatment Technique
  - § 1412(b)(7): "…in lieu of establishing a maximum contaminant level, if…it is not economically or technologically feasible to ascertain the level of the contaminant."
  - Enforceable

- For some contaminants, especially microbiological contaminants, there is no reliable method that is economically and technically feasible to measure a contaminant at particularly low concentrations. In these cases, EPA establishes ***treatment techniques***.
- A treatment technique is an enforceable procedure or level of technological performance that public water systems must follow to ensure control of a contaminant. Examples of rules with treatment techniques are the surface water treatment rule and the lead and copper rule.

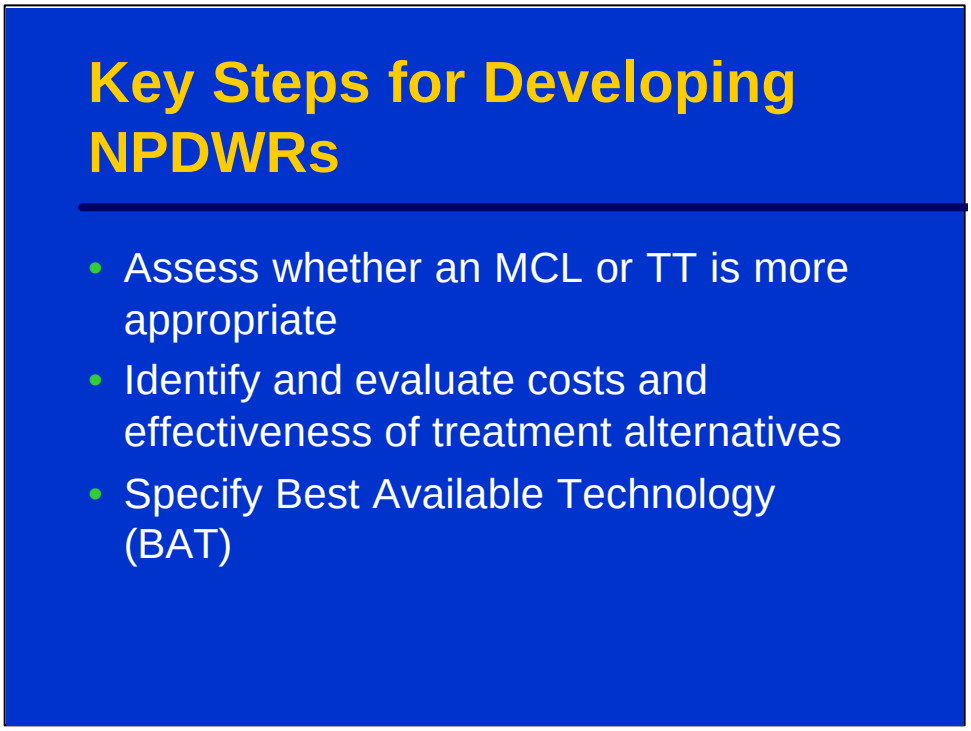


- A ***maximum residual disinfectant level (MRDL)*** is similar in concept to an MCL. It sets enforceable limits on the levels of residual disinfectants in the distribution system. This term was not specifically defined in the 1996 SDWA Amendments, but has come into use as an indicator of the level of disinfection applied.
- EPA sets a nonenforceable ***maximum residual disinfectant level goal (MRDLG)*** for residual disinfectants. This is analogous to setting an MCLG.

Key Steps for Developing NPDWRs

- Setting the MCLG
  - Health effects information
  - Exposure information
  - Relevant information and procedures developed by EPA for risk assessment and characterization

- In concept, the MCLG precedes the MCL, though both are usually proposed and finalized at the same time.
- In developing the MCLG, EPA:
  - Evaluates the health effects of the contaminant (i.e., hazardous identification and dose-response assessment); and
  - Examines the size and nature of the population exposed to the contaminant, and the length of time and concentration of the exposure.
- We'll come back to each of these steps in more detail later.

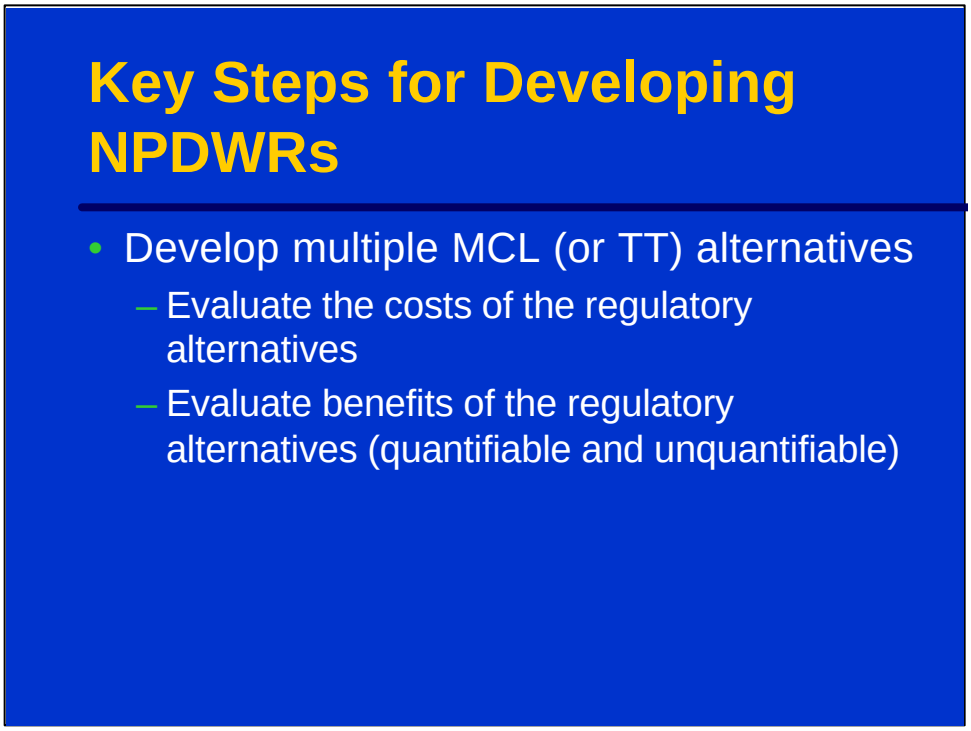


- These are the steps from the MCLG to the MCL. Depending on the risk characteristics, EPA:
  - Assesses the appropriateness of setting a MCL or TT standard;
  - Identifies and evaluates the costs and effectiveness of treatment technologies; and
  - Specifies BAT to ensure that systems can, in most cases, treat to meet the standard.

Key Steps for Developing NPDWRs

- Evaluate contaminant occurrence (number of systems affected and to what degree)
- Evaluate contaminant exposure (number of people affected and to what degree)
- Characterize compliance choices for regulatory alternatives

- To support a rulemaking, EPA staff must perform a series of analyses:
  - Evaluate occurrence of the contaminant (number of systems affected by a specific contaminant and concentrations of the contaminant);
  - Evaluate the number of people exposed and the ingested dose; and
  - Characterize choices for water systems to meet regulatory standards (treatment technologies).



- In developing an MCL or TT, EPA assesses multiple possible MCL or TT alternatives in terms of costs (for example, by installing new treatment equipment).
- EPA also assesses benefits resulting from the various regulatory alternatives. Some of the benefits can be quantified (for example, cost of illness avoided), but some are unquantifiable (for example, cost savings associated with the removal of other contaminants, gaining economies of scale by merging with other water systems).

- EPA then compares benefits and costs associated with the proposed MCL or TT alternatives, and address uncertainty of the data and estimation procedures.
- EPA develops detailed technical documents on the data and methodologies used in the analyses:
  - Health Criteria Document
  - Occurrence and Exposure Document
  - Cost and Technology Document
  - Economic Analysis

Opportunities for Public and Other Involvement in Developing Rules

- Stakeholder and early involvement meetings
- Notice of Data Availability
- Negotiated rulemaking under the Federal Advisory Committee Act
- Small business and Tribal government consultations
- Public comment period after formal rule proposal in the *Federal Register*

- Federal rulemaking procedures allow the public several opportunities to participate in the development of these rules.
- Opportunities for the public to get involved in the development of drinking water regulation include:
  - Stakeholder meetings and early involvement meetings;
  - Review of data used in the process (through a NODA published by EPA in the *Federal Register*);
  - Provide input to a negotiated rule development process (under the Federal Advisory Committee Act (FACA)); and
  - Submit comments on the proposed rule (published in the *Federal Register*).
- Before the proposed rule can be published, it must go through reviews by other EPA programs and the Office of Management and Budget.

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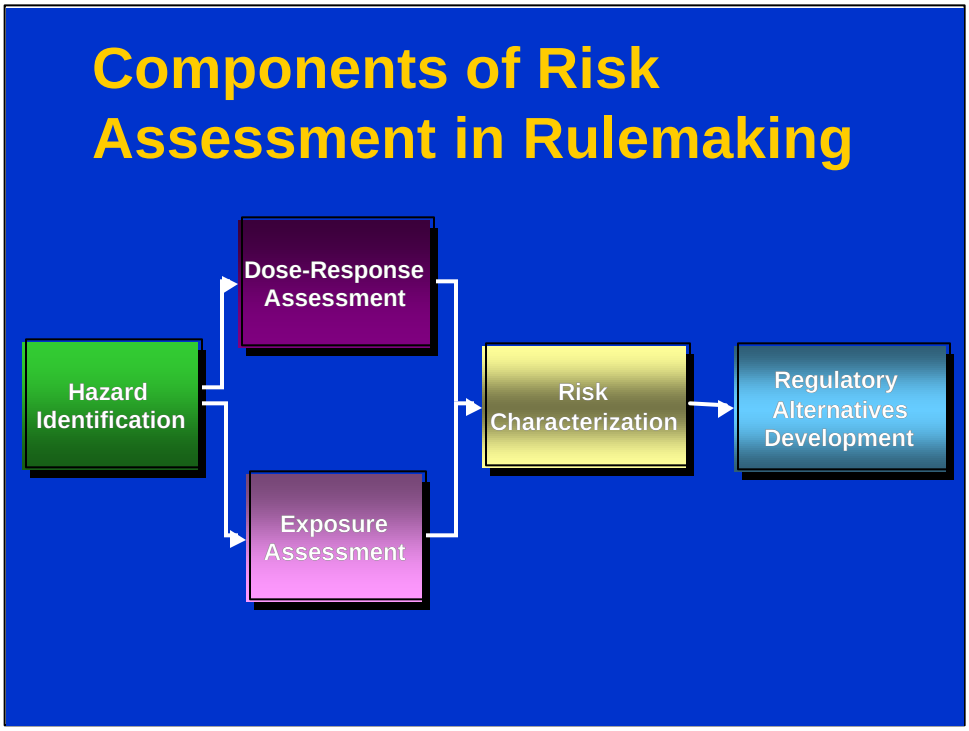
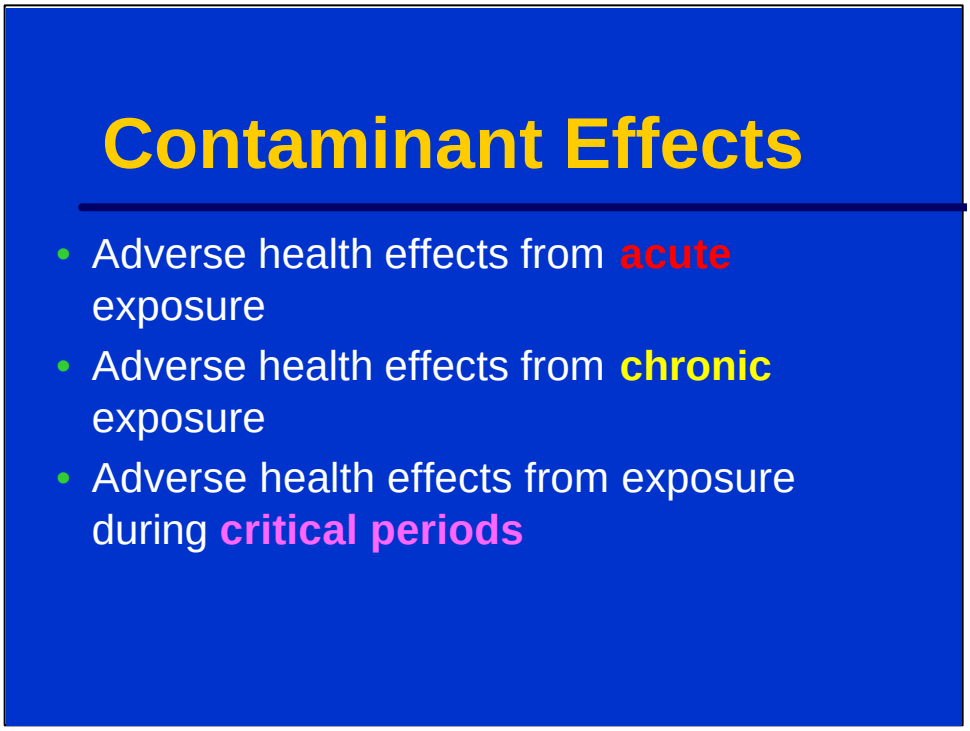
Lesson 3: Health Hazards

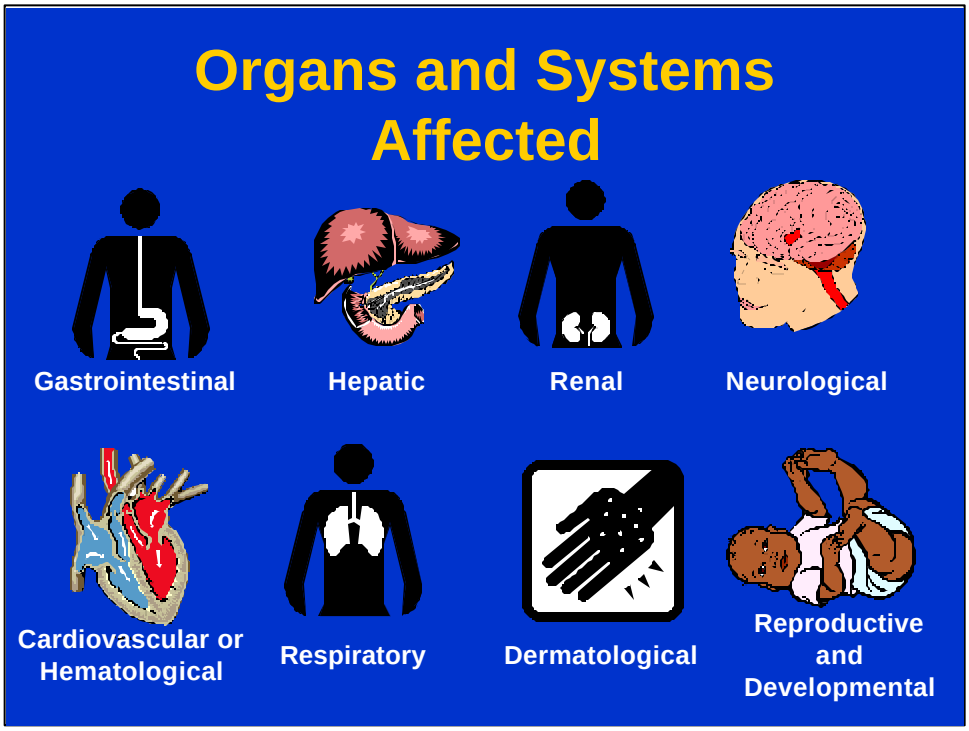
- The purpose of Lesson 3 is to discuss the various types health concerns associated with drinking water contamination.



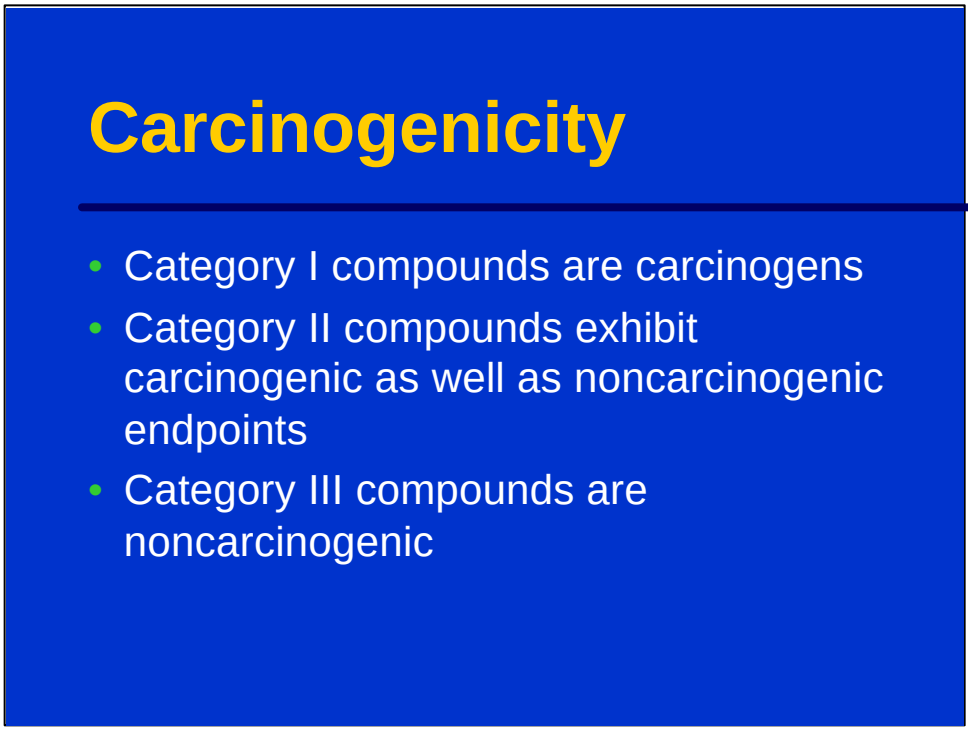
- This slide provides a graphical overview of EPA's risk-based rulemaking process.
- ***Hazard Identification*** - Determine if a contaminant is causally linked to particular health effects (e.g., cancer or birth defects), usually using data from other animals or test organisms.
- ***Dose-Response Assessment*** - Characterize the relationship between the dose of a contaminant and incidence of an adverse health effect. There can be many different relationships depending on varying responses (cancer, acute illness).
- ***Exposure Assessment*** - Determine the size and nature of the population exposed to the contaminant, and the length of time and concentration of the contaminant (need to consider age and health of the exposed population, and other factors).
- ***Risk Characterization*** – Integrate the first three components, resulting in an estimate of the magnitude of the public health problem.
- ***Regulatory Alternative Development*** – Formulate options to achieve compliance by evaluating multiple MCLs or TTs, comparing costs and benefits, and developing the regulatory structure.



- There are three major categories of health effects:
  - ***Acute exposure health effects*** are immediate effects (i.e., they occur within hours or days) that may result from exposure to certain contaminants such as pathogens (disease causing organisms) or nitrate.
    - ***Pathogens*** are usually associated with gastrointestinal illness and, in extreme cases, can be fatal.
    - ***Nitrate*** in drinking water poses an acute health threat to infants. Certain bacteria commonly found in the intestinal tract of infants can convert nitrate to nitrite that interfere with the ability of an infant's blood to carry oxygen. This potentially fatal condition is called methemoglobinemia or "blue baby syndrome." Nitrates may also indicate the possible presence of other more serious residential or agricultural contaminants such as bacteria or pesticides.
  - ***Chronic exposure health effects*** are associated with exposure over many years (perhaps a lifetime) to a contaminant. Chronic health effects include cancer and other long-term health effects.
  - ***Critical exposure period effects*** may involve a single or multiple exposures but they occur during specific periods that relate to the risk. Examples include reproductive and developmental effects, such as the effect of lead on children's neural development.



- Contaminants causing long-term health effects are mostly chemical contaminants and include, among others, byproducts of solvents used by commercial and industrial facilities, pesticides, disinfectants, and lead and other metals. For example, some disinfection byproducts are toxic and some are probably carcinogens. Exposure to lead can impair the mental development of children.
- Below are general categories of toxicity, based on the organs or systems in the body affected:
  - Gastrointestinal: affecting the stomach and intestines.
  - Renal: affecting the kidneys.
  - Hepatic: affecting the liver.
  - Neurological: affecting the brain, spinal cord, and nervous system.
  - Cardiovascular or Hematological: affecting the heart, circulatory system or blood.
  - Respiratory: affecting the nose, trachea, and lungs.
  - Dermatological: affecting the skin and eyes.
  - Reproductive or developmental: affecting the ovaries or testes, or causing birth defects or miscarriages. This includes contaminants with genotoxic effects; i.e., capable of altering Deoxyribonucleic acid (DNA). This can have mutagenic effects (changes in the genetic materials causing cells to misfunction) which can cause cancer or birth defects (teratogens).



- Substances that cause cancer are known as ***carcinogens***. Compounds are classified as carcinogens based on evidence gathered in studies. EPA has a three-category approach to classifying compounds as carcinogenic:
  - ***Category I*** compounds are carcinogens.
  - ***Category II*** compounds exhibit limited evidence of carcinogenic endpoints and also exhibit noncarcinogenic endpoints.
  - ***Category III*** compounds are noncarcinogenic, based on evidence of carcinogenicity, pharmacokinetics (the absorption, distribution, metabolism, and excretion of substances from the body), potency, and exposure.
- Previous categories are based on "the weight of evidence" for potential carcinogens and put in five groups. A weight of evidence evaluation is a collective evaluation of all pertinent information so that the full impact of biological plausibility and coherence are adequately considered. Identification and characterization of human carcinogencity are based on human and experimental data. Judgment about the weight of evidence involves consideration of the quality and adequacy of data and consistency of responses by the agent in question.
  - Group A - Human carcinogen
  - Group B - Probable human carcinogen
  - Group C - Possible human carcinogen
  - Group D - Not Classified
  - Group E - Evidence of noncarcinogenicity

Question to the Class

- What does EPA do in setting regulations that differentiates between acute and chronic effects?

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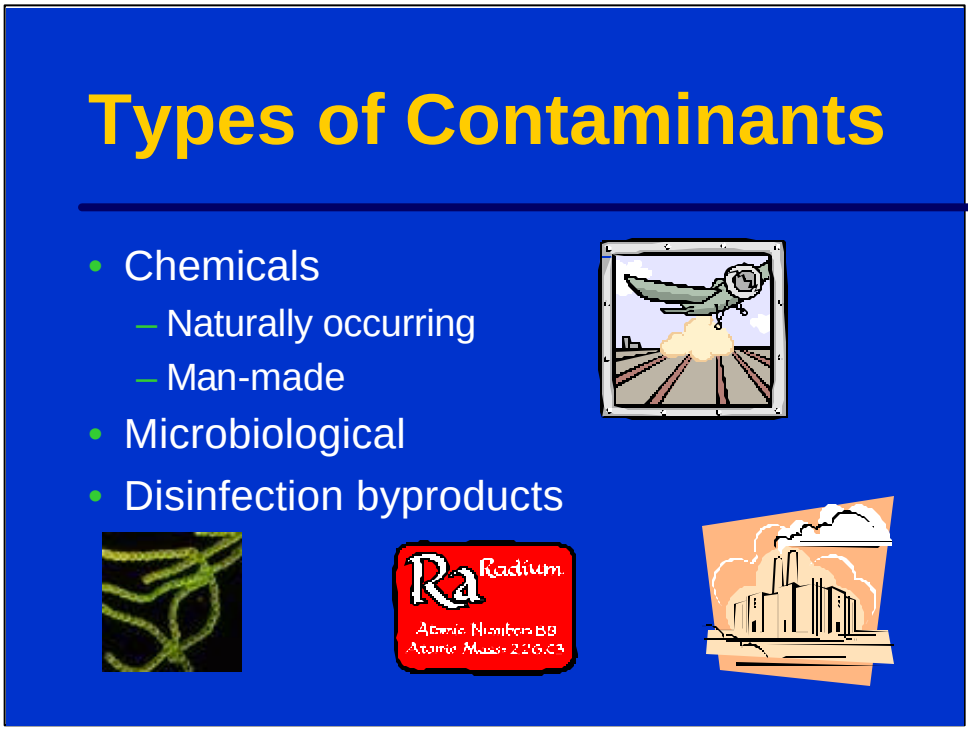
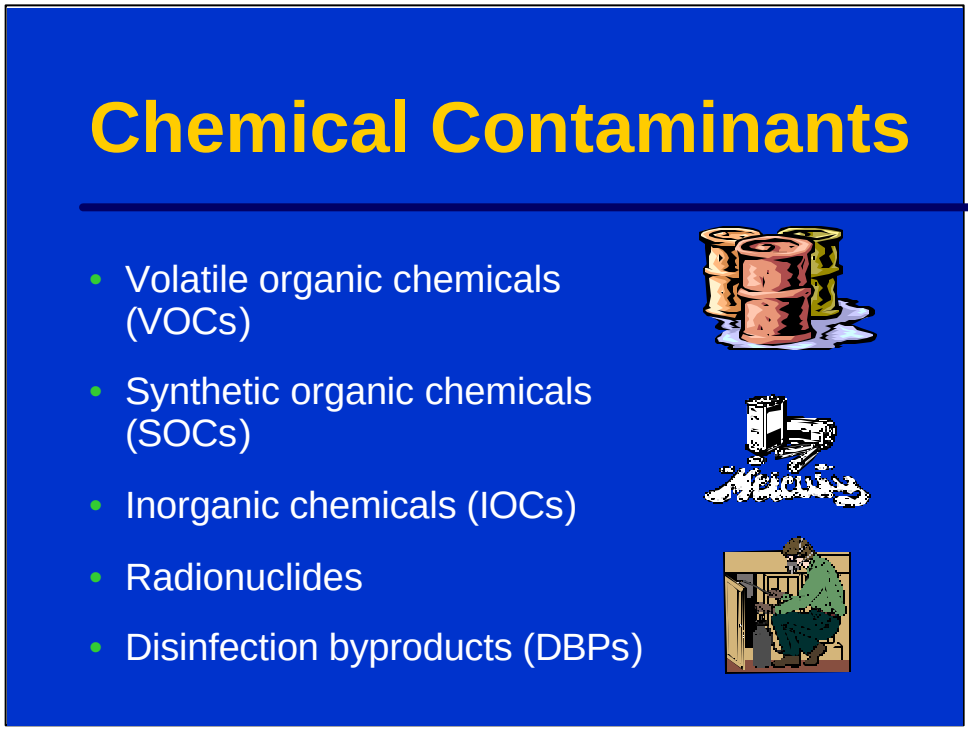
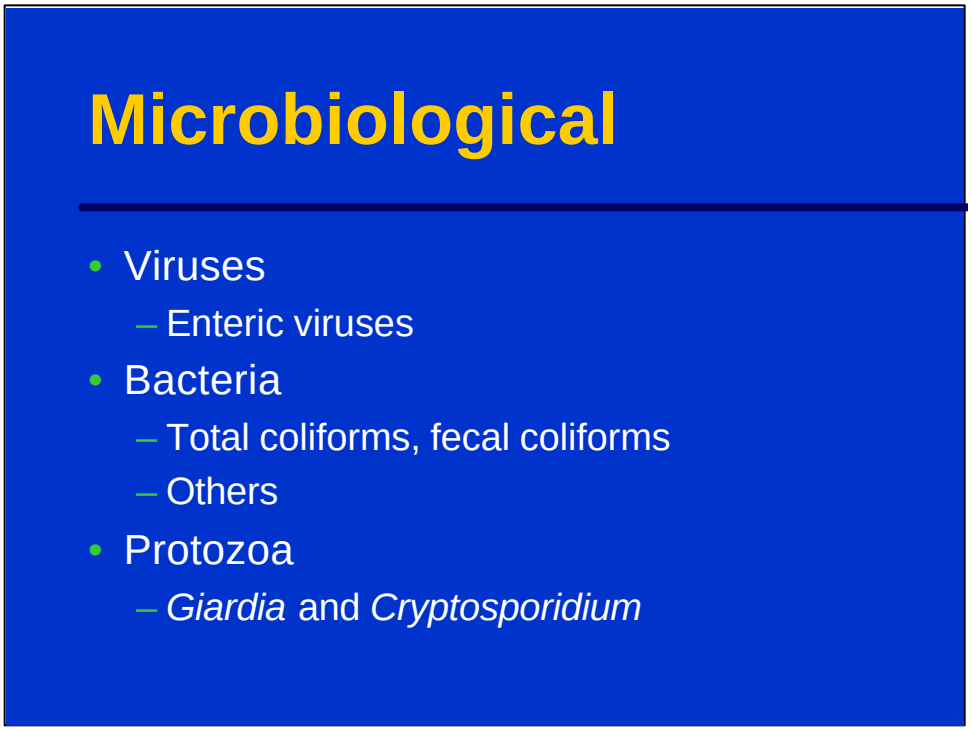


- Note that not all contaminants of concern in drinking water are man-made or due to human activities.
- Examples of each type of contaminant that EPA currently regulates are as follows:
  - Naturally occurring chemicals: arsenic, radon, and lead (though lead exposure reflects human use of it in materials).
  - Man-made chemicals: chlordane and dioxin, VOCs and SOCs.
  - Microbiological: *Cryptosporidium*, *Giardia lamblia*, bacteria and viruses (especially from fecal sources).
  - Disinfection byproducts: Trihalomethanes and haloacetic acids.



- Contaminants causing chronic health effects include byproducts of disinfection, lead and other metals, pesticides, and solvents used by commercial and industrial facilities.
- ***Volatile organic chemicals*** (VOCs) include mostly industrial and chemical solvents such as benzene and toluene. Benzene has the potential to cause chromosome aberrations and cancer from a lifetime exposure at levels above the MCL. Toluene has the potential to cause pronounced nervous disorders such as spasms; tremors; impairment of speech, hearing, vision, memory, and coordination; and liver and kidney damage from a lifetime exposure at levels above the MCL.
- ***Inorganic chemicals*** (IOCs) include metals and minerals. Some of these have the potential to cause chronic health effects. For example, lead has the potential to cause stroke, kidney disease, and cancer from a lifetime exposure at levels above the MCL.
- ***Synthetic organic chemicals*** (SOCs) include pesticides such as atrazine and alachlor. Atrazine has the potential to cause weight loss; cardiovascular damage; retinal and some muscle degeneration; and cancer from a lifetime exposure at levels above the MCL. Alachlor can cause eye, liver, kidney, or spleen problems; anemia; and an increased risk of cancer.
- While disinfectants are effective in controlling many microorganisms, they react with natural organic and inorganic matter in source water and distribution systems to form ***disinfection byproducts (DBPs)***. Results from toxicology studies have shown several DBPs (e.g., bromodichloromethane, bromoform, chloroform, dichloroacetic acid, and bromate) to be carcinogenic in laboratory animals. Other DBPs (e.g., chlorite, bromodichloromethane, and certain haloacetic acids) have also been shown to cause adverse reproductive or developmental effects in laboratory animals. Several epidemiology studies have suggested a weak association between certain cancers (e.g., bladder) or reproductive and developmental effects, and exposure to chlorinated surface water.



- ***Pathogens*** are microorganisms that can cause disease in humans, animals and plants. They may exist as bacteria, viruses, or parasites and are found in sewage, in runoff from animal farms or rural areas populated with domestic and/or wild animals, and in water used for drinking and swimming. Fish and shellfish contaminated by pathogens, or the contaminated water itself, can cause serious illnesses.
  - A ***virus*** is the smallest form of microorganism capable of causing disease. A virus of fecal origin that is infectious to humans by waterborne transmission is of special concern for drinking water regulators. Many different waterborne viruses can cause gastroenteritis, including Norwalk virus, and a group of Norwalk-like viruses, plus hepatitis A, rotaviruses, enteroviruses such as poliovirus, echovirus, coxsakievirus.
  - ***Bacteria*** are microscopic living organisms usually consisting of a single cell. Waterborne disease-causing bacteria include *E. coli* and *Shigella*.
  - ***Protozoa*** or ***parasites*** are also single cell organisms. Examples include *Giardia lamblia* and *Cryptosporidium*.

Protozoa

Giardia

Cryptosporidium

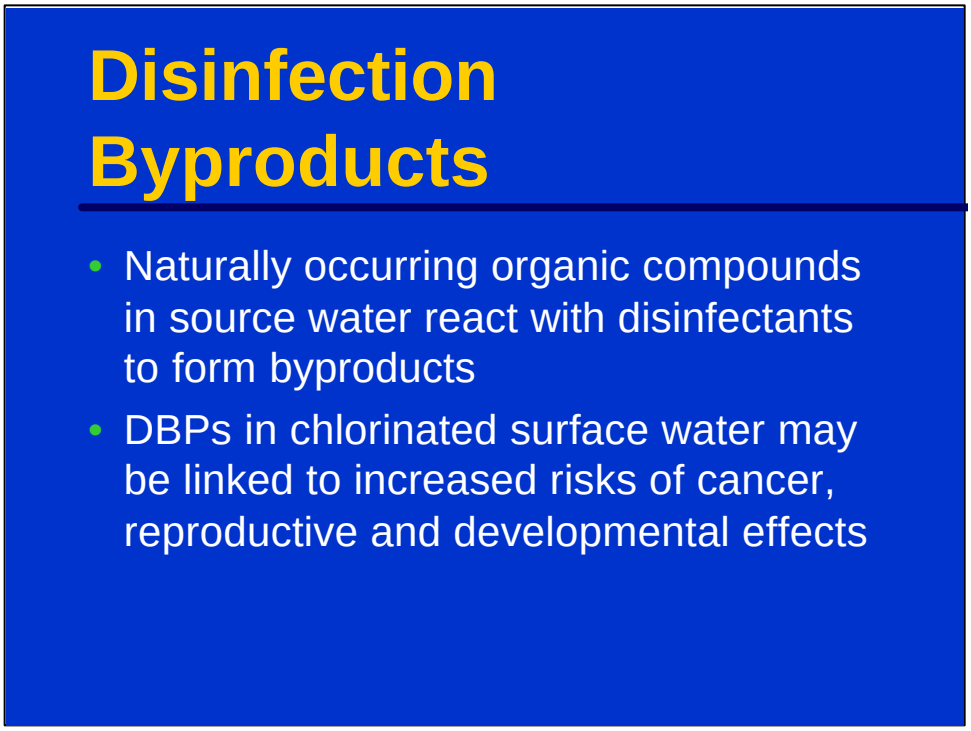
- *Giardia lamblia* was only recognized as a human pathogen capable of causing waterborne disease outbreaks in the late 1970s. Its occurrence in relatively pristine water as well as waste water treatment plant effluent called into question water system definitions of "pristine" water sources. During the past 15 years, *Giardia lamblia* has become recognized as one of the most common causes of waterborne disease in humans in the United States. This parasite is found in every region of the U.S. and throughout the world. In 1995, outbreaks in Alaska and New York were caused by *Giardia*. The outbreak of giardiasis in Alaska affected 10 people, and was associated with untreated surface water. The outbreak in New York affected an estimated 1,449 people, and was associated with surface water that was both chlorinated and filtered. The symptoms of giardiasis include diarrhea, bloating, excessive gas, and malaise.
- *Cryptosporidium* (often called "crypto"), which cannot be seen without a very powerful microscope, is so small that over 10,000 of them would fit on the period at the end of this sentence. The infectious dose for crypto is less than 10 organisms and, presumably, one organism can initiate an infection. As late as 1976, it was not known to cause disease in humans. In 1993, more than 400,000 people in Milwaukee, Wisconsin, became ill with diarrhea after drinking water contaminated with the parasite. Since then, attention has been focused on determining and reducing the risk of cryptosporidiosis from public water supplies. Crypto is commonly found in lakes and rivers and is highly resistant to disinfection with chlorine. People with severely weakened immune systems are likely to have more severe and more persistent symptoms than healthy individuals.

Recent Waterborne Disease Outbreaks in the U.S.

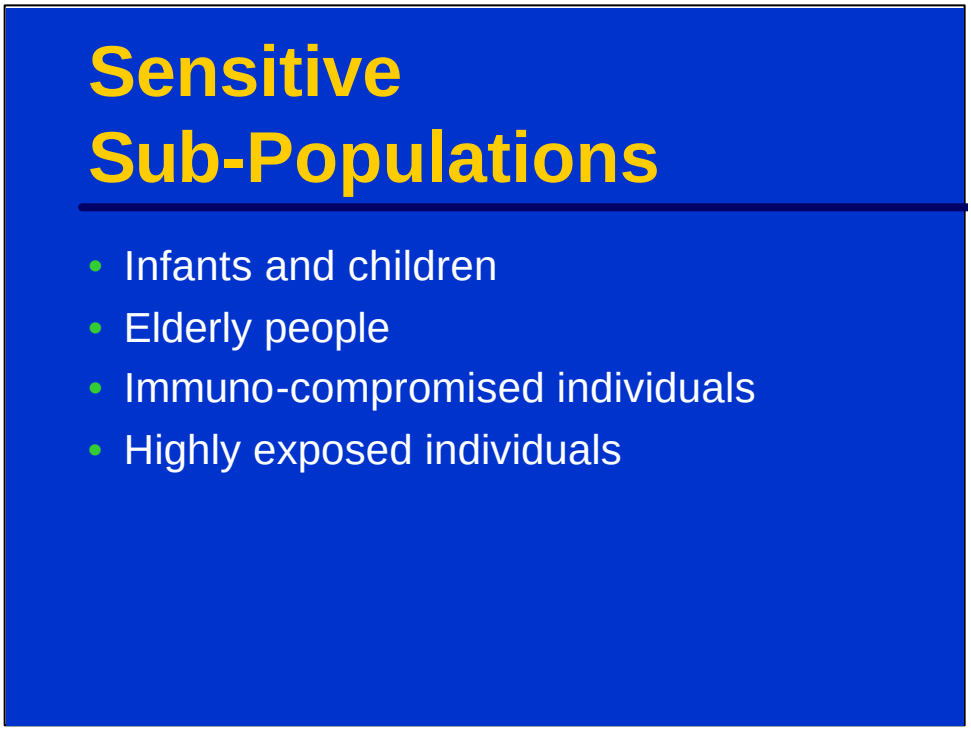
Year	Location	Cause of Disease	No. Affected
1985	MA	*Giardia lamblia* (protozoan)	703 illnesses
1987	GA	*Cryptosporidium* (protozoan)	13,000 illnesses
1987	PR	*Shigella sonnei* (bacterium)	1,800 illnesses
1989	MO	*E. coli* 0157 (bacterium)	243 illnesses; 4 deaths
1993	MO	*Salmonella typhimurium* (bacterium)	650 illnesses; 7 deaths
1993	WI	*Cryptosporidium* (protozoan)	400,000 illnesses; 50+ deaths
1995	NY	*Cryptosporidium* (protozoan)	1,500 illnesses

- The Centers for Disease Control and Prevention (CDC) defines an outbreak of waterborne disease caused by microorganisms as occurring when:
  - Two or more persons experience a similar illness after consumption or use of drinking water; and
  - Epidemiologic evidence implicates the water as a source of illness.
- The CDC also defines a single case of illness as a waterborne disease outbreak if a study indicates that the water has been contaminated by a chemical.

Note: Epidemiology is the study of the incidence rate of diseases in real populations, through studying the relationship between exposure and risk.



- A large portion of the U.S. population is potentially exposed to DBPs through its drinking water. More than 240 million people in the United States are served by public water systems that apply a disinfectant to water to protect against microbial contaminants.
- Epidemiological and toxicological studies involving DBPs have provided indications that these substances may have a variety of adverse effects across the spectrum of reproductive and developmental toxicity:
  - Early-term miscarriage;
  - Still birth;
  - Low birth weight;
  - Prematurity; and
  - Some congenital birth defects.
- Approximately 15 percent of births each year are considered to be low birth weight (under 2.5 kilograms or 5.5 pounds), with 7 percent considered very low birth weight (1.0 kilogram or 2.2 pounds). Also, congenital abnormalities are reported to occur in just over 1 percent of all live births each year.



- Some groups of people may be more susceptible to the effects of contaminants in drinking water. If evidence shows that a specific subpopulation is more sensitive to a contaminant than the population at large, then safe exposure levels are based on that population. If no such scientific evidence exists, pollution standards are based on the group with the highest exposure level.
- For example:
  - People with severely weakened immune systems are likely to have more severe and more persistent symptoms of waterborne diseases than healthy individuals.
  - Nitrates put infants at special risk for methemoglobinemia or "blue baby syndrome."
- Some commonly identified sensitive subpopulations include infants and children, the elderly, pregnant and lactating women, and immuno-compromised individuals. The particular concerns for these three groups are described on the following slides.

Infants and Children

- The bodies and organ systems of infants and young children process chemicals differently than those of adults. Organs develop throughout childhood and some are not completely mature until puberty. This affects the body's ability to recover from damage due to environmental toxins and affects the rates at which our bodies metabolize, distribute, or excrete substances.
  - Exposure to environmental toxins can cause malformations of developing organs. Contaminants may overwhelm the ability of organs or body systems to process them or repair the damage they cause. The nervous system, which develops throughout childhood, is particularly vulnerable to exposure.
  - The immature organs of children may not be able to metabolize or neutralize foreign substances as rapidly or efficiently as those of adults.
  - The unique habits of children, for example the amount of time they spend outdoors playing or tendencies toward putting things in their mouths, may make certain pathways of exposure more significant for children than for adults. Also, pound-per-pound, children ingest more food, drink more water, and breathe more air than adults.

Elderly People

- Internal biological changes associated with aging, state of health, and genetic predisposition can increase the potential for elderly people to be more sensitive to environmental conditions than other members of the population. Metabolic, excretory, and other bodily functions change as people age due to changes in organ function and reduction in lean body mass and the percentage of body fat, and total body water. For example, blood flow, which limits metabolic rates, decreases and kidney function in the elderly is reduced by an average of 50 percent, limiting elimination of substances from the body.

Immuno-Compromised Individuals

- Individuals who are severely immuno-compromised (that is, have weakened immune systems) may include those who are infected with HIV/AIDS, cancer and transplant patients taking immunosuppressive drugs, and people born with weakened immune systems.
- These people are particularly susceptible to pathogens such as *Cryptosporidium* or *Giardia* in drinking water, or waterborne diseases. Pathogens make exposed people sick with gastrointestinal illness, with symptoms that include diarrhea, nausea, and/or stomach cramps. While otherwise healthy people recover from these symptoms in a matter of days or weeks, people with weakened immune systems are likely to have more severe and more persistent symptoms or may never recover.

Highly Exposed Populations

- In addition to considering the exposure of sensitive populations, risk assessors must also consider those groups who are exposed to contaminants at the highest level. Individuals who consume certain foods or drink water in amounts significantly higher or in greater proportion than the general population will intake associated contaminants at higher levels.
  - Examples of people who may have higher exposure to contaminants in drinking water include athletes or people working at strenuous occupations. These people drink much more than the two-liter per day average for the population at large.

From Risk to Rule: How EPA Develops Risk-Based Drinking Water Regulations

Lesson 4: Setting MCLGs

- The purpose of Lesson 4 is to describe how EPA evaluates health effects information to set MCLGs.

What is an Adverse Health Effect?

- **EPA definition (from Integrated Risk Information System):**

  "… any biological, physiological, anatomical, pathological, and/or behavioral change that may affect the performance of the whole organism or reduce the ability of the organism to respond to additional challenges."

- At some levels of exposure biological effects may occur that are not considered to be "adverse." Distinctions are made by health scientists using best professional judgment.

Identifying Adverse Health Effects

- Different adverse effects can occur with different magnitude, frequency and durations of exposure
- Typically, two broad categories of adverse health effects are considered:
  - Cancer
  - Non-cancer

- A contaminant may cause more than one type of toxic effect, and those can be a function of the magnitude, frequency, and duration of exposure. Observed effects can also reflect susceptibility of sensitive subgroups.
- For drinking water assessment purposes, types of adverse health effects are usually considered in two categories: cancer (carcinogenic) effects and non-cancer effects.
- Determining whether a substance poses a cancer or non-cancer risk to humans is based on evidence from epidemiological (human) studies and/or toxicological (animal) studies.
- A weight-of-evidence approach is generally used to determine whether a substance is expected to cause particular adverse effects

"All substances are poisons; there is none which is not a poison. The right dose differentiates a poison and a remedy." - Paracelsus (1493-1541)

Key Terms

- Dose
- Reference Dose (RfD)
- Drinking Water Equivalent Level (DWEL)
- Relative Source Contribution Factor (RSC)
- No Observable Adverse Effects Level (NOAEL)
- Lowest Observable Adverse Effects Level (LOAEL)

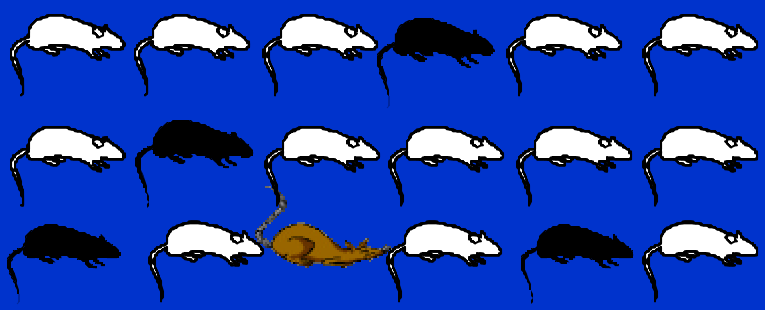
- ***Dose*** – A measure of intake of a substance, usually expressed in units of mg/kg-day (milligrams per kilogram body weight per day).
- ***Reference Dose*** (RfD) – The daily exposure level which, during an entire lifetime of a human, appears to be without appreciable risk.
- *Drinking Water Equivalent Level* (DWEL) – The RfD converted to a drinking water concentration assuming 2 liter per day and 70 kg body weight.
- ***Relative source contribution*** (RSC) – the fraction of total intake of the contaminant that is typically associated with water (as opposed to food, air, and other specific sources).
- ***No Observable Adverse Effect Level*** (NOAEL) – A dose based on experimental data that appears to result in no adverse effects.
- ***Lowest Observable Adverse Effect Level*** (LOAEL) – The lowest dose used in a study that results in an observed adverse effects.

Maximum Contaminant Level Goals

- Considerations in setting an MCLG:
  - End-point – cancer or noncancer
  - Acute or chronic exposure concerns
  - Sensitive populations
- Data obtained from epidemiological and toxicological studies

- The maximum contaminant level goal (MCLG) is the maximum level of a contaminant in drinking water at which no known or anticipated adverse health effects would occur, and which allows an adequate margin of safety. MCLGs do not take cost and technologies into consideration.
- EPA considers whether the contaminant is a carcinogen (i.e., causes cancer) or a non-carcinogen when setting the MCLG.
- EPA also considers whether the effects are acute (effects caused within a short period of time after a single exposure to the contaminant) or chronic (effects that take place after prolonged exposure).
- MCLGs must take sensitive populations into concern. Some commonly identified sensitive subpopulations include infants and children, the elderly, pregnant and lactating women, and immuno-compromised individuals.
- Risk assessors have two tools available to assess the health effects of pollutants: laboratory studies of toxicology and epidemiological studies. Each type of study has inherent strengths and weaknesses, which are described on the next few slides.

Toxicological Studies

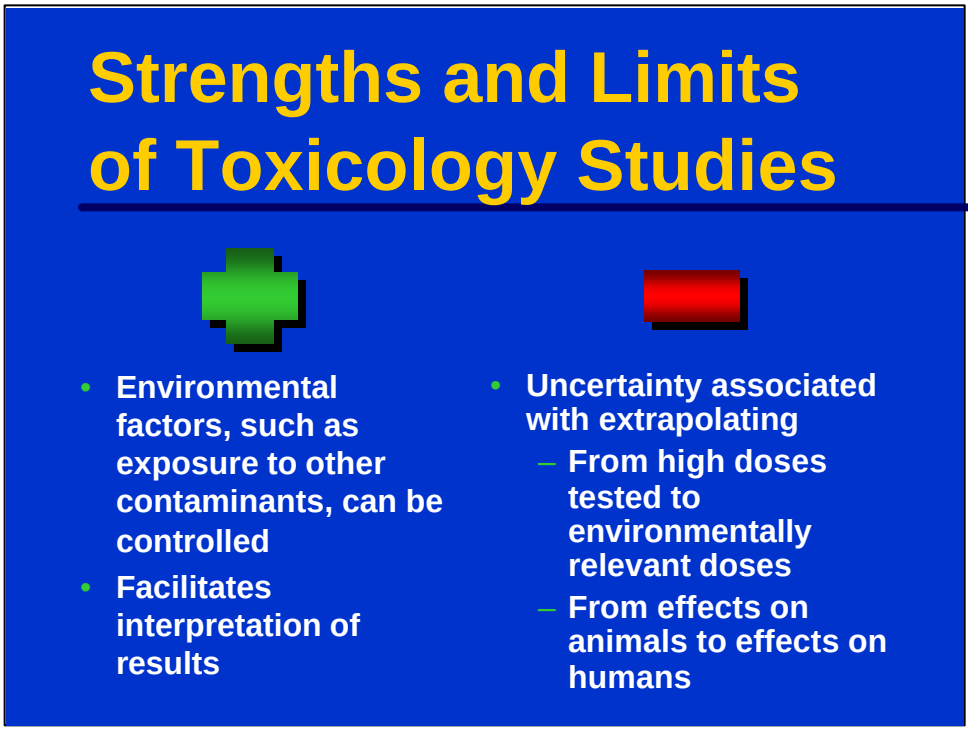


- ***Toxicology*** is the science and study of poisons and their actions. Toxicological studies generally involve animal (non-human) experiments.
- Experiments on animals are often used to try to determine the level of a chemical that would cause an additional case of cancer (or another disease) in a million animals. To detect a relevant numbers of cases, in an ideal experiment, millions of animals would be exposed to chemicals at concentrations typical of environmental conditions. Because investigations of such a scale are impractical, most experiments involve exposing smaller numbers of animals (several hundred) to higher doses of chemicals.
- Toxicologists use mathematical models to extrapolate incidences of diseases within a small number of animals exposed to high concentrations to determine the concentration of the chemical that would cause one incidence of disease in a million people. The mathematical model chosen is the one that provides the greatest ***margin of safety***; that is, the model that overestimates (rather than underestimates) the ability of the chemical to cause disease.
- Ethical considerations generally preclude conducting experiments of the effects of exposing humans to potentially toxic or carcinogenic chemicals. However, paid subjects have been exposed to *Cryptosporidium* and *Giardia* for the purpose of studying the infectivity of these protozoans.

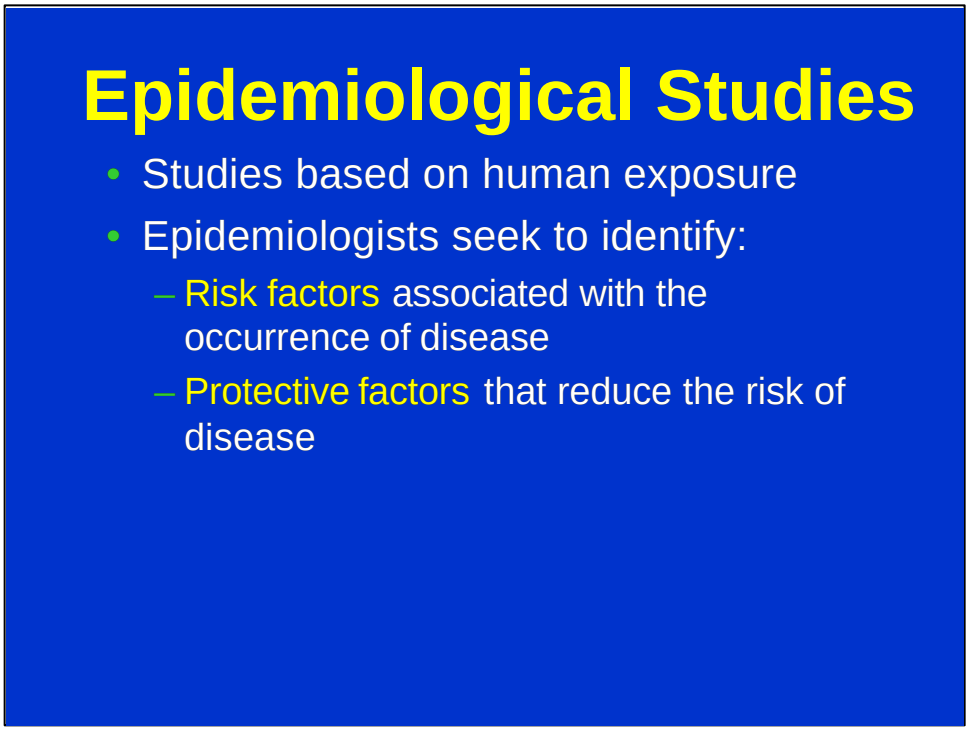
Toxicology Study Methods

- Some animals subjected to high doses of chemicals
  - Necessary to observe statistically significant rates of disease
- Other animals exposed to lower doses of chemicals
  - Necessary to provide data inputs for a dose-response curve

- Long-term carcinogenicity studies assess malignant and benign tumor growth, pre-cancerous lesions, or other toxic effects in animals that could be related to tumor production.
- Some animals are subjected to high doses of chemicals to detect carcinogenicity. These high doses are often necessary to produce observable rates of disease in the smaller number of subjects that have statistical significance.
- Other animals are exposed to lower doses; unexposed controls are also included.
- Together, the results provide data inputs for constructing a dose-response curve.

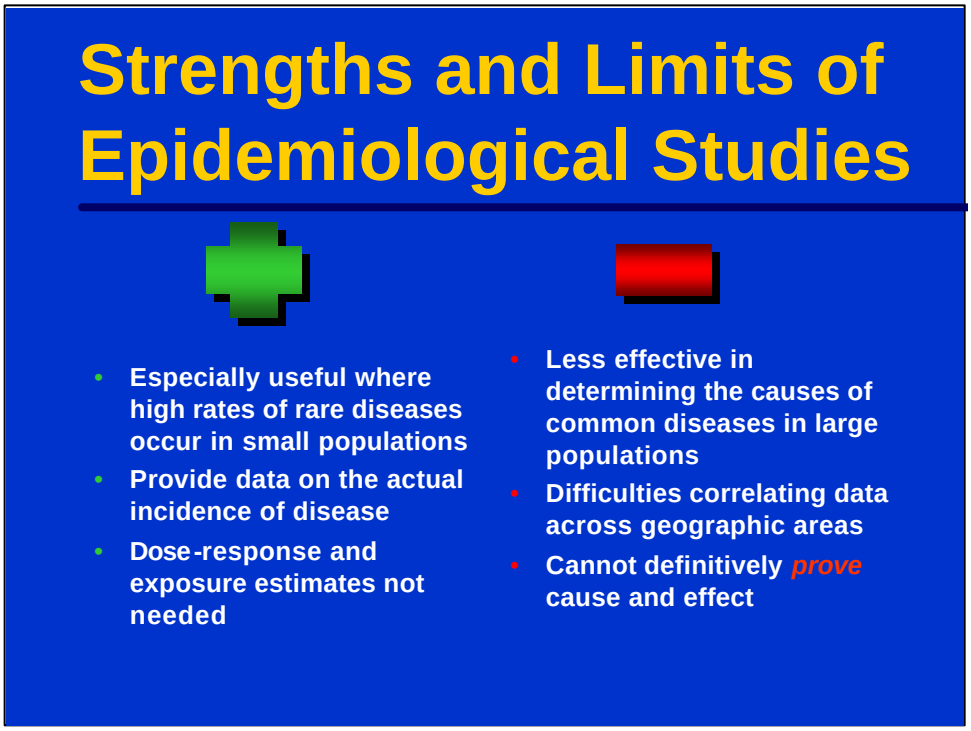


- The main strength of laboratory studies is that they are easier to interpret than epidemiological studies. This is because other environmental factors, including exposure to other chemicals, can be controlled in a laboratory situation.
- Laboratory studies are limited by the inherent uncertainty in extrapolating the high doses used in laboratory experiments to the lower doses likely to occur in the environment in order to determine at what dose exposure would cause one case of cancer or other disease in a million people.
- Another uncertainty associated with laboratory species is interspecies differences. That is, whether the effects demonstrated in animals in the lab are likely predictors of effects on humans.



- ***Epidemiology*** is the study of how, when, and where diseases occur in populations of humans, and the application of study results to control a public health problem.
- Epidemiological studies are based on human exposure. Data may be gathered from medical records and hospital admissions, causes of death recorded on death certificates, or surveys.
- Epidemiologists try to identify either ***risk factors*** (factors that are associated with causing disease) or ***protective factors*** (factors that protect against disease). In the early days of epidemiology, scientists tried to discover the causes of contagious diseases; today epidemiology also focuses on diseases (such as cancer) and poisonings resulting from environmental exposure.
- It is important that the epidemiologist pick the right behavioral, environmental, or health factors to study as possible risk factors or protective factors. If inappropriate factors are studied and the real risk or protective factors are missed, the study will not yield useful information.

- Epidemiological studies can never definitively prove that a specific factor causes a certain disease. What these studies can show is whether a risk factor is associated or correlated with a higher incidence of a disease in the population exposed to that factor. The strength of an epidemiological study depends on the number of cases and controls in a study–the more cases included in the study, the more likely it is that a significant association between a risk factor and a disease will be discovered.
- Like laboratory studies, epidemiological studies rely heavily on statistics to describe the relationships between risk factors and diseases.
- Epidemiological studies are either retrospective or prospective. Retrospective (often called case-control) studies focus on events that have already occurred; prospective (often called cohort) studies attempt to determine the likelihood of events happening in the future based on different attributes of population groups.

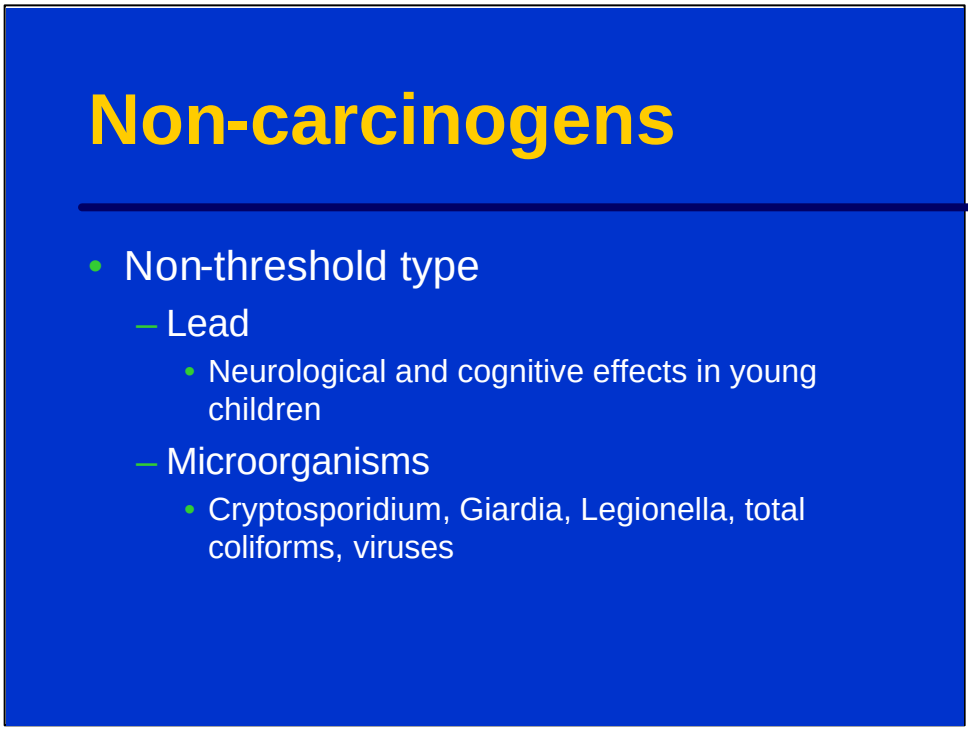


- Epidemiological studies have been particularly useful in identifying links between exposure to chemicals and disease in occupational settings where workers are exposed to very high levels of a small number of chemicals. This is especially so when high rates of rare diseases occur among a small population, such as rare types of cancer or tumors among workers in a single factory.
- Using data on the actual incidence of disease is preferable to estimating risk based on exposure and intake assumptions of contaminants. Epidemiological data provide a better indicator of health impacts without the need for dose-response and exposure estimates.
- Epidemiological studies work less effectively, however, for determining the causes of common diseases, e.g., cardiovascular disease, in large populations. This is basically because there are too many other variables beside the risk or protective factor that may be associated with the disease being studied.
- It may be difficult to correlate incidence data for one geographic area to other similar areas. Extrapolation to other geographic areas or beyond a small area may be necessary and the relationship between the cause and effect may be less clear as a result.
- While epidemiological studies can establish a link between a chemical and disease, they can never definitively prove that a specific factor causes a certain disease; nor can they determine at exactly what level of exposure disease will result. Rather, they are limited to correlating a risk factor with a higher incidence of a disease in the exposed population.

Non-carcinogens

- Threshold type:
  - RfD (mg/kg-day) is determined from toxicological or epidemiological data
  - DWEL (mg/L) is computed from the RfD assuming 2 L/day consumption and 70 kg body weight
  - RSC is applied to DWEL to get MCLG
  - Essentially all of the non-zero MCLGs in place today have gone through this procedure

- A key assumption for noncarcinogens is there is usually an exposure-effect threshold; that is, a level below which exposures would be expected to show no increase in adverse health effects.
- In evaluating threshold noncarcinogens, EPA assumes a drinking water intake of two liters per day and a body weight of 70 kilograms (≅ 154 pounds).
- Exposure from other sources is also considered. The drinking water program commonly uses a "percentage" method in deriving MCLGs. That is, the percentage of total exposure accounted for by drinking water, referred to as the RSC, is applied to the RfD to determine the maximum amount of the RfD "allocated" to drinking water. A ceiling level of 80 percent of the RfD and a floor level of 20 percent of the RfD are used as defaults. In other words, the MCLG cannot account for more than 80 percent of the RfD, nor less than 20 percent of the RfD.

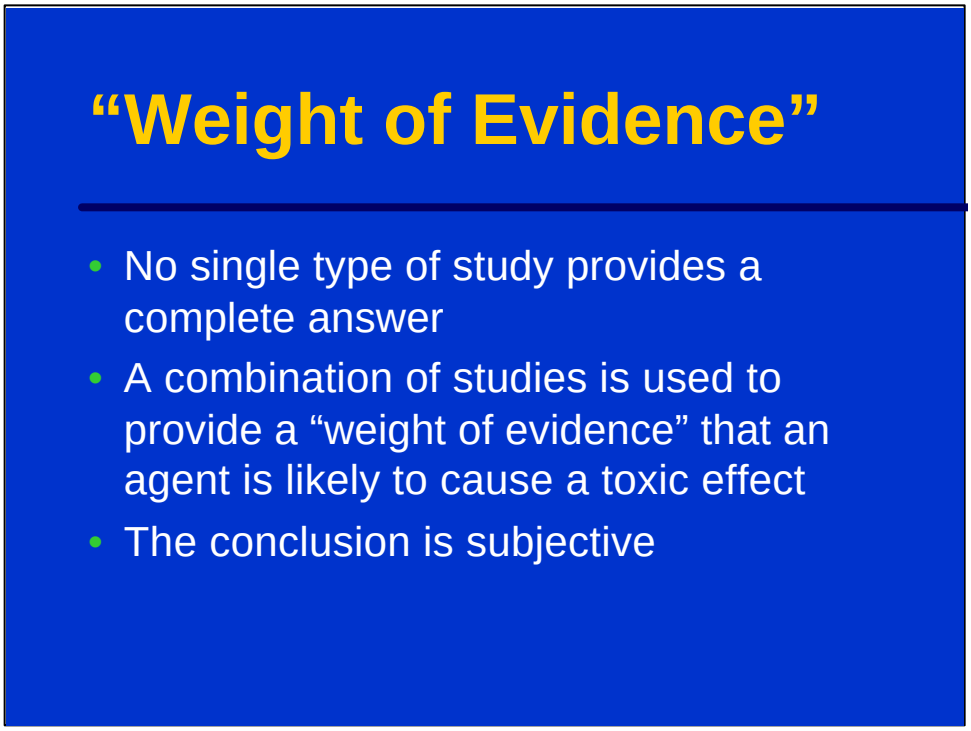


- Lead is the only chemical treated as a non-threshold non-carcinogen. That is, adverse health effects can occur at any level of exposure.
- A great deal of information on the health effects of lead has been obtained through decades of medical observation and scientific research. By comparison to most other environmental toxicants, the degree of uncertainty about the health effects of lead is quite low.
- It appears that some of these effects, particularly changes in the levels of certain blood enzymes and in aspects of children's neurobehavioral development, may occur at blood lead levels so low as to be essentially without a threshold. EPA determined that it is inappropriate to develop an RfD.
- All of the microorganisms are treated as non-threshold non-carcinogens.

Carcinogens

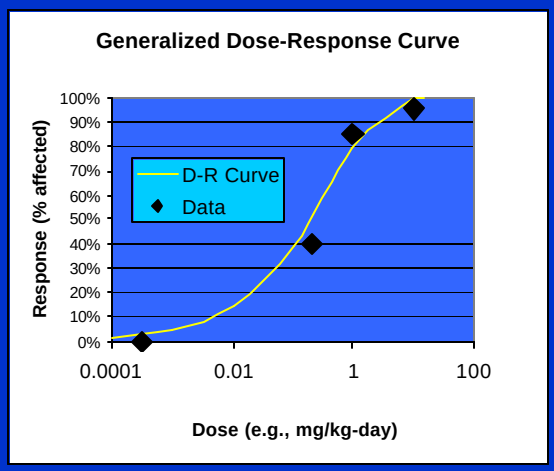
- The MCLG is traditionally set at zero for all carcinogens
  - Assumed to be genotoxic
  - No threshold
- Non-zero MCLGs are possible, reflecting non-genotoxic mode of action considerations discussed in the 1996 Draft Carcinogen Assessment Guidelines

- For genotoxic carcinogens, exposure to any amount is assumed to involve a risk of producing cancer; that is, there is no threshold.
- Genotoxic refers to carcinogens that interact directly with DNA.
- Non-genotoxic refers to carcinogens that produce genotoxic effects by any of a variety of other processes, such as interfering with normal growth control mechanisms, or affecting enzymes involved in DNA synthesis, recombination, or repair.



- Determining whether a substance poses a risk of disease in humans is based on evidence from human epidemiological studies and animal studies, as well as on other relevant information. No single type of study provides a complete answer.
- A combination of studies is used to provide a "weight of evidence" that an agent is likely to cause a toxic effect. EPA has developed a weight-of-evidence approach to classify the likelihood of human carcinogenicity.
- For example, one study might demonstrate significant numbers of tumors resulting from exposure to a contaminant. A second study might not show *significantly* more tumors in the dose group than in the control group (there may be an increase in tumor incidence, it may not be statistically significant). A third study may demonstrate growth of benign tumors, but not malignant ones.
- If available, other evidence of carcinogenicity from other studies should be reviewed. For example:
  - Does the agent cause DNA mutations or somehow react with DNA?
  - Does the agent affect cell death or cell division rates?
  - How is the agent metabolized? Where does it go in the body? Does it break down into other toxic chemicals?

Dose Response Relationships



- Once the data has been collected from the toxicological and epidemiological studies, a dose-response curve can be drawn. A dose-response curve is a quantitative or semi-quantitative relationship describing the dose (exposure) and response (adverse effect incidence).
- Dose-response curves are derived by plotting the incremental risk of cancer (or illness) on the y-axis and the lifetime daily dose on the x-axis.
- Mathematical curves are fitted to the observed data (curve fitting).
- For genotoxic carcinogens, the curve goes through the 0,0 origin (that is, no threshold).
- The slope of the dose-response curve is called the slope factor or potency factor (PF). This can be thought of as the risk corresponding to a chronic daily intake of 1 mg/kg-day of the contaminant involved.
- Incremental lifetime cancer risk = chronic daily intake x slope factor.
- The relationship between dose and response may be linear (proportional) or non-linear (disproportional). Using the curve, the corresponding responses can be estimated for specific doses.

Review of Current MCLGs

- Handout of National Primary Drinking Water Regulations from: www.epa.gov/safewater
  - Microorganisms
  - Disinfection byproducts
  - Disinfectants
  - Inorganic chemicals
  - Organic chemicals
  - Radionuclides

From Risk to Rule: How EPA Develops Risk-Based Drinking Water Regulations

Lesson 5: Setting MCLs and TTs

- Lesson 5 describes how EPA sets MCLs or establishes Treatment Technique requirements for drinking water contaminants.

Maximum Contaminant Level

- An MCL is an enforceable standard
- Set as close to the MCLG as feasible
- SDWA provides guidance on the meaning of feasible in §1412(b)(4)(E)
- Requires a determination as to whether the benefits justify the costs (1996 Amendments)

- EPA establishes ***maximum contaminant levels (MCLs)***, which are enforceable limits that finished drinking water must meet. MCLs are set as close to the MCLG as feasible.
- SDWA defines "feasible" as the level that may be achieved:
  - With the use of the best available technology (BAT), treatment technique, and other means that EPA determines to be available;
  - After examination for efficiency under field conditions and not solely under laboratory conditions; and
  - Taking cost into consideration.

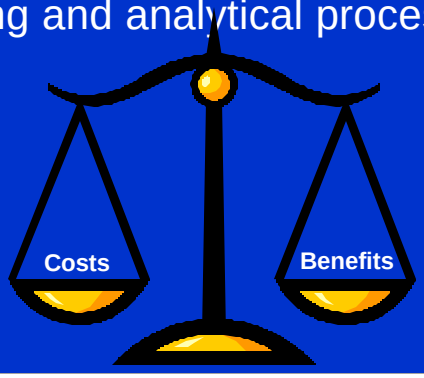
Treatment Technique

- Alternative to an MCL when it is not economically and technologically feasible to ascertain the level of the contaminant
- A TT is also an enforceable standard involving a measurable procedure or level of technological performance (e.g., "Action Level")

- For some contaminants, especially microbiological contaminants, there is no reliable method that is economically and technically feasible to measure a contaminant at particularly low concentrations. In these cases, EPA establishes treatment techniques.
- A ***treatment technique*** is an enforceable procedure or level of technological performance that public water systems must follow to ensure control of a contaminant.
- Examples of rules that include treatment technique are the Surface Water Treatment Rule and Lead and Copper Rule.

Benefit and Cost Analyses

- Regardless of whether it's an MCL or a Treatment Technique, the information gathering and analytical processes are similar

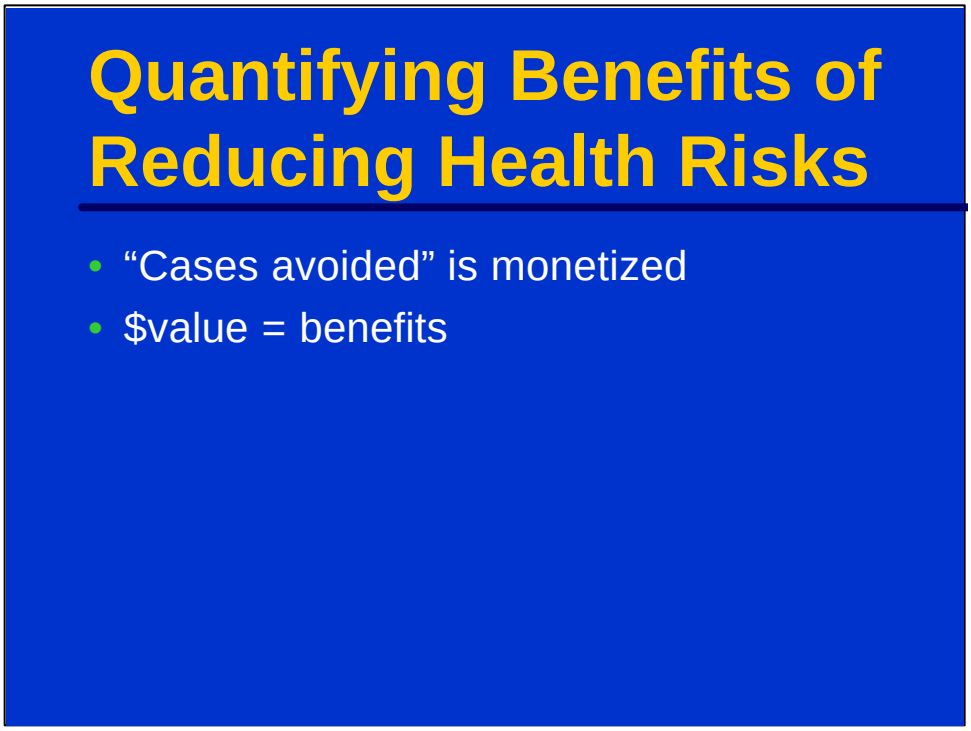


- The 1996 SDWA Amendments added section 1412(b)(6), Additional Health Risk Reduction and Cost Considerations, which states, ". . . if the Administrator determines. . . that the benefits of a maximum contaminant level . . . would not justify the costs of complying with the level, the Administrator may, after notice and opportunity for public comment, promulgate a maximum contaminant level that maximizes health risk reduction benefits at a cost that is justified by the benefits."
- This was a significant change from the previous language as it allows the cost of compliance to be an explicit consideration is setting MCLs. EPA used this rationale when setting the arsenic rule and the uranium MCLs.
- EPA set the standard at a level that "maximizes health risk reduction benefits at a cost that is justified by the benefits." In other words, although technology would allow lower levels of arsenic and uranium to be reached, EPA determined that the potential health benefits did not justify the added cost.
- Prior to the 1996 Amendments, benefit-cost analysis did not enter into rule development explicitly, although it was still done to help inform the decision.

Quantifying Benefits of Reducing Health Risks

- Occurrence and exposure information
  - Reduced exposure
- Dose-response information
  - Deaths or disease avoided

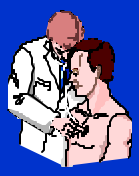
- Benefits estimation uses occurrence and exposure information to determine how many people currently exposed above some critical threshold would have their exposure reduced below it as a result of the rule.
- Where dose-response information is available, estimates are made of the number of cases of disease or death avoided.



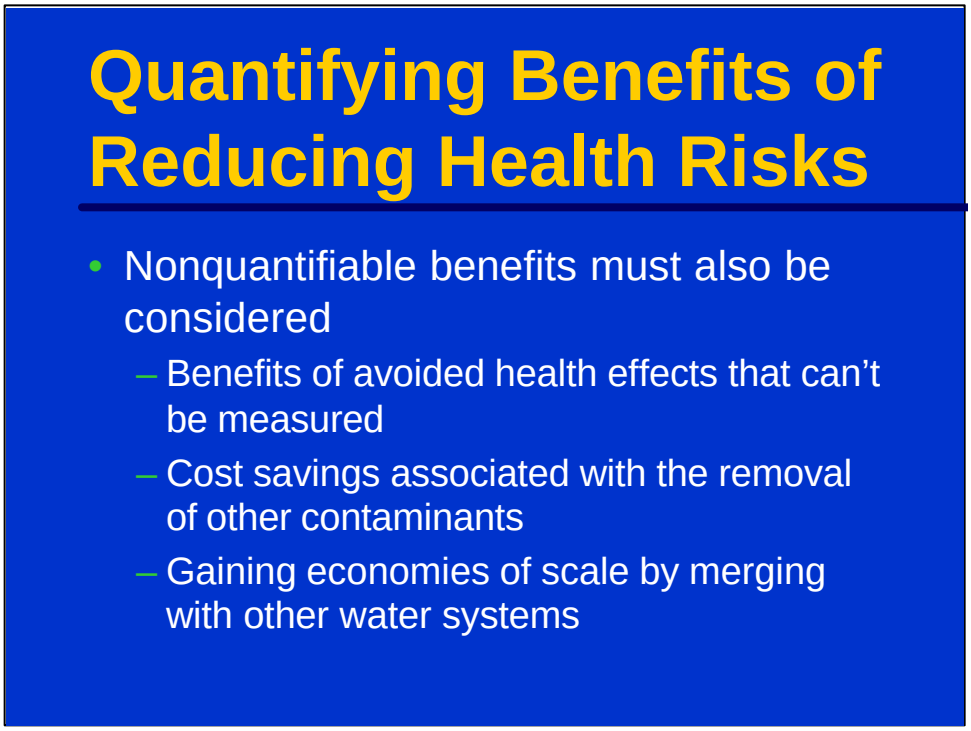
- EPA determines the monetary value of the cases of illness or death that would be avoided as a result of the regulatory action.
- The monetary value of those avoided cases is the quantitative measure of the benefits of a rule.
- It is very important to note that there are high degrees of difficulty and uncertainty in putting monetary value on illness and human life.

Quantifying Benefits of Reducing Health Risks

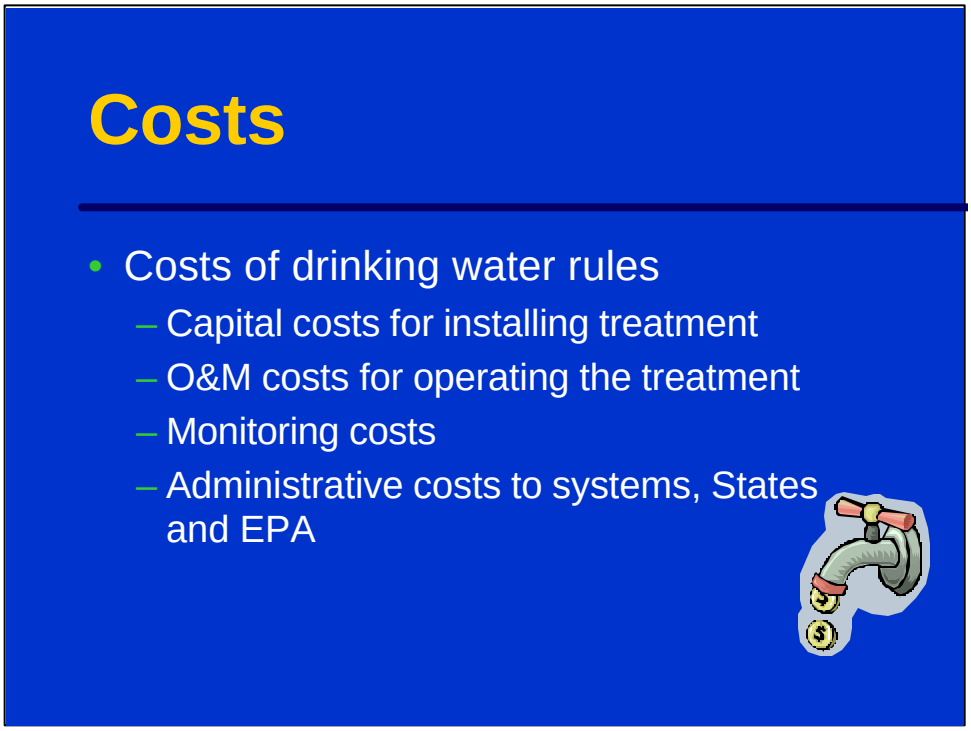
- **Cost of illness avoided**: medical costs, lost pay
- **Willingness to pay**: an aggregate estimate of what individuals are willing to pay to avoid an increase risk of disease



- To facilitate comparing the costs of added technology to the benefits of reducing adverse health effects, health benefits are quantified by valuation of cost of illnesses (COI) avoided and willingness to pay (WTP) to reduce the suffering associated with the adverse health effect.
- COI is easier to quantify. This includes the cost of medical care (doctor and hospital visits, laboratory testing fees, and medication) and indirect costs such as the cost of lost work or leisure time.
- WTP estimates are based on what individuals reveal that they willing to pay to avoid an incremental risk of the adverse effect. These amounts are aggregated across the population to estimate what society as a whole is willing to pay to avoid the estimated cases that would occur.
- WTP includes the notion that illness is undesirable and that a person would be willing to pay to avoid the risk of experiencing the consequences associated with it.



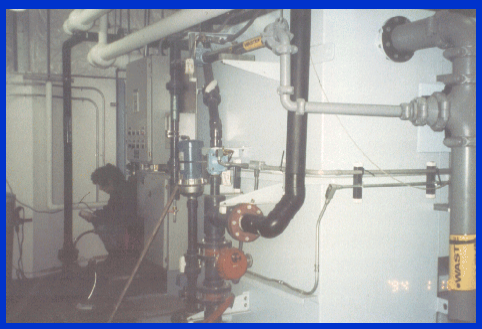
- SDWA section 1412(3)(C)(1) requires EPA to consider benefits that can't be quantified.
- EPA assesses benefits resulting from the various regulatory alternatives. Some of the benefits are nonquantifiable, for example:
  - Cost savings associated with the removal of other contaminants; or
  - Gaining economies of scale by merging with other water systems.



- In developing the costs of a drinking water rule, EPA must consider:
  - Capital costs for installing treatment equipment, and other costs such as acquiring land and construction of new buildings. Capital costs are based on the design flow of a water system (that is, the capacity of the system in producing potable water).
  - Operational and maintenance (O&M) costs are for the ongoing operation and maintenance of the treatment system. O&M costs are based on the average daily flow rate to more closely capture the day-to-day operation of the water system.
  - Monitoring costs of the specific contaminant according to a specified schedule and analytical method.
  - Recordkeeping and reporting costs to the systems for reading the rule, understanding the monitoring procedure, submitting monitoring results to States or EPA, maintaining records, and responding to inquiries.
  - Recordkeeping and reporting costs to the States to review monitoring results from system, maintain records, submit summaries to EPA, and respond to inquiries.
  - Costs to EPA to review summaries from States, maintain records, and respond to inquiries.

Costs: System Level

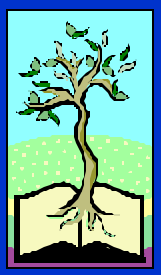
- Cost and Technology Documents
  - Examine technologies
  - Consider limitations
  - Assess unit costs
    - Capital
    - Operation and maintenance



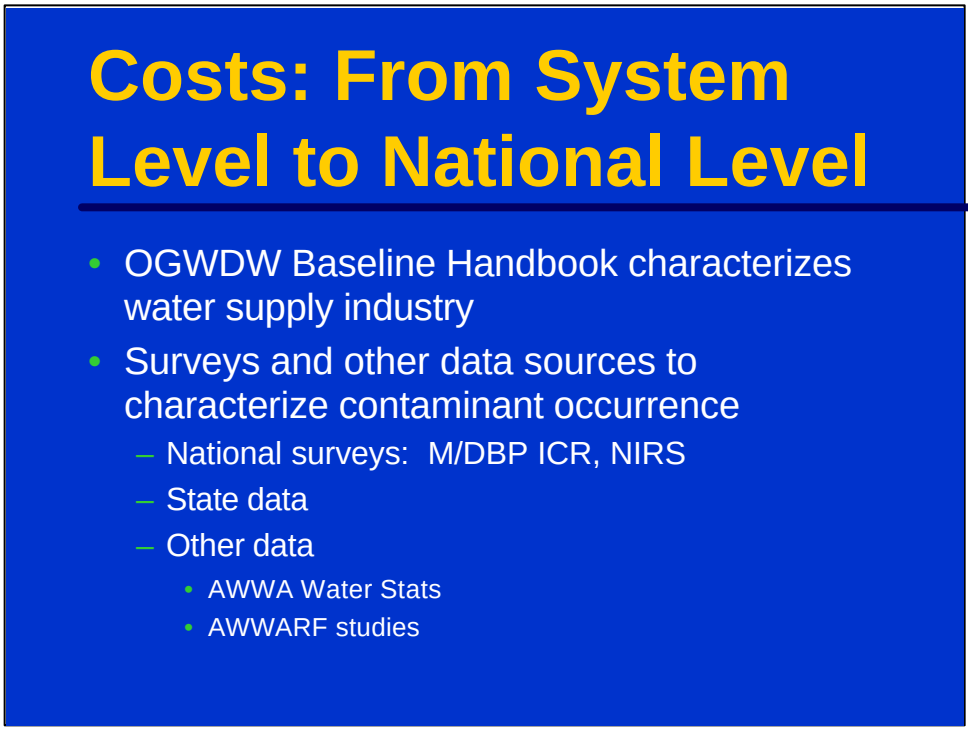
- As part of a rulemaking, EPA estimates the costs to water systems to implement a rule.
- ***Cost and Technology Documents*** examine the available technologies for removing, reducing, or preventing the unwanted material from being present in drinking water. They also consider limitations to the application of each technology due to water quality characteristics, or practicality from an operator perspective.
- Cost and Technology Documents also assess the unit costs, both capital costs and operation and maintenance costs, associated with the treatment technologies.
- These are generally modeled as a function of flow and reflect achieving a particular removal percentage of the target contaminant.
  - Costs typically show economies of scale (lower $/kgal for higher flows -- larger systems).

Costs: From System Level to National Level

- Decision tree or matrix – how many systems select various treatments?
- Modeling treatment selection



- EPA takes estimates of system-level costs and uses them to generalize across systems in the U.S.
  - EPA assigns probabilities based on different system size categories (large, medium, small), system type (community, non-community, transient, and non-transient), source type (surface and ground), and other factors (geography) that will affect selection of a specific treatment method.
  - EPA uses modeling approaches to estimate the occurrence of certain contaminant associated with different system sizes and types for various regulatory alternatives.
    - For example, EPA used the Surface Water Analytical Tool (SWAT) to estimate DBP concentrations in distribution systems under various regulatory alternatives.
    - While SWAT estimates are most reliable for large surface water systems, EPA considered the occurrence estimates are reasonable for all other systems.
- Note: System level information is scaled-up to the national in a statistical sense.



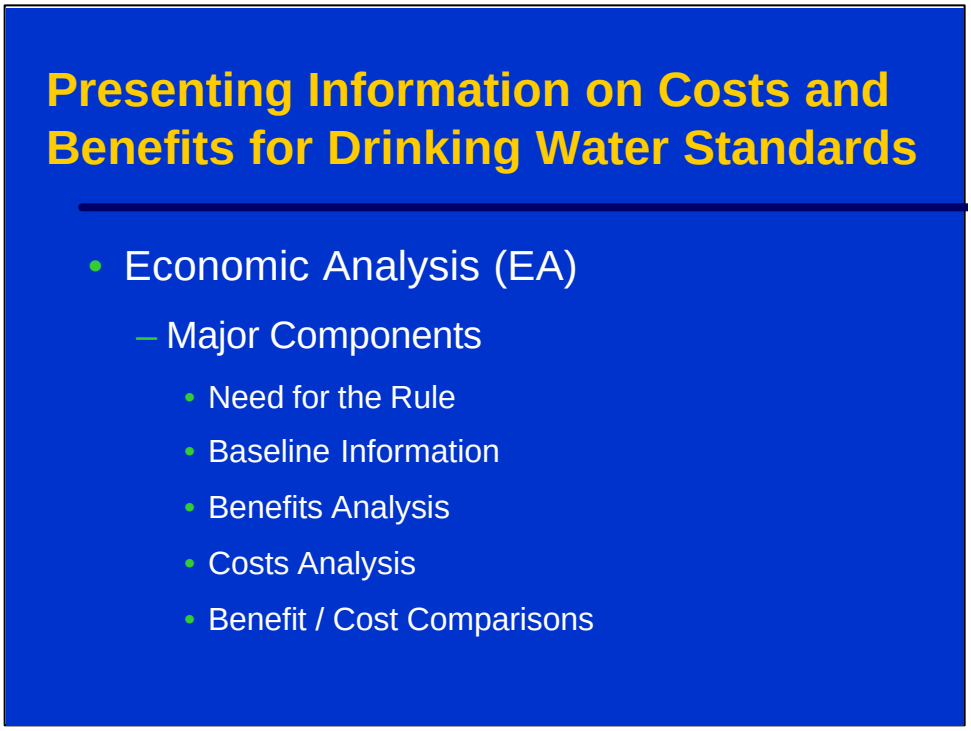
- EPA's Drinking Water Baseline Handbook (EPA, 2000b) provides information on the characteristics of water systems of different sizes, types, and sources, for example, treatment in place.
- EPA uses different national surveys to support rulemaking activity. For example:
  - The Community Water System Survey, most recently conducted in 2000, contains operating and financial characteristics of community water systems;
  - Information Collection Rule data on microbial and DBP
- EPA also uses State occurrence data, data collected by other programs (for example, USGS and) to characterize contaminant occurrence (that is, the number and nature of systems affected by the rule).
- Other data sources include water industry studies by AWWA (e.g., Water Stats)

- Contaminant occurrence information is combined with treatment cost information to build up the national cost estimates.
- Occurrence assessment -- how many systems are affected?
- Generally, occurrence is described as national probability distributions, usually lognormal (Note: The lognormal distribution is commonly used to model environmental data. A random variable is lognormally distributed if the logarithm of the random variable is normally distributed, that is, the distribution forms a normal bell curve.)
- The integration of the occurrence data and the treatment costs through the decision tree or matrix produces the national cost estimates for each of the regulatory alternatives:
  - Annual national costs;
  - System level costs; and
  - Household costs (costs passed down from the system to individual households served by the system, generally as a part of the water bill).

Benefit and Cost Comparisons

- No one single method for comparing benefits and costs
- Important concepts
  - Net benefits
  - Incremental costs
  - Incremental benefits
  - Benefit-to-cost ratio

- To compare costs and benefits, EPA may use a number of methods:
  - Net benefits – benefits minus costs for specific alternatives;
  - Incremental costs – increase of costs between two end points (for example, from no action to a MCL alternative, or from a MCL alternative to another MCL alternative);
  - Incremental benefits – increase of benefits between two end points (for example, from no action to a MCL alternative, or from a MCL alternative to another MCL alternative); or
  - Also, benefits-to-cost ratio (if over 1, benefits are greater than costs).



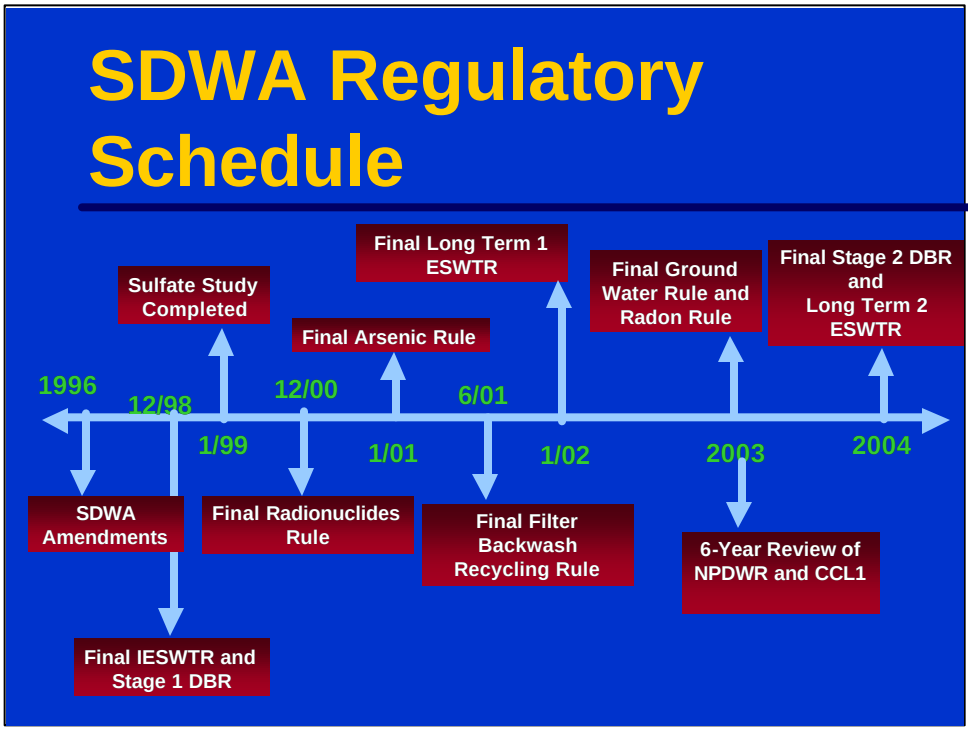
- Pass out copies of recent EAs for class to review.

Review of Current MCLs and TTs

- Handout of National Primary Drinking Water Regulations from: www.epa.gov/safewater
  - Microorganisms
  - Disinfection Byproducts
  - Disinfectants
  - Inorganic Chemicals
  - Organic Chemicals
  - Radionuclides

From Risk to Rule: How EPA Develops Risk-Based Drinking Water Regulations

Lesson 6: Discussion of Recent and Current Regulations


SDWA Regulatory Schedule
Final Long Term 1 ESWTR
Sulfate Study Completed
Final Arsenic Rule
Final Ground Water Rule and Radon Rule
Final Stage 2 DBR and Long Term 2 ESWTR
1996
12/98
12/00
6/01
1/99
1/01
1/02
2003
2004
SDWA Amendments
Final Radionuclides Rule
Final Filter Backwash Recycling Rule
6-Year Review of NPDWR and CCL1
Final IESWTR and Stage 1 DBR

Recent Regulations

- Stage 1 Disinfection Byproducts
- Interim Enhanced Surface Water Treatment Rule (IESWTR)
- Long Term 1 ESWTR
- Filter Backwash Rule
- Radionuclides
- Arsenic

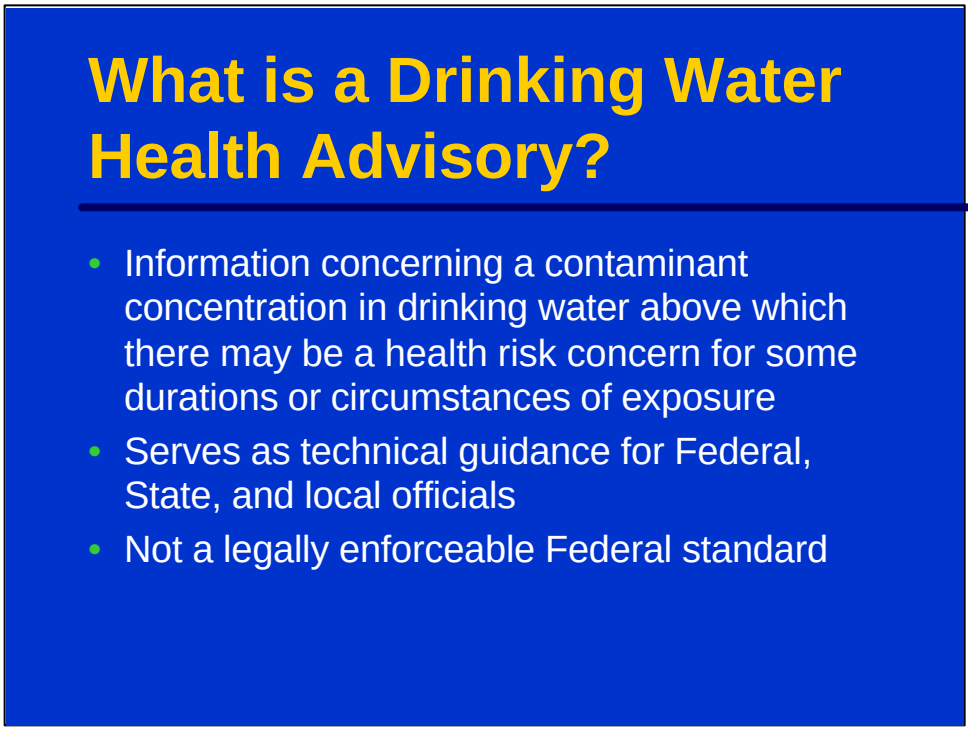
Regulations Currently Being Developed

- Stage 2 Disinfection by-products
- Long Term 2 Enhanced Surface Water Treatment Rule
- Ground Water Rule
- Radon
- Total Coliform / Distribution System Rule

From Risk to Rule: How EPA Develops Risk-Based Drinking Water Regulations

Lesson 7: Health Advisories

- Lesson 7 addresses the development of Health Advisories prepared by EPA addressing drinking water contaminants.



- Health advisories provide an estimate of acceptable levels of a chemical substance in drinking water, based on health effects information. Health advisories address contaminants that can cause human health effects and are known or anticipated to occur in drinking water.
- They are guidance values based on noncancer health effects for different durations of exposure. Health Advisories are not legally enforceable Federal standards, but they provide technical guidance to EPA Regional Offices, State governments and other public health officials on health effects, analytical methodologies, and treatment technologies associated with drinking water contamination.

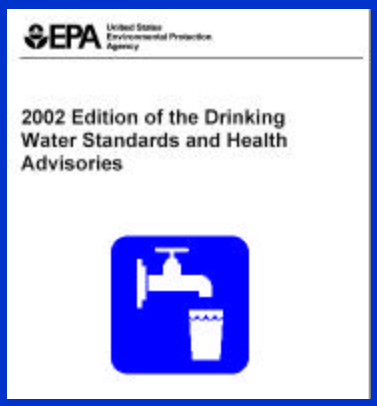
Types of Health Advisories

- Lifetime Health Advisory
- Ten-day Health Advisory
- One-day Health Advisory

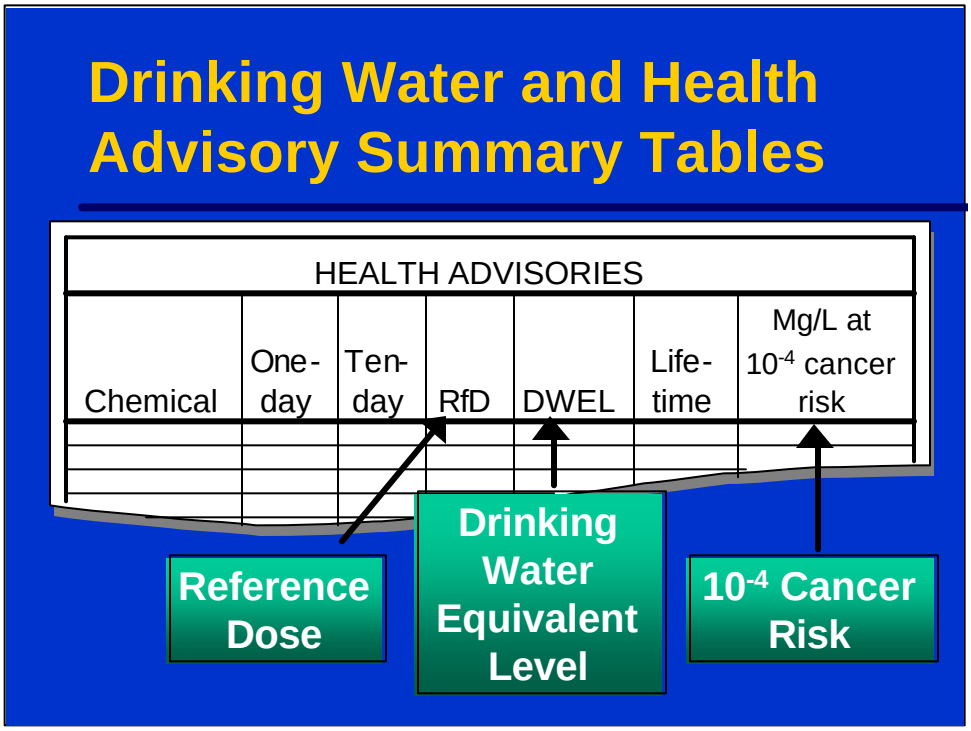
- ***Lifetime HA***: The concentration of a chemical in drinking water that is not expected to cause any adverse noncarcinogenic effects for a lifetime of exposure. This level is like an MCL or MCLG.
- ***Ten-day HA***: The concentration of a chemical in drinking water that is not expected to cause any adverse noncarcinogenic effects for up to ten days of exposure.
- ***One-day HA***: The concentration of a chemical in drinking water that is not expected to cause any adverse noncarcinogenic effects for up to one day of exposure. If chemicals appear in drinking water at this level, consumers need to be informed immediately.

Drinking Water Standards and Health Advisories

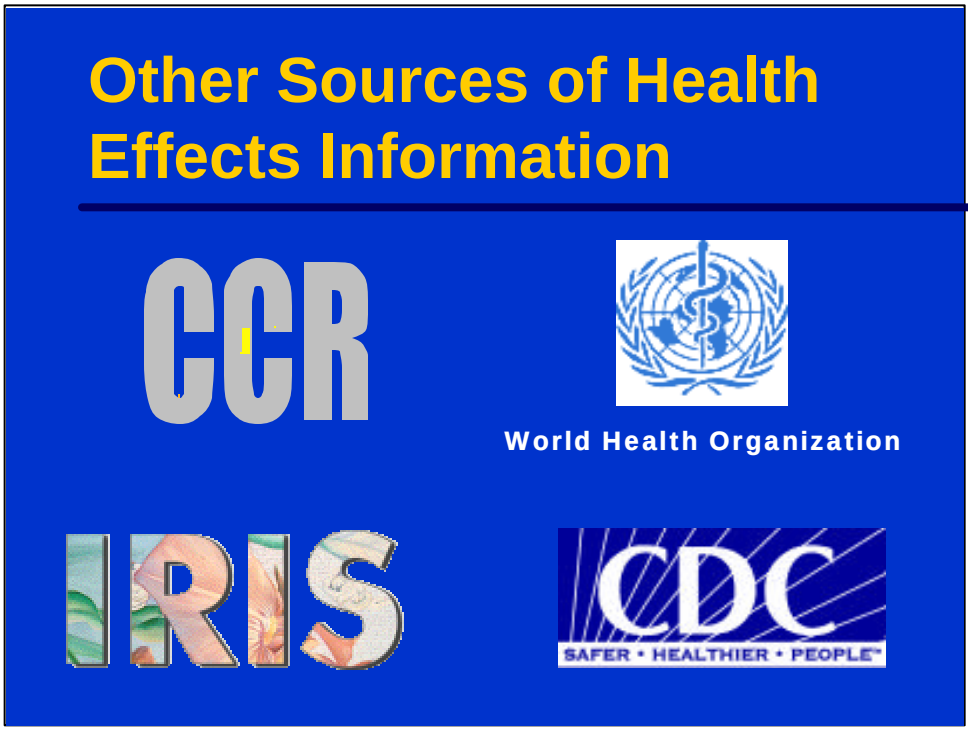
- Prepared semi-annually by EPA's Office of Science and Technology
- Contain HA's, MCLGs, MCLs and other information for each contaminant



- Health Advisories can be downloaded for free from the Web (**http://www.epa.gov/ost/drinking/standards/summary.html**).
- Drinking Water and Health Advisory tables provide information on contaminants, both regulated and unregulated substances, that can cause human health effects and are known or anticipated to occur in drinking water.



- Summary tables are divided into two sections, "standards" and "health advisories," the latter of which is shown above.
- The tables include one-day, ten-day, and lifetime HAs.
- They also include reference doses, drinking water equivalent levels and 10^{-4} cancer risks for each contaminant.
  - A reference dose is an estimate of a daily oral exposure to the human population that it likely to be without an appreciable risk of deleterious effects during a lifetime.
  - A ***drinking water equivalent level*** is a lifetime exposure concentration protective of adverse, non-cancer health effects, that assumes all of the exposure to a contaminant is from drinking water.
  - A ***10^{-4} cancer risk*** is the concentration of a chemical in drinking water corresponding to an estimated lifetime cancer risk of 1 in 10,000. Other information not included in this sample table is Heath Advisory status column.
- Other information not included in sample table is the Health Advisory Status column which gives the year of publication.
- Supporting technical documents for each contaminant can be ordered from OST.



- ***Consumer Confidence Reports*** are another useful source of information regarding drinking water and source water quality. The 1996 SDWA Amendments require water suppliers to prepare annual reports for their customers. The reports contain important information on contaminants, health effects, and water sources.
- The ***Integrated Risk Information System*** (IRIS), prepared and maintained by EPA's Office of Research and Development, is an electronic data base containing information on human health effects that may result from exposure to various chemicals in the environment.
- The ***Centers for Disease Control and Prevention*** (CDC) maintains an abundance of information on diseases and their etiologies and treatments. Their Web site (http://www.cdc.gov) contains information on waterborne parasitic, infectious, and bacterial diseases and links to other resources. The CDC publishes the Morbidity and Mortality Weekly Report based on weekly reports to CDC by State health departments, and compiles annual reports titled, "Surveillance for Waterborne Disease Outbreaks – United States."
- The ***World Health Organization*** (WHO) focuses on health issues (including the provision of safe drinking water) in developing countries. WHO publishes the three-volume "Guidelines for Drinking Water Quality." Volume 1 contains health-based guideline values for potential drinking water contaminants. Volume 2 contains monographs on the health effects of potential contaminants, elaborating on the health risk assessment of the contaminants in Volume 1. Volume 3 provides recommendations for small communities, particularly those in rural areas of developing countries, on measures to safeguard their drinking water supplies.

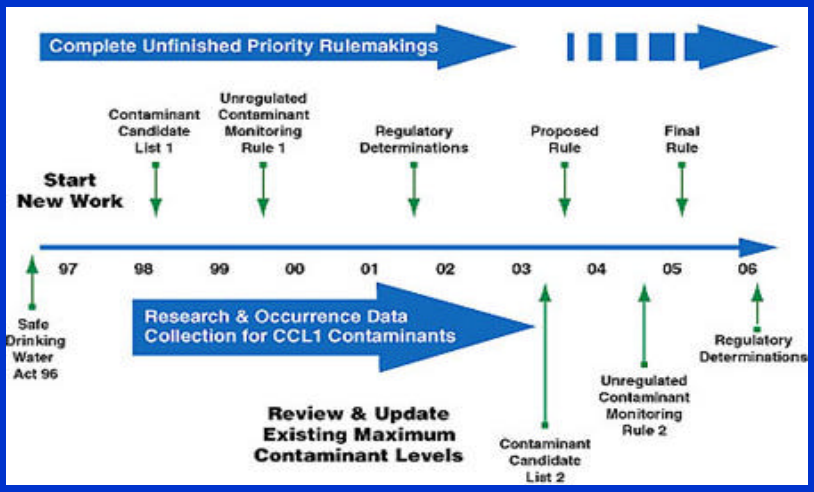
From Risk to Rule:

How EPA Develops Risk-Based Drinking Water Regulations

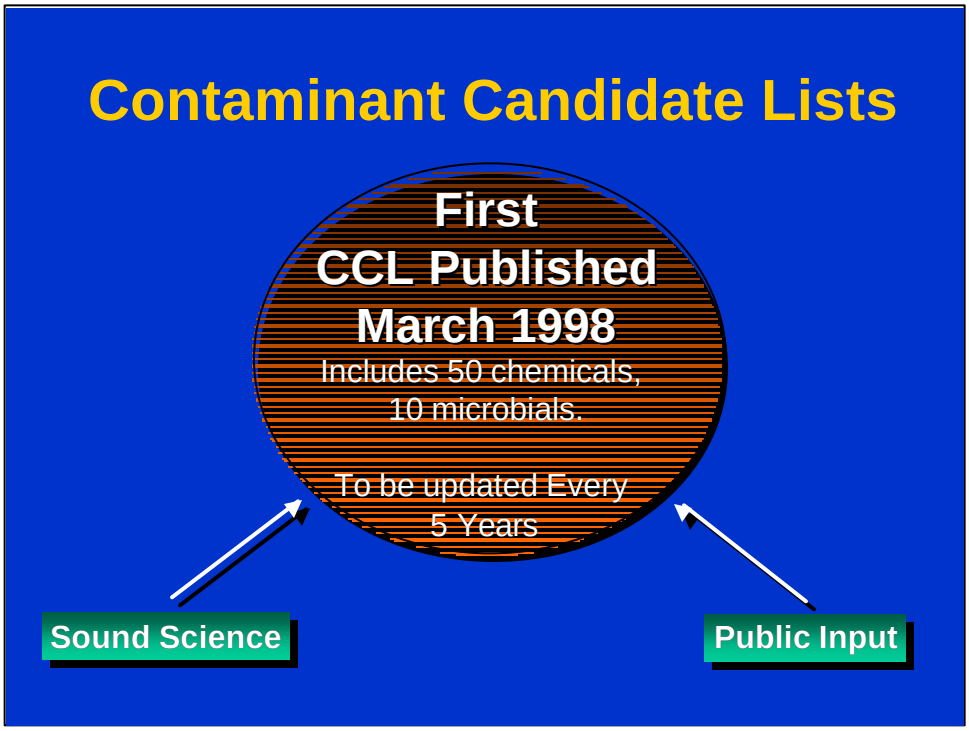
Lesson 8: Identifying and Prioritizing Contaminants for Future Regulations

- Lesson 8 addresses the SDWA programs and processes being implemented by OGWDW to identify and prioritize contaminants for possible future regulations.

Timeline and Elements of Future Regulatory Determinations

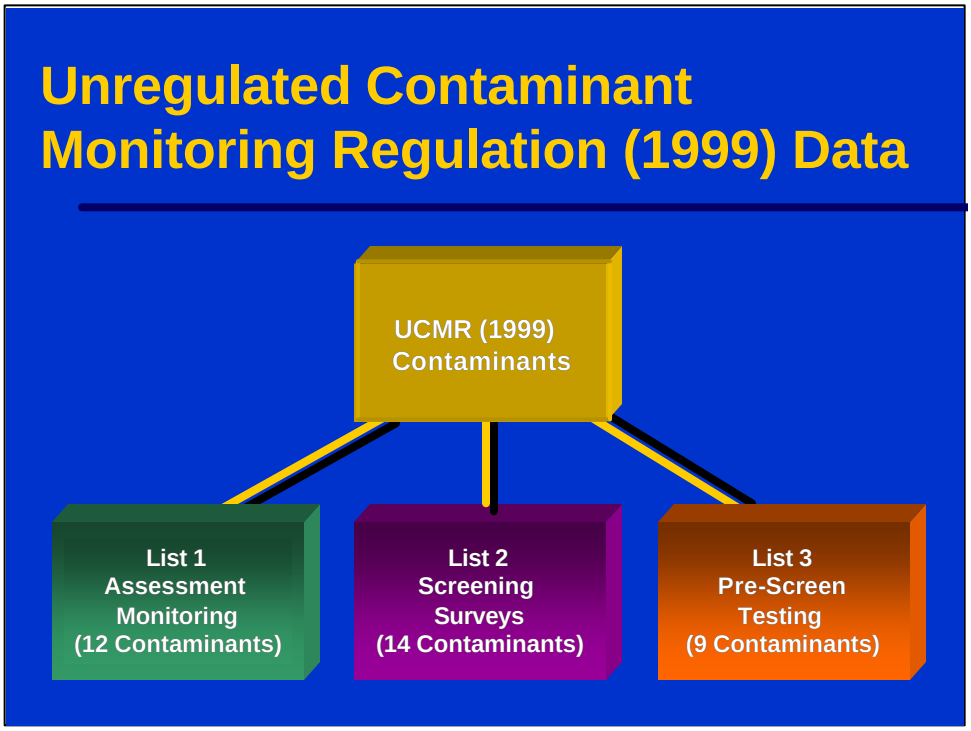


- This timeline shows the proposed general progression that a contaminant would take from the Contaminant Candidate List (CCL), to regulatory determination, to proposed rule to final rule.
- In some cases, when contaminants are identified as priorities from CCL and more occurrence data are needed for those contaminants, they move through the Unregulated Contaminant Monitoring Rule (UCMR) process to generate the data.

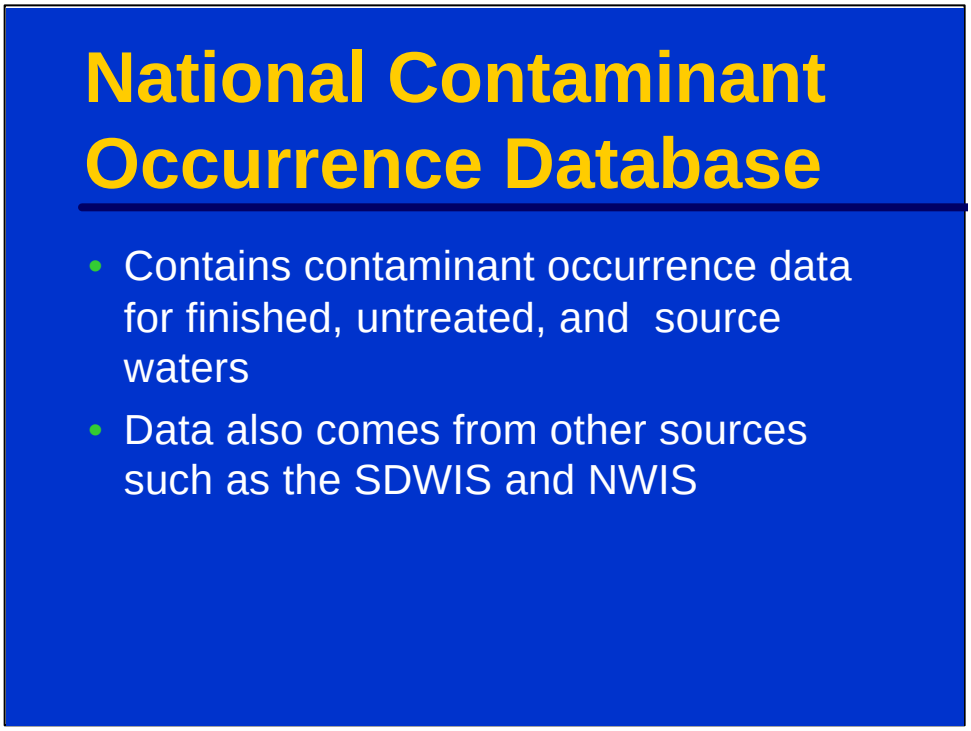


- The approach outlined in the SDWA 1996 Amendments for developing new standards requires ***broad public and scientific input*** to ensure that contaminants posing the greatest risk to public health will be selected for future regulation. A contaminant's presence in drinking water and public health risks associated with a contaminant must be considered in order to determine whether a public health risk is evident. Contaminants on the CCL are prioritized for regulatory development, drinking water research (including studies of health effects, treatment effects, and analytical methods), and occurrence monitoring. In addition, the new contaminant selection approach explicitly takes into account the needs of sensitive populations such as children and pregnant women.
- The NDWAC *Working Group on Occurrence and Contaminant Selection* developed the first CCL list of contaminants by considering the negative health effects of the contaminants and the likeliness of the contaminants to occur in PWSs widespread geographically and at concentrations high enough to pose a risk to public health. The stakeholders and Working Group included representatives of public water utilities, environmental and public interest groups, state regulatory agencies, public health offices, and other interested parties. EPA and the Working Group developed criteria to identify contaminants for the CCL.
- EPA published the initial CCL on March 2, 1998, consisting of 50 chemicals and 10 microbials. The CCL must be ***updated every five years***, providing a continuing process to identify contaminants for future regulations or standards and prevention activities.
- EPA published preliminary determinations for 9 contaminants in March 2002 (Acanthamoeba, aldrin, dieldrin, hexachlorobutadiene, manganese, metribuzin, naphthalene, sodium and sulfate). EPA concluded that no further action is needed for these 9; finalization of this anticipated in late 2002.

- The National Research Council (NRC) has called for consideration of "a broad universe" of potential contaminants, comprising "tens of thousands of substances and microorganisms." The CCL database will be a master list of these potential contaminants, assembling data by electronic import from dozens of external data sources (e.g. IRIS, NAWQA) into one "universe" system.
- The next step is the development and use of screening criteria such as aqueous solubility to "cull the universe of contaminants to a much smaller preliminary CCL (PCCL)", comprising "a few thousand substances."
- To move from PCCL to CCL, NRC recommends the development of a set of attributes, such as potency and prevalence, by which contaminant profiles can be quantified and analyzed by a "prototype classification algorithm" (e.g. Bayesian network). This step will involve the designation of a "training set" of contaminants used to calibrate the algorithm.
- When complete, the CCL machinery will be a powerful analytical tool for the development of future CCLs. The NRC envisions the CCL system as a living project, to be updated and expanded for long-term support of EPA's regulatory determination activities.



- In 1999, EPA promulgated the Unregulated Contaminant Monitoring Rule (UCMR) (1999). EPA will use the data generated by the new UCMR to evaluate and prioritize the contaminants EPA is considering for possible new drinking water standards. This will also help ensure that future decisions on drinking water standards are based on sound science. The UCMR includes a list of contaminants for which public water systems must monitor, analytical methods for some of these contaminants, and requirements to submit the monitoring data to EPA and the States for inclusion in the National Contaminant Occurrence Database.
- The UCMR (1999) Monitoring List comprises three separate lists based on the readiness of analytical methods and current contaminant occurrence data:
  - *List 1 (Assessment Monitoring)* includes twelve chemical contaminants for which analytical methods exist or will soon be established. While EPA has information on the occurrence of these contaminants at some PWSs, there is no estimate of the extent of their occurrence nationwide.
  - *List 2 (Screening Surveys)* includes 12 organic chemicals, one inorganic chemical and one microorganism for which analytical methods are under development and for which EPA has less occurrence data than the contaminants on *List 1*.
  - *List 3 (Pre-Screen Testing)* includes seven microorganisms and 2 inorganic chemicals that have recently emerged as drinking water concerns and for which, in most cases, analytical methods are still in the early stages of development.



- The National Drinking Water Contaminant Occurrence Database (NCOD) is a collection of data on the occurrence of drinking water contaminants in finished, untreated, and ambient (source) waters associated with public water systems across the United States.
- The NCOD is intended to assist EPA in assembling a comprehensive set of drinking water contaminant data for analysis. The database supports the evaluation of contaminants considered for future regulation and regulation development, as well as the review of existing regulations for possible modification. The NCOD also provides the public with information on contaminants in drinking water.
- The NCOD database currently contains information from a number of sources, including: public water systems that report to EPA's Safe Drinking Water Information System and source water information collected by the U.S. Geological Survey and stored in the National Water Information System. NCOD also holds historical unregulated contaminant data and regulated contaminant data for public water systems.

Six Year Review of Drinking Water Standards

- 1996 Amendments require EPA to review each NPDWR at least once every six years and revise if necessary
- In April 2002 EPA completed its review of all pre-1997 NPDWRs
- Preliminary determinations
  - Revise total coliform rule
  - No action for 68 other contaminants

- Section 1412(b)(9) states: *"The Administrator shall, not less often than every six years, review and revise, as appropriate, each national primary drinking water regulation promulgated under this title. Any revision of a national primary drinking water regulation shall be promulgated in accordance with this section, except that each revision shall maintain, or provide for greater, protections of the health of persons."*
- Finalization of the April 2002 preliminary determinations anticipated late in 2002.
- EPA has initiated efforts to revise the Total Coliform Rule (Distribution System Rule).