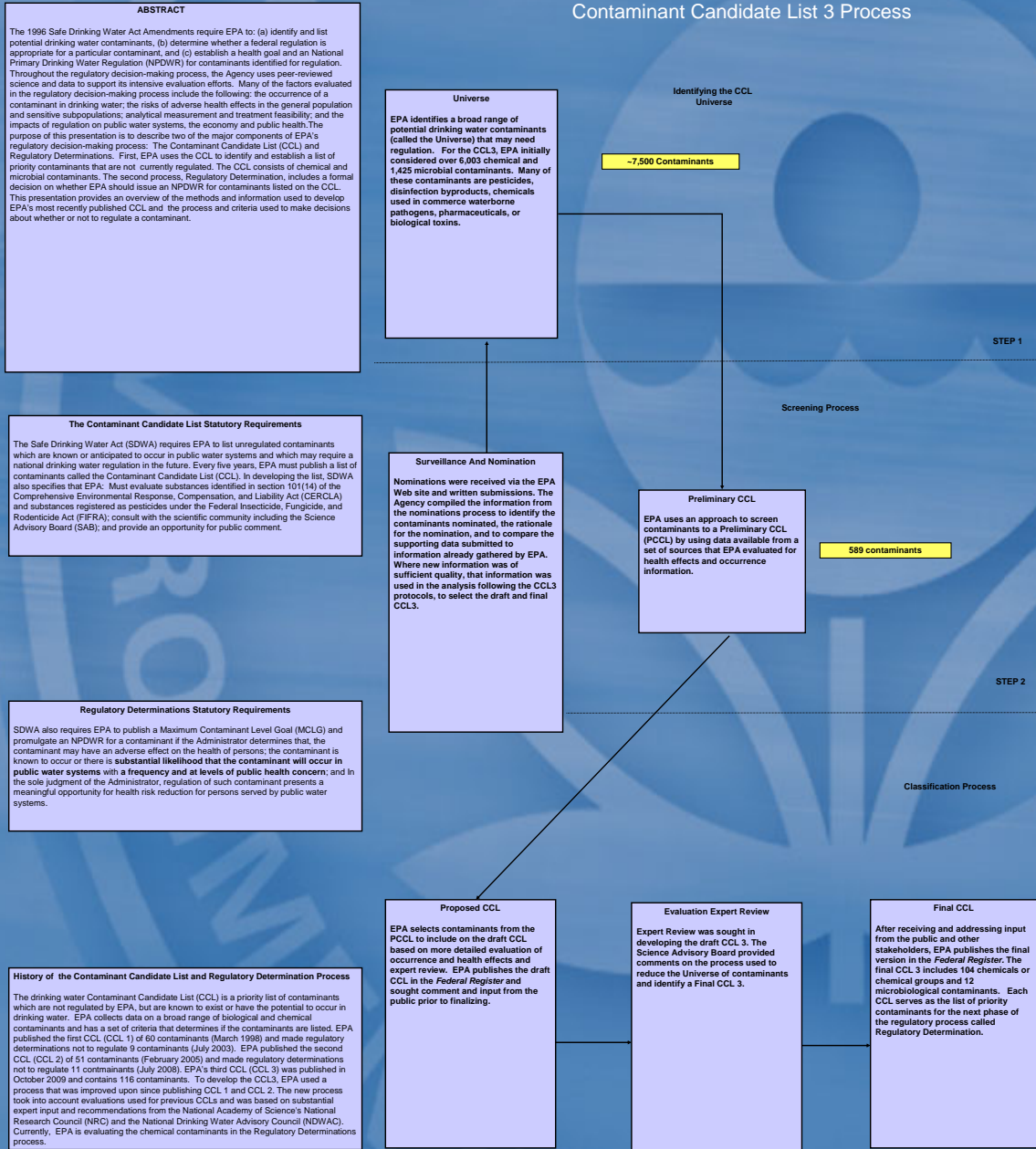# USEPA's Drinking Water Contaminant Candidate List and Regulatory Determinations Process

C.C. Townsend MSPH, J.L. Ellis MS
Office of Ground Water and Drinking Water
Target and Analysis Branch

ABSTRACT

The 1996 Safe Drinking Water Act Amendments require EPA to: (a) identify and list potential drinking water contaminants, (b) determine whether a federal regulation is appropriate for a particular contaminant, and (c) establish a health goal and an National Primary Drinking Water Regulation (NPDWR) for contaminants identified for regulation. Throughout the regulatory decision-making process, the Agency uses peer-reviewed science and data to support its intensive evaluation efforts. Many of the factors evaluated in the regulatory decision-making process include the following: the occurrence of a contaminant in drinking water; the risks of adverse health effects in the general population and sensitive subpopulations; analytical measurement and treatment feasibility; and the impacts of regulation on public water systems, the economy and public health. The purpose of this presentation is to describe two of the major components of EPA's regulatory decision-making process: The Contaminant Candidate List (CCL) and Regulatory Determinations. First, EPA uses the CCL to identify and establish a list of priority contaminants that are not currently regulated. The CCL consists of chemical and microbial contaminants. The second process, Regulatory Determination, includes a formal decision on whether EPA should issue an NPDWR for contaminants listed on the CCL. This presentation provides an overview of the methods and information used to develop EPA's most recently published CCL and the process and criteria used to make decisions about whether or not to regulate a contaminant.

The Contaminant Candidate List Statutory Requirements

The Safe Drinking Water Act (SDWA) requires EPA to list unregulated contaminants which are known or anticipated to occur in public water systems and which may require a national drinking water regulation in the future. Every five years, EPA must publish a list of contaminants called the Contaminant Candidate List (CCL). In developing the list, SDWA also specifies that EPA: Must evaluate substances identified in section 101(14) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and substances registered as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); consult with the scientific community including the Science Advisory Board (SAB); and provide an opportunity for public comment.

Regulatory Determinations Statutory Requirements

SDWA also requires EPA to publish a Maximum Contaminant Level Goal (MCLG) and promulgate an NPDWR for a contaminant if the Administrator determines that, the contaminant may have an adverse effect on the health of persons; the contaminant is known to occur or there is **substantial likelihood that the contaminant will occur in public water systems** with **a frequency and at levels of public health concern**; and In the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

History of the Contaminant Candidate List and Regulatory Determination Process

The drinking water Contaminant Candidate List (CCL) is a priority list of contaminants which are not regulated by EPA, but are known to exist or have the potential to occur in drinking water. EPA collects data on a broad range of biological and chemical contaminants and has a set of criteria that determines if the contaminants are listed. EPA published the first CCL (CCL 1) of 60 contaminants (March 1998) and made regulatory determinations not to regulate 9 contaminants (July 2003). EPA published the second CCL (CCL 2) of 51 contaminants (February 2005) and made regulatory determinations not to regulate 11 contaminants (July 2008). EPA's third CCL (CCL 3) was published in October 2009 and contains 116 contaminants. To develop the CCL3, EPA used a process that was improved upon since publishing CCL 1 and CCL 2. The new process took into account evaluations used for previous CCLs and was based on substantial expert input and recommendations from the National Academy of Science's National Research Council (NRC) and the National Drinking Water Advisory Council (NDWAC). Currently, EPA is evaluating the chemical contaminants in the Regulatory Determinations process.

Contaminant Candidate List 3 Process

Identifying the CCL Universe

Universe

EPA identifies a broad range of potential drinking water contaminants (called the Universe) that may need regulation. For the CCL3, EPA initially considered over 6,003 chemical and 1,425 microbial contaminants. Many of these contaminants are pesticides, disinfection byproducts, chemicals used in commerce waterborne pathogens, pharmaceuticals, or biological toxins.

~7,500 Contaminants

STEP 1

Screening Process

Surveillance And Nomination

Nominations were received via the EPA Web site and written submissions. The Agency compiled the information from the nominations process to identify the contaminants nominated, the rationale for the nomination, and to compare the supporting data submitted to information already gathered by EPA. Where new information was of sufficient quality, that information was used in the analysis following the CCL3 protocols, to select the draft and final CCL3.

Preliminary CCL

EPA uses an approach to screen contaminants to a Preliminary CCL (PCCL) by using data available from a set of sources that EPA evaluated for health effects and occurrence information.

589 contaminants

STEP 2

Classification Process

Proposed CCL

EPA selects contaminants from the PCCL to include on the draft CCL based on more detailed evaluation of occurrence and health effects and expert review. EPA publishes the draft CCL in the *Federal Register* and sought comment and input from the public prior to finalizing.

Evaluation Expert Review

Expert Review was sought in developing the draft CCL 3. The Science Advisory Board provided comments on the process used to reduce the Universe of contaminants and identify a Final CCL 3.

Final CCL

After receiving and addressing input from the public and other stakeholders, EPA publishes the final version in the *Federal Register*. The final CCL 3 includes 104 chemicals or chemical groups and 12 microbiological contaminants. Each CCL serves as the list of priority contaminants for the next phase of the regulatory process called Regulatory Determination.

116 contaminants

STEP 3

Regulatory Determination Process

Contaminants from CCL

Regulatory Determination Phase

Health Effects and Occurrence Data Evaluation

Are/will data be available via an Agency-approved process to determine whether an adverse health effect exists and the potential health risk level within the specified timeframe?
And
Are/will finish water data be available via Unregulated Contaminant Monitoring Rule (UCMR) study or other Agency-approved database to evaluate likely occurrence (level and frequency) in Public Water Systems?

Yes → **Potential Candidate for Regulatory Determination.**

No →

- ID health effects and/or occurrence data gaps.
- Identify other factors or gaps that need to be considered for the regulatory determination phase.

Preliminary Data Evaluation Phase

Three statutory questions to make Regulatory Determination for contaminant/contaminant group:

- Is it likely to cause an adverse health effect?
- Is it likely to occur at a level and frequency of concern at PWSs?
- Will regulation present a meaningful opportunity for health risk reduction?

No to any 1 → **Not appropriate for regulation**

Yes to all 3 → **Consider for regulation and ID other factors that need to be considered (e.g. method/treatment).**

Not appropriate to consider for Regulatory Determination at this time.

- Publish *FR* notice with preliminary decisions and rationale.
- Review Public Comments and consider revising decisions in context of new information.
- Publish *FR* notice with final Regulatory Determination decisions. Publish proposed NPDWR within 2 years (if necessary).