

Overview of the Contaminant Candidate List 3

**EPA's Chemical Prioritization
Community of Practice
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Draft CCL 3: Overview

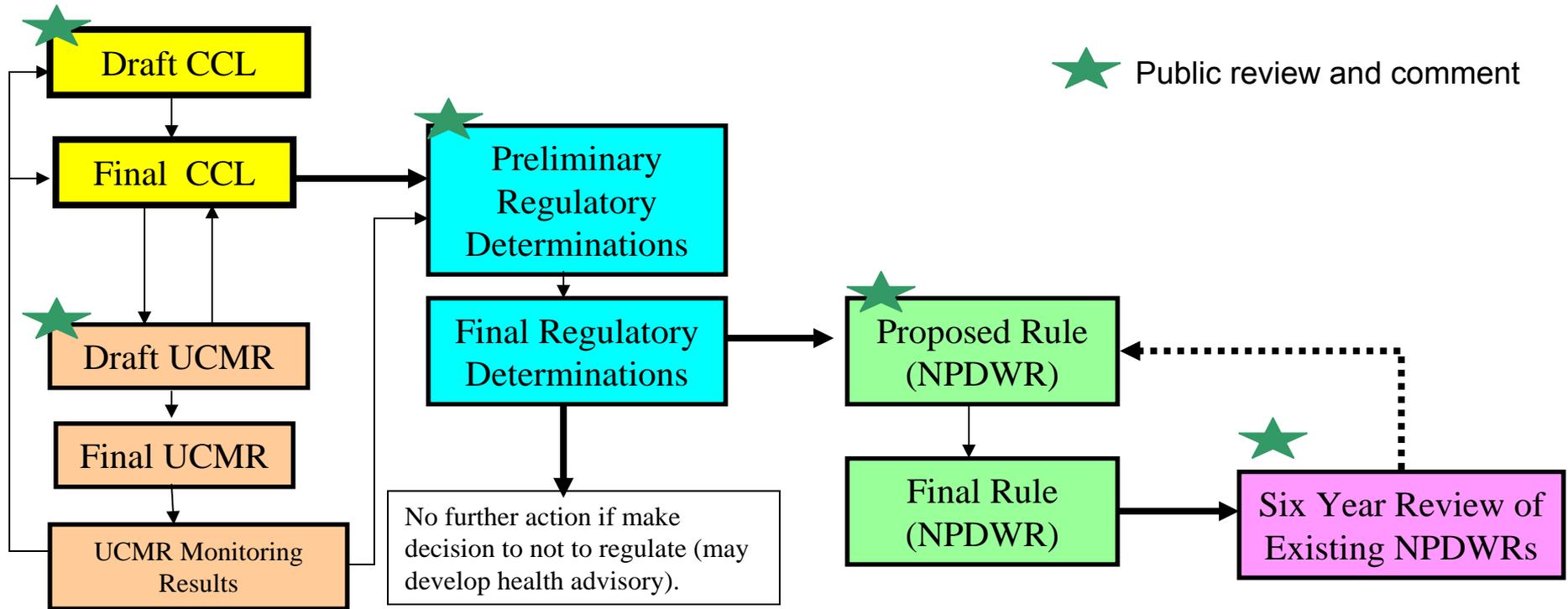
CCL

- Statutory Requirements
- Preliminary CCL
- Protocols
- Models
- Draft CCL3 Chemical Selection

Appendices



Generalized Flow of Regulatory Processes



At each stage, need increased specificity and confidence in the type of supporting data used (e.g. health and occurrence).



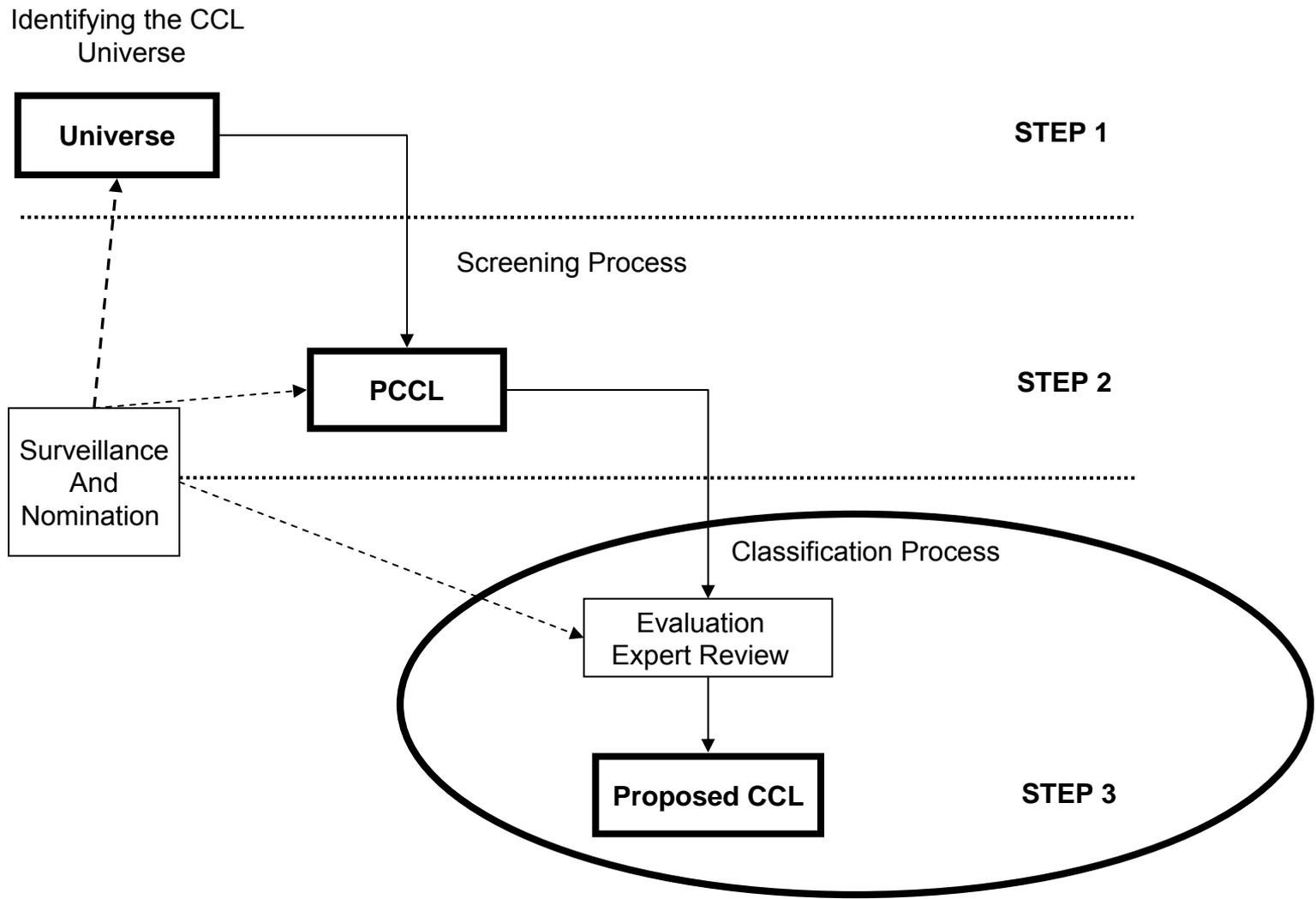
CCL Statutory Requirements

- **1996 Safe Drinking Water Act (SDWA) Amendments require EPA:**
 - Every 5 years, publish a list of unregulated contaminants (the CCL) which may require regulation and are known or anticipated to occur in public water supplies.
- **In developing the list, SDWA also specifies that EPA:**
 - Consider substances listed on CERCLA and FIFRA.
 - Consult with the scientific community including the Science Advisory Board (SAB).
 - Provide an opportunity for public comment.
- The decision to list a contaminant is not judicially reviewable.





CCL 3 Process





Screening Framework

Health Effects (e.g. LD ₅₀ , RfD, LOAEL, Cancer Classifications)	Occurrence (finished water, ambient water, release, production)					
	No Detect	Very Low	Low	Moderate	High	Very High
 Increasing Toxicity						



Classification of the PCCL Contaminants

Attribute Scoring Protocols

- Occurrence
- Health Effects
- Classification Models
 - Performance and Evaluation
 - Training Data Set
 - Predicted Decision
 - L, L?, NL, NL?



Model Principles and Objectives I

The CCL3 Training Data Set :

- represent a range of outcomes and decisions likely to be encountered in developing a CCL
- include a variety of input data ensuring adequate coverage of attribute scores combinations and combinations in order to train the classification models
- contain enough contaminants to adequately train the classification models being considered



Model Principles and Objectives II

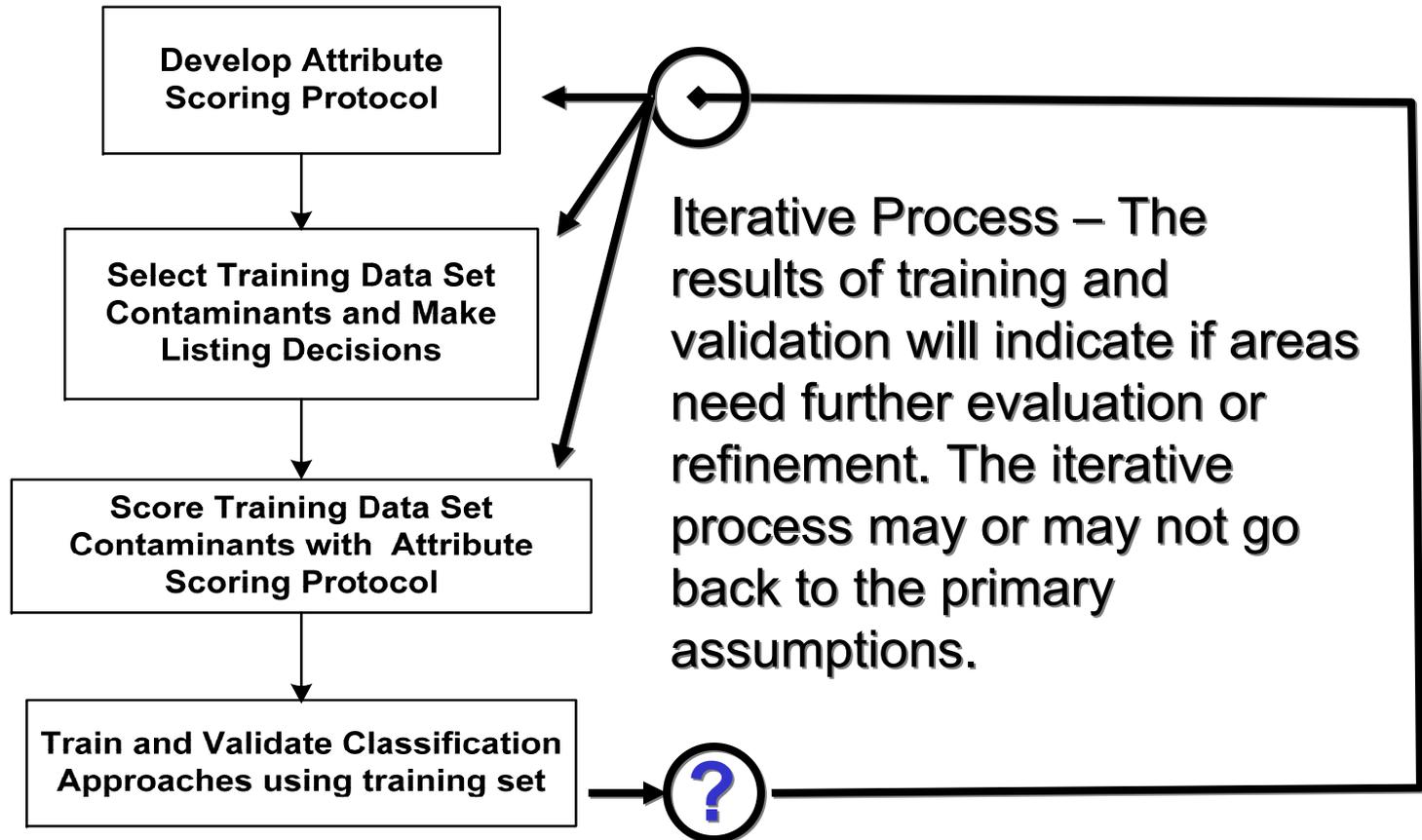
Subject Matter Expert Decisions	No List	No List?	List?	List
Model Decisions				
No List	⊕	2	5	10
No List?	1	⊕	2	5
List?	2	1	⊕	2
List	3	2	1	⊕

Models were evaluated on the basis of

- (a) total TDS misclassifications and
- (b) weighted sum of TDS misclassifications.

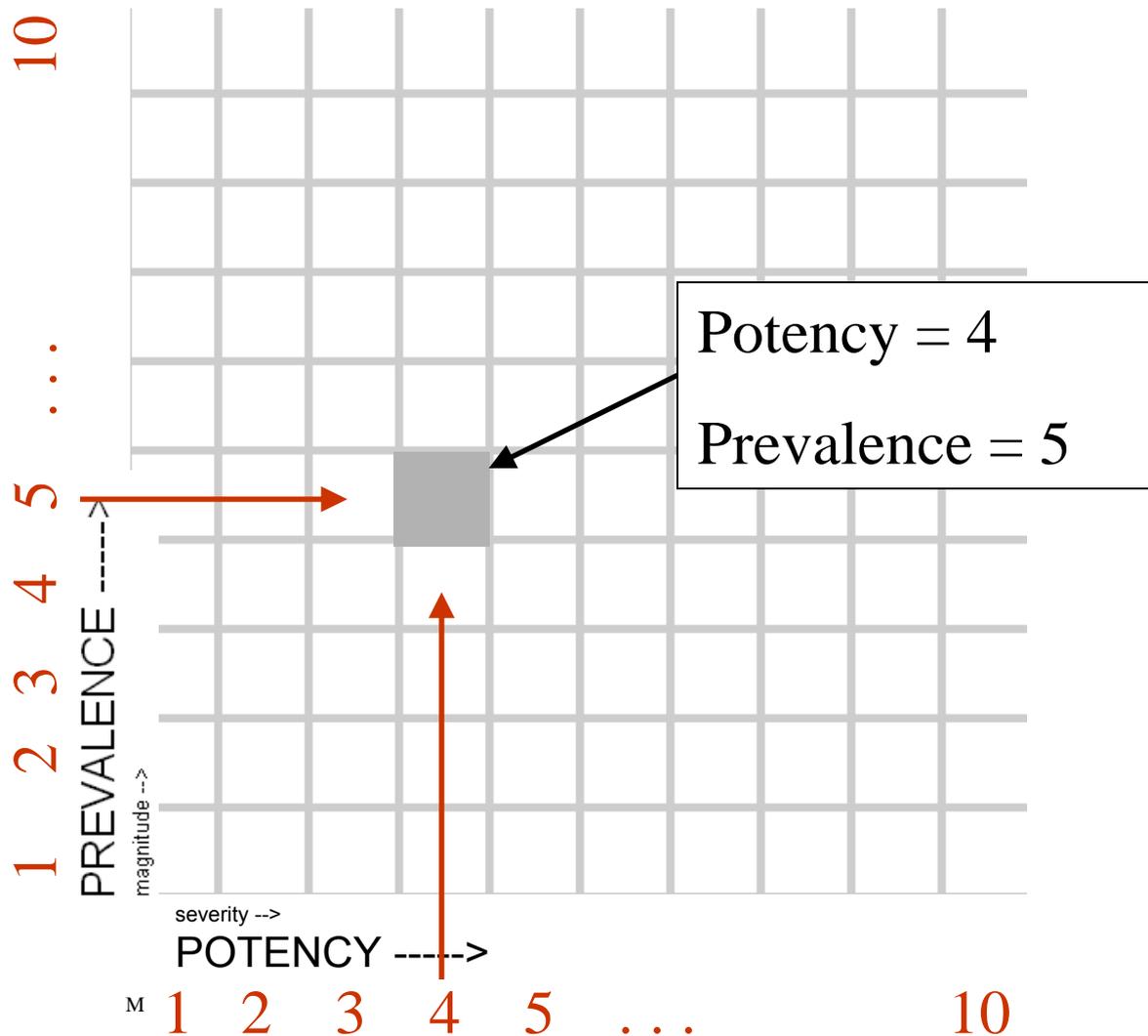


Classification Approach Development



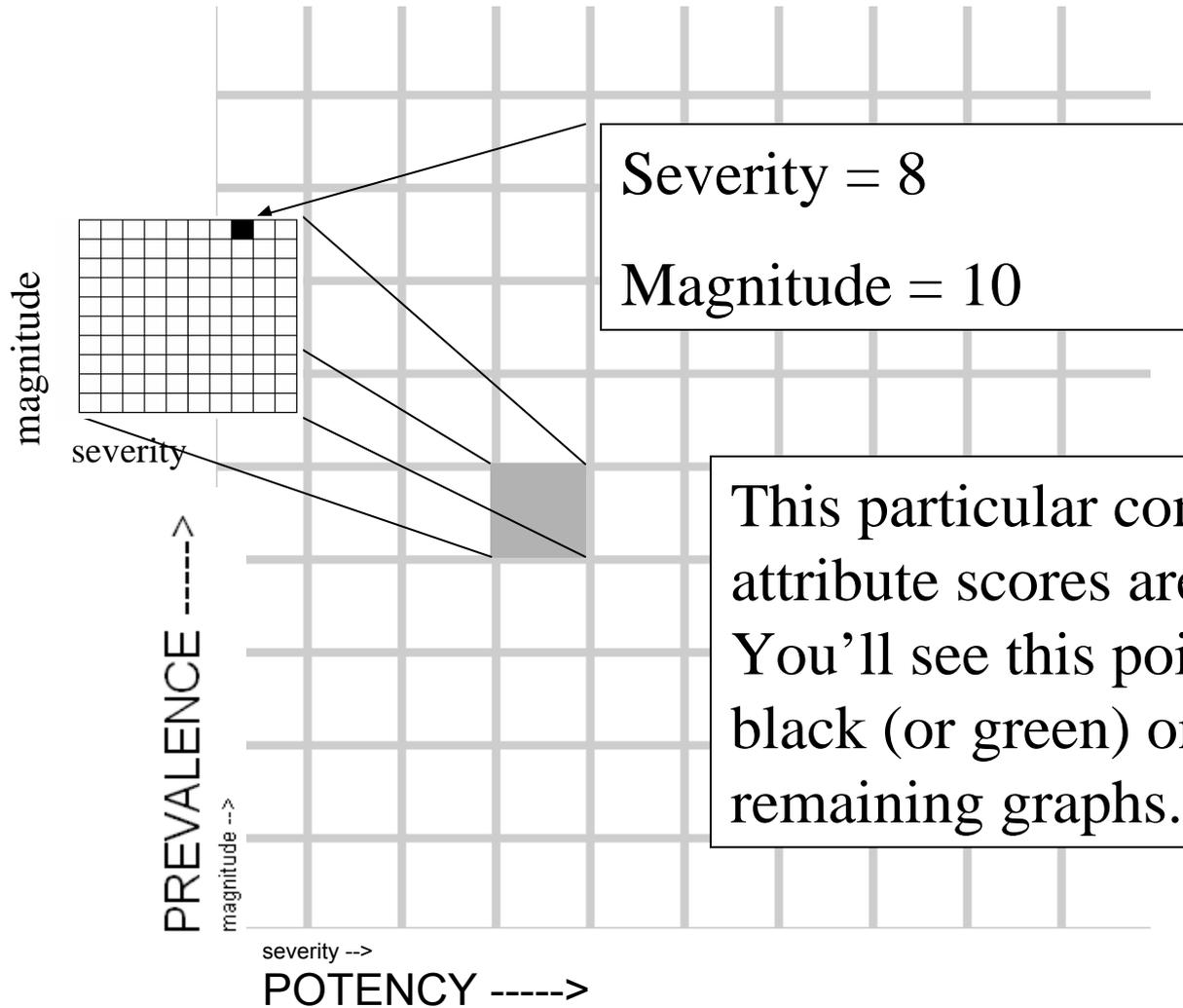


Orientation 1 - The BIG Axes





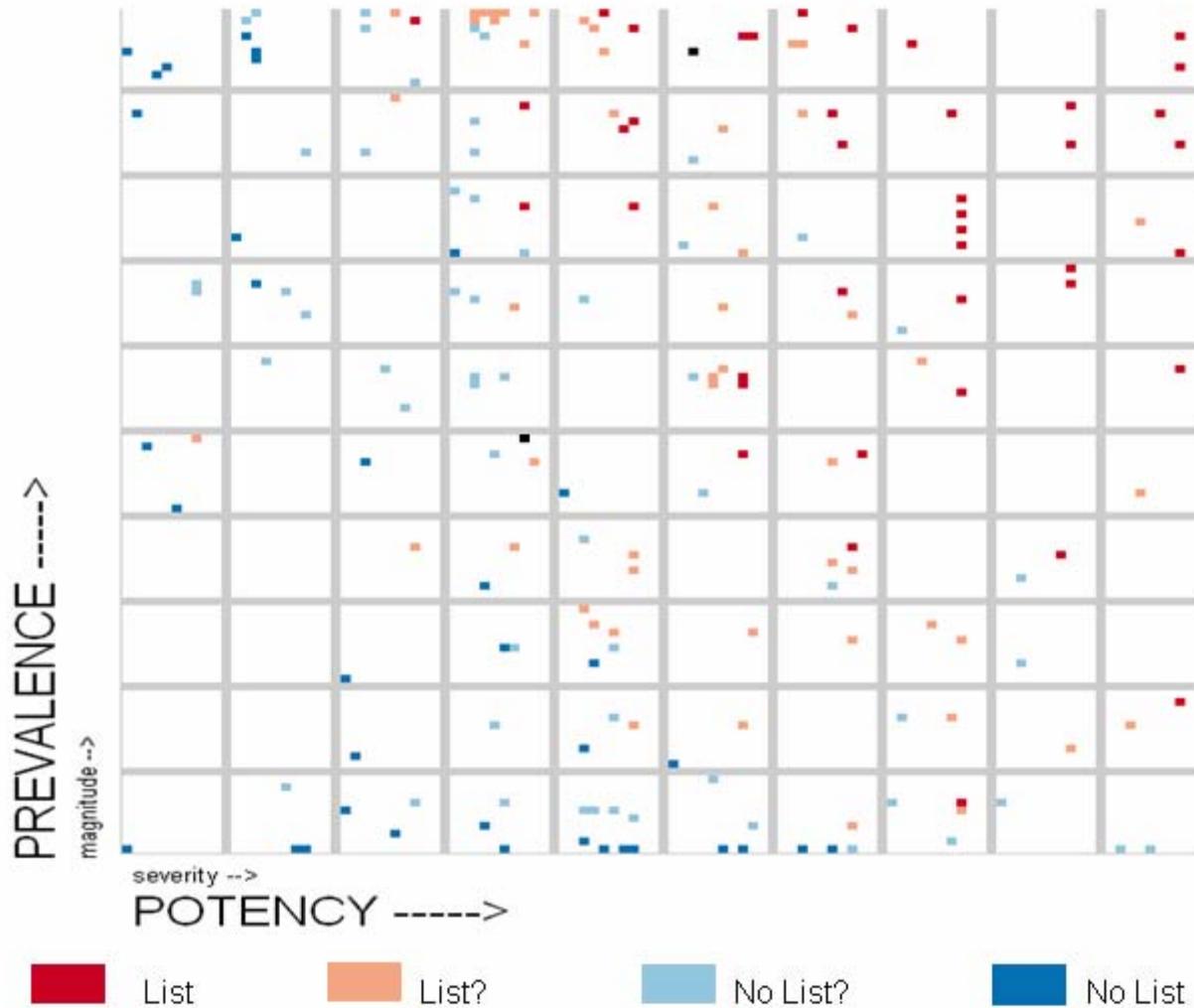
Orientation 2 - The little axes



M



Training Data Set



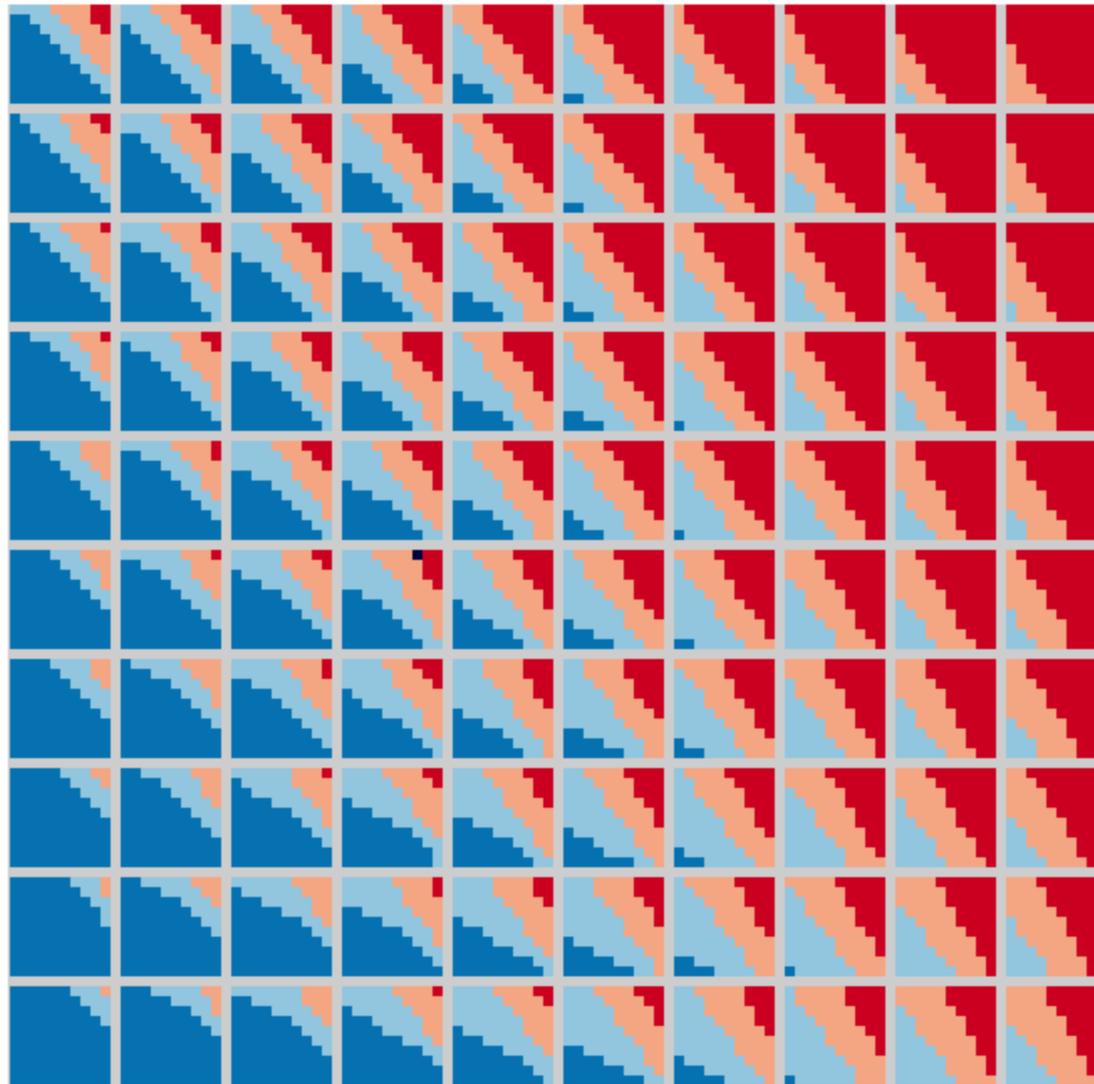


Combining Results

- ANN, Linear, and QUEST models perform well
 - Reasonable TDS agreement
 - Monotonic Results - increasing classifications with increasing attribute scores
- Each PCCL contaminant has attribute score combination like one of the 10,000.
 - Look up its average classification.
 - See how contaminants are categorized by the three models.
 - Do this for all PCCL contaminants, graph the results, and look at their distribution.
- These three models provide predictions that categorize strongest to weakest contaminant.



QUEST





Draft CCL3 Chemical Selection

- Contaminants with finished, ambient or modeled water data
 - Selected Contaminants with a HRL/Concentration ratio ≤ 10
- Contaminants with release data
 - Selected contaminants with L or L? classification model projections based on potential occurrence
- Contaminants with production data
 - Did not select contaminants with only production data



Appendices





Regulatory Determination Statutory Requirements

Every 5 years, EPA shall publish a determination to regulate/not regulate not fewer than 5 contaminants based upon the findings for the following criteria.

- i. The contaminant may have an adverse effect on the health of persons;*
 - ii. 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*
 - iii. 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.*
- EPA must provide an opportunity for public comment
 - The decision not to regulate a contaminant is judicially reviewable





Regulatory Determination Outcomes

- **Positive Determination**

- Affirmative determination for all three criteria.
- Propose a drinking water regulation within 2 years and promulgate within 3 and a half years of determination.

#	Outcome
1	✓
2	✓
3	✓

- **Negative Determination**

- Negative determination for any one the three criteria.
- No action taken to develop a drinking water regulation.
- May publish a health advisory* or take other appropriate action.

#	Outcome
1	✓
2	X
3	X

*Health Advisory (HA) - an estimate of the acceptable drinking water levels for a chemical substance based on health effects information; an HA is not a Federal legally enforceable standard, but serves as technical guidance for Federal, State, and local officials.



General Approach for Evaluating the Statutory Criteria

#	Statutory Criteria	Information To Consider During Evaluation
1	Is the contaminant likely to cause an adverse effect on the health of humans?	<ul style="list-style-type: none"> • Identify most recent Agency risk assessment (IRIS,OPP,OW), the potential health effects, and the Reference Dose (RfD) and/or cancer slope factor. • Use health information to estimate a health reference level (HRL) to evaluate occurrence; typically for cancer – dose associated with 1×10^{-06} risk; non-cancer – RfD, Body Weight-70 kg, DWI-2 L/day, 20% RSC default used as screening).
2	Is the contaminant known or likely to occur in public water systems (PWSs) at a frequency and level of concern?	<ul style="list-style-type: none"> • Evaluate drinking water occurrence data at the HRL. • Primary source for drinking water occurrence data is from the Unregulated Contaminant Monitoring Program (i.e., UCMR and previous UCM surveys; also National Inorganics and Radionuclides Survey). • If available, review supplemental information (e.g. USGS, State data).
3	In the sole judgment of the Administrator, does regulation of the contaminant present a meaningful opportunity for health risk reduction for persons served by PWSs?	<p>Consider variety of factors which include:</p> <ul style="list-style-type: none"> • Population exposure at the health level of concern; typically based on drinking water occurrence information; for non-carcinogens, consider relative exposure from drinking water and other sources (e.g., RSC). • Sensitive populations. • National distribution of occurrence. • Supplemental sources of exposure information could also be considered (e.g., urine/blood biomonitoring) –.



Statutory Requirements for the Various Drinking Water Regulatory Processes

(1996 SDWA Amendments)

- 1) **Contaminant Candidate List (CCL)** – SDWA requires EPA to develop a list of contaminants that are known or anticipated to occur in drinking water and to publish the list every five years.
- 2) **Unregulated Contaminant Monitoring (i.e., UCMR)** – SDWA requires EPA to establish criteria for a program to monitor unregulated contaminants and to identify no more than 30 contaminants to be monitored, every five years.
- 3) **CCL Regulatory Determinations** – EPA must decide whether to regulate at least five CCL contaminants with a national primary drinking water regulation (NPDWR) after evaluating three statutory criteria; Publish determinations on a five year cycle.
- 4) **Regulation Development** - If EPA decides to regulate a contaminant, the Agency has 24 months to propose and 18 months to finalize the Maximum Contaminant Level Goal (MCLG) and the NPDWR. SDWA requires that we evaluate a number of components as part of the standard setting process.
- 5) **Six Year Review** – Once a contaminant is regulated, every six years EPA is required to review and, if appropriate, revise the NPDWR.



EPA Activities

CCL and Regulatory Determinations

- CCL 1 and its Regulatory Determinations
 - March 1998 - Published final list of 60 contaminants in the FR.
 - July 2003 - Published regulatory determinations for 9 of the 60 CCL 1 contaminants in the FR.
- CCL 2 and its Regulatory Determinations
 - Feb 2005 - Published final list of 51 remaining CCL 1 contaminants in the FR (listed on slide 9).
 - May 1, 2007 – Published preliminary regulatory determinations for 11 of the 51 CCL 2 contaminants in the FR; Received 9 comments.
 - Statutory deadline for final determinations is July 2008.
- CCL 3
 - Published draft final list of 104 contaminants in the FR.
 - 90-day comment period ends May 21, 2008



CCL 3 Information available at:

www.epa.gov/safewater/ccl

www.regulations.gov

The image displays two overlapping web browser windows. The left window is the EPA website for the Drinking Water Contaminant Candidate List and Regulatory Determinations. The right window is the Regulations.gov search results page for the search term '2007-1189'.

Left Window (EPA Website):

- Page Title: Drinking Water Contaminant Candidate List and Regulatory Determinations
- Search: All EPA This Area
- Text: EPA has drinking water regulations for more than 90 contaminants. The Safe Drinking Water Act (SDWA) includes a process that we must follow to identify and list unregulated contaminants which may require a national drinking water regulation in the future. EPA must periodically publish this list of contaminants (called the Contaminant Candidate List or CCL) and decide whether to regulate at least five or more contaminants on the list (called Regulatory Determinations). EPA uses this list of unregulated contaminants to prioritize research and data collection efforts to help us determine whether we should regulate a specific contaminant.
- Text: In February 2005, we published the second CCL (CCL 2) contaminants. In May 2007, the Agency published a Federal Register notice announcing its preliminary determination that no regulatory action is appropriate or necessary for 11 of the 51 CCL 2 contaminants.
- Text: **New!** In February 2008, we announced the [draft third Drinking Water Contaminant Candidate List \(CCL 3\)](#) process and rationale used to develop the list.
- Text: The links below provide more information about Contaminant Candidate Lists and Regulatory Determinations.
- Links:
 - Basic Information - This page answers questions about how the CCL is developed, how it fits in development process and links to data and information on CCL contaminants.
 - CCL 3 List - This page describes the CCL 3 process and offers an opportunity to comment on the contaminants included on the draft CCL 3.
 - CCL 2 List and Regulatory Determinations - These pages provide the contaminants listed on the CCL 2 Regulatory Determinations.
 - CCL 1 List and Regulatory Determinations - These pages provide the contaminants listed on the Regulatory Determinations.

Right Window (Regulations.gov):

- Search Again: 2007-1189
- You Searched: (click entry to remove)
- Search Term(s): 2007-1189
- Start Over
- Sort By: Title (A to Z)
- Display Results: 1 to 10 (55 Documents found)
- Narrow Results: Click on item to Add to Search List
- Agency:
 - EPA (53)
 - FERC (1)
 - SEC (1)
- Document Type:
 - Supporting & Related Materials (50)
 - Notices (3)
 - Public Submissions (2)
- Docket Type:
 - Nonrulemaking (53)
- Comment Period:
 - Open (3)
 - Closed (52)
- Results:
 - Announcement of Preliminary Regulatory Determinations for Priority Contaminants on the Drinking Water Contaminant Candidate List (Notification)
 - Federal Register of June 3, 2002 (67 FR 38222) (FRL-7221-8) ...
 - Agency: EPA Document Type: SUPPORTING & RELATED MATERIALS Comments Due: Docket ID: EPA-HQ-OW-2007-1189 Document ID: EPA-HQ-OW-2007-1189-0036
 - View this Document
 - Announcement of Regulatory Determinations for Priority Contaminants on the Drinking Water Contaminant Candidate List; Notice (Notification)
 - Federal Register of July 18, 2003 (68 FR 42898) [FRL-7529-2] ...

