

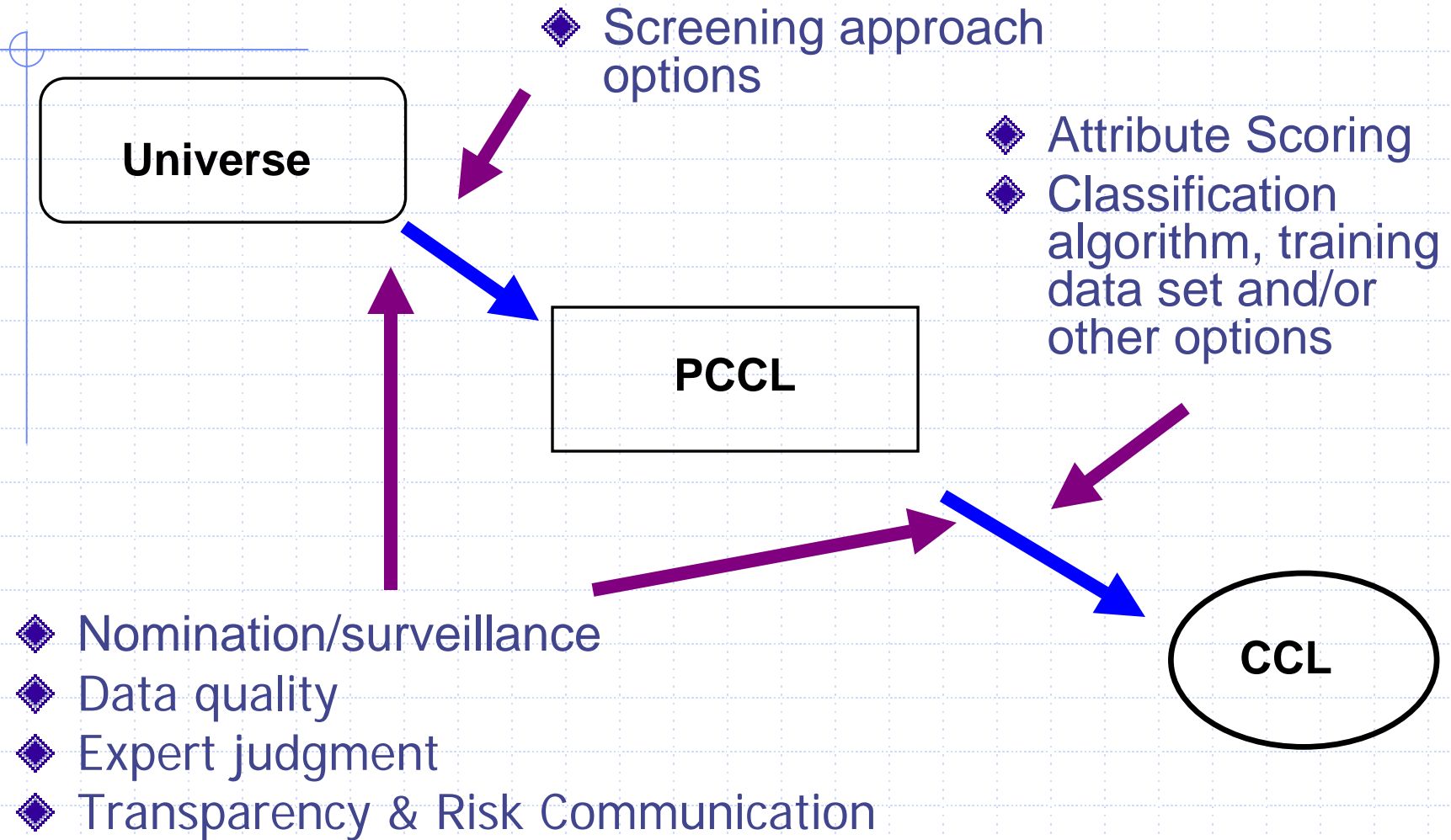


Attribute Scoring

Introduction to Scoring, Summary
of Workshop, and Observations

Presentation to CCL WG November 13, 2003

Critical path decisions



Scoring protocols

- ◆ Purpose is to develop consistent method for scoring each attribute
- ◆ Need to deal with:
 - Diverse data sources
 - How to give scored values to the diverse types of data
 - Need for consistent and reproducible outcome

Elements of scoring protocols

- ◆ Preferred data elements and data sources
- ◆ Hierarchy: Order they should be used in
 - ◆ When to use surrogates for preferred data elements
- ◆ Scaling: How to give scored values (typically 1 to 10) to these data
- ◆ Draft protocols available for review by work group

Potency Attribute Scoring

- ◆ Definition: reflects amount of contaminant required to cause an adverse health effect
- ◆ Data elements: noncancer and cancer toxicity values
 - Reference dose preferred for non cancer;
 - 1 per 10,000 cancer risk preferred for cancer
- ◆ Data hierarchy
 - Noncancer
 - ◆ RfD > NOAEL > LOAEL > LD50
 - ◆ Measured > Modeled
 - Cancer data

Potency Scaling (assigning score)

◆ Scaling or assignment of score:

- $10 - (\text{Log}_{10}(\text{RfD}) + 7)$
- $10 - (\text{Log}_{10}(\text{NOAEL or LOAEL}) + 4)$
- $10 - (\text{Log}_{10}(\text{LD50}) + 2)$
- $10 - (\text{Log}_{10}(\text{"E-4" Cancer Risk}) + 6)$
- Choose the higher of the noncancer or cancer value as the potency attribute score.

Severity Attribute Scoring

- ◆ Definition: degree of harm caused by the contaminant based on the magnitude of the most sensitive health end-point in affected individuals.
- ◆ Data elements: critical effect
- ◆ Data hierarchy: not specified

Two Scaling Approaches

◆ Severity Score Scale A (HECD 9/03/03)

- 1 = No adverse effect
- 2 = Cosmetic effects
- 3 = Reversible, transient, adaptive effects
- 4 = Cellular / physiological changes that could lead to disorders
- 5 = Significant (but reversible) functional changes or permanent changes of minimal significance
- 6 = Significant irreversible, non-lethal conditions
- 7 = Developmental or reproductive effects
- 8 = Tumors or disorders likely leading to death
- 9 = Death

Two Scaling Approaches (cont.)

◆ Severity Score Scale B (HECD 10/21/03)

- 1 = Cosmetic effects, no cytological or histological changes or functional effects identified; hematological or blood chemistry changes. 2 = Changes in
- absolute/relative organ weights; organ damage, lesions, toxicity; specific cytopathological or histopathological effects.
- 3 = Reduced fertility; mild CNS signs, behavioral changes (other than neurodevelopmental); other mild functional impairments.
- 4 = Reproductive toxicity, teratogenicity, neurodevelopmental effects; effects on viability, survival of offspring; severe CNS and other functional impairments.
- 5 = Malignancy; reduced survival / increased mortality.

Prevalence Attribute Scoring

- ◆ Definition: indicates the commonness of a contaminant in drinking water.
- ◆ Data elements and hierarchy:
 - hierarchy of seven data elements
 - reflects preference for measurements in drinking water or source water, followed by environmental release and production / use information

Prevalence Hierarchy

- P1: Finished drinking water, % systems with detections from national scale data.
- P2: Ambient/raw/source water sites, % sites with detections from national scale data.
- P3: Ambient/raw/source water sites, % samples with detections from national scale data.
- P4: Finished drinking water, % systems with detections from state / regional scale data.
- P5: Ambient/raw/source water sites, % sites with detections from state / regional scale data

Prevalence Hierarchy (cont.)

P6: Environmental release data (Toxics Release Inventory) or Hazardous substance release data (ATSDR HazDat).

P7: Production or use data

Prevalence Scaling

- ◆ Prevalence attribute scores ranged from 1 to 10.
- ◆ Attribute score assigned based on “look up” tables prepared for each of the above prevalence data elements (*see handouts*).

Magnitude Attribute Scoring

- ◆ Definition: concentration or expected concentration of the contaminant in drinking water.
- ◆ Note that NRC defined magnitude as a concentration relative to a level causing a health effect – but scoring was based on scoring only as described in 10/1/03 discussion draft “Scoring the Attribute Magnitude Based on Concentration Only.”

Magnitude Data elements and hierarchy

- M1: Finished drinking water median of detected concentration for systems from national scale data.
- M2: Ambient/raw/source water median of detected concentration for sites from national scale data.
- M3: Ambient/raw/source water median of detected concentration for samples from national scale data.
- M4: Finished drinking water median of detected concentration for systems from state / regional scale data.
- M5: Ambient/raw/source water median of detected concentration for samples from state / regional scale data.

Magnitude Data elements and Hierarchy (cont.)

- M6: Environmental release data (Toxics Release Inventory) or Hazardous substance release data
- M7: Pesticide use / application data.
- M8: Production / import data for manufactured chemicals.

Magnitude Scaling

- ◆ Magnitude attribute scores ranged from 1 to 10.
- ◆ Attribute score assigned based on “look up” tables prepared for each of the above magnitude data elements (*see handouts*).

Persistence - Mobility

- ◆ Definition: likelihood that a contaminant will be found in the aquatic environment based solely on physical properties.
- ◆ Persistence and mobility have separate data elements that are scored individually, and those scores are then combined to produce the overall persistence – mobility attribute score.

Persistence Data Elements and Hierarchy

- P1: Half life ($T_{1/2}$)
- P2: Stability (abiotic and biotic degradation)
- P3: Measured biodegradation rate
- P4: Estimated biodegradation rate

Mobility Data Elements and Hierarchy

- M1: Organic carbon partition coefficient (K_{oc})
- M2: Log octanol-water partition coefficient (Log K_{ow})
- M3: Dissociation constant (K_d cm³/g)
- M4: Henry's Law Constant (atm m³/mol)
- M5: Solubility (mg/L)

Persistence - Mobility Scaling

- ◆ The data elements for persistence and mobility are scored with values of 1, 2 or 3 (corresponding to low, medium and high values for the data elements).
- ◆ The overall persistence-mobility attribute score is computed as the average of the individual persistence and mobility values, multiplied by 10/3.
 - Example: If persistence = 2 and mobility = 3, the overall score is $[(2 + 3) / 2] \times (10/3) = 8.3 \Rightarrow 8$

Review of scoring

- ◆ Comments from work group accepted today or after further review during December
- ◆ Also consider principles for scoring, in addition to any specific comments

Possible principles for scoring

- ◆ Attribute score should increase with concern
- ◆ Scoring should be able to discriminate
- ◆ Should be sufficient scoring categories to capture the range of the data
- ◆ Number of categories shouldn't be so great as to create false sense of precision
- ◆ The best data source should be considered for each element

Possible principles for scoring

- ◆ Scoring across elements for an individual attribute should be consistent
- ◆ The best source of data should be used for each element
- ◆ Scoring protocol should be transparent
- ◆ Scoring protocol should be simple

Purpose and Goals of Workshop

- ◆ To test the attribute scoring protocols as developed by EPA.
- ◆ To assess whether:
 - There are appropriate data upon which to base the scores
 - the data are provided in a clear, understandable format.

Purpose and Goals (cont.)

- ◆ To identify issues or problems with individual protocols
- ◆ Assess whether attribute scoring is amenable to being automated in a model.
- ◆ Assess implications on timing for implementation in the CCL process.

Summary of Attribute Scores

Potency and Severity

	Potency				Severity			
	Group 1	Group 2	Group 3	Group 4	Group 1	Group 2	Group 3	Group 4
Bisphenol A	4	4			3 (2)			
1,3 Dichlorobenzene	4		4	4	3 (1-2)			4
Aluminum oxide								
(E)-2-Hexenyl butyrate	3		3	3			NA	
17a-Estradiol							7	7
Boron	4			4	7 (4)			7
Heptachlorodibenzo-p-dioxin	10				8 (5)			
Flamprop	5							
Metolachlor	4				3 (2)			
Isobutyric acid	6				9 (5)			

Summary of Attribute Scores

Prevalence and Magnitude

	Prevalence				Magnitude			
	Group 1	Group 2	Group 3	Group 4	Group 1	Group 2	Group 3	Group 4
Bisphenol A		10				3		
1,3 Dichlorobenzene		4	3	4		4	4	4
Aluminum oxide		9	9	9		9	10	9
(E)-2-Hexenyl butyrate		NA	5			NA	NA	
17a-Estradiol		7	7	7		1	1	1
Boron				10				10
Heptachlorodibenzo-p-dioxin								
Flamprop								
Metolachlor								
Isobutyric acid								

Summary of Attribute Scores Combined Persistence and Mobility

	Combined Persistence & Mobility			
	Group 1	Group 2	Group 3	Group 4
Bisphenol A		3		
1,3 Dichlorobenzene		3	8	5
Aluminum oxide		3	3	3
(E)-2-Hexenyl butyrate	7	5	5	5
17a-Estradiol		7	7	7
Boron				10
Heptachlorodibenzo-p-dioxin				
Flamprop				
Metolachlor				
Isobutyric acid				

Potency Attribute Scoring Issues and Challenges

- ◆ Some concerns about the appropriateness of the route of exposure for the critical study – for example, the 17 α -estradiol RfD was by subcutaneous injection, not by an oral route.
- ◆ Some concerns about clarity of units for some data sources – for example, from RTECS).
- ◆ Some concerns about the chemical moiety of concern – for example, aluminum oxide as Al₂O₃ or just the Al component?

Severity Attribute Scoring Issues and Challenges

- ◆ Some concerns that the information for potency and severity are “de-coupled” – that is, come from different sources.
- ◆ Some situations when the critical effect for potency is not available to score severity, including when a QSAR value is used for potency.
- ◆ Some concerns that the severity descriptors may not be clear in all situations.

Prevalence Attribute Scoring Issues and Challenges

- ◆ Some concern that data elements based on % observation of detects ought to reflect the number of observations – for example, 17a-estradiol got a 7 for prevalence based on a 5.7% of detects, but from an N count of only 70.
- ◆ Some concern about data presentation – ensure clarity of percent versus decimal formats.

Magnitude Attribute Scoring Issues and Challenges

- ◆ Some concerns about the protocol scale
 - some getting high scores at concentrations below current regulatory concerns.
- ◆ Some concerns that the protocol uses a median of concentrations without consideration of the number of values and non-detects.

Persistence-Mobility Attribute Scoring Issues and Challenges

- ◆ Relatively straightforward
- ◆ Based upon chemical properties that are generally available
- ◆ In some instances, only vague textual information available

Key Observations and Lessons Learned

- ◆ Given the availability of data for these chemicals and defined protocols, consistent attribute scoring was feasible.
- ◆ It required considerable effort to get the data in a format that allowed the scoring to proceed in a consistent manner:
 - Data compilation could be more efficient based upon the experience

Key Observations and Lessons Learned (cont.)

- ◆ There are a number of outstanding technical issues critical to the scoring protocol:
 - Ensuring that data/information from various sources is applied consistently.
 - Ensuring the equivalency of scores from different data elements
 - Reviewing the scales (e.g., 10 point vs. 3 point)
 - Understanding assumptions made during data extraction and compilation
 - Understanding the extent of the effort for data extraction

Key Observations and Lessons Learned (cont.)

- ◆ It is not entirely clear whether or to what extent the scoring process can be “automated”
 - Some interpretation was helpful
- ◆ The participants discussed at some length the potential need for the attribute scoring process to evolve over time.

PCCL to CCL: Questions for work group on attributes scoring

- ◆ What are your views about the general approaches proposed for the scoring protocols?
- ◆ Do you have any comments or suggestions for further development of the scoring approaches?
- ◆ What is your reaction to the report from the scoring workshop?
- ◆ Do you have comments about principles for scoring?
- ◆ When should we take up the question about how many attributes need to be scored (3, 5 or another number)?