Methods Activity Group

Status Report for the CCL Work Group

Plenary Meeting

March 27-28, 2003

The Methods Activity Group has had two conference calls since the February plenary mtg.

Participants:

- Laura Anderko
- Douglas Crawford-Brown
- Mike Dourson
- Alan Elzerman
- Brian Ramaley
- Colin Stine
- Craig Stow
- Lynn Thorp
- Dan Wartenberg
- Nancy Kim (Data Group liaison)
- Tom Carpenter and other EPA staff
- Jo Anne Shatkin and other Cadmus staff
- Steve Via, AWWA
- Abby Arnold and Sara Litke

Deliverables Scheduled for March

- Task 4: Evaluate screening processes
  - Deliverable: Proposed alternatives for screening from the universe to the PCCL
  - Deliverable: Identify and evaluate screening models and algorithms for estimating parameters
- Task 7: Identify decision methods and prototype approaches
  - Deliverable: Recommended decision method and associated prototype approach(es) for classifying from the PCCL to the CCL

Progress toward Deliverables

- Deliverable: Proposed alternatives for screening from the universe to the PCCL
  - The group has drafted a rule-based, gate approach to screen from the universe of chemicals to the PCCL.
  - Next steps: Agree on revisions to draft approach and present to plenary for review
  - Next steps: Continue to develop the proposed approach (identify additional gates, decide on rules or sorting criteria for gates, etc.)

To discuss: (after EPA)

- 1) What criteria define "known" occurrence and “known” health effects?
- 2) Alternatives for "potential" occurrence and health effects

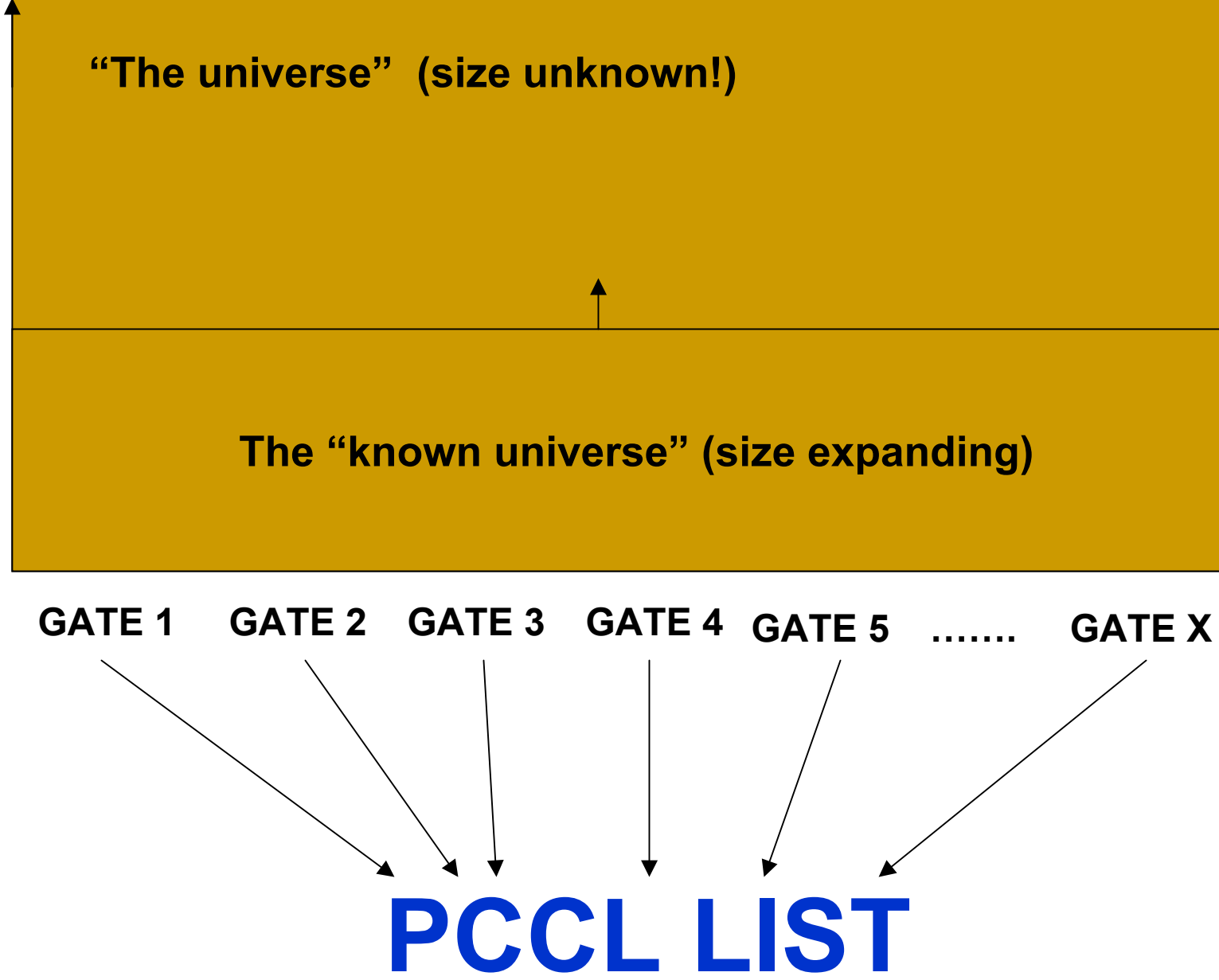
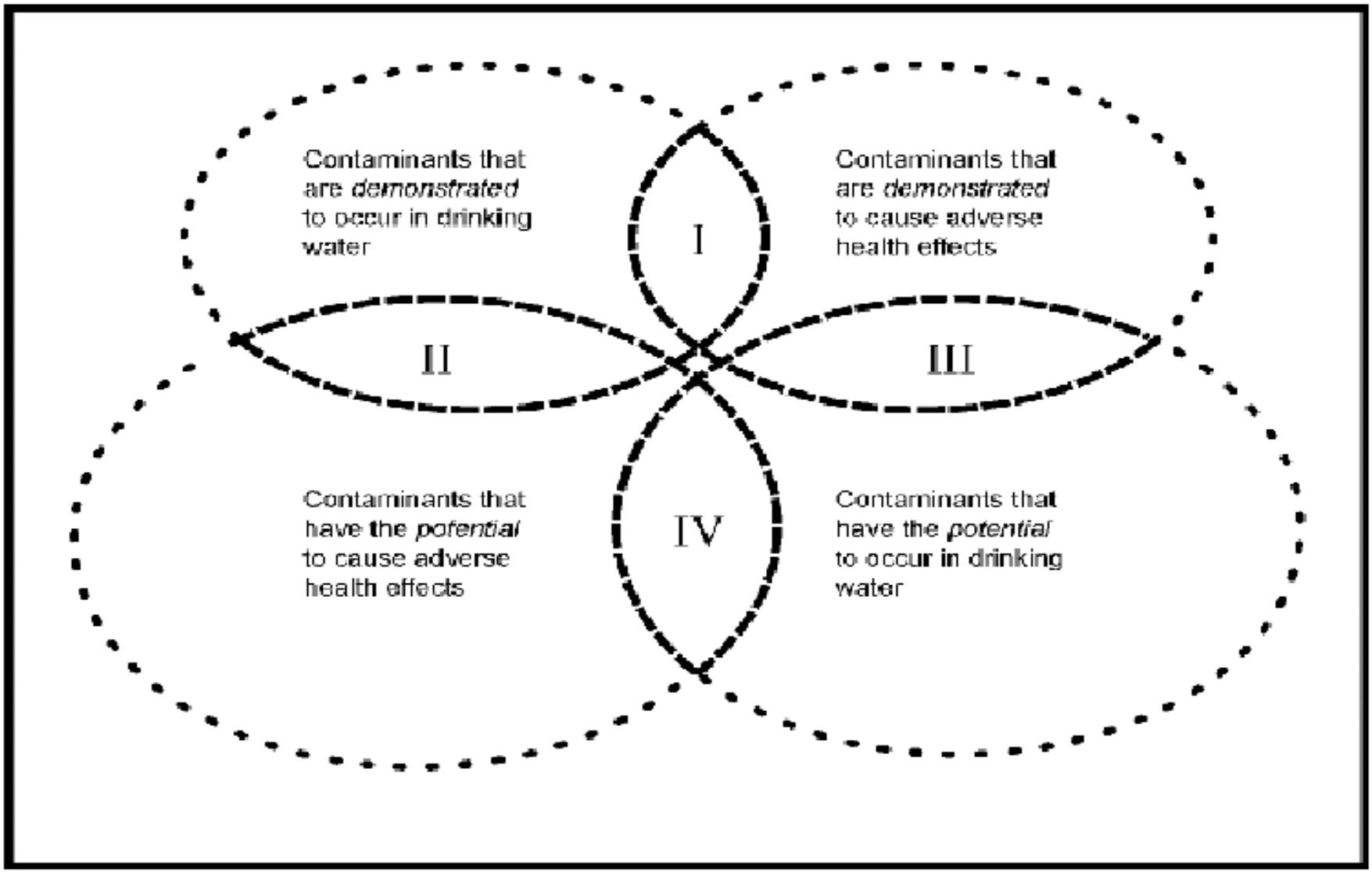

"The universe" (size unknown!)
The "known universe" (size expanding)
GATE 1
GATE 2
GATE 3
GATE 4
GATE 5
…….
GATE X
PCCL LIST

Exhibit 1. Graphical Representation of the Universe



Progress toward Deliverables (cont.)

- Deliverable: Recommended decision method and associated prototype approach(es) for classifying from the PCCL to the CCL
  - The group has reviewed an attribute scoring approach to be used on an example data set to test various approaches.
  - Next steps: Review example data set and test various approaches with raw and scored data.

Attributes:

- Health Effects
  - ***Severity***
  - ***Potency***
- Occurrence Categories
  - ***Prevalence***
  - ***Magnitude***
  - ***Persistence***
  - ***Mobility***

Exhibit 1. Example Severity Scale

Score	HECD DRAFT Scoring Scheme	NRC Scoring Scheme
0	No effect	No effect
1	Cosmetic effects	Changes in organ weights with minimal clinical significance
2	Transient, reversible effects	Biochemical changes with minimal clinical significance
3	Cellular/physiological changes that could lead to disease/disorder (risk factors or precursor effect)	Pathology of minimal clinical significance (e.g. fluorosis, warts, common cold)
4	Mild, permanent functional changes	Cellular changes that could lead to disease; minimal functional change
5	Curable diseases or disorders	Significant functional changes that are reversible (e.g. diarrhea)
6	Treatable, uncurable diseases or disorders	Irreversible changes; treatable disease
7	Chronic, untreatable, nonlethal diseases or disorders	Single organ system pathology and function loss
8	Effects leading to sterility, miscarriage, stillbirths (population effects)	Multiple organ system pathology and function loss
9	Disease likely leading to death	Disease likely leading to death
10	Death	Death

Exhibit 4. Attribute Scoring for Prevalence for Example Data Set

Prevalence Range (% Samples w/ Detects)	Corresponding Score
0.0 - 0.046	1
>0.046 - 0.075	2
>0.075 - 0.11	3
>0.11 - 0.17	4
>0.17 - 0.29	5
>0.29 - 0.63	6
>0.63 - 1.1	7
>1.1 - 5.0	8
>5.0 - 10	9
>10 - 100	10

Exhibit 3. Overall Prevalence score based on Temporal and Spatial Prevalence

		Temporal Prevalence (%)				
		<25	25–50	50–75	75–90	90–100
Spatial Prevalence (%)	<25	1	2	3	4	6
	25–50	2	4	5	7	8
	50–75	3	5	8	9	9
	75–90	4	7	9	10	10
	90–100	6	8	9	10	10

Source: NRC. 2001. *Classifying Drinking Water Contaminants for Regulatory Consideration.* Washington, DC: National Academy Press, pg. 69.

Progress toward Deliverables (cont.)

- Identify and evaluate screening models and algorithms for estimating parameters (e.g., QSAR, VFAR?)
  - Next steps: Review surrogate data
  - Next steps: Consider which parts of process to use these approaches

Tasks and Deliverables Scheduled from Now Until May

- Task 6: Recommend a process to screen from universe to PCCL
  - Review of sensitivity analysis
- Task 7: Identify decision methods and prototype approaches
  - Summary of prototype models selected
- Task 8: Identify attributes for recommended decision method and prototype approach
  - Summary of attributes and data elements
- Task 12: Build, test and perform sensitivity analysis on decision approach(es)
  - Prototype model