WEIGHT-OF-EVIDENCE APPROACHES

INVITED EXPERT MEETING ON REVISING USEPA'S GUIDELINES FOR DERIVING AQUATIC LIFE CRITERIA

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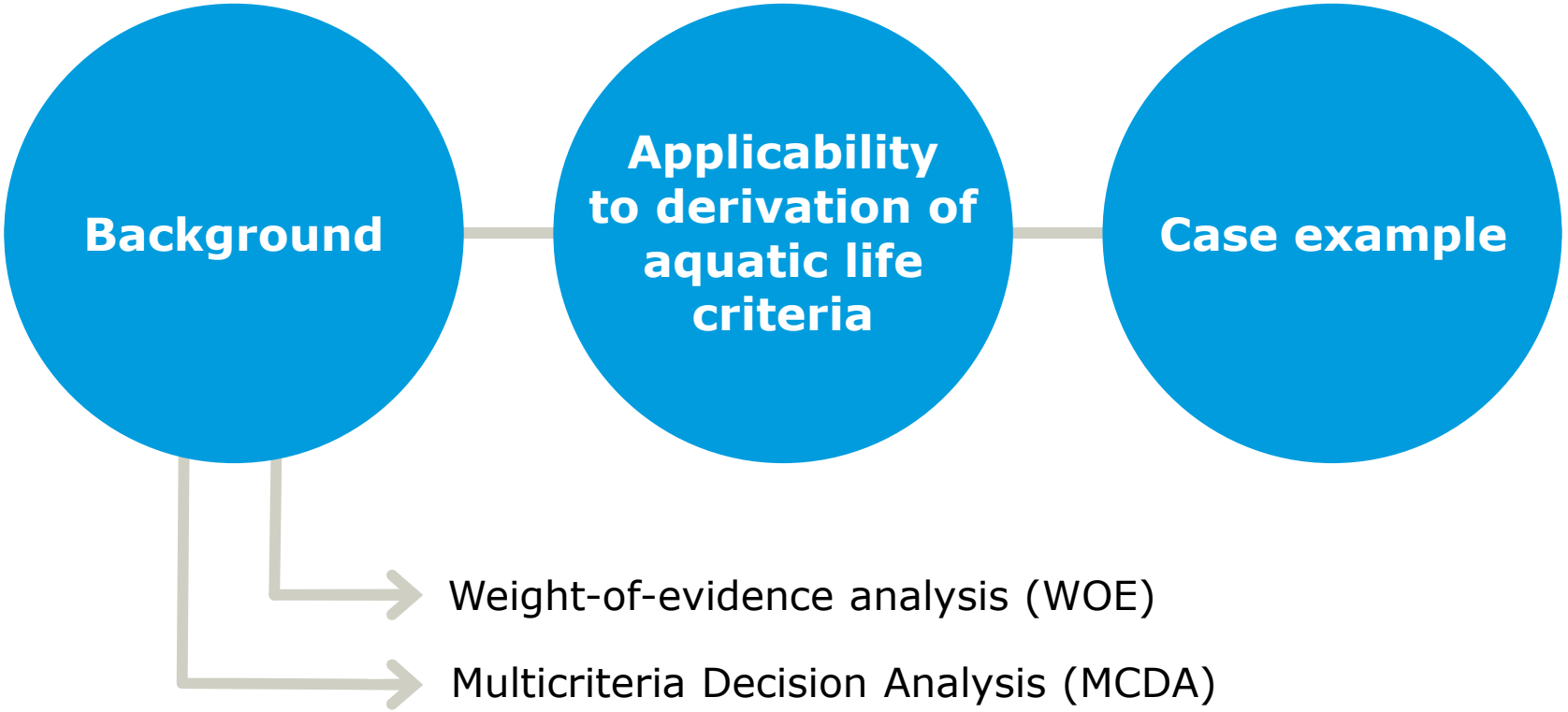
PRESENTATION OVERVIEW



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WOE CONCEPT

Wise to consider multiple lines of evidence

- But often outcomes conflict
- And professional opinions differ

Weighing each line of evidence systematically allows

- Transparent characterization of uncertainty
- Explicit documentation of professional judgment
- Balanced conclusion

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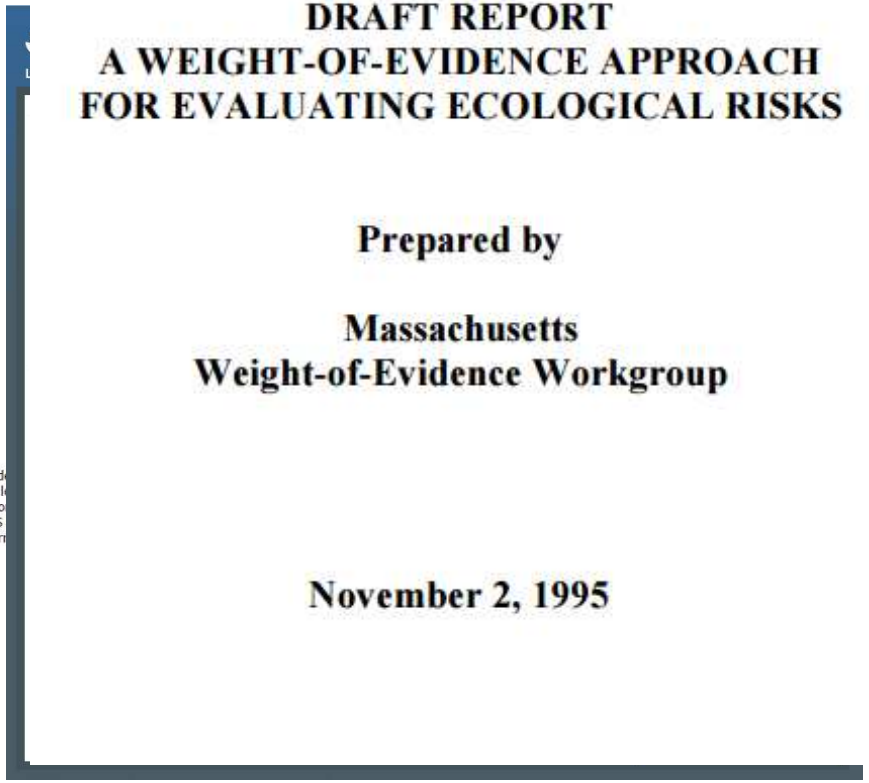
WOE PRECEDENTS

- USEPA Integrated Risk Information System
- CADDIS
- MADEP WOE Work Group



_II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — alpha-Hexachlorocyclohexane (alpha-HCH)
CASRN — 319-84-6
Last Revised — 07/01/1993

Section II provides information on three aspects of the carcinogenic assessment for the substance in question; the weight-of-evid
inhalation exposure. The quantitative risk estimates are presented in three ways. The slope factor is the result of application of a l
risk per ug/L drinking water or risk per ug/cu.m air breathed. The third form in which risk is presented is a drinking water or air co
carcinogenicity information in IRIS are described in The Risk Assessment Guidelines of 1986 (EPA/600/8-87/045) and in the IRIS
Assessment also utilize those Guidelines where indicated (Federal Register 61(79):17960-18011, April 23, 1996). Users are refer

_II.A. Evidence for Human Carcinogenicity

__II.A.1. Weight-of-Evidence Characterization

Classification — B2; probable human carcinogen

Basis — Dietary alpha-HCH has been shown to cause increased incidence of liver tumors in five mouse strains and in Wistar rats.

DRAFT REPORT
A WEIGHT-OF-EVIDENCE APPROACH
FOR EVALUATING ECOLOGICAL RISKS

Prepared by

Massachusetts
Weight-of-Evidence Workgroup

November 2, 1995

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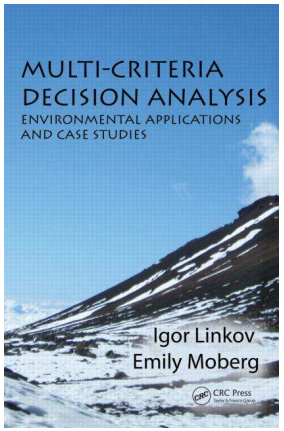
MCDA BACKGROUND

- Sub-discipline of operations research since 1970s, drawing on mathematics, behavioral decision theory, economics, software engineering, and information systems
- 2011 publication of Linkov & Moberg mainstreamed MCDA's application to environmental decision making
- Many MCDA methods exist:
  - Aggregated Indices Randomization Method
  - Analytic hierarchy process
  - Analytic network process
  - Best worst method
  - Characteristic Objects Method
  - Choosing By Advantages
  - Data envelopment analysis
  - Disaggregation – Aggregation Approaches
  - Dominance-based rough set approach
  - Outranking
  - Evidential reasoning approach
  - Goal programming
  - Inner product of vectors
  - Multi-Attribute Global Inference of Quality
  - Multi-attribute utility theory
  - New Approach to Appraisal
  - Potentially all pairwise rankings of all possible alternatives
  - Superiority and inferiority ranking method
  - Technique for the Order of Prioritisation by Similarity to Ideal Solution
  - Value analysis
  - Value engineering
  - VIKOR method
  - Fuzzy VIKOR method
  - Weighted product model
  - Weighted sum model
  - Rembrandt method



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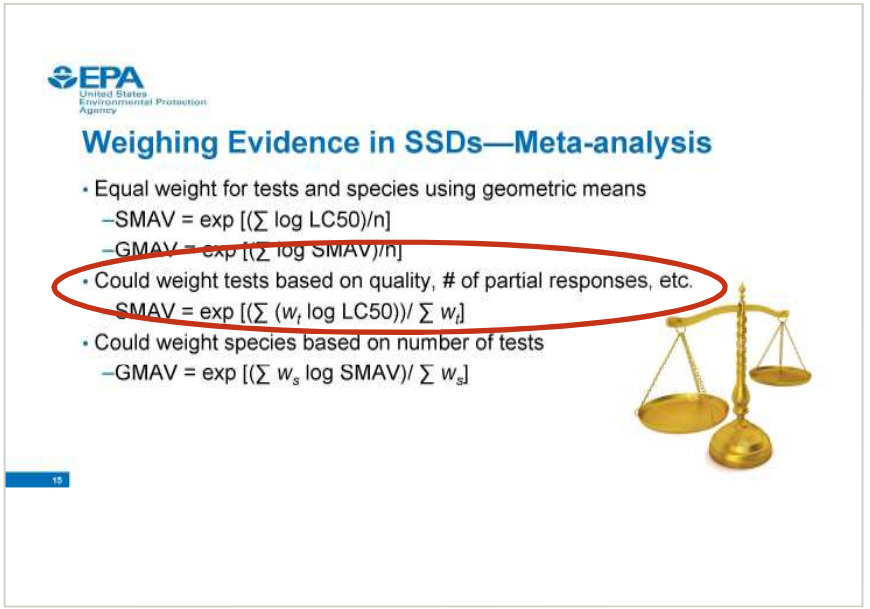
PROPOSED APPLICATION IN ALC DERIVATION

From Suter's WOE presentation

Illustrated here with a constructed dataset for a hypothetical substance lacking an ALC or with an outdated ALC



EXAMPLE ATTRIBUTES FOR WEIGHING STUDY QUALITY, DEFINED A PRIORI

1. **Test organisms**
   sensitivity, similarity to target species with respect to taxonomy and feeding guild
2. **Endpoints**
   effects measured are most sensitive, diagnostic, and relevant to population sustainability
3. **Study design**
   sample size, acclimation, dosing methods, exposure duration
4. **Data quality**
   QA/QC, statistical analysis, confounding factors
5. **Study execution**
   methodological contributions to uncertainty

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Score → / Attribute ↓	1	2	3	4	5
Test organisms	Insensitive species, not native or closely related	Insensitive, native species	Sensitive species, not native or closely related	Sensitive species closely related to native species	Sensitive, native species
Endpoints	Insensitive, nondiagnostic endpoint	Somewhat diagnostic and sensitive endpoint	Moderately diagnostic and sensitive endpoint, not closely tied to population sustainability	Diagnostic and sensitive endpoint, linked to population sustainability	Highly diagnostic and sensitive endpoint that drives population sustainability
Study design	Meets $\leq$1 of 5 key aspects of study design (as described under Score 5)	Meets 2 of 5 key aspects of study design (as described under Score 5)	Meets 3 of 5 key aspects of study design (as described under Score 5)	Meets 4 of 5 key aspects of study design (as described under Score 5)	Strong sample size, acclimation, dosing methods, number of dose groups, and exposure duration
Data quality	Inappropriate statistical analyses and/or errors and/or unaddressed confounding factors	Analyses and/or QA/QC are questionable but errors not definitively identified	Statistical analyses appropriate though potential confounding factors not fully addressed and discussion of QA/QC limited	Robust statistical analyses and confounding factors addressed, but limited discussion of QA/QC	Robust statistical analyses and QA/QC; any potential confounding factors addressed
Study execution	Flaws in study execution preclude reliance on all conclusions	Flaws in study execution preclude reliance on some conclusions	Minor flaws in study execution, but not adequately explained	Minor flaws in study execution are adequately explained	No flaws in study execution identified

EXAMPLE WEIGHING OF STUDIES

Attribute	Study1	Study2	Study3	Study4	Study5
Test organisms	1	3	4	2	4
Endpoints	2	4	5	4	5
Study design	1	2	3	3	5
Data quality	2	5	2	3	3
Study execution	1	2	3	4	5
Average score (weights)	**1.4**	**3.2**	**3.4**	**3.2**	**4.4**

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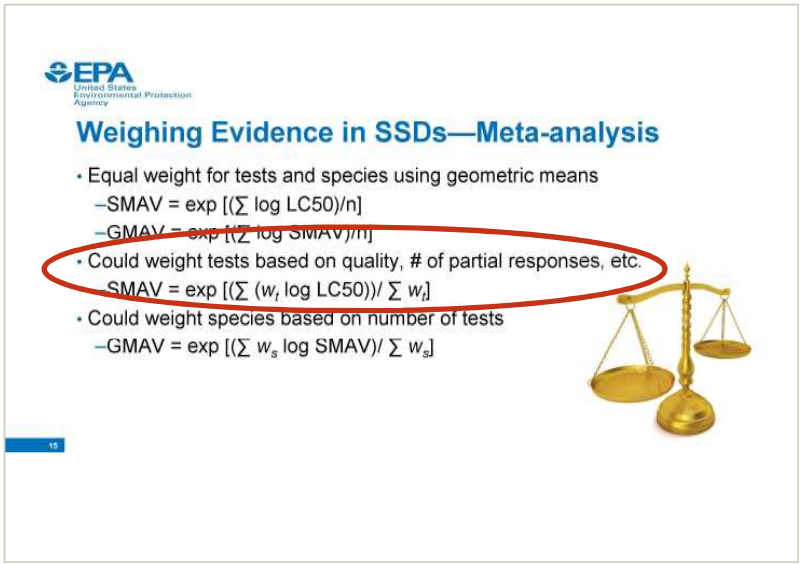
RESULTANT WEIGHTS THEN APPLIED TO SMAV CALCULATION

- Scores derived above serve as w_t

Study	Weight	LC50
1	1.4	5
2	3.2	15
3	3.4	2
4	3.2	25
5	4.4	10



- Unweighted SMAV = 8.2
- Weighted SMAV = 8.7

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OTHER POTENTIAL WOE APPLICATIONS IN ALC DERIVATION

Cases where QSAR indicates toxicity of Chem1≤Chem2, but tier II paradigm prevents consideration of that information

Overcoming technical challenges in deriving aquatic life criteria for contaminants of emerging concern (CECs)

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CONCLUSIONS

Tool for reconciling conflicting lines of evidence and appropriately considering each line of evidence

Acknowledges that quality in studies varies and professional judgment is used when deriving ALC

- We currently use professional judgment when we assume all studies are of equal quality (i.e., in not weighing evidence)

MCDA/WOE widely applied and accepted

Not difficult to understand or implement

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THANK YOU

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