

Comments on the Meaning of “...as appropriate...”

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“EPA shall incorporate, as appropriate, based on chemical- specific datasets and biological effects, the recommendations...of the National Research Council’s Review of the Environmental Protection Agency’s Draft IRIS Assessment of Formaldehyde into the IRIS process”

The House Report (112-151) accompanying the Consolidated Appropriations Act of 2012 (Public Law 112-74)

NRC, Review of EPA’s Integrated Risk Information System (IRIS) Process, Page 3: *Emphasis added*

The burden of proof is on the advocates of these new approaches, even though they are based on exciting and intellectually stimulating methodological advances, to show they will be helpful in the management of risk.

(Goldstein, BD. Risk assessment of environmental chemicals: If it ain't broke... Risk Analysis 31:1356-62, 2011)

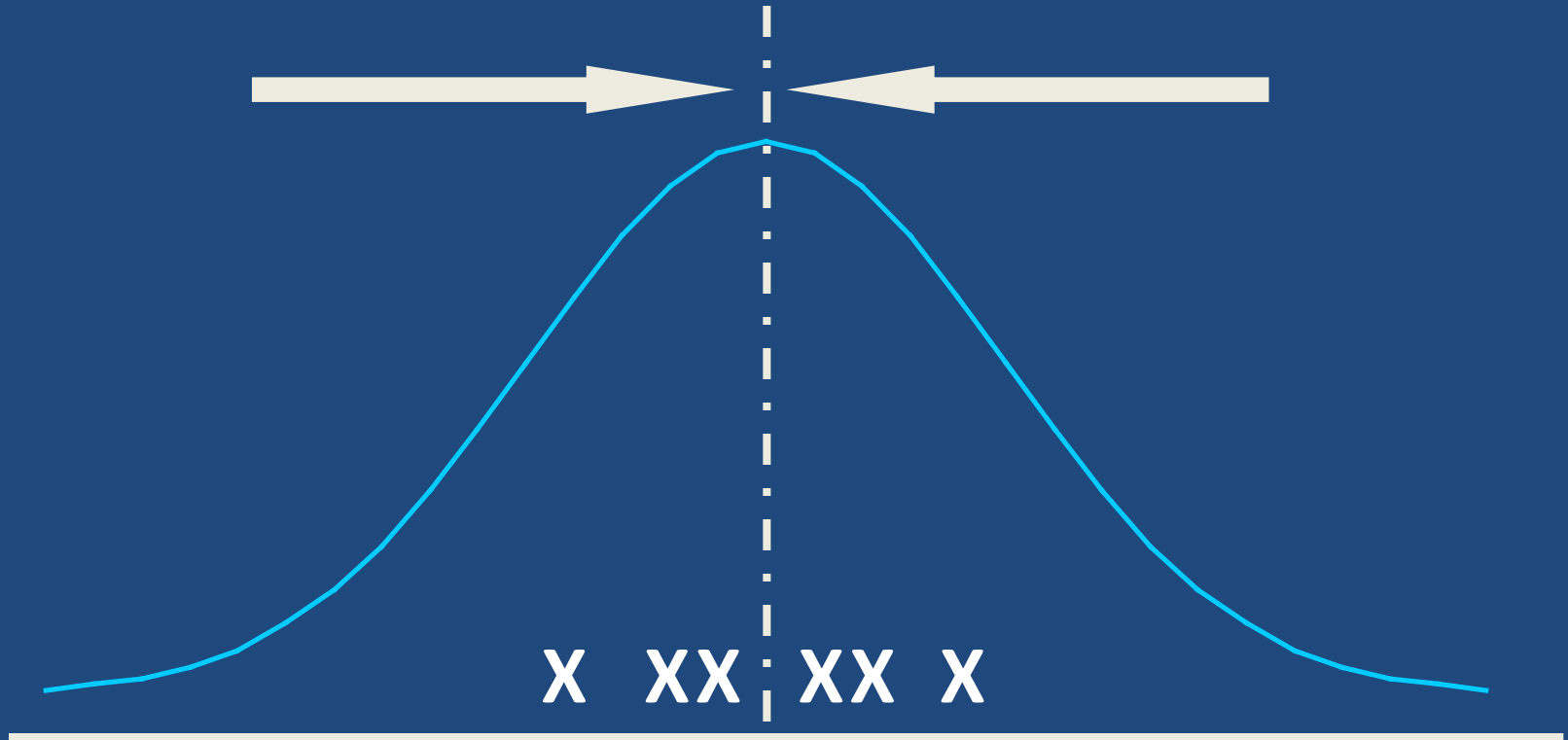
Integrating evidence rationally requires an implicit or explicit set of guidelines...Such frameworks range from ones that involve a rigid, algorithmic integration process to ones that provide loose guidelines and allow experts substantial freedom in applying them.

NRC, Review of EPA's Integrated Risk Information System (IRIS) Process, Page 91

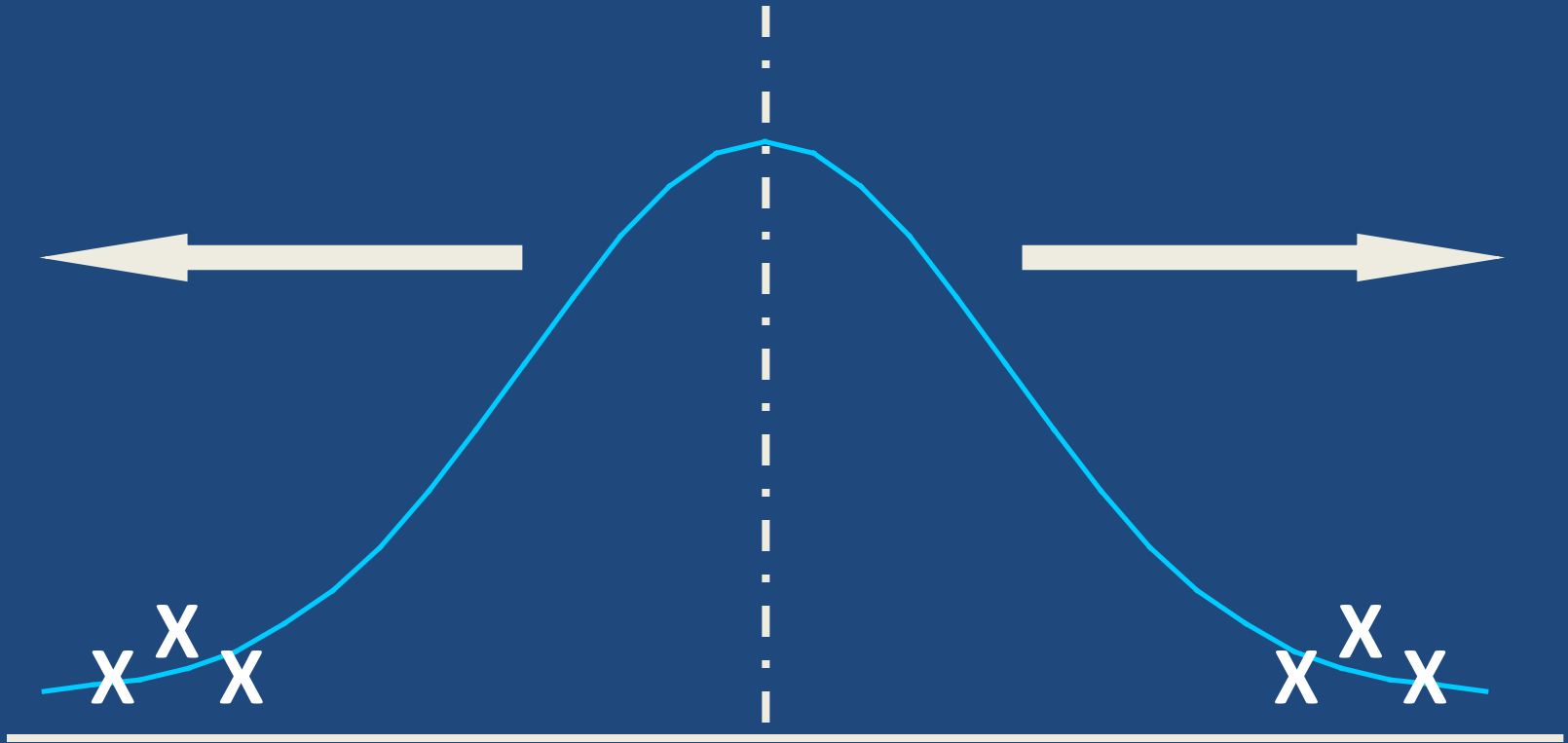
All steps of the IRIS process, **especially the evidence integration and conclusions reached**, are necessarily laden with human judgment, as are most scientific endeavors.

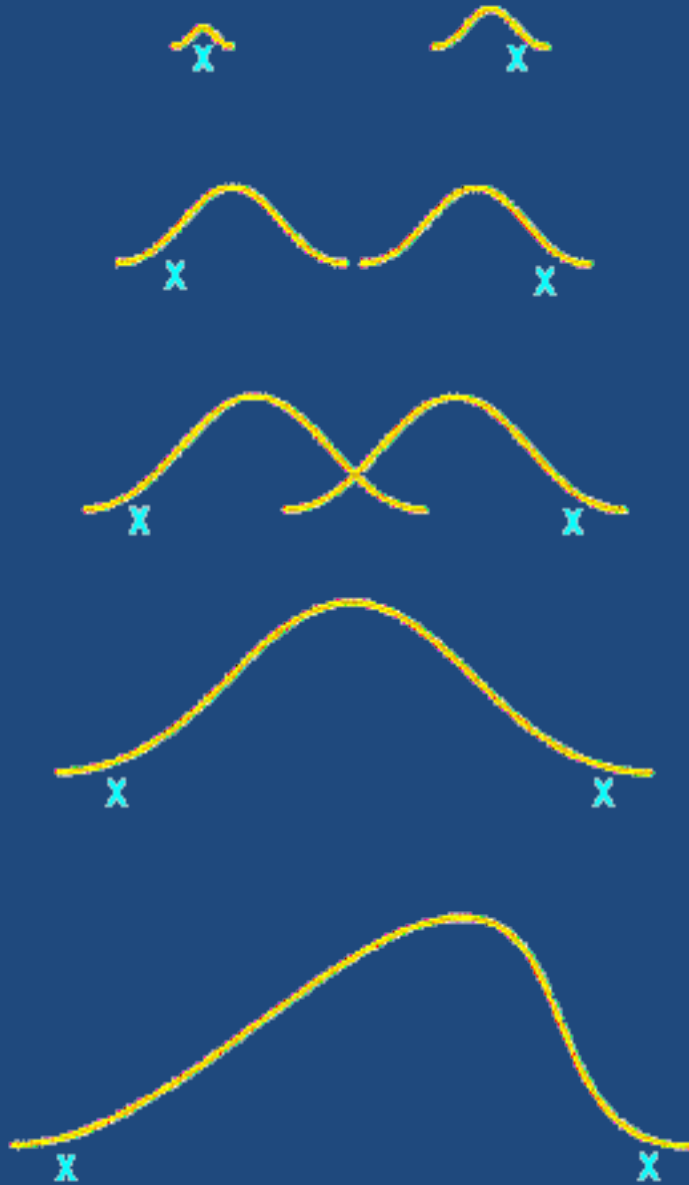
NRC, Review of EPA's Integrated Risk Information System (IRIS) Process, Page 25 *Emphasis added*

Range of Expert Judgment



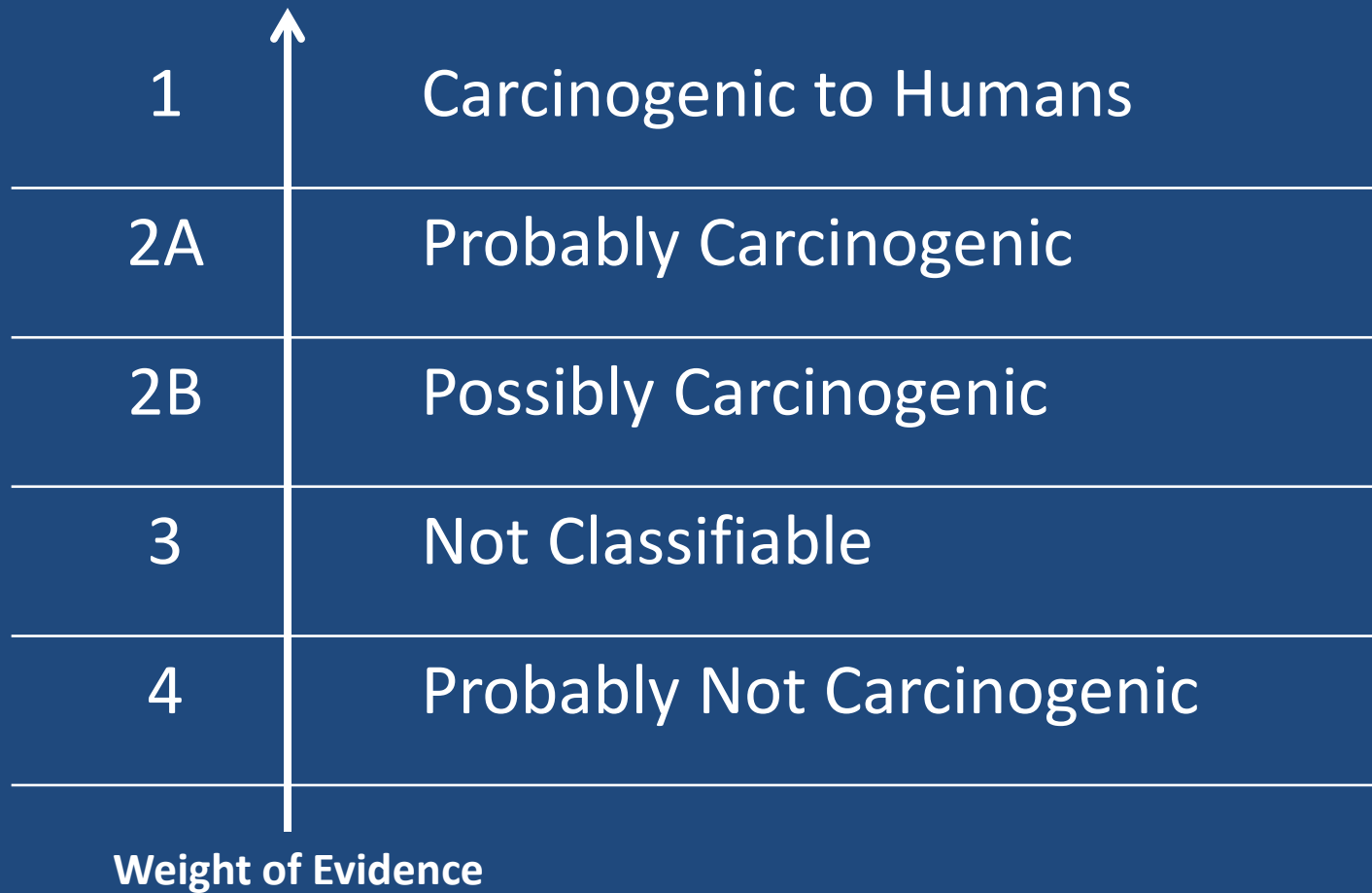
Range of Expert Judgment





Communication of Science

IARC Overall Evaluation of Carcinogenicity to Humans



Steps in Developing a Data Quality Objective

1. State the problem
2. Identify the decision
3. Identify inputs to the decision
4. Define the study boundaries
5. Develop a decision rule
6. Specify limits on decision errors
7. Optimize the design for obtaining data

(From EPA QA/G-4HW: EPA Hazardous Waste Office)

What are the Problems with IRIS?

(NRC Review of IRIS: Summary)

- Rigorous editing needed to reduce redundancies, inconsistencies and text volume
- Assessment methods should be described more fully
- QC processes should be enhanced
- Review and evaluation processes should be standardized
- Appropriate expertise on evaluation teams should be assured

What are the Problems with IRIS?

(NRC Review of IRIS: Chapter 8)

- Assessment methods need to be updated in a continuing strategic fashion
- Inefficiencies in the IRIS program need to be systematically identified and addressed
- Evolving competencies that reflect new scientific directions are needed

What are the Problems with IRIS?

(NRC Review of IRIS: Repetitive throughout document)

The IRIS process takes too long!!!

Missing from the problem statement:

A proposal to change risk assessment methodology should be accompanied by some analysis of what adverse environmental or human health impact risk managers could have avoided if only the risk assessment had been more accurate or appropriate.

(Goldstein, BD. Risk assessment of environmental chemicals: If it ain't broke... Risk Analysis 31:1356-62, 2011)

Problem Formulation

- The problem formulation step requires stakeholder involvement, including elicitation and careful attention to their perception of a problem and their needs for a solution.
- For a decision tool, stakeholders include both those affected by the decision tool and those who use the tool in their decision process.

The NAS/NRC contribution to the problem

- We fail to fully recognize that EPA and state/local agencies need to be responsive in a timely fashion to decisions that are best made sooner rather than later
- We fail to fully recognize that EPA and state/local agencies have now and for the foreseeable future limitations in resources that force them to focus on highest risk issues
- We seem to believe that because something is possible to accomplish scientifically, it is appropriate to add unneeded decimal places to risk estimates.

The NRC Formaldehyde Committee did not make Recommendations about the IRIS Process

- Preface: “The committee closes with recommendations for improving the IRIS assessment of formaldehyde and provides some general comments on the IRIS development process”
- Chapter 7. “The committee offers some suggestions for improvement in the IRIS development process that might help the ... EPA if it decides to modify the process”

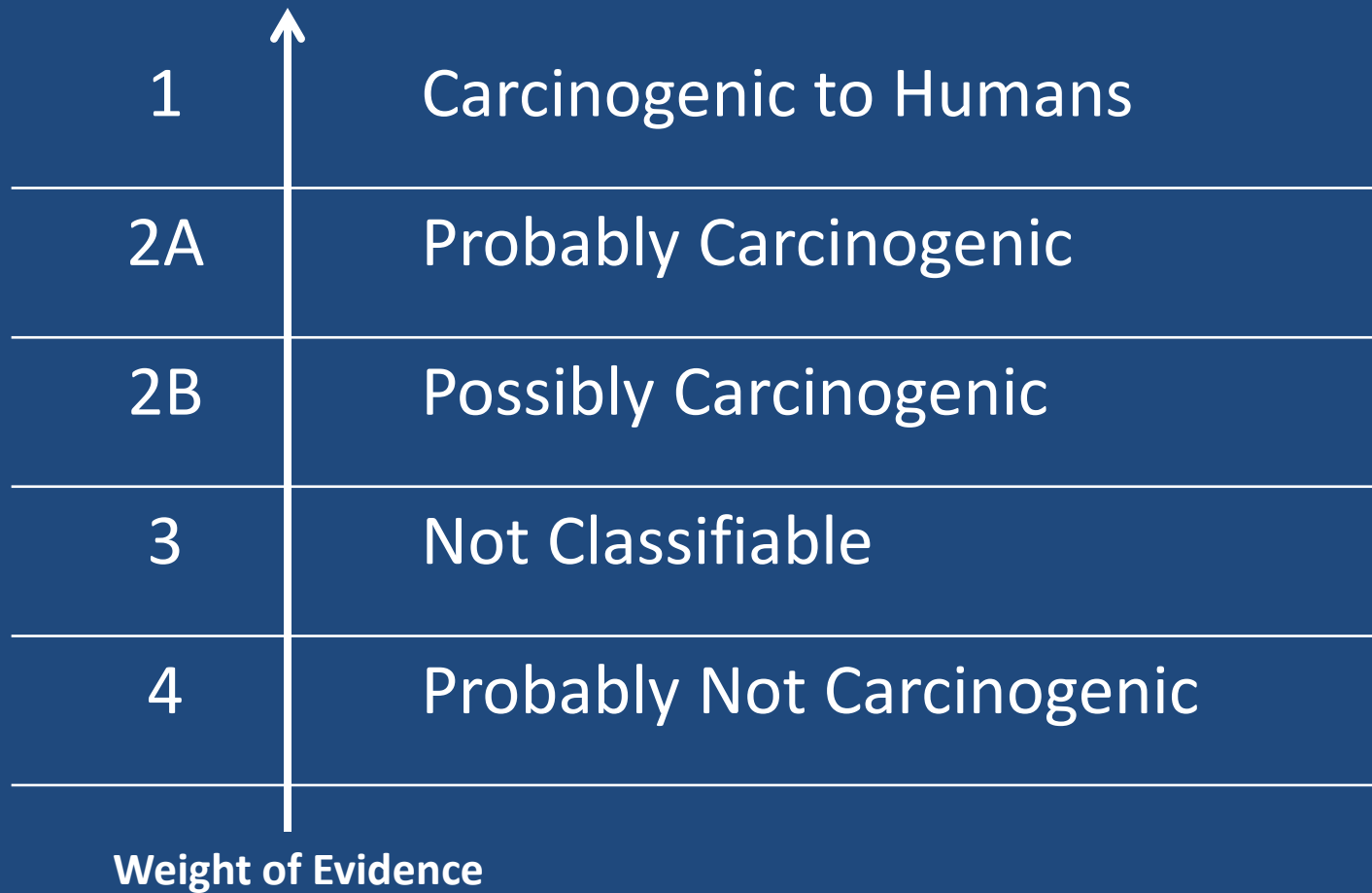
Review of the Environmental protection Agency's Draft IRIS Assessment of Formaldehyde Committee

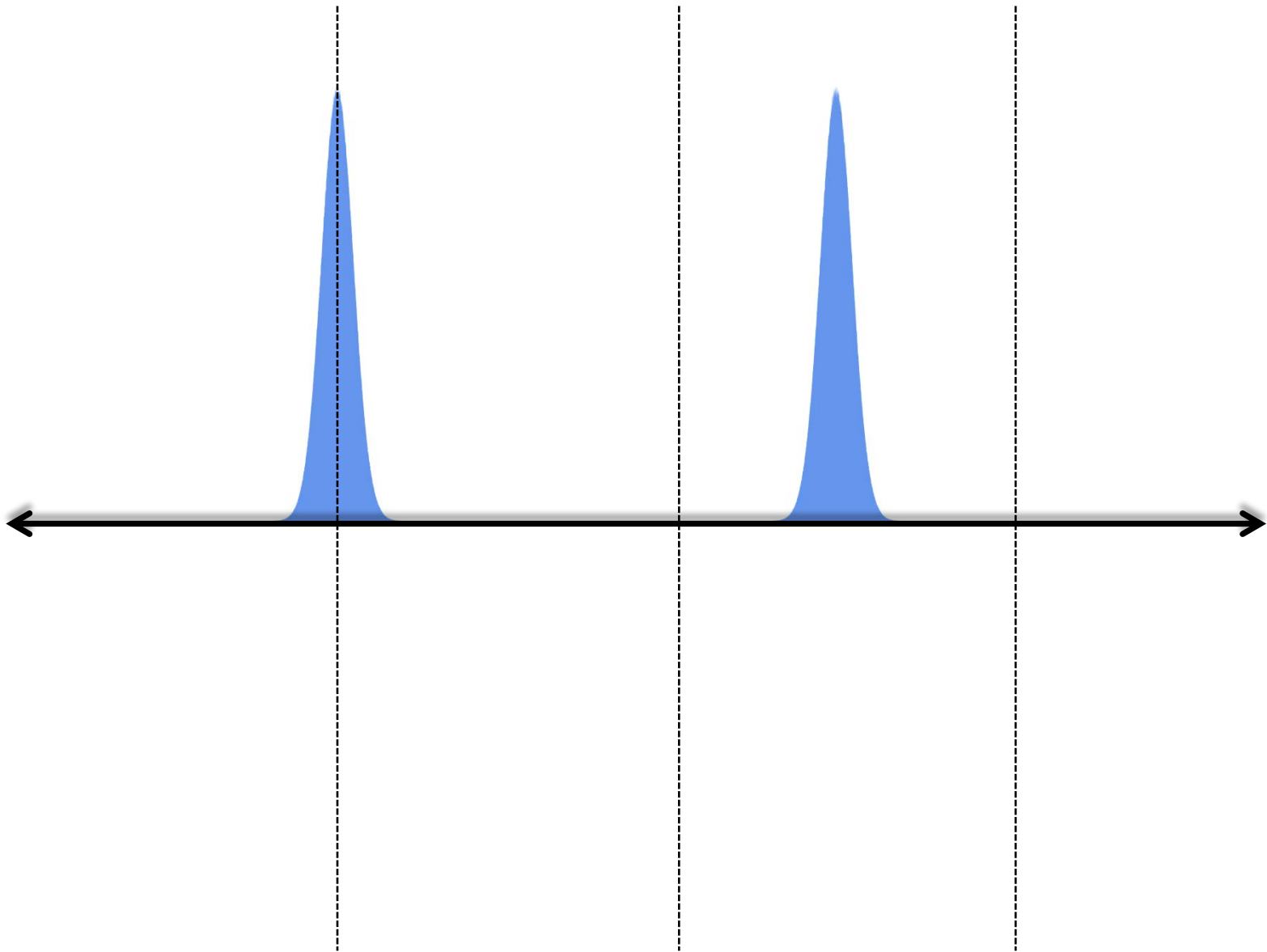
1. Chair, University of Southern California, Los Angeles
2. Vice-Chair, University of North Carolina at Chapel Hill
3. Miami University, Oxford, OH
4. Massachusetts Department of Environmental Protection, Boston
5. University of Washington School of Public Health and Community Medicine, Seattle
6. Pacific Northwest National Laboratory, Richland, WA
7. North Carolina State University, Raleigh
8. Lovelace Respiratory Research Institute, Albuquerque, NM
9. University of Wisconsin, Milwaukee
10. University of North Carolina at Chapel Hill
11. University of Georgia, Athens
12. University of Illinois, Chicago
13. National Opinion Research Center, University of Chicago, IL
14. University of South Florida, Tampa
15. The University of Texas M. D. Anderson Cancer Center, Houston

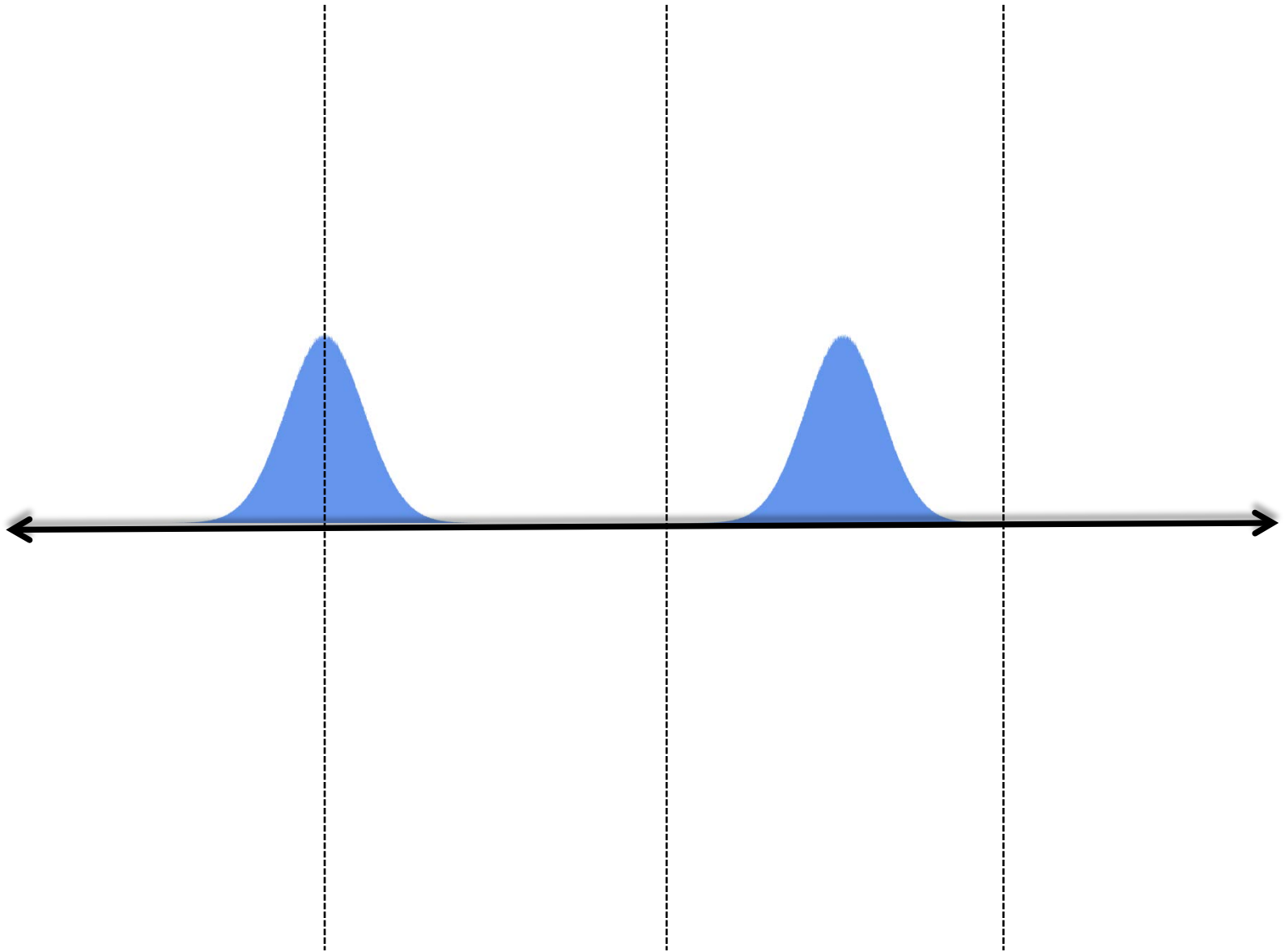
Review of EPA's Integrated Risk Information System (IRIS) Process Committee

1. Chair, University of Southern California
2. University of California, Irvine
3. University of California San Francisco
4. University of Washington
5. Johns Hopkins School of Public Health, MD
6. North Carolina State University
7. University of Washington
8. University of Arizona
9. Harvard School of Public Health, MA
10. University of Michigan
11. Argonne National Laboratory, IL
12. Carnegie Mellon University, PA
13. Center for Public Environmental Oversight, CA
14. University of Iowa College of Public Health
15. University of South Florida

IARC Overall Evaluation of Carcinogenicity to Humans







What else should be done?

- What percentage of chemicals are “on the line”, or how broad is the expert opinion on most agents; i.e., are there many problem cases indicating that every chemical should be extensively reviewed, or are there so few that they could be singled out for more extensive review? (Bad cases make bad process)
- What can be learned from review of those agents for which “weight of evidence” classification by IRIS, EPA, NTP, FDA, IARC, OSHA etc has been upgraded or downgraded
- What can be learned from estimating the risk averted if decisions had been made earlier?

Examples of Lack of Specificity. Are these an opportunity for EPA?

- Risk-of-bias assessments on all studies used by EPA as primary data sources: “Whatever approach is adopted”
- Quantitative approaches to evidence integration include meta-analysis; probabilistic bias analysis and Bayesian analysis: “The committee is not recommending a particular approach”
- Uncertainty analysis: multiple options throughout

“If it ain’t broke don’t fix it”

- Bert Lance

“If it ain't broke, don't fix it' is the slogan of the complacent, the arrogant or the scared. It's an excuse for inaction, a call to non-arms.”

-Colin Powell

"If it ain't broke... the government will fix it until it is."

-Dell Hunt, 2001