

TOWARD HARMONIZATION OF A SUITE OF TOOLS FOR OCCUPATIONAL HEALTH RISK ASSESSMENTS

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Learning Objectives



- Highlight occupational risk assessment resources as a Continuum of tools for the IH
- Describe key risk assessment trends that are improving access to resources
 - ▣ Problem Formulation and Tiered Risk Assessment
 - ▣ Harmonization in Risk Assessment Methods
 - ▣ Emphasis on Collaborative Resources

“We Can Do More”

□ Science Drivers

- ▣ Improved understanding of basic sciences
- ▣ Improved Information Technology
 - Incorporation of biomathematics
 - Information sharing capacity increased



Toxicity Testing in the 21st Century: A Vision and a Strategy

Committee on Toxicity Testing and Assessment of Environmental Agents, National Research Council

ISBN: 0-309-10993-0, 216 pages, 6 x 9, (2007)

This PDF is available from the National Academies Press at:
<http://www.nap.edu/catalog/11970.html>

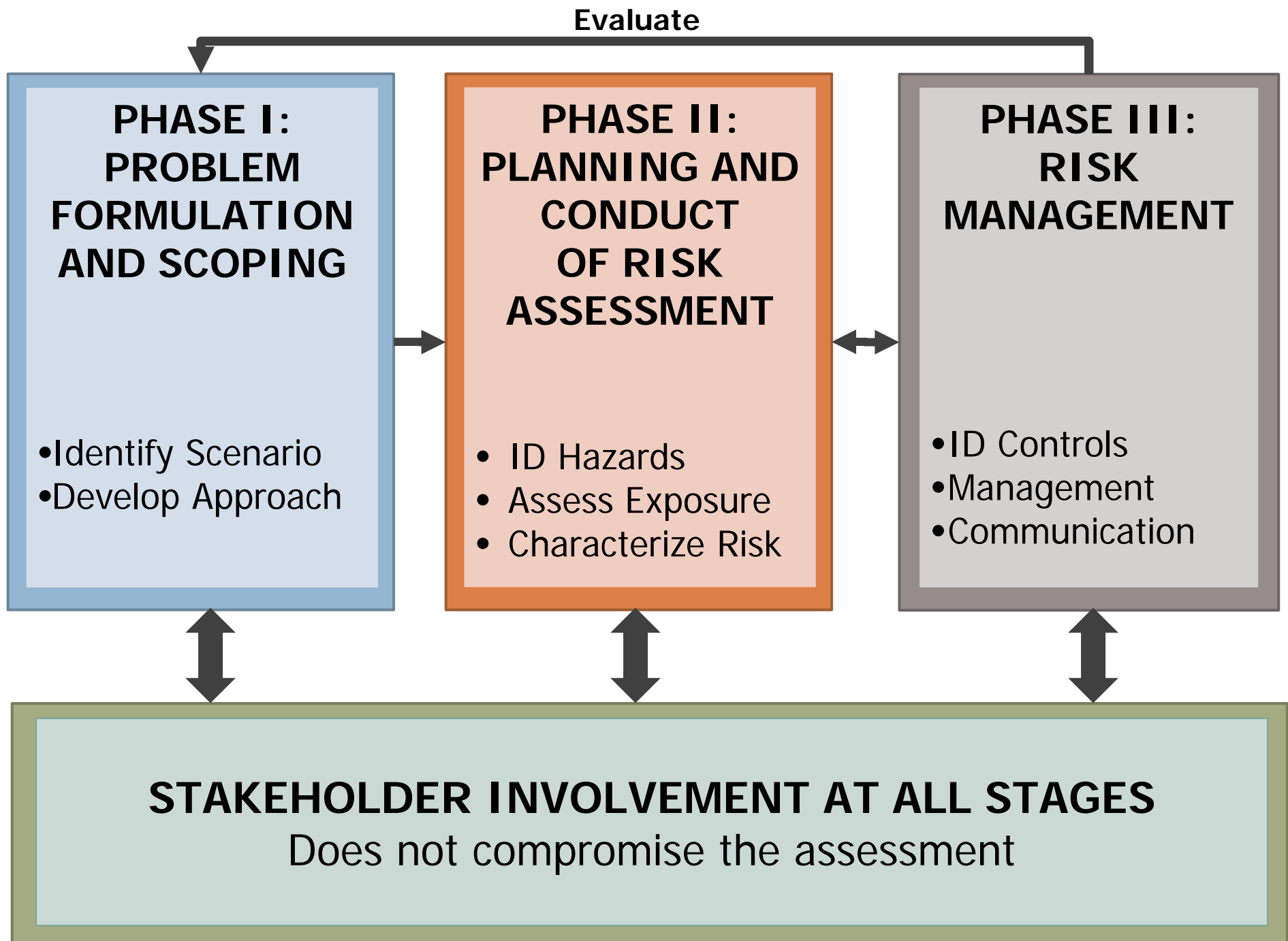
“We Are Expected to Do More”

- Regulatory and Social Drivers
 - ▣ Recognition that output needs to increase
 - Collaboration and Harmonization
 - ▣ Global Data Fusion
 - Focus on MOA and Decision Frameworks
 - Animal Welfare and Systems biology



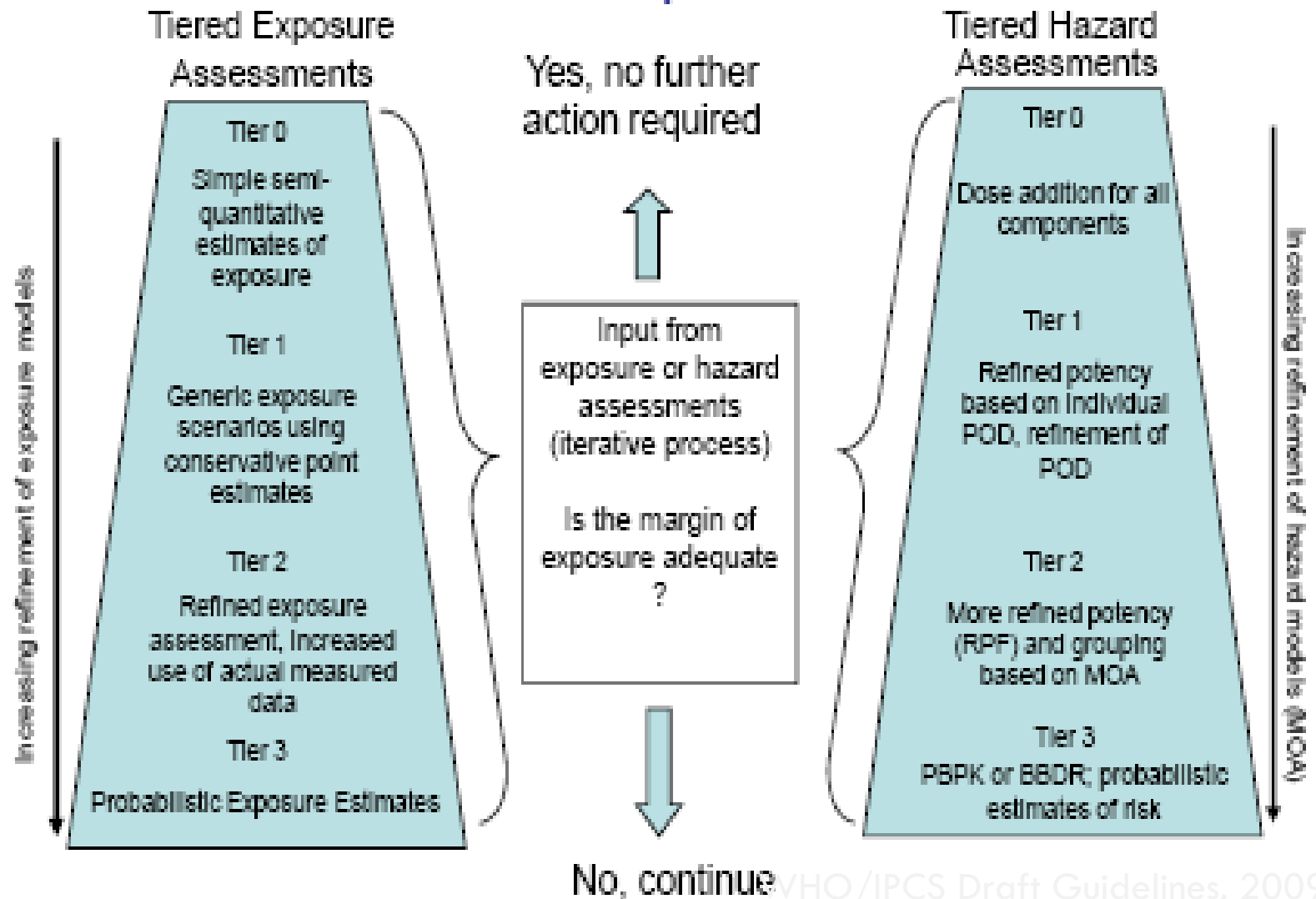


Problem Formulation and Tiered Risk Assessments



Sample Tiered Exposure and Hazard Considerations

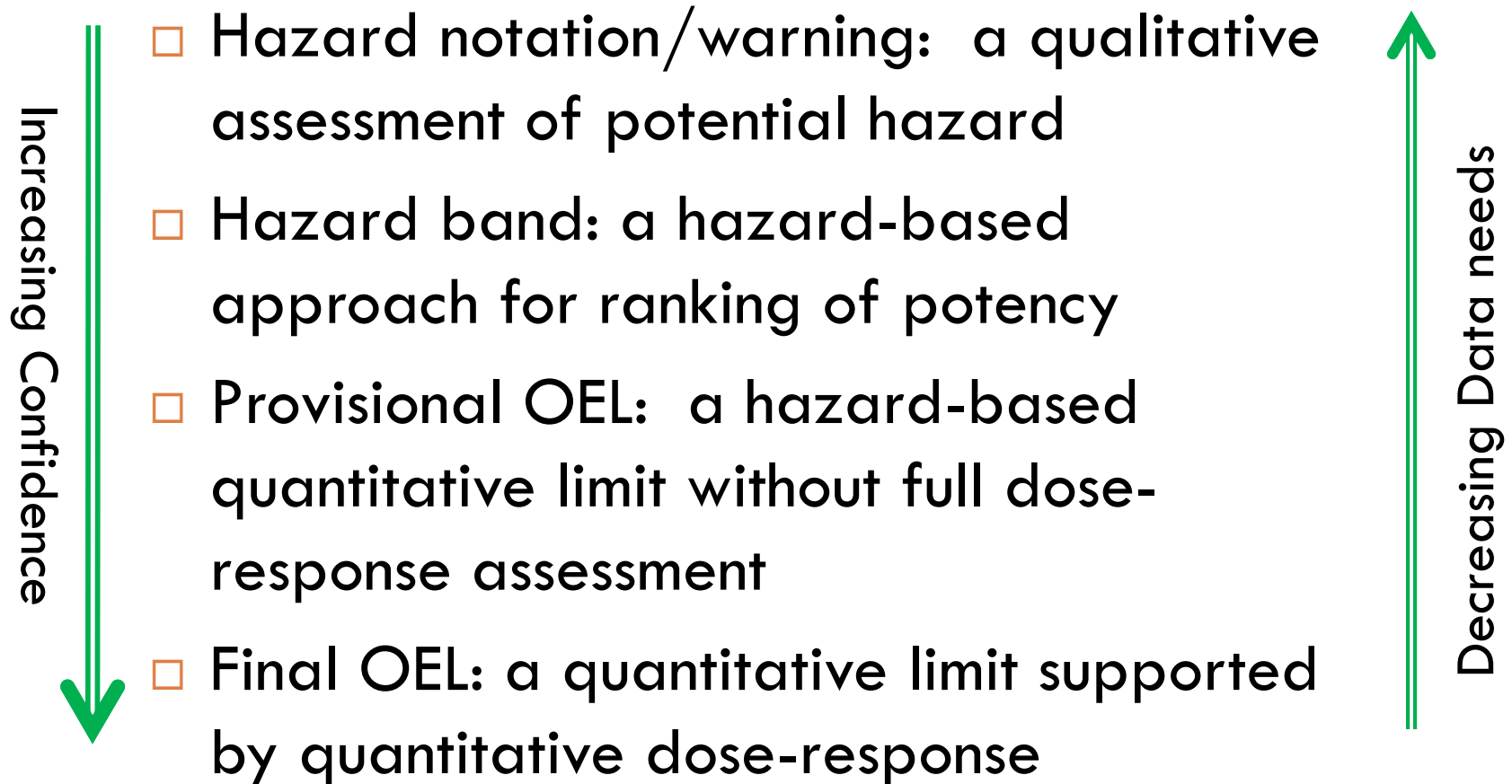
Mixture or Component Based



WHO/IPCS Draft Guidelines, 2009

From WHO 2009

Progression in Risk Metrics



For High Priority Assessments



- Progression from qualitative hazard-based approaches to quantitative risk-based assessments
- Hazard approach
 - ▣ Advantage: rapid assessment allows for initial action to be taken quickly to address most likely health concerns
 - ▣ Disadvantage: absence of an objective measure of likelihood for health concern can lead to: 1) inadequate protection, 2) less confidence in the assessment, 3) difficulty in communicating risks.
- Periodic evaluations needed to determine if data are adequate to move to a quantitative approach

Hopper Process

Potential Agents for Inclusion in Hopping Process



Meet Filter Criteria

Bin 1

Agents of Interest



Meet Additional Filter Criteria

Bin 2

Agents Under Investigation



Adequate Data

Bin 3



Pending
ERPG Author
Assignment



Pending
BEEL Author
Assignment



Pending
WEEL Author
Assignment

What is the Bottom Line?



- Our risk assessment tools provide a suite of resources
 - ▣ Exposure estimation - modeling - sampling
 - ▣ Hazard banding - occupational exposure limits
- We pick the **right** tool for the job based on systematic and documented applications of:
 - ▣ Problem Formulation
 - ▣ Tiered Risk Assessment Methods



Harmonization of Occupational Exposure Guidelines and Methods

Exposure Guideline Disharmony?

n-Hexane Exposure Guidelines

Type of Limit	Value (ppm)
DNEL – Derived No Effect Level	4.7
IOELV - Indicative Occupational Exposure Limit Values	20
TLV [®] – Threshold Limit Value	50
AEGL2 – Acute Exposure Guideline Level (2)	3300 (30-min to 8-hr)
IDLH – Immediately Dangerous to Life and Health	1100
RFC – Inhalation Reference Concentration	0.2

Types of Exposure Guidance

- There are many sources and types of exposure limit information that can be applied to different scenarios:
 - ▣ Purpose of assessment
 - Priority setting, Registration, Worker exposure assessment
 - ▣ Exposure duration
 - Acute versus chronic
 - ▣ Exposure population
 - Responders, workers, general population
 - ▣ Exposure frequency
 - Routine or infrequent
- How do you find these and select one for your scenario?

Why OELs Differ



- Difference in the underlying data set
 - ▣ New data has become available
 - Most groups update their OELs over a cycle of years
 - ▣ Policies regarding use of different sources
 - Some groups use unpublished if vetted, others do not
 - ▣ Literature search methods vary and key results may not have been identified
 - There is no uniform list of all relevant resource databases

Why OELs May Differ



□ Risk Policy Choices

- Assumptions about low-dose behavior
- Tolerance for residual risk (protect all versus nearly all workers)

□ Risk Method Preferences

- POD selection and Dosimetry
- Uncertainty Factors

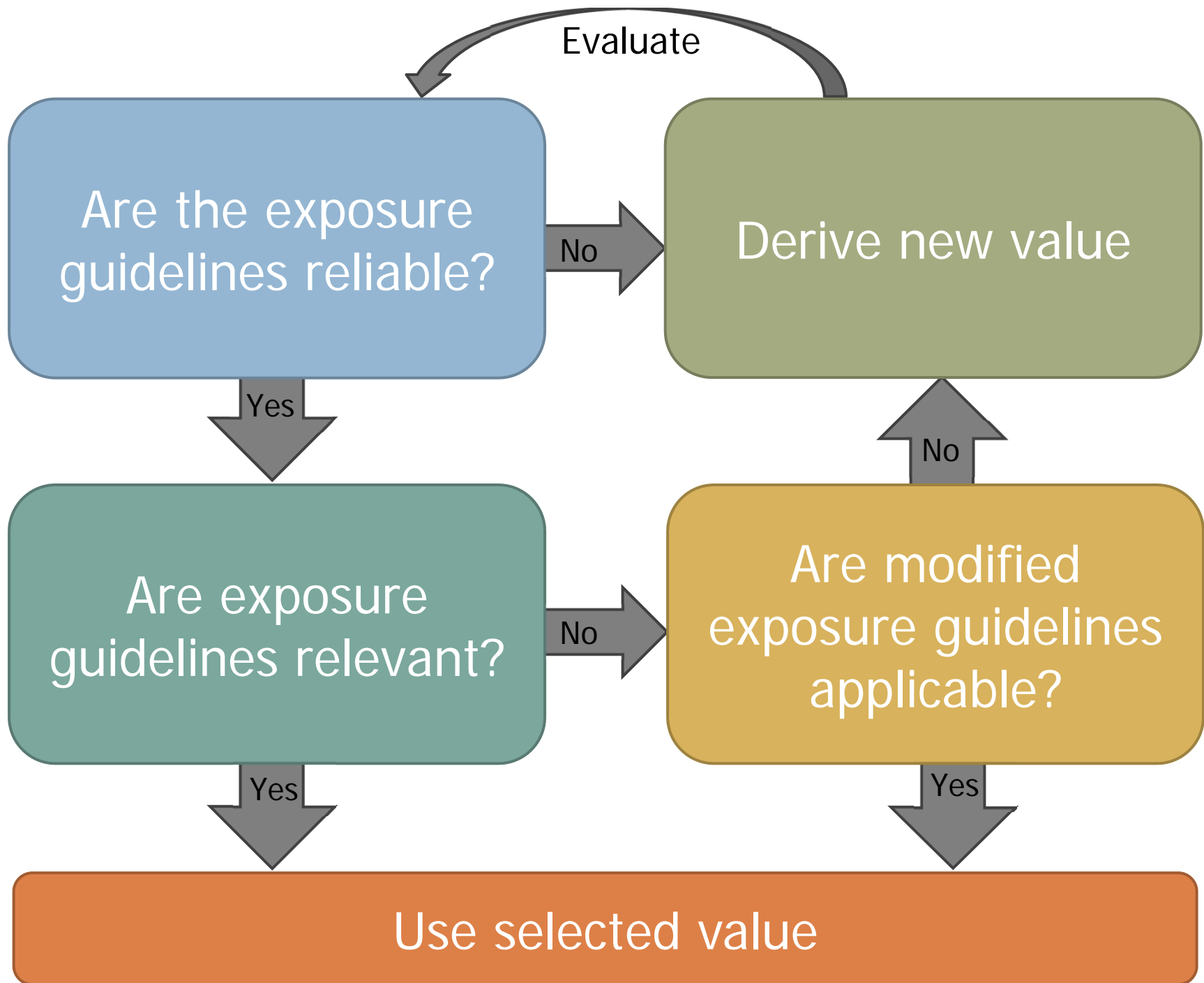
□ Science Judgments

- Weight of Evidence and Value of Information

Selecting Among Resources



- How to decide which value among many?
- Mandated regulatory hierarchy in-place?
- Other considerations to weigh in decision:
 - ▣ Relevance of the guide value to the scenario or use of interest
 - ▣ The degree to which the exposure guidance includes current literature and methods
 - ▣ Confidence in the value



The International Programme on Chemical Safety (IPCS)


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IPCS Harmonization Project

Harmonization of approaches to the assessment of risk from exposure to chemicals

The International Programme on Chemical Safety (IPCS) (WHO/ILO/UNEP) is leading a project to harmonize approaches to the assessment of risk from exposure to chemicals. The goal of this project is to globally harmonize approaches to risk assessment by increasing understanding and developing basic principles and guidance on specific chemical risk assessment issues. Harmonization enables efficient use of resources and consistency among assessments.

About the Project

- [Harmonization Project information brochure: A4 format \[pdf 104kb\]](#)
- [Harmonization Project information brochure: Trifold format \[pdf 115kb\]](#)
- [Strategic Plan](#)
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Project focus areas

- [Aggregate/cumulative risk assessment](#)
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- [Mutagenicity](#)
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RELATED PUBLICATIONS

Harmonization Project publications
[Full text](#)

Descriptions of key generic terms
[Full text](#)

Risk assessment model for insecticide treatment and subsequent use of mosquito nets
[Full text](#)

Contact us

Click [here](#) to sign up for updates to the site about selected topics of interest.

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 Organization (WHO)
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 1211 Geneva 27
 Switzerland

<http://www.who.int/ipcs/methods/harmonization/en/>

NIOSH OEL Methods Series



- Effort to provide documentation on science issues in OEL setting
- 10 topical manuscripts to be published in 2012
 - ▣ OEL Derivation methods
 - Dosimetry; biomarkers, dose-response modeling, UFs
 - ▣ OELs for challenging endpoints
 - Setting OELs for irritants; sensitizers
 - ▣ Occupational Risk
 - OEL risk probability; cumulative risk; task-based assessments
 - ▣ OEL harmonization
 - Global OEL perspectives

Key Points on Harmonization



- OELs play a critical role in occupational health
- Methods and resulting OELs differ among agencies
- There is growing emphasis on harmonization of methods
- Shared information facilitates harmonization
- Numerous sources of information are available, but no unified source has been compiled
- Decision guides assist to sort through the confusing landscape of guidance

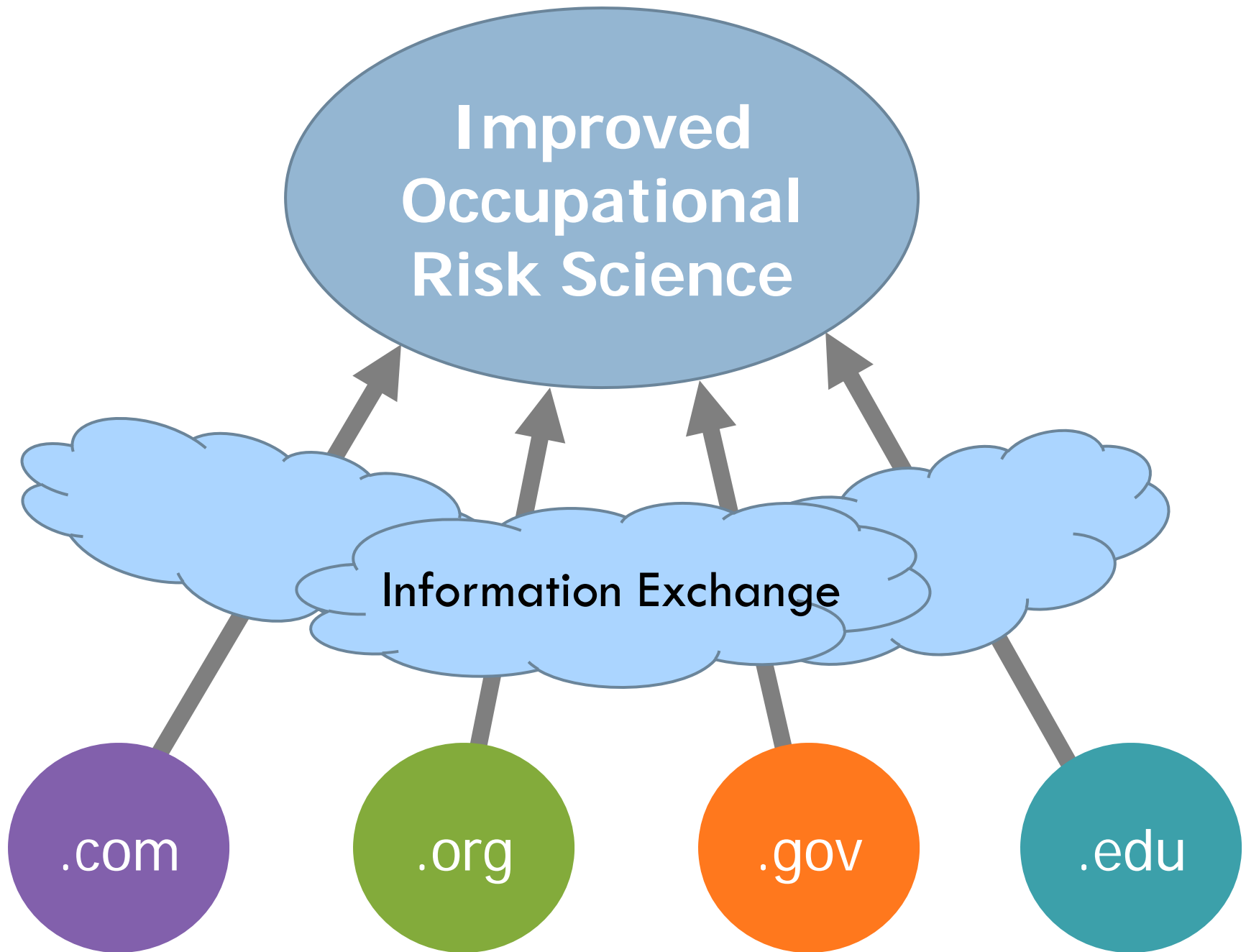
What is the Bottom Line?



- Understand the basis for apparent differences and how to evaluate them
- Understand that an OEL value is not arbitrary, but it is imprecise
- Develop a systematic approach for OEL use and selection as part of your occupational risk management policy



Collaborative Resources for Occupational Risk Assessment



Key Benefits of Collaboration




- Promotes science-based decision making to protect human health by ensuring all key data and ideas are fully considered
- Enhances harmonization and consistency in risk assessments thru an open, transparent, multi-stakeholder approach that ultimately foster harmonization and information sharing
- Makes use of groups of experts that are normally not available within a single organization
- Shares costs and human resources among multiple stakeholders to increase output for the broader risk community
- This can all be achieved while allowing groups to control their own process and can receive broad acceptance with thoughtful management of biases

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TOXNET - Databases on toxicology, hazardous chemicals, environmental health, and toxic releases.

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Env. Health & Toxicology



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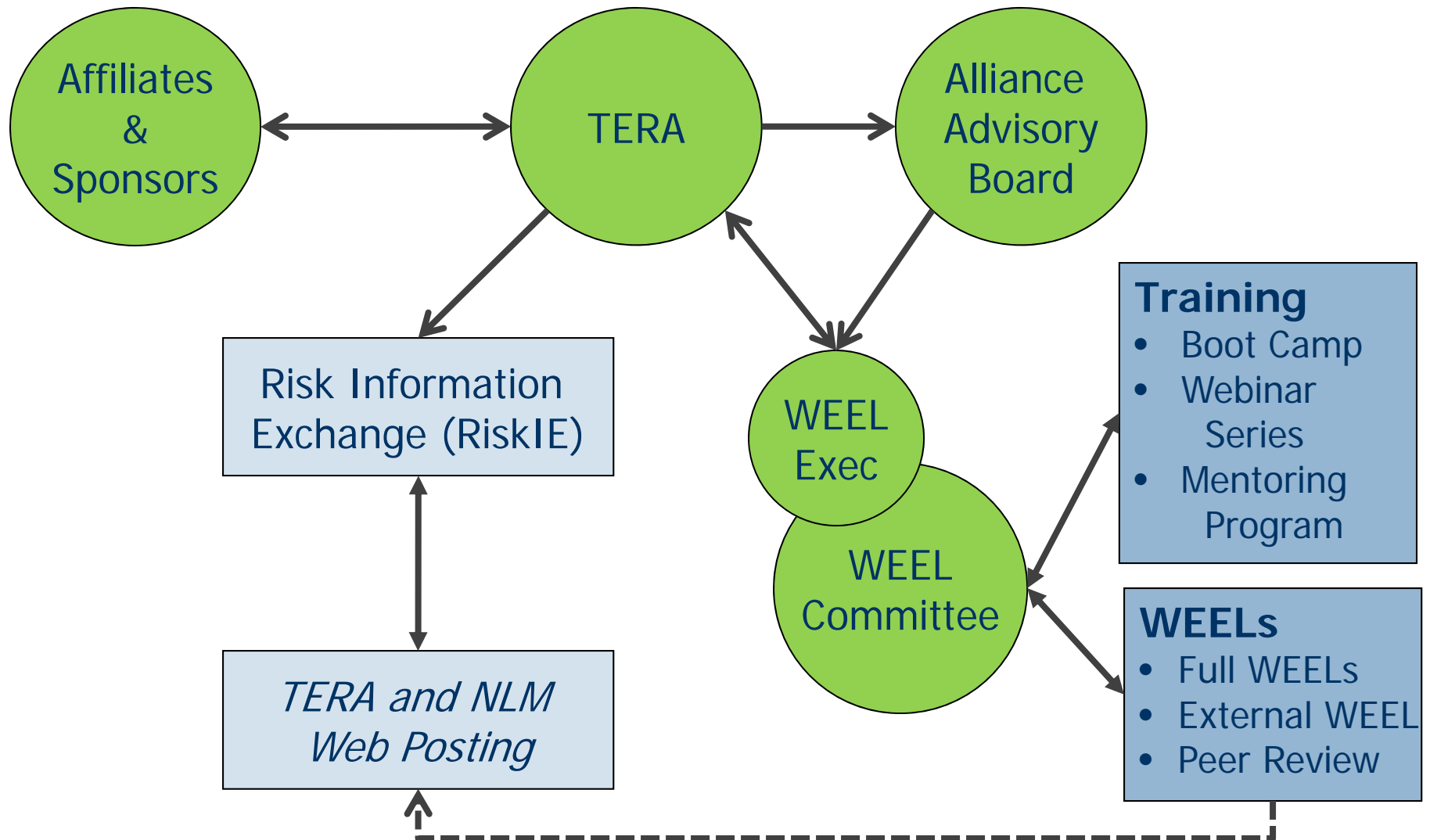
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Occupational Alliance for Risk Science



Occ RiskIE

Occupational Risk Information Exchange

www.allianceforrisk.org/RiskIE.htm



- An interactive Database to Communicate In-Progress Risk & Toxicity Assessments
- Includes over 7000 projects being conducted by more than 27 organizations representing 13 countries
- Available free at the Alliance for Risk Assessment (ARA) website

Some Key Risk Methods Resources



□ Tool Kits

- ▣ OECD: Environmental Risk Assessment Toolkit
- ▣ WHO: Human Health Risk Assessment Toolkit
- ▣ U.S. EPA: Risk Assessment Portal


□ Databases

- ▣ ILO: Safety and Health at Work databases
- ▣ E.U. OSHA: Risk Assessment Tools Database

□ Publications and Links

- ▣ Federal Agencies: U.S. NIOSH, U.S. OSHA, CCOHS
- ▣ Science Non-Profits: AIHA, ACGIH, TERA and more for publications

Evolving Data Needs

- 
- Individual study data
 - ▣ E.g. PubMed/Toxline
 - Compilations for a single substance – multiple studies
 - ▣ E.g. IRIS
 - Comparisons of content among integrated compilations
 - ▣ E.g. ITER
 - Application resources
 - ▣ E.g. CHEMM

Goals for ORA Information Resources



- One-stop shopping
 - ▣ Rich source of toxicology data, *and*
 - ▣ Rich source of methodology information, *and*
 - ▣ User algorithms (or at least exports to user tools)
- Tools to identify the most relevant content
 - Need access to everything, but want most relevant first: relevance sorting, quality filters, value of information tools, decision logics and smart assists
- Compatibility with mobile technology
 - Do we have an App for that?

What is the Bottom Line?



- The array of resources available is vast ...and growing!
- With more data comes the challenge of variable interpretation
- There are increasing opportunities to coordinate content
- The next wave of resources will support data integration - more than data access