Chemical Risk Assessment
تقييم المخاطر الكمياوية

عبدالرزاق قدري

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U.S. Environmental Protection Agency

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UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

المراكز المختلفة لمكتب البحوث والتنمية

EPA United States Environmental Protection Agency

National Health and Environmental Effects Research Laboratory

Research on mechanisms and susceptibility to identify hazards and dose-response

National Exposure Research Laboratory

Research to measure, characterize and assess exposures and to support compliance with environmental regulations and policies

National Risk Management Research Laboratory

Research and technology transfer to prevent, mitigate and control pollution

National Center for Computational Toxicology

Application of computational tools and models to improve understanding of toxicity and risks posed by environmental agents.

National Center for Environmental Assessment

Development of human health assessments, research on risk assessment methods, and guidance development

National Homeland Security Research Center

Research to help decision-makers prepare and respond to chemical and biological attacks

National Center for Environmental Research

Extramural program - grants, fellowships, and national centers of excellence - to complement ORD's in-house research program

National Center for Environmental Assessment (NCEA)

المركز القومي لتقيم المخاطر

مهمة المركز هو توفير التوجيه (التقييم والمبادئ التوجيهية) حول كيفية ملوثات قد تؤثر على صحة الإنسان والبيئة.

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- The mission of NCEA is to provide guidance (assessments and guidelines) about how pollutants may impact human health and the environment.
- NCEA occupies a critical position between scientists in ORD and management in EPA's program and regional offices supporting regulatory, enforcement, and remedial-action decisions.
- NCEA administers three high-profile programs: the Global Change Research Program, the Report on the Environment (ROE Database), Integrated Science Assessment (ISA) and the Integrated Risk Information System (IRIS) Program & Database.
- NCEA's diverse staff includes biologists, chemists, ecologists, engineers, epidemiologists, geneticists, statisticians, and toxicologists.

يحتل المركز موقعا حيويا بين الباحثون والادرات التي تشرع القوانين

occupies a critical position in EPA's Office of Research and Development between:

- the researchers in other ORD components who are generating new findings and data

AND

- the regulators in the EPA program offices and regions who must make regulatory, enforcement, and remedial action decisions

تقييم المخاطر في وكالة حماية البيئة الامريكية

EPA United States Environmental Protection

1970s

- Beginnings of the field of risk assessment
- Emphasis on oral route per U.S. Food and Drug Administration (FDA) precedent
- General acceptance of Safety Factors (10x10)
- Beginnings of cancer guidelines

1980s

- Adopt NAS Risk Assessment/Risk Management paradigm (1983)
- EPA publishes five risk assessment guidelines
- First paper on Reference Dose
- Integrated Risk Information System (IRIS)

1990s

- Inhalation RfC methodology
- Oral RfD methodology
- Applications of PBPK models
- BBDR models developed
- BMD models developed and applied

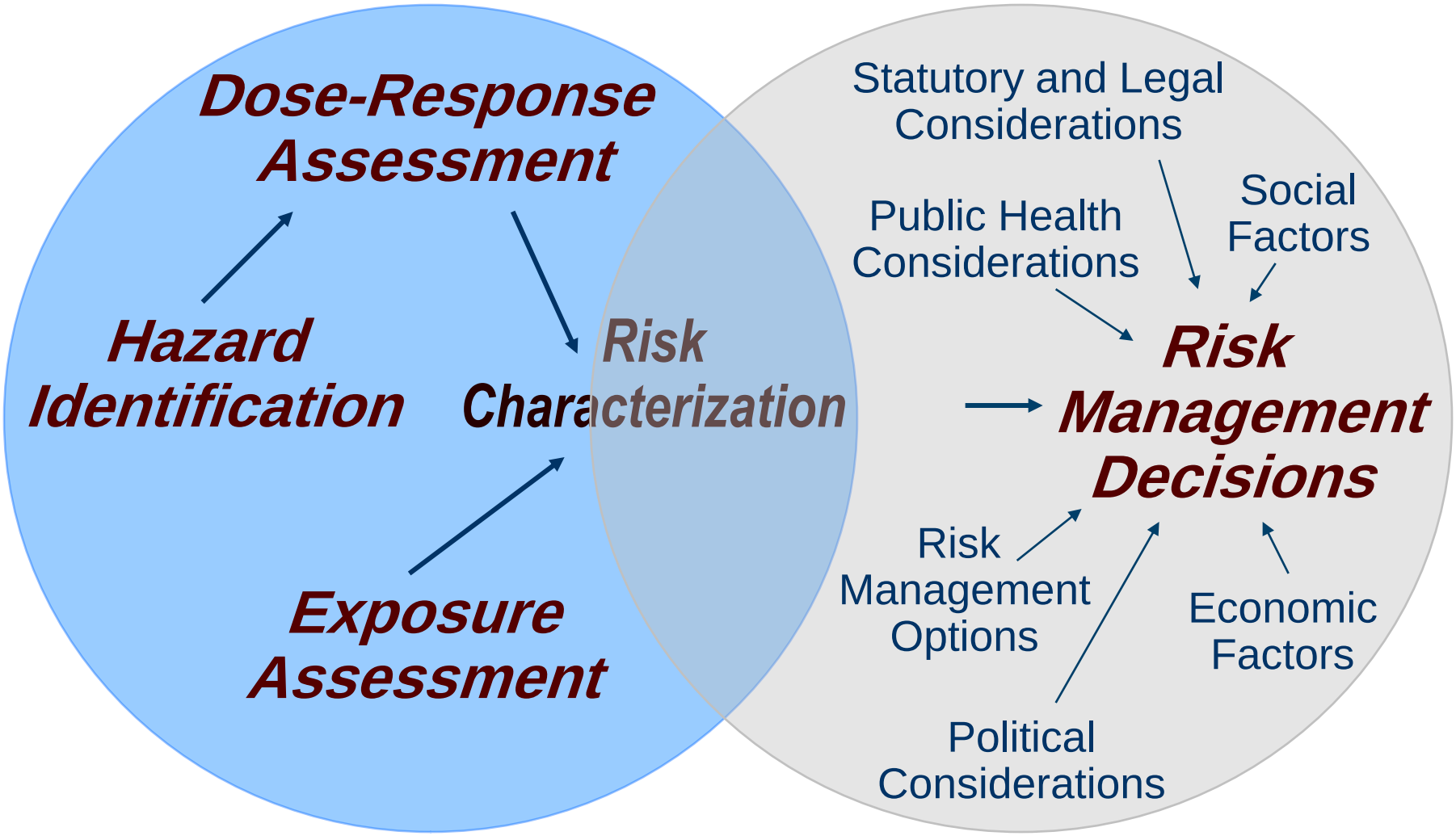
2000s

- Re-examination of non-cancer methods
- Susceptible populations
- Cumulative assessment approaches
- Probabilistic approaches
- Uncertainty analysis

Risk Analysis تحليل المخاطر

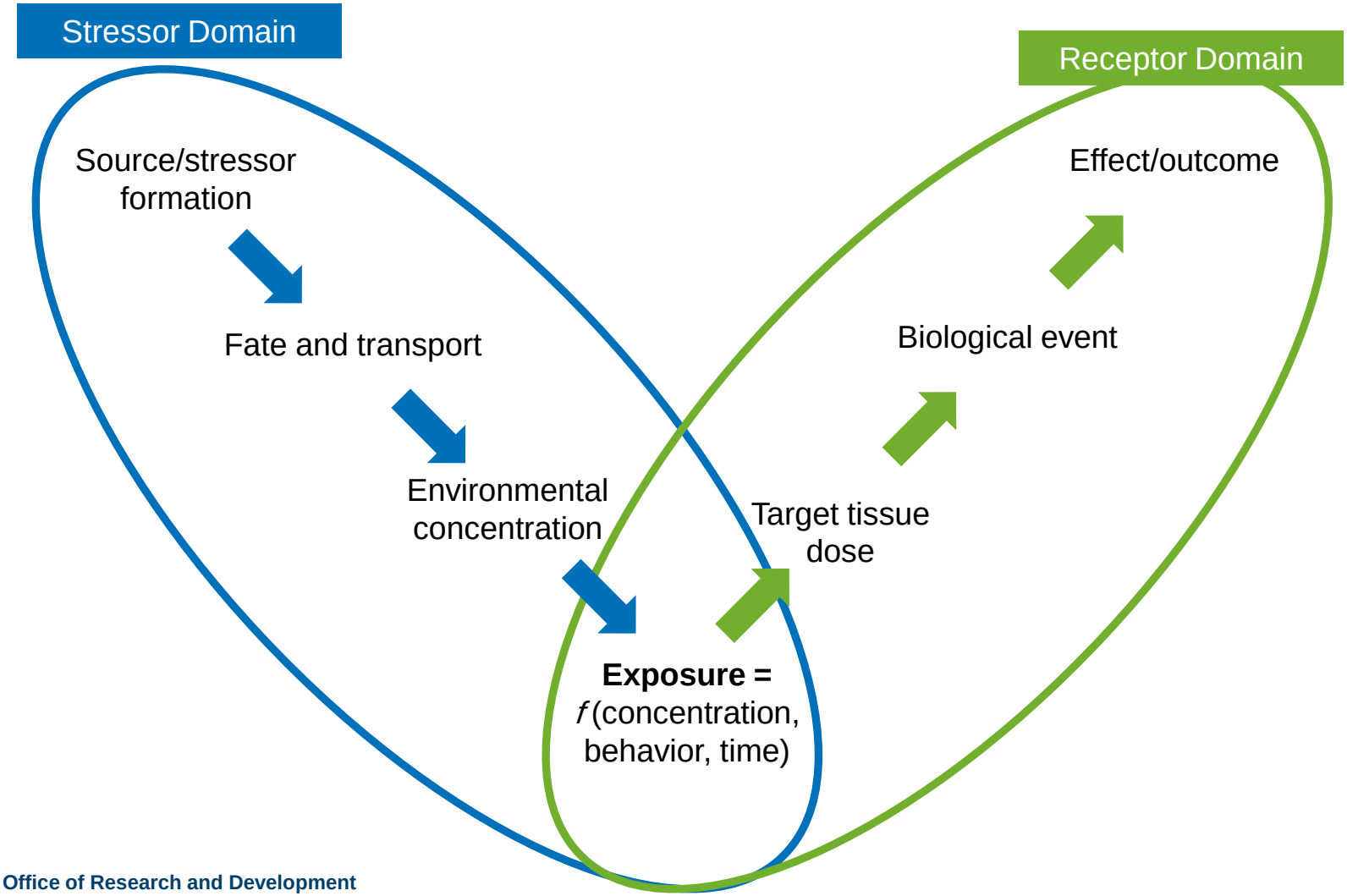
العلاقة بين تقييم وادارة المخاطر

Environmental Protection Agency



Risk Assessment in the Federal Government: Managing the Process
U.S. National Academy of Sciences (1983)

Source-to-Effect Continuum -التواصل من المصدر الي الاثر

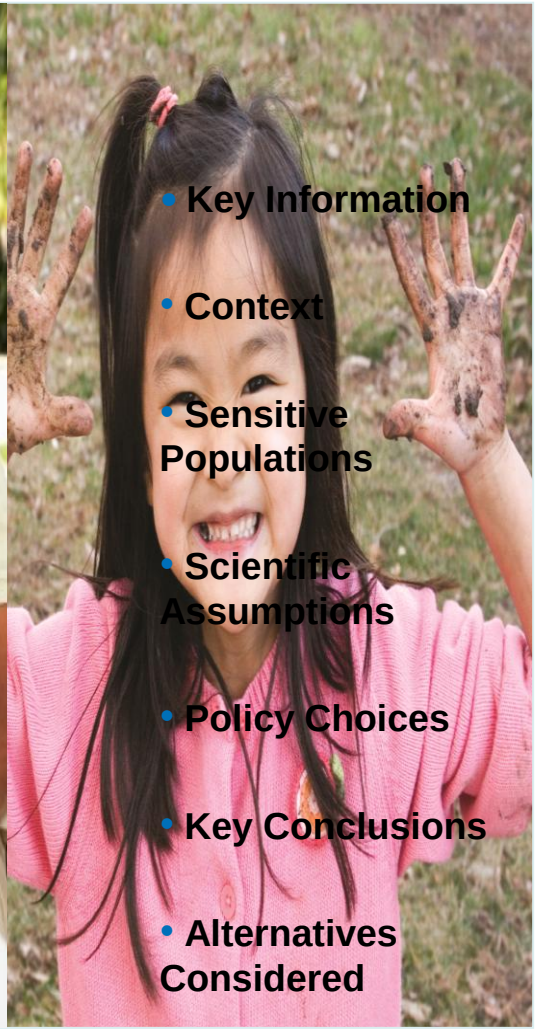


تقييم المخاطر ليست مجرد تقييم الاستجابة للجرعة وحده

تقييم المخاطر هو دمج المعلومات النوعية والكمية على:

- toxicity
- severity of effects
- geographic extent
- exposure
- magnitude of response
- and many other factors

- Variability
- Uncertainty
- Bias and Perspective
- Strengths and Weaknesses
- Confidence Statements
- Research Needs

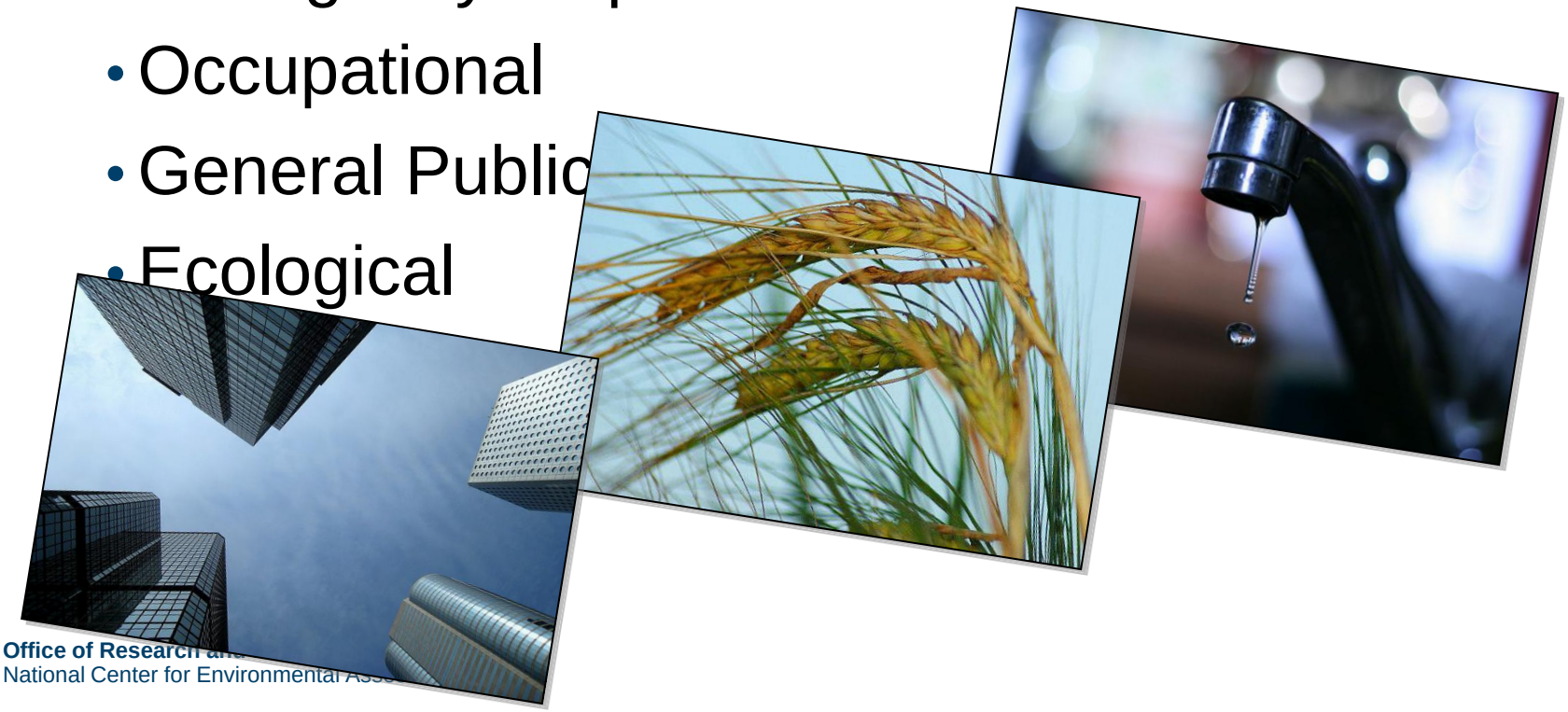


- Key Information
- Context
- Sensitive Populations
- Scientific Assumptions
- Policy Choices
- Key Conclusions
- Alternatives Considered

References Values: Standards and Guidelines

ا لقيم المرجعية: المعايير والمبادئ التوجيهية الاستجابة للطوارئ- مهني –العمومية- بيئي

- Emergency response
- Occupational
- General Public
- Ecological



Reference Values: Levels of Enforceability القيم المرجعية: مستويات وجوب النفاذ

Exposure Standards معايير التعرض	Exposure Guideline المبادئ التوجيهية
Relatively few	Numerous
Mandated by statute and legally enforceable	Not legally enforceable
Rigid development process	Flexible development process
Developed by government agencies specified in statutes	Developed by many types of entity
Intended to protect health and the environment, but balances other considerations	Intended to protect human health and the environment

معايير التعرض

Medium	Standard	Regulated Contaminants	Regulatory Authority
Air	National Ambient Air Quality Standards (**NAAQS**)	6 Criteria Pollutants in ambient air	EPA, as mandated by the Clean Air Act
	Permissible Exposure Limits (**PELs**)	~500 contaminants in workplace air	OSHA, as mandated by the Occupational Safety and Health Act
Water	Maximum Contaminant Levels (**MCLs**)	90 chemical, microbiological, radiological, and physical contaminants in drinking water	EPA, as mandated by the Safe Drinking Water Act
Food	Maximum Residue Limits (**MRLs**)	Hundreds of pesticide chemicals in food and feed commodities	EPA, as mandated by the Federal Food, Drug, and Cosmetics Act, as amended by the Food Quality Protection Act

Entities that Develop Reference Values

القيم المرجعية

Federal Agencies

ATSDR

OSHA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FDA

National Institute for Occupational Safety and Health NIOSH

State Agencies

Office of Environmental Health Hazard Assessment OEHHA State of California

TCEQ

Other Entities

ACGIH®

AIHA Protecting Worker Health

مواصفات التعرض

Exposure Medium and Route

- Inhalation – air
- Oral – water, soil, food
- Dermal – soil, water, food, air

Exposure Duration

- Acute
- Short-term
- Longer-term
- Chronic (continuous)

Potentially Exposed Population

- Workers
- Emergency responders or victims
- Pregnant women
- Children or the elderly

Exposure Contexts-سياقات التعرض

- الاستجابة للطوارئ
- مهني
- المحيط أو العمومية
- Emergency Response
- Occupational
- Ambient or General Public

Emergency Response Values: Applicability

تطبيق قيم الاستجابة للطوارئ

(A) To communicate to the general public when chemical concentrations following a disaster might be harmful to human health

(B) To inform workers on a routine basis if chemical concentrations in the workplace are of concern to health

(C) To allow emergency planners to develop systems and policies to prevent and prepare for catastrophic chemical releases

(D) To support laws and regulations mandating chemical concentration levels that result in “acceptable” risk

للتواصل مع الجمهور عند تركيزات الكيميائية التالية كارثة قد تكون ضارة على صحة الإنسان

(ب) إعلام العمال على أساس روتيني إذا التركيزات الكيميائية في مكان العمل هي التي تهم الصحة

)C(للسماح مخططي الطوارئ لتطوير أنظمة وسياسات لمنع والاستعداد لإطلاق الكيميائية الكارثية

(د) دعم القوانين واللوائح تجيز مستويات تركيز المواد الكيميائية التي تؤدي إلى خطر "مقبول"

Emergency Response Values: Characteristics خصائص قيم الاستجابة - للطوارئ

- **Exposure Type:** Workplace or general public
- **Duration:** Generally acute
- **Medium:** Generally concentrations in air (but not always)
- **Enforceability:** Not legally enforceable
- **Applicability:** Inform emergency response and public health planning
- **Adaptability:** Often specify levels of harm



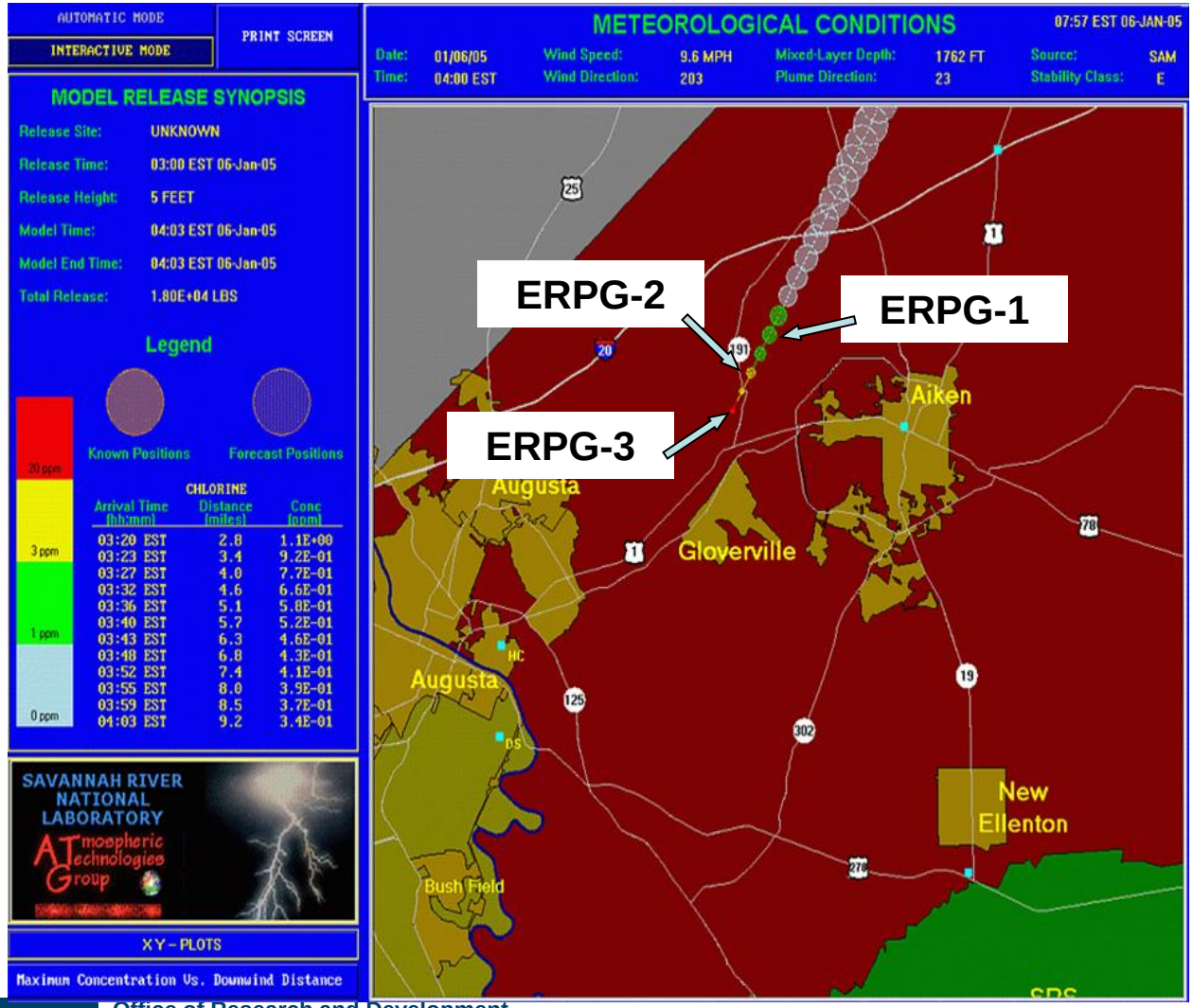


Emergency Response Values: Examples امثلة لقيم الاستجابة للطوارئ

(مباديء توجيهيه)Guideline	Organization and Context
AEGL Acute Exposure Guideline Level	Developed to describe the risk to humans resulting from once-in-a-lifetime, or rare, exposure to airborne chemicals. *Developed by committee managed by EPA
PAL Provisional Advisory Level	Developed for high-priority hazardous chemicals and chemical warfare agents in air and drinking water following a disaster.
ERPG Emergency Response Planning Guideline	Used in community emergency planning to develop guidelines for responding to potential releases of airborne substances
EEGL Emergency Exposure Guidance Level	Developed for military personnel operating under emergency conditions to prevent irreversible harm or serious impairment of judgment or performance.
EU-AETL European Union Acute Exposure Threshold Level	Used to support emergency-response and land-use planning following accidental chemical releases from industrial facilities.

Emergency Response Values: قيم الاستجابة للطوارئ
Graniteville, SC Chlorine Spill

Emergency Response Values: Graniteville, SC Chlorine Spill



The maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to one hour without experiencing or developing. . .

ERPG-3 . . .life-threatening health effects.

ERPG-2 . . .irreversible or other serious health effects or symptoms which could impair an individual's ability to take protective action.

ERPG-1 . . .other than mild, transient adverse health effects or without perceiving a clearly defined objectionable odor.

Emergency Response Planning Guidelines (ERPGs)

Occupational Values: Characteristics
خصائص القيم المهنية

- **Exposure Type:** Healthy adult workers in occupational settings
- **Duration:** Acute to chronic. Generally include two types of values
  - Not to exceed – “ceiling”
  - Time-weighted average
- **Medium:** Generally concentrations in workplace air
- **Enforceability:** Some are legally enforceable
- **Applicability:** Inform risk management policies in the workplace
- **Adaptability:** Sometimes derived for special environments




Occupational Values: Examples
امثلة للقيم المهنية

Guideline	Organization and Context
REL Recommended Exposure Limit	Developed for hazardous substances or conditions in the workplace considering a continuous exposure during a normal 40-hour workweek.
IDLH Immediately Dangerous to Life or Health value	Developed only for the purpose of respirator selection under emergency conditions in the workplace.
PEL Permissible Exposure Level	Mandated to address hazardous substances or conditions in the workplace considering a continuous exposure during a normal 40-hour workweek.
TLV Threshold Limit Value	Developed to enable industrial hygienists to make decisions regarding safe values of exposure to chemical substances and physical agents found in the workplace.
CEGL Continuous Exposure Guidance Level	To protect workers on submarines from chemical exposures in an enclosed and isolated environment.

Ambient and General Public Values: Characteristics

خصائص القيم المحيطة والعمومية

- **Exposure Type:** Ambient
- **Duration:** Generally long-term
- **Medium:** Developed for air, water, and food
- **Enforceability:** Some are legally enforceable
- **Applicability:** Prevent harm from chemical exposures over the course of a lifetime; must protect sensitive subgroups
- **Adaptability:** Frequently developed for protection of human health and the environment





General Public Values: IRIS

القيم العمومية

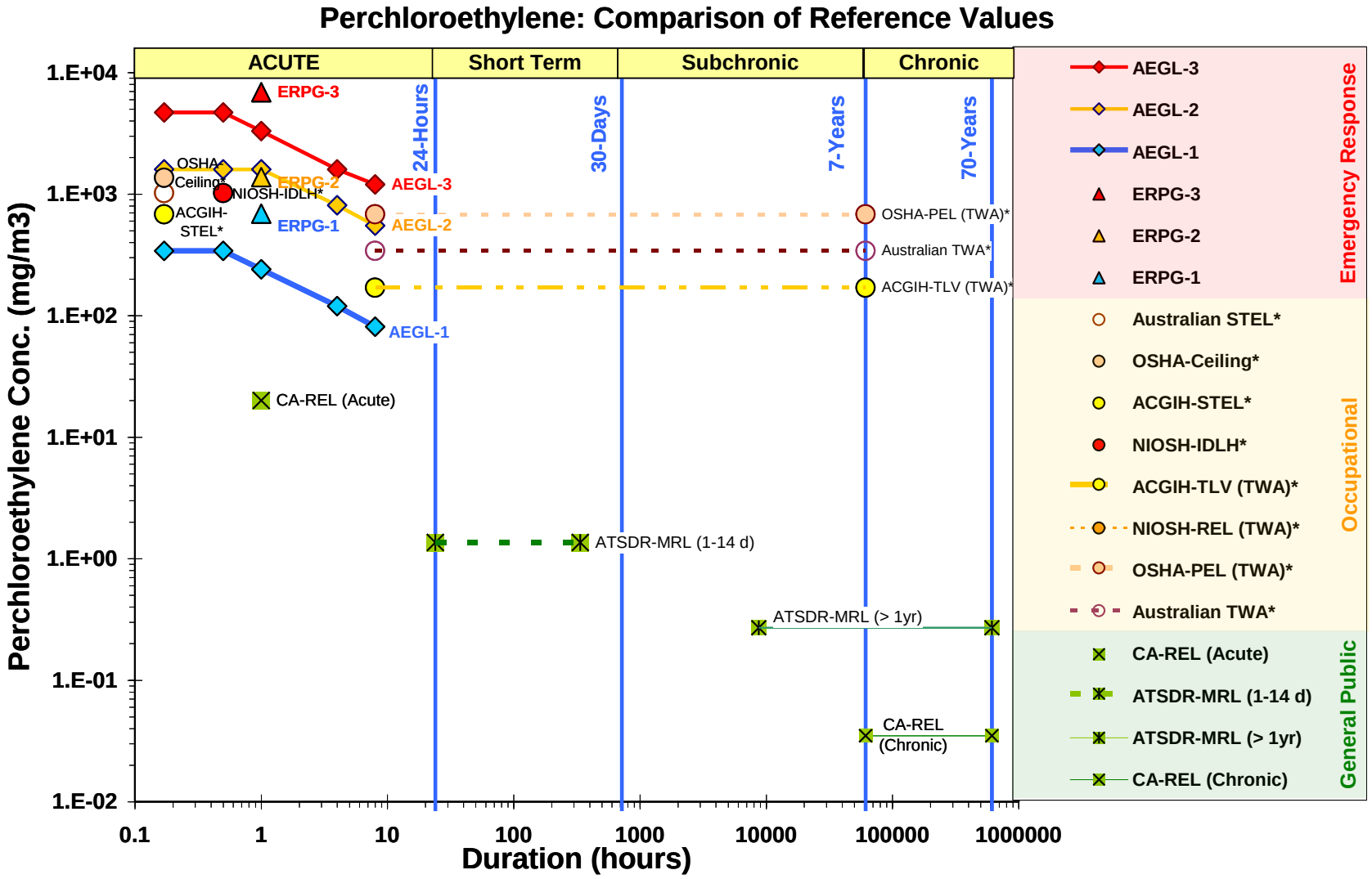
Guideline	Organization and Context
RfD Reference dose	Integrated Risk information System (IRIS) values are: Developed to support hazard identification and dose-response assessment. Used to characterize public health risks of a given substance in a given situation. Used to form the basis for risk-based decision-making, regulatory activities, and other risk management decisions.
RfC Reference concentration	
OSF Oral slope factor	
IUR Inhalation Unit Risk	

United States Environmental Protection Agency

Reference Value Arrays
صفائف القيم المرجعية

- **Reference Value Arrays** are graphical arrays that compare human health effect reference values across:
  - Multiple Agencies & Organizations
  - Durations of exposure
  - Populations of concern
  - Severity of effect
- A report on the purpose and development of reference value arrays is available from the U.S. EPA (2009).

Reference Value Arrays
صفائف القيم المرجعية



* Indicates an occupational value; expert judgment necessary prior to applying these values to the general public.

EPA
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Agency

المعلومات المتاحه لتقييم المخاطر

NCEA Available Resources for Risk Assessment Evaluation

- IRIS
- ISA & PPRTV
- HERO
- Guidance Documents
- Exposure-Response Arrays



EPA United States Environmental Protection Agency

Integrated Risk Information System (IRIS)

شبكة المعلومات المتكاملة عن المخاطر

- Provides scientific information on potential adverse health effects that may result from exposure to chemical substances found in the environment
- Develops oral reference doses and inhalation reference concentrations for non-cancer endpoints
- Develops a weight of evidence descriptor (carcinogenic to human), oral slope factors, and inhalation unit risks for cancer
- EPA risk assessors combine IRIS toxicity values with scenario-specific exposure values to estimate risk
- Source of toxicity information to inform risk-based decision-making; founded on EPA guidelines for health risk assessment
- Fosters consistent risk assessments across EPA Programs and Regions
- Follows National Academy of Sciences (NAS) risk assessment paradigm

IRIS Program Users

EPA Programs

المستخدمون

Academia & the
Scientific community

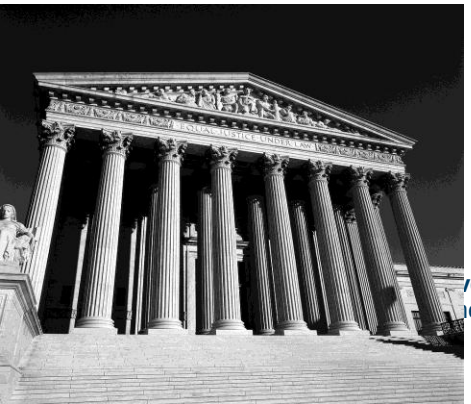
Industry
Trade associations

International Organizations

Federal Agencies
States
Public

Public interest groups
Environmental organizations
Advocacy groups

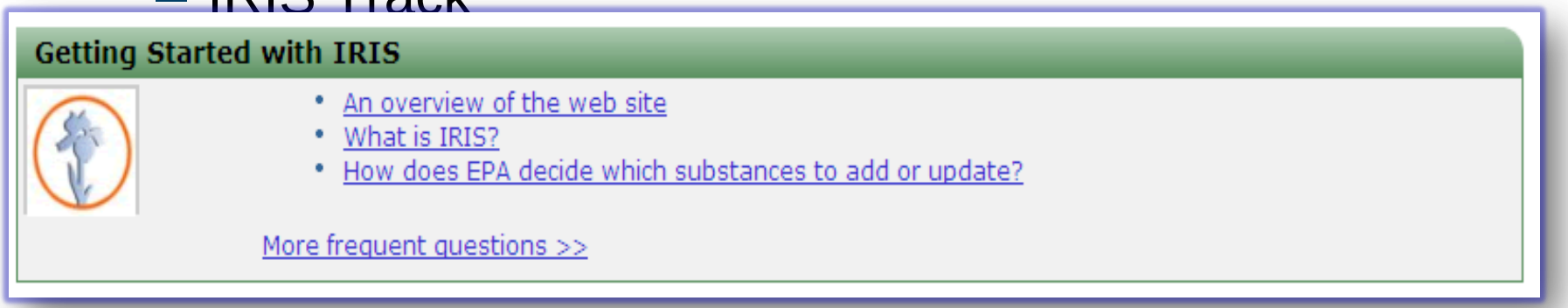
Courts



Federal and State law Makers

Accessing IRIS Data

- IRIS website (www.epa.gov/IRIS) contains:
  - IRIS Assessments, including:
    - Toxicological Review
    - IRIS Summary
    - "QuickViews"
  - IRIS Track



Integrated Science Assessments (ISA)
الشبكة العلميه لتقدير المخاطر

United States Environmental Protection Agency

Integrated Science Assessments:

- Provide the scientific basis for the National Ambient Air Quality Standards (NAAQS) for the six criteria air pollutants.

- Evaluates and integrates evidence from across scientific disciplines – atmospheric sciences, dosimetry, exposure, toxicology, controlled human exposure, epidemiology, ecology or welfare effects.

- Conclusions, causal judgments (e.g., “causal relationship,” “likely to be a causal relationship,” “suggestive evidence of a causal relationship,” “inadequate to infer a causal relationship,” and “not likely to be a causal relationship”) drawn for health and ecological or environmental effects.

- Are vetted through a rigorous peer review process, including review by the Clean Air Scientific Advisory Council and public comment periods.

Provisional Peer Reviewed Toxicity Value (PPRTV) Documents

شبكة القيم السميه المدروسه

- PPRTVs are dose-response assessment documents which provide provisional reference doses and reference concentrations (sub-chronic and chronic), and cancer values (oral and inhalation unit risks) to support remediation decisions by Superfund site managers.
- Chemicals are selected according to priorities defined by the Superfund program.
- The process includes a literature search, review and evaluation of all relevant studies, determination of critical studies and critical effects, consideration of uncertainty factors, and quantification of toxicity values under a well defined Standard Operating Procedure.
- Once established, PPRTVs are reviewed in 5 years
- They are used to support decisions on acceptable levels of human exposure, establish remediation strategies, and set clean-up goals that are appropriate for protecting human health while not overly conservative and costly.
- The Office of Superfund Remediation and Technology Innovation (OSRTI) has defined a 3-tiered hierarchy of toxicity values for use by the Regions and States in conducting assessments: Tier I, IRIS values; Tier II, PPRTVs; and Tier III, other peer-reviewed values available, e.g., Agency for Toxic Substances and Disease Registry (ATSDR) minimal risk levels (MRLs)

United States Environmental Protection Agency

The Health and Environmental Research Online (HERO)
شبكة بحوث الصحة و البيْة

- HERO database provides an easy way to view the scientific literature behind EPA science assessments.
- The database includes more than 300,000 scientific articles from the peer-reviewed literature used by EPA to develop its Integrated Science Assessments (ISA)
- It also includes references and data from the Integrated Risk Information System (IRIS).
- Most journal article entries in HERO have a link to a DOI (Digital Object Identifier) . This link will direct the reader to a journal or publisher website.

EPA Guidance Documents

مستندات القيم التوجيهيه

EPA Cancer Guidelines

- U.S. EPA. 2005. Guidelines for Carcinogen Risk Assessment EPA/630/P-03/001F, Mar 2005.
- U.S. EPA. 2005. Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens EPA/630/R-03/003F, Mar 2005.
- U.S. EPA. 1999. Guidelines for Carcinogen Risk Assessment Review draft. NCEA-F-0644, Jul 1999.
- U.S. EPA. 1996. Proposed Guidelines for Carcinogen Risk Assessment (PDF) (143 pp, 649K) EPA/600/P-92/003C, Apr 1996.
- U.S. EPA. 1986. Guidelines for Carcinogen Risk Assessment

EPA Risk Guidelines (Other than Cancer)

- U.S. EPA. 2000. Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures. EPA/630/R-00/002, Aug 2000.
- U.S. EPA. 1998. Guidelines for Neurotoxicity Risk Assessment EPA/630/R-95/001F, Apr 1998.
- U.S. EPA, 1996. Guidelines for Reproductive Toxicity Risk Assessment EPA/630/R-96/009, Oct 1996.
- U.S. EPA. 1991. Guidelines for Developmental Toxicity Risk Assessment EPA/600/FR-91/001, Dec 1991.
- U.S. EPA. 1987. Risk Assessment Guidelines of 1986. EPA/600/8-87/045, Sep 1987.
- U.S. EPA. 1986. Guidelines for Mutagenicity Risk Assessment EPA/630/R-98/003, Sep 1986.
- U.S. EPA. 1986. Guidelines for the Health Risk Assessment of Chemical Mixtures (PDF) EPA

Other Guidance Documents and Technical Panel Reports

- U.S. EPA. 2011. Exposure Factors Handbook. EPA 600/R10-030
- U.S. EPA. 2011. Recommended Use of Body Weight 3/4 as the Default Method in Derivation of the Oral Reference Dose. EPA/100/R11/0001
- U.S. EPA. 2002. A Review of the Reference Dose and Reference Concentration Processes. EPA/630/P-02/002F, Dec 2002.
- U.S. EPA. 2000. Benchmark Dose Technical Guidance Document (PDF) (96 pp, 830Kb). External Review Draft. EPA/630/R-00/001, Oct 2000.
- U.S. EPA. 1994. Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry. EPA/600/8-90/066F, Oct 1994.
- U.S. EPA. 1994. Interim policy for particle size and limit concentration issues in inhalation toxicity studies: Notice of availability. Federal Register Notice 59(206): 53799.
- U.S. EPA. 1988. Recommendations for and Documentation of Biological Values for use in Risk Assessment. EPA 600/6-87/008, Feb 1988.

Risk Assessment Training and Experience (RATE)

التدريب و الخبره في تقييم المخاطر

United States Environmental Protection Agency

The Challenge: The risk assessment community needs up to date information and training on principles and practices of risk assessment, especially in an era of scarce resources and evolving scientific knowledge.

The Solution: EPA is partnering with a coalition of states, federal agencies, industry and other stakeholders to develop the Risk Assessment Training and Experience (RATE) program.

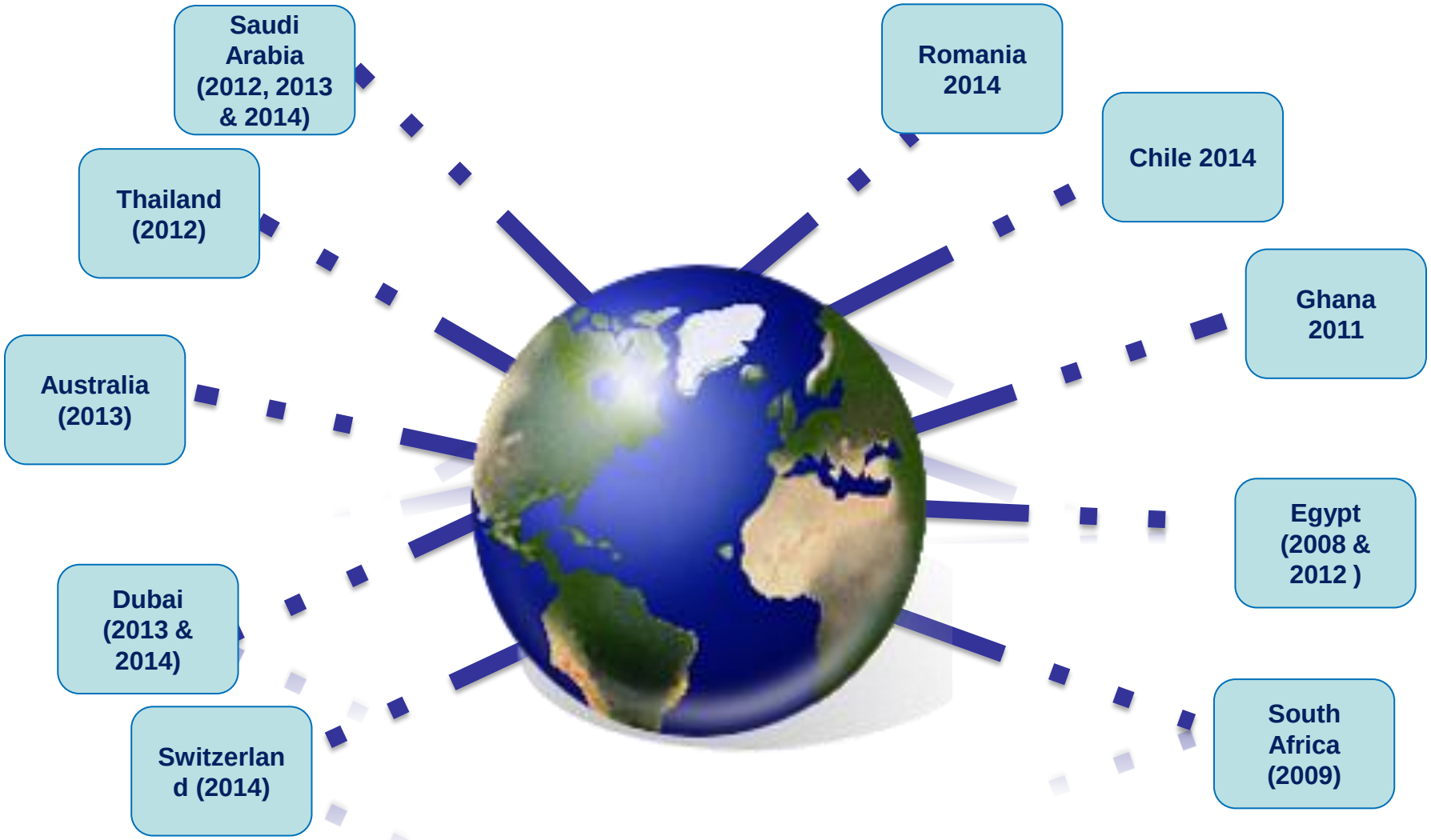
The RATE program:

- Provides comprehensive risk assessment instruction in a classroom setting; will eventually include a web-based platform.
- Includes modules on the fundamentals of risk assessment; hazard identification; dose-response; exposure assessment; and risk characterization, communication and management.

This innovative program will:

- Help ensure that state-of-the-art methods are incorporated into risk assessment practice.
- Train the next generation of risk assessors and environmental leaders, ensuring that decisions are based on sound science and the most current risk assessment practices.

International Training Classes



Conclusions الخلاصه

- Risk Assessment is an integrated and dynamic process that utilizes scientific estimates to inform environmental and public health risk management decisions.
- Risk Assessment requires diverse scientific team.
- Internet is valuable tool to use in Risk Assessment

EPA United States Environmental Protection Agency

شكرا Thank you

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