Environmental Health Assessment in the United States

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https://bit.ly/3EE6r3l

Risk Assessment in the Context of Environmental Policy

- Standardized process to evaluate potential human and/or ecological harms of an exposure
- Relation to policy
  - Set priorities
  - Inform regulations
  - Conduct site-specific assessments
  - …and more!

https://www.epa.gov/risk/conducting-human-health-risk-assessment

Russell, Milton, and Michael Gruber. "Risk assessment in environmental policy-making." *Science* 236.4799 (1987): 286-290.

Overview of Federal Chemical Evaluations and Assessments in the United States

https://doi.org/10.1021/acs.est.1c01955

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Where is the chemical found or used?

Key

Agency Abbreviation
Full Agency Name

Relevant Legislation (If applicable)

Evaluation/ Assessment[1]
Overview of the evaluation/ assessment

Key purpose or regulations/ standards resulting from the evaluation/ assessment[2]

*Underlined text indicates presence of active hyperlink

**Outlined bottom box indicates formal regulation/standard that directly results from the assessment; non-outlined box indicates non-binding guidance or recommendations

the environment

EPA
Environmental Protection Agency

any chemical substance/mixtures in commerce

Toxic Substances Control Act (TSCA) / Lautenberg Chemical Safety for the 21st Century Act

New Chemicals

Risk Determination
Determination of whether the chemical or significant new use of the chemical is likely to present "unreasonable risk of injury to health or environment," including risks to susceptible subpopulations under the conditions of use

Existing Chemicals

Risk Prioritization
Designation of chemical as "high" or "low" priority based on potential for "unreasonable risk" to health or environment, including risks to susceptible subpopulations, under the conditions of use

High priority chemicals

Risk Evaluation
Determination of whether high priority chemical presents "unreasonable risk of injury to health or the environment," without consideration of cost or other non-risk factors, under the conditions of use

Integrated Risk Information System (IRIS) Assessment
Hazard and dose-response assessment to provide toxicity information for chronic chemical exposures

Source of toxicity information for EPA and state/local health and environmental agencies

Risk management (e.g., restriction, ban)

Risk management (e.g., restriction, ban)

[1] Only high priority chemicals are advanced to the risk evaluation stage. As of 2019, EPA must have at least 20 risk evaluations for high priority substances in process at any time.

as an active ingredient[2] in pesticides

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) / Federal Food, Drug, and Cosmetic Act (FFDCA)/ Food Quality Protection Act (FQPA)

Risk Assessment
Human and ecological risk assessment to determine whether the "pesticide can perform its intended function without unreasonable adverse effects on human health or the environment"

Risk management (e.g., registration and/or label revision)

Tolerance setting or revision[3]

[2] An active ingredient is defined as the chemical that is intended to be toxic to the target species. There is no evaluation of any other ingredients, termed "inerts," that are added to the product to improve effectiveness.

[3] A tolerance level is the maximum residue or concentration allowable on or in food. The tolerance is the residue level that triggers enforcement actions

in drinking water

Safe Drinking Water Act (SDWA)

Contaminant Candidate List (CCL)[4]
List of unregulated drinking water contaminants known or anticipated to occur in public water systems

Unregulated Contaminant Monitoring Rule (UCMR)[5]
Monitoring of up to 30 unregulated contaminants to determine occurrence in drinking water

Health Advisory
Hazard and dose-response assessment to identify concentrations of the contaminant that are expected to be without adverse effects on health and aesthetics

Regulatory Determination[4]
Decision to initiate regulations, based on health risk, high occurrence, and opportunity for risk reduction

National Primary Drinking Water Regulations (NPDWRs)[6]

Technical guidance to inform federal, state, and local officials for emergency spills or contamination

[4] Required every 5 years

[5] Required for at least 5 chemicals every 5 years.

[6] If the Regulatory Determination does not result in a decision to initiate National Primary Drinking Water Regulations, EPA may consider a Health Advisory

[7] EPA must review NPDWRs every 6 years to determine if there is new information to support a regulatory revision that will improve or strengthen public health protection

in surface/ambient water

Clean Water Act (CWA)

Ambient Water Quality Criteria
Determination of criteria levels to protect human and environmental health, without consideration of economic impacts or technological feasibility

Non-binding guidance for state actions and/or federal water quality standards

in ambient air

Clean Air Act (CAA)[8]

Hazardous Air Pollutants (HAPs)

Maximum Achievable Control Technology (MACT) standards
Technology based standards for industrial/stationary sources, guided by feasibility

Risk and Technology Review[9]
Evaluation of whether standards protect public health with ample margin of safety and protect against adverse environmental effects

Updated National Emissions Standards for Hazardous Air Pollutants (NESHAPs)

Criteria Air Pollutants

Integrated Science Assessment (ISA)[10]
Evaluation and synthesis of policy-relevant studies of health and environmental effects

Risk/Exposure Assessment (REA)
Characterization of exposure and risks to human health and the environment

Policy Assessment (PA) and National Ambient Air Quality Standards (NAAQS)

[8] Under the CAA, EPA also conducts assessments of substitutes for ozone-depleting substances, as part of the Significant New Alternatives Policy (SNAP) Program

[9] Must be conducted within 8 years of MACT standards

[10] Mandated re-review every 5 years

at hazardous waste sites

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) / Superfund / Resource Conservation and Recovery Act (RCRA)

Human Health Risk Assessment
Site-specific assessment to evaluate and estimate current and future risks to human health

Risk management (e.g., Superfund site clean-up or containment)

Ecological Risk Assessment
Site-specific assessment to evaluate and estimate current and future risks to ecological resources

Provisional Peer-Reviewed Toxicity Value (PPRTV) Assessment
Hazard and dose-response assessment for chemicals of relevance to the Superfund and RCRA programs

Source of provisional toxicity information for chemicals with limited data

in potentially hazardous industrial waste

Resource Conservation and Recovery Act (RCRA) / Hazardous and Solid Waste Amendments (HSWA) / Federal Facility Compliance Act (FFCA) / Land Disposal Program Flexibility Act (LDPFA)

Waste Streams Risk Assessment
Assessment of human health risks from waste streams

Hazardous waste listing/de-listing and associated risk management/ regulations

Hazardous Waste Facilities Risk Assessment[11]
Site-specific assessment of human health risks attributable to releases from hazardous waste treatment, storage, and disposal facilities

Operating and post-closure permits

Beneficial Use Secondary Material Assessment[12]
Comparative assessment of hazardous constituent concentrations; modeling potential adverse impacts in secondary materials

Use/reuse of secondary materials in products, processes, or other applications

[11] Not all facilities need to conduct a site-specific risk assessment. This decision is made by state or regional permitting officials after evaluating factors identified in 40 CFR 270.10(j)

[12] EPA has completed several Beneficial Use Technical Material Assessments, with complete environments in progress, but does not anticipate conducting additional assessments in the future

anywhere with public health concern

NIH/NIEHS/DNTP
National Institutes of Health/ National Institute of Environmental Health Sciences/ Division of the National Toxicology Program

Public Health Service Act

Report on Carcinogens (RoC)
Cancer hazard assessment

NTP Noncancer Monographs
Noncancer hazard assessment

Informs standards or regulations implemented by other agencies and organizations

Communicates information on potential human health concerns

the workplace

NIOSH
National Institute for Occupational Safety and Health

Occupational Safety and Health Act (OSH Act)

Criteria Documents
Review and risk assessment of occupational hazards

Current Intelligence Bulletin
Updated review and risk assessment of previously identified occupational hazards

Immediately Dangerous to Life or Health (IDLH) Value Profile
Review of technical data to identify risks based on acute exposure

Skin Notation Profile
Determination of hazards resulting from dermal exposure

Health Hazard Evaluations (HHE)
Evaluation of hazards at specific workplace sites

Hazard Alert
Hazard identification

Informs occupational safety and health standards and risk management actions to reduce exposures

Recommendations to reduce site-specific workplace-related hazards / exposures

Rapid alert for specific hazard (usually) not yet covered by existing NIOSH guidance

OSHA
Occupational Safety and Health Administration

Occupational Safety and Health Act (OSH Act)

Risk Assessment
Evaluation of human health risk, considering exposures over a working lifetime

Technologic and economic feasibility analysis

Risk management[13] (e.g., exposure standards)

[13] Federal or national consensus standards available in 1970 were selected as enforceable OSHA standards; most of these have not undergone a substantive update

hazardous waste sites

ATSDR
Agency for Toxic Substances and Disease Registry

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) / Superfund

Public Health Assessment
Evaluation of specific hazardous waste sites for potentially hazardous exposures and related community health concerns

ToxProfile
Examination and summary of available toxicological and epidemiological data for substances on the Substance Priority List (SPL)[14]

Public health actions, such as health studies, education, or guidance to reduce exposure

Information used by health assessors and responders to identify potential risks at hazardous waste sites

[14] List of substances found at National Priorities List (NPL) hazardous sites, identified by their frequency, toxicity, and potential for human exposure

food or cosmetics

FDA
Food and Drug Administration

added to food

Federal Food, Drug, and Cosmetic Act (FFDCA) / Food Additives Amendment (FAA) / Color Additives Amendment (CAA) / Fair Packaging and Labeling Act (FPLA) / Food and Drug Administration Modernization Act (FDAMA)

Food Additive

Safety Determination
Safety evaluation, considering chronic and cumulative exposures through the food supply, to ensure 1) "reasonable certainty of no harm" under intended conditions of use; 2) does not cause cancer in animals or humans

1) Food additive regulation
2) Tolerance levels

"Generally Recognized As Safe" (GRAS) Ingredients

Voluntary, Non-Binding FDA Review
Optional FDA review, considering chronic and cumulative exposures to ensure 1) "reasonable certainty of no harm" under intended conditions of use; 2) does not cause cancer in animals or humans

Use in food products, given manufacturer adherence to post-market responsibilities

Prior-Sanctioned Substances[15]

Pre-1958 FDA/ USDA Review
Evaluation based on unknown standard

Use in food products, given manufacturer adherence to post-market responsibilities

in cosmetics

Federal Food, Drug, and Cosmetic Act (FFDCA) / Fair Packaging and Labeling Act (FPLA) / Color Additives Amendment (CAA)

Color Additives

Review of Color Additive Petition
Determination of whether there is "convincing evidence" of reasonable certainty of no harm under the intended conditions of use

1) Color additive regulation
2) Batch certification

Non-Color Ingredients[16]

N/A
No pre-market review

Use in cosmetics; manufacturers responsible for product safety and labeling

[15] Approximately 120 substances "grandfathered" in, based on approval by FDA or the US Department of Agriculture (USDA) prior to 1958

[16] Except for the following ingredients, which are prohibited or restricted for use in cosmetics: bithionol, mercury compounds, vinyl chloride, halogenated salicylanilides, zirconium complexes, chloroform, methylene chloride, chlorofluorocarbon propellants, & hexachlorophene

consumer products

CPSC
Consumer Product Safety Commission

Consumer Product Safety Act (CPSA) / Federal Hazardous Substances Act (FHSA)/ Consumer Product Safety Improvement Act (CPSIA)

Pre-Market

N/A
[manufacturers must ensure either that their products are not hazardous under the FHSA or that they are labeled as required by the FHSA][17]

Response to Agency-Identified Emerging Hazard or Public Petition

Hazard Assessment
Determination of whether the chemical "has the capacity to produce personal injury or illness through ingestion, inhalation, or absorption through any body surface"

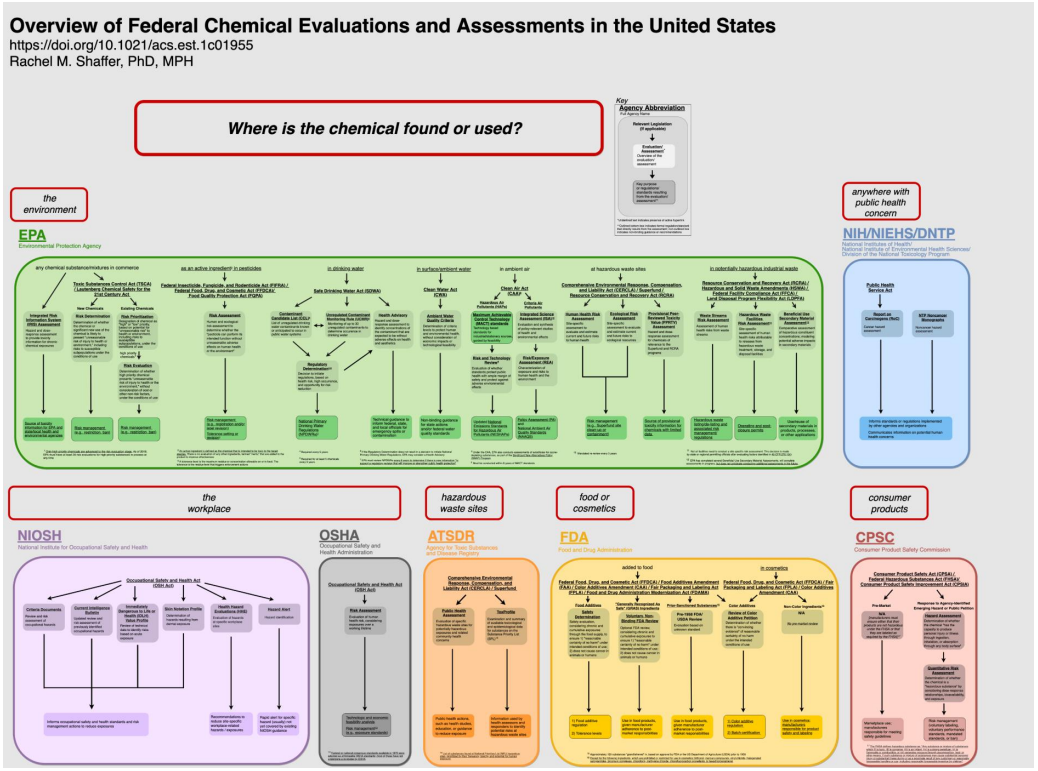
Quantitative Risk Assessment
Determination of whether the chemical is a "hazardous substance" by considering dose-response relationships, bioavailability, and exposure

Marketplace use; manufacturers responsible for meeting safety guidelines

Risk management (voluntary labeling, voluntary performance standards, mandated standards, or ban)

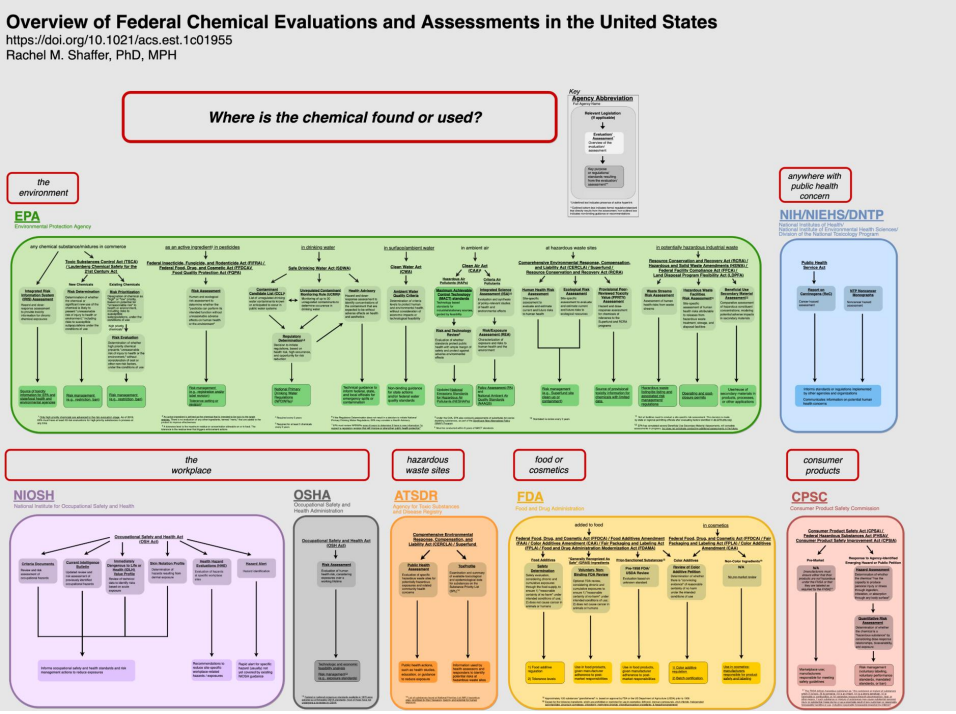
[17] The FHSA defines hazardous substances as: "Any substance or mixture of substances which (1) is toxic, (2) is corrosive, (3) is an irritant, (4) is a strong sensitizer, or (5) is flammable or combustible, or (6) generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children"

Infographic Basics (1)



- >30 different assessment and evaluation processes relevant to environmental health at the federal level in the United States
- Does not include relevant overlapping state processes

Infographic Basics (2)



- Regulatory vs. non-regulatory agencies
  - Regulatory
    - **Environmental Protection Agency (EPA)**
    - **Consumer Product Safety Commission (CPSC)**
    - **Food & Drug Administration (FDA)**
    - **Occupational Safety & Health Administration (OSHA)**
  - Non-regulatory:
    - **Division of the National Toxicology Program (DNTP)**
    - **National Institute for Occupational Safety & Health (NIOSH)**
    - **Agency for Toxic Substances and Disease Registry (ATSDR)**

Go to HTML demo

- https://bit.ly/3EE6r3l

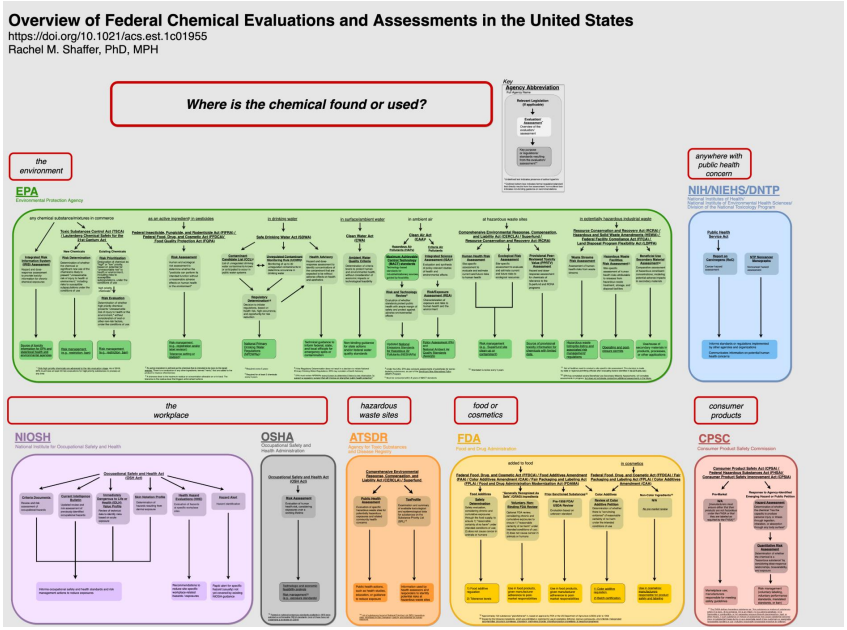
Comparison between selected assessments

	ATSDR ToxProfile	EPA IRIS Assessment	EPA TSCA Risk Evaluation
Chemicals covered	Chemicals on Substance Priorities List (SPL), found at hazardous sites	Any chemical/group of chemicals/complex mixture found in the environment	High priority existing chemicals in commerce
Exposure scenarios	Acute; subacute; chronic	Chronic	Acute; chronic
Health effects	Noncancer*	Cancer & noncancer	Cancer & noncancer
Toxicity value	Minimal Risk Levels (MRLs)	Cancer: oral slope factor (OSF)/inhalation unit risk (IUR) Noncancer or nonlinear cancer: reference dose (RfD)/reference concentration (RfC)	Cancer: inhalation unit risk (IUR)/dermal slope factor Noncancer: Margin of Exposure (MOE)
Downstream purpose	Screening information to identify potential health risks at hazardous waste sites	Source of toxicity information for EPA programs & international/ state/local governments	Informs risk management steps under TSCA (e.g., restriction, ban)

**ATSDR reviews cancer health effects also, but MRLs are only developed for noncancer health effects*

How this graphic can be useful to the environmental health community

- ***Educational tool:*** for use in EH courses & seminars (e.g., environmental health policy)
- ***Research ideas:*** to highlight opportunities for targeted research to advance public health policy
- ***Getting involved in the policy process***: to help you understand and track opportunities for public comment



Key points from commentary (https://bit.ly/3EE6r3l)

- Need for improved coordination for chemical assessments
  - Echoing National Research Council (NRC) & Government Accountability Office (GAO)
  - E.g. “interagency task force” (NRC, 1983)

- Agency-specific / domain-specific assessments may underestimate scope of exposures
  - Consider aggregate risk
  - Potential model: EU 2020 *Chemicals Strategy for Sustainability Towards a Toxic-Free Environment* – “one substance, one assessment”

Current Efforts in Coordination & Communication

- Systematic Review
  - Harmonization of methods
  - Sharing resources, tools, etc

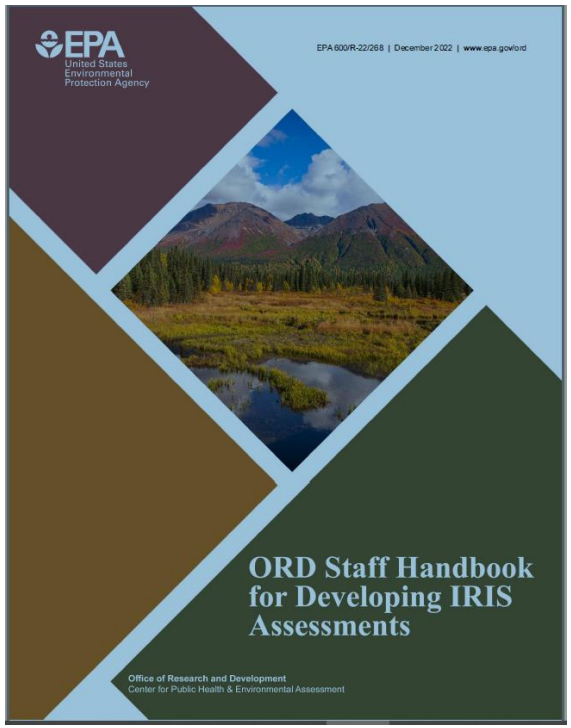
- New Chemicals Collaborative Research Program
  - Partnership between ORD & OCSPP to develop and implement New Approach Methodologies (NAMs) for risk assessment of new chemicals

IRIS Handbook (Dec 2022)

- Methods for evaluating studies, evidence synthesis and integration with other types of evidence

- IRIS Handbook is specific for EPA IRIS assessments and does not represent Agency Guidance.

- Primary intents are to:
  - Increase transparency of methods
  - Foster consistency in assessment development
  - Try not to duplicate methods publicly available elsewhere (e.g., EPA guidelines)



Slide from Kris Thayer

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Questions? Comments?

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