

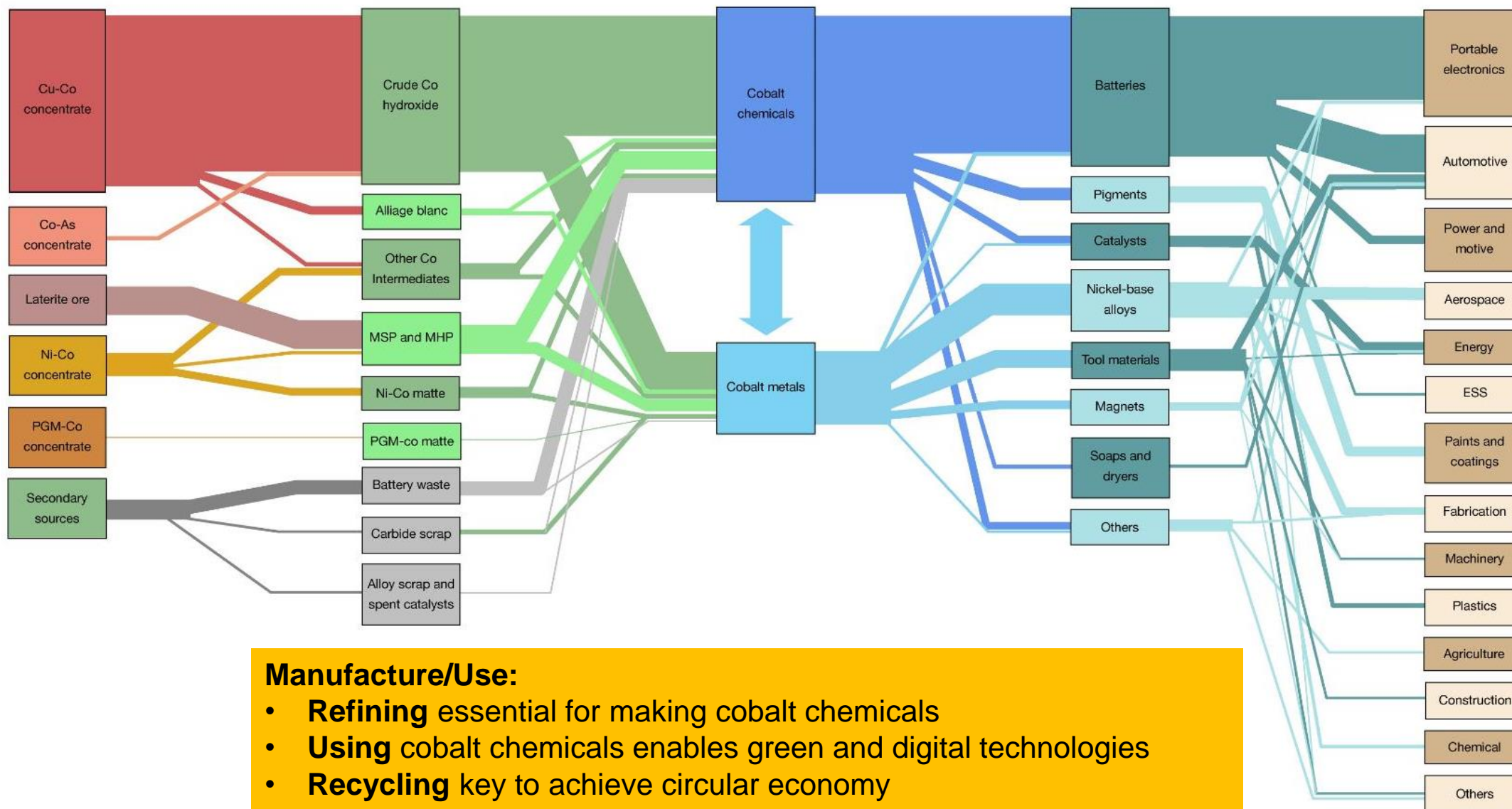


## The Impact Of Chemicals Management On The Global Cobalt Supply Chain

*US Environmental Protection Agency Integrated Risk Information System (IRIS) As A Case Study*

Tuesday, 14<sup>th</sup> May 2024

# GLOBAL COBALT VALUE CHAIN (2021)



## Manufacture/Use:

- **Refining** essential for making cobalt chemicals
- **Using** cobalt chemicals enables green and digital technologies
- **Recycling** key to achieve circular economy

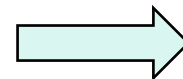
**Chain is inter-connected – with impacts felt by all!**

# COBALT CHEMICALS MANAGEMENT HORIZON?



An incorrectly set toxicity value will **have large and wide-spread impacts** on the cobalt industry

- **Large costs** to comply without higher health benefits
- **Close of industries OR regrettable substitution**
- **Impact** on other global regulatory decisions



Cobalt industry needs to:

- **Defend** a robust scientific foundation AND importantly,
- **Generate** up-to-date industry-led socioeconomic assessment

# CHEMICALS MANAGEMENT FOR METALS (COBALT)

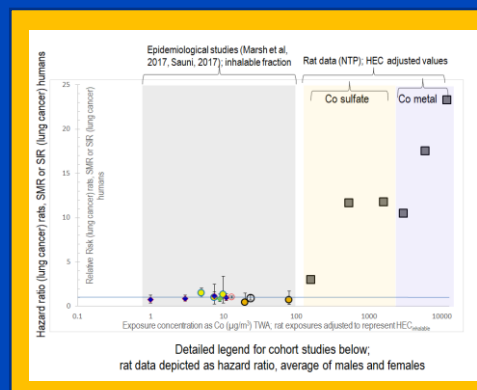
## RISK ASSESSMENT PROCESS STEPS



- **Natural occurrence** of metals
- **Adaptation** of organisms to metals
- **Essentiality** of metals
- **Background exposure** and consideration of this in risk assessment



## Cobalt Specific Considerations



***Cobalt has a safe level for exposure (where cancer does not occur).***

# WHAT DOES THE EPA IRIS PROGRAM DO?

EPA's IRIS Program supports the wider agency's mission to protect health and the environment by...

- *identifying and characterizing the health hazards of chemicals found in the environment.*

IRIS assessments at high level focus on:

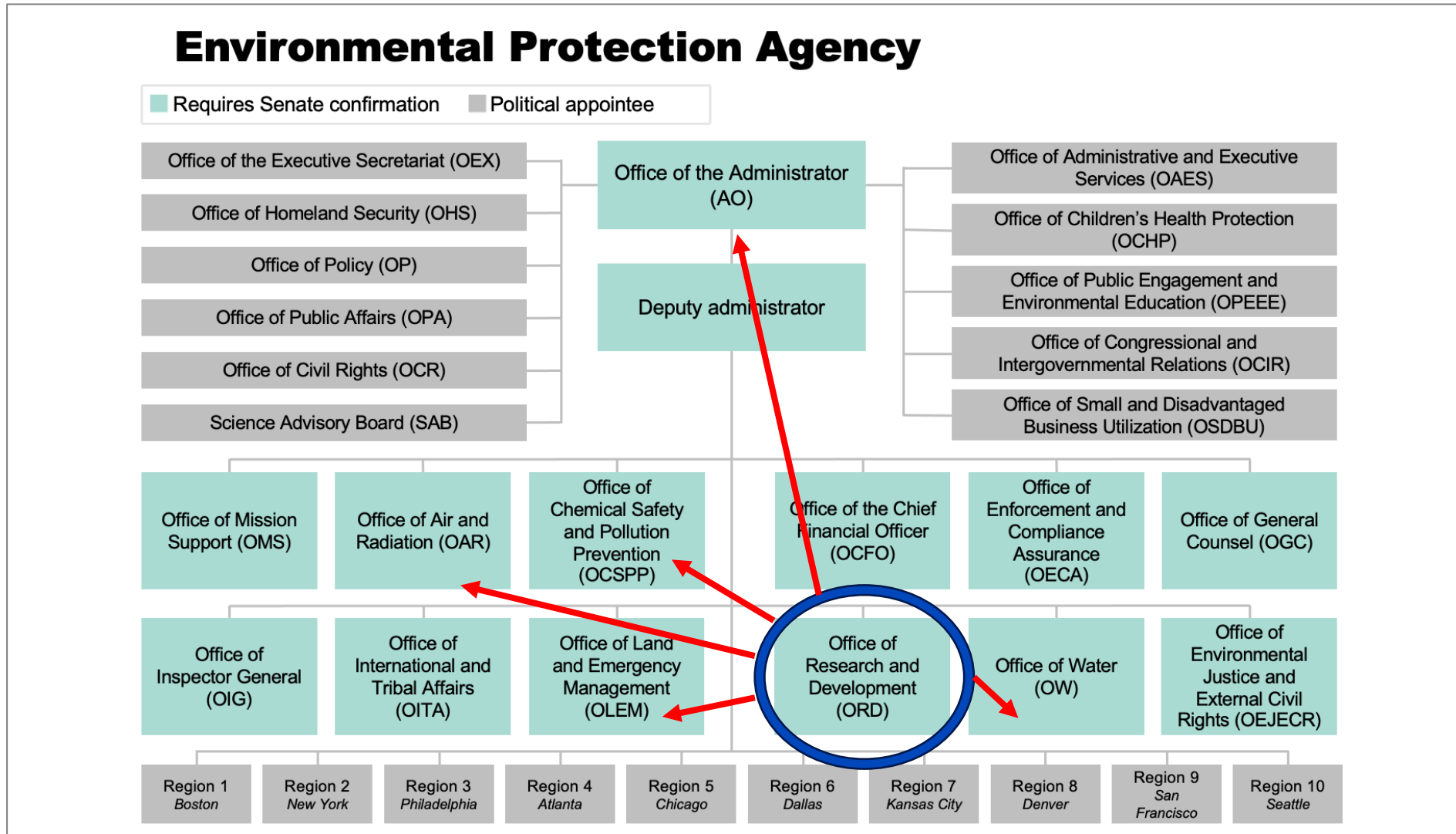
- **Chemicals** – they may cover a chemical, a group of related chemicals, or a complex mixture; and
- **Toxicity Values** – the assessment is serves as a reputable source of toxicity information via **toxicity values** that are used by EPA, state and local health agencies, other federal agencies, and international health organizations.



Location in the ORD aims to ensure it remains independent and impartial from standard-setting and EPA's program offices

Pre-regulatory – meaning it does not generate rules with legal authority

# WHERE DOES THE IRIS PROGRAM FIT IN AT EPA?



# IMPACTS OF IRIS ON OTHER EPA REGULATORY PROGRAMS

1

## Safe Drinking Water Act

IRIS toxicity values are the scientific basis for setting Maximum Contaminant Levels (MCLs) for nationwide drinking water standards.

2

## Clean Water Act

IRIS Assessments are used to set ambient water quality criteria for surface waters and inform new pollutant discharge standards.

3

## Toxic Substances Control Act

IRIS information and toxicity values are relied upon to determine unreasonable risks from toxic substances and set standards or restrictions for workplace and consumer exposures.



4

## Clean Air Act

IRIS values are used to inform national ambient air quality standards and air toxics emission standards for industrial sources.

5

## CERCLA "Superfund" Site Clean Up

IRIS information directly drives remediation levels for hazardous waste sites and guides how cleanups are managed.

6

## FIFRA Pesticides and Insecticides

IRIS toxicological data is used to assess health risks from various chemical exposures, setting tolerances and imposing

# HOW IRIS IMPACTS GLOBAL DECISION MAKING

1

## US State / Local Regulatory Agencies

Serves as a  
resource for  
regulatory  
decisions

2

## US Public Health Departments

Aids local health  
agencies and  
leaders

3

## International Bodies and Agencies

Informs other  
authoritative  
bodies worldwide

4

## Academic and Research Institutions

Utilized by experts  
in health and  
environmental  
research globally

5

## NGO and Advocacy Organizations

Embraced by  
NGOs in the US  
and worldwide



# CURRENT CHEMICALS UNDER REVIEW IN THE IRIS PROGRAM

	Chemical	Docket ID
1.	<a href="#">General Docket</a>	<a href="#">EPA-HQ-ORD-2014-0211</a>
2.	<a href="#">Arsenic, Inorganic (iA)</a>	<a href="#">EPA-HQ-ORD-2012-0830</a>
3.	<a href="#">Chloroform</a>	<a href="#">EPA-HQ-ORD-2017-0497</a>
4.	<a href="#">Chromium VI (CrVI)</a>	<a href="#">EPA-HQ-ORD-2014-0313</a>
5.	<a href="#">Cobalt and Cobalt Compounds</a>	<a href="#">EPA-HQ-ORD-2022-0833</a>
6.	<a href="#">Ethylbenzene</a>	<a href="#">EPA-HQ-ORD-2014-0526</a>
7.	<a href="#">Formaldehyde (Inhalation)</a>	<a href="#">EPA-HQ-ORD-2010-0396</a>
8.	<a href="#">Mercury Salts, Inorganic</a>	<a href="#">EPA-HQ-ORD-2019-0504</a>
9.	<a href="#">Methylmercury (MeHg)</a>	<a href="#">EPA-HQ-ORD-2018-0655</a>
10.	<a href="#">Naphthalene</a>	<a href="#">EPA-HQ-ORD-2014-0527</a>
11.	<a href="#">Nitrate</a>	<a href="#">EPA-HQ-ORD-2017-0496</a>
12.	<a href="#">Nitrite</a>	<a href="#">EPA-HQ-ORD-2017-0496</a>
13.	<a href="#">Perfluorodecanoic Acid (PFDA)</a>	<a href="#">EPA-HQ-ORD-2019-0287</a>
14.	<a href="#">Perfluorohexanesulfonic Acid (PFHxS)</a>	<a href="#">EPA DOCKET EPA-HQ-ORD-2021-0562</a>
15.	<a href="#">Perfluorononanoic Acid (PFNA)</a>	<a href="#">EPA-HQ-ORD-2021-0560</a>
16.	<a href="#">Polychlorinated Biphenyls (PCBs)</a>	<a href="#">EPA-HQ-ORD-2011-0676</a>
17.	<a href="#">Uranium, natural</a>	<a href="#">EPA-HQ-ORD-2017-0747</a>
18.	<a href="#">Vanadium and Compounds (Inhalation)</a>	<a href="#">EPA-HQ-ORD-2020-0182</a>
19.	<a href="#">Vanadium and Compounds (Oral)</a>	<a href="#">EPA-HQ-ORD-2020-0183</a>

## IRIS External Peer Review Reports

IRIS Assessment Peer Review Reports:

- [IRIS Toxicological Review of Formaldehyde \(External Review Draft, 2022\)](#).
- [IRIS Toxicological Review of Hexavalent Chromium \(External Review Draft, 2022\)](#).
- [IRIS Toxicological Review of Perfluorodecanoic Acid \(PFDA\) and Related Salts \(External Review Draft\)](#).

See the [Full List of updates and recent additions](#)

## IRIS Assessments

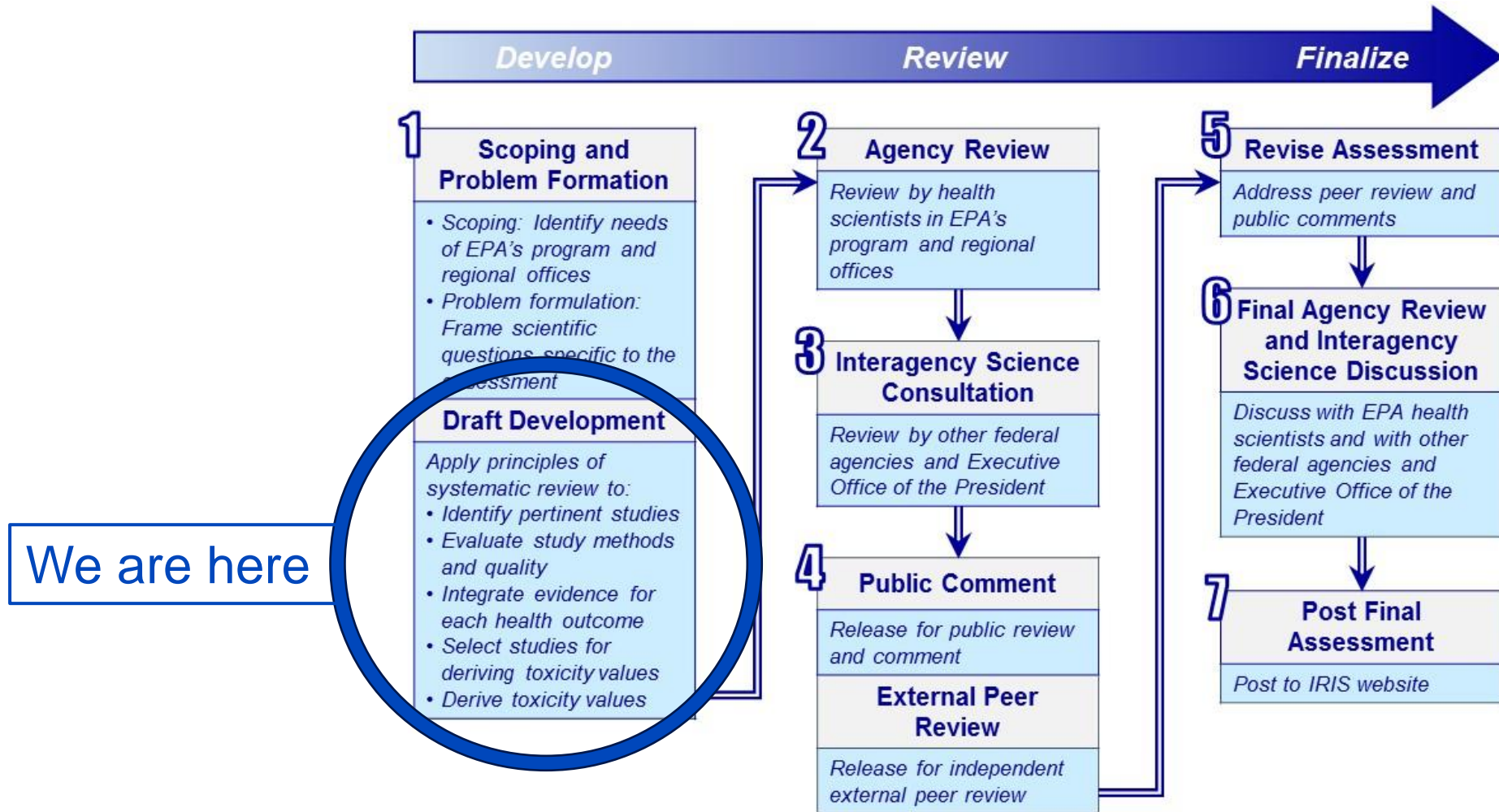
Assessments in Development:

- [PFNA \(Public Comment Draft\)](#).
- [Uranium \(Protocol\)](#).
- [Nitrate/Nitrite \(Protocol\)](#).
- [Inorganic Arsenic \(Public Comment Draft\)](#).
- [Vanadium - Inhalation\(Protocol\)](#).

See the [Full List of Assessments in Development](#)

Approximately 18 chemicals under review – including Cobalt and Cobalt Compounds

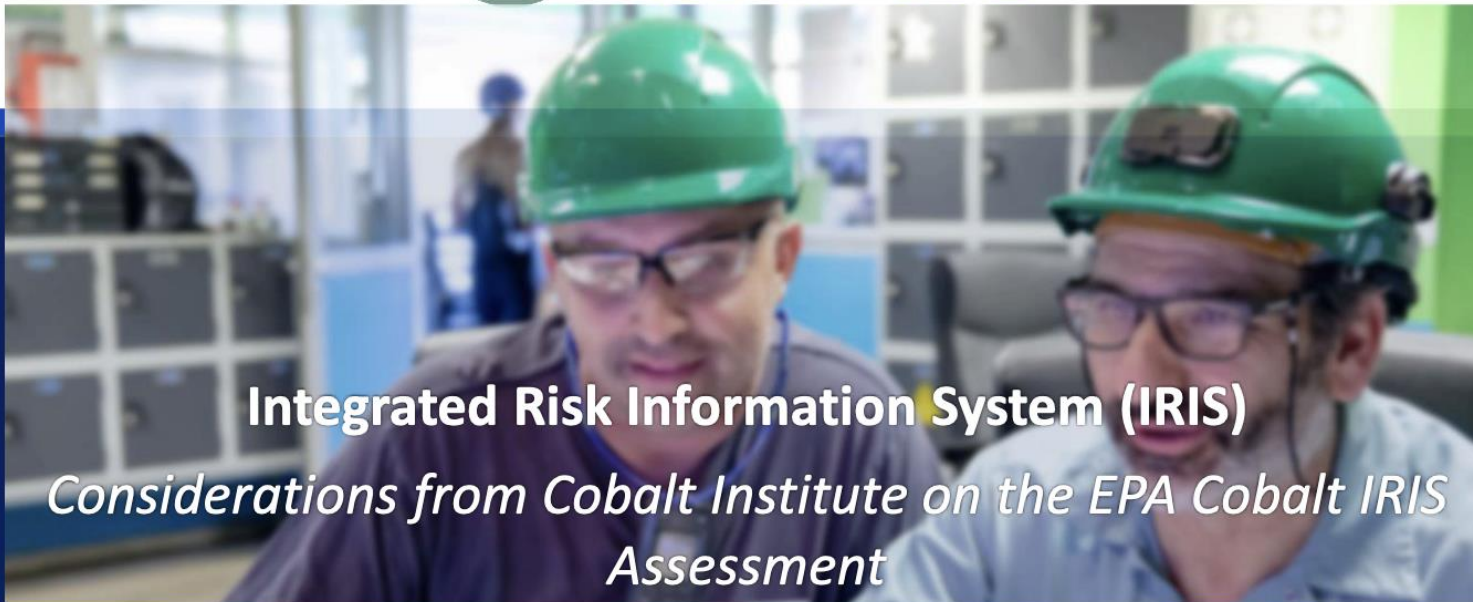
# HOW EARLY ARE WE IN THE IRIS PROCESS FOR COBALT?



## IRIS ASSESSMENT DEVELOPMENT PROCESS

The 7-step process has not changed. This figure refines earlier versions and includes the 2013 IRIS enhancements and the incorporation of systematic review approaches.

# CI ENGAGEMENT WITH IRIS PROGRAM



## Integrated Risk Information System (IRIS)

*Considerations from Cobalt Institute on the EPA Cobalt IRIS Assessment*

Monday, 6<sup>th</sup> November 2023

Andrew Maier, ChemRisk/Stantec, Principal Health Scientist

Lynne Marshall, ChemRisk/Stantec, Supervising Health Scientist

Marisa Kreider, ChemRisk/Stantec, Principal Health Scientist

Vanessa Viegas, Cobalt Institute, Deputy Head of Scientific and Regulatory Affairs & Principal Toxicologist (Human Health)

Using human/workplace data is critical.

Existence of safe exposure level (with no cancer).

Significant and key data generation in next 3 – 5 years.

# IRIS PROGRAM – MAIN AREAS TO TACKLE

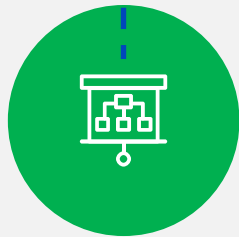
TRANSPARENCY



STAKEHOLDER ENGAGEMENT



ECONOMIC IMPACTS

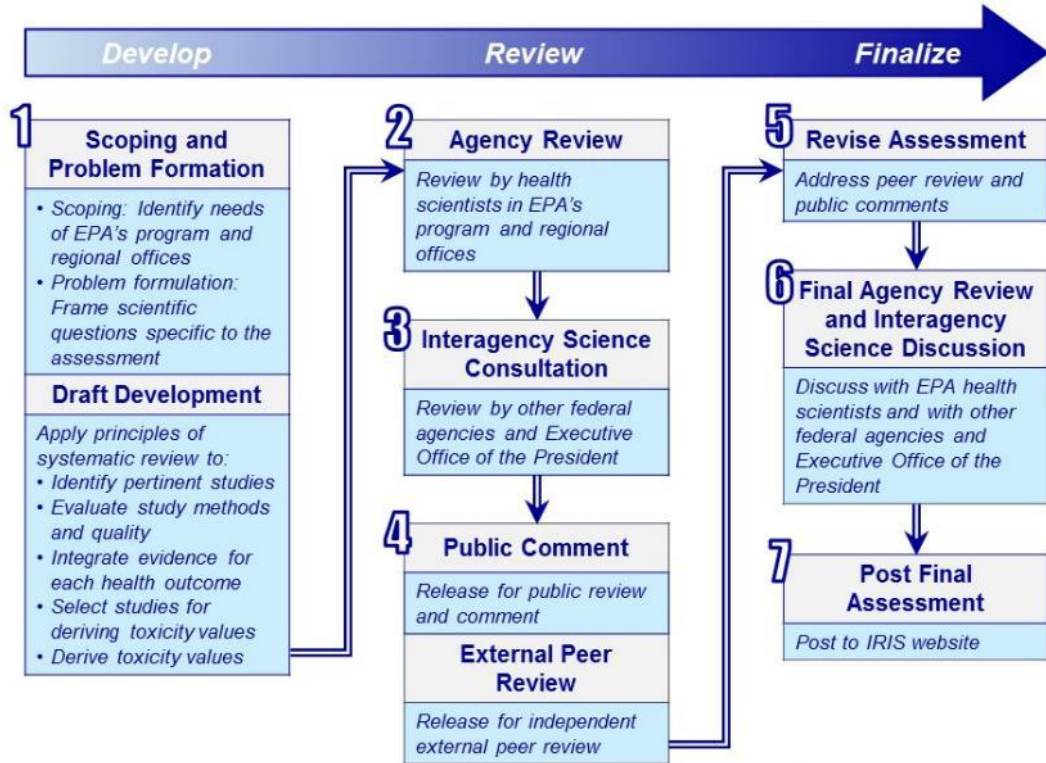


SCIENCE AND DEFAULT  
CONSERVATISM

FINAL TOXICITY VALUES

TIMELINE

# A LONG ROAD AHEAD...



## IRIS ASSESSMENT DEVELOPMENT PROCESS

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## OFFICE OF AIR & RADIATION

Table 2-1. EPA Program Office Interest in a Cancer Assessment of Cobalt Compounds.

EPA program or regional office	Oral	Inhalation	Statutes/regulations	Anticipated uses/interest
OAR		✓	Clean Air Act (CAA)	Cobalt compounds are listed as a hazardous air pollutant (HAP) under section 112 (b) (42 U.S.C. § 7412) of the CAA. CAA Section 112 has a number of regulatory requirements, including the requirement

Outcome to inform on federal air emission controls?

## TSCA Work Plan for Chemical Assessments: 2014 Update

U.S. Environmental Protection Agency

October 2014

	Chemical Name	When was the chemical added?	Hazard Criteria Met	Hazard Score	Exposure Criteria Met	Exposure Score	Persistence & Bioaccumulation Criteria Met	Persistence & Bioaccumulation Score	Use	Risk Assessment Status and Other Actions	CASRN
21	Cobalt & Cobalt Compounds	Added 2012	Cardiovascular and central nervous system effects Acute and chronic toxicity from inhalation exposures	3	Used in consumer products Present in biomonitoring, surface water, ambient air, soil High reported releases to the environment	3	High environmental persistence Moderate bioaccumulation potential	3	Industrial	Not yet initiated	Category

Potentially significant restrictions and controls (including workplace) under TSCA?

*Sound scientific foundation and socio-economics is crucial to support position.*



**For more information:**  
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