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An IRIS No One Wants To See Bloom: Formaldehyde and EPA's IRIS Assessment

August 7, 2024

IRIS: What Could Happen

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

UNITED STATES OF AMERICA,

Plaintiff,

v.

DENKA PERFORMANCE ELASTOMER, LLC and DUPONT SPECIALTY PRODUCTS USA, LLC,

Defendants.

Civil Action No. 2:23-cv-735

COMPLAINT

Plaintiff, the United States of America ("United States"), by authority of the Attorney General of the United States and through the undersigned attorneys, acting at the request of the Administrator of the United States Environmental Protection Agency ("EPA"), files this Complaint and alleges:

NATURE OF ACTION

1. This is a civil action alleging that carcinogenic chloroprene emissions from Defendant Denka Performance Elastomer, LLC's ("Denka's") neoprene manufacturing operations at the Pontchartrain Works Site in St. John the Baptist Parish, Louisiana (the "Facility") present an imminent and substantial endangerment to public health and welfare. The Facility's address is in LaPlace, Louisiana, but its chloroprene emissions also travel into other nearby communities in the Parish, such as Reserve and Edgard, Louisiana. People living in these

41. In 2010, the EPA IRIS program published its peer-reviewed assessment of chloroprene (the "2010 IRIS Assessment"). In the 2010 IRIS Assessment, the EPA concluded that chloroprene is "likely to be carcinogenic to humans" and determined that it acts through a mutagenic mode of action. The 2010 IRIS Assessment also provided a quantitative estimate of carcinogenic risk from breathing (*a.k.a.* "inhalation exposure") chloroprene. The 2010 IRIS Assessment was based on a comprehensive review of the available evidence on chloroprene toxicity, including animal toxicology data, evidence of chloroprene's mutagenic properties, and human epidemiological data. The 2010 IRIS Assessment was subject to a rigorous review process within the EPA, by other federal agencies and White House offices, and the public. The conclusions of the 2010 IRIS Assessment were subsequently confirmed by an independent external peer review panel.

42. In the 2010 IRIS Assessment, the EPA also quantified the cancer risks associated with long-term chronic inhalation exposure to chloroprene. Breathing is the primary pathway by which people living near the Facility are exposed to chloroprene. The EPA's 2010 IRIS Assessment establishes 0.2 $\mu g/m^3$ as the average concentration of chloroprene that a person may

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Denka Consistently Emits Chloroprene at Levels That Cause Unacceptably High Cancer Risk in the Surrounding Communities

43. The EPA has determined that Denka's chloroprene emissions are presenting an imminent and substantial endangerment because the average chloroprene concentrations in the ambient air near the Facility from the period of April 2018 through January 2023 at Denka's

What is IRIS?

- The IRIS Program was created by EPA in 1985 to provide an internal database of human health assessments for chemicals found in the environment.
- The goal of the IRIS Program was to foster consistency in the evaluation of chemical toxicity across EPA.
- The IRIS Program is located within EPA's Center for Public Health and Environmental Assessment (CPHEA) in the Office of Research and Development (ORD).
- IRIS assessments includes the first two steps of the risk assessment process:
  - Hazard Identification, which identifies credible health hazards associated with exposure to a chemical, and
  - Dose-Response Assessment, which characterizes the quantitative relationship between chemical exposure and each credible health hazard. These quantitative relationships are then used to derive toxicity values.

Integrated Risk Information System

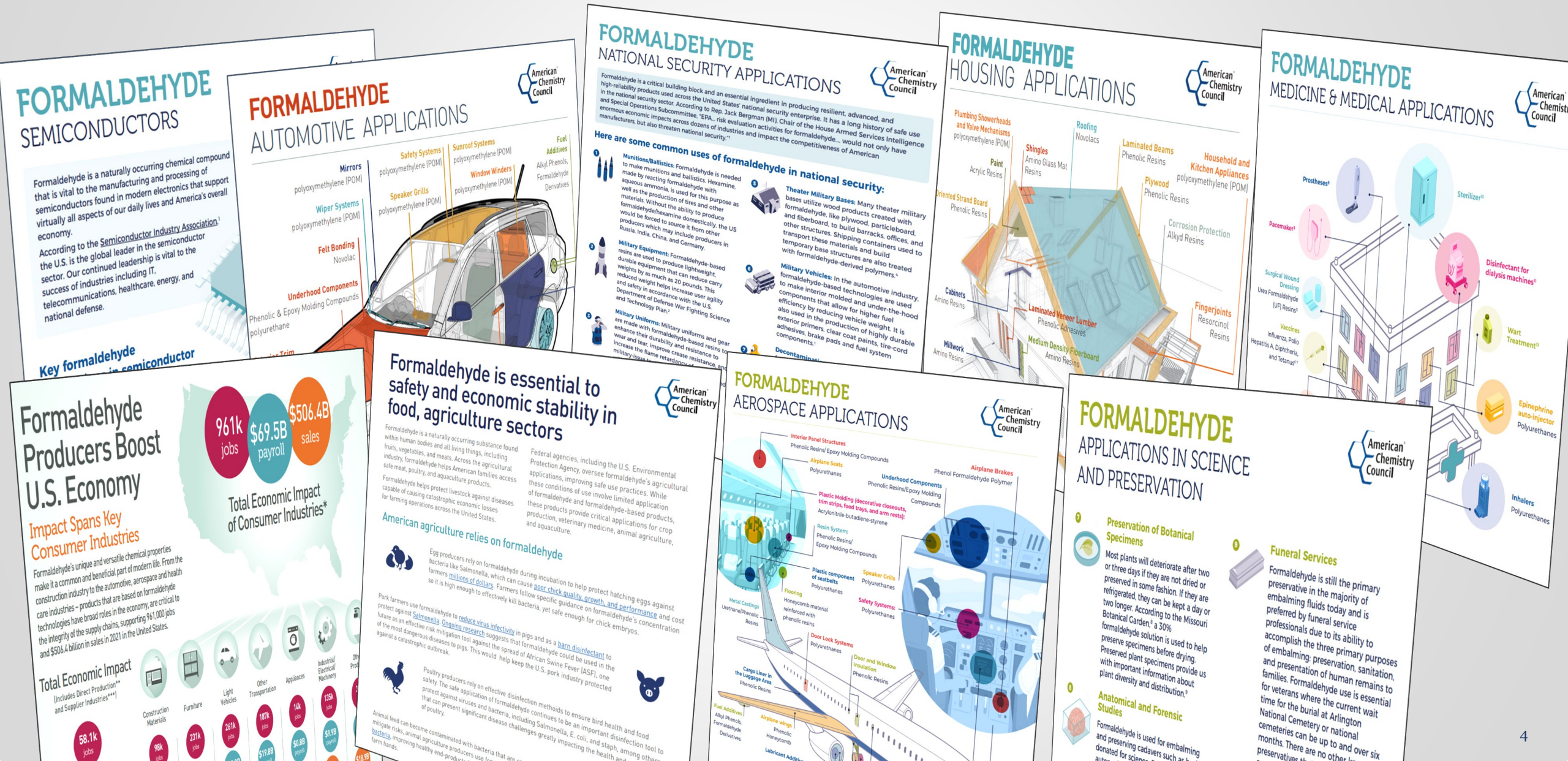
- IRIS provides information on potential adverse health effects that may result from exposure to chemical substances found in the environment.
- Toxicity values for effects other than cancer: Reference Doses (RfDs) and Reference Concentrations (RfCs).
- Cancer risk: Hazard characterization, Oral Slope Factors, and Inhalation Unit Risks.

www.epa.gov/iris

IRIS
Integrated Risk Information System

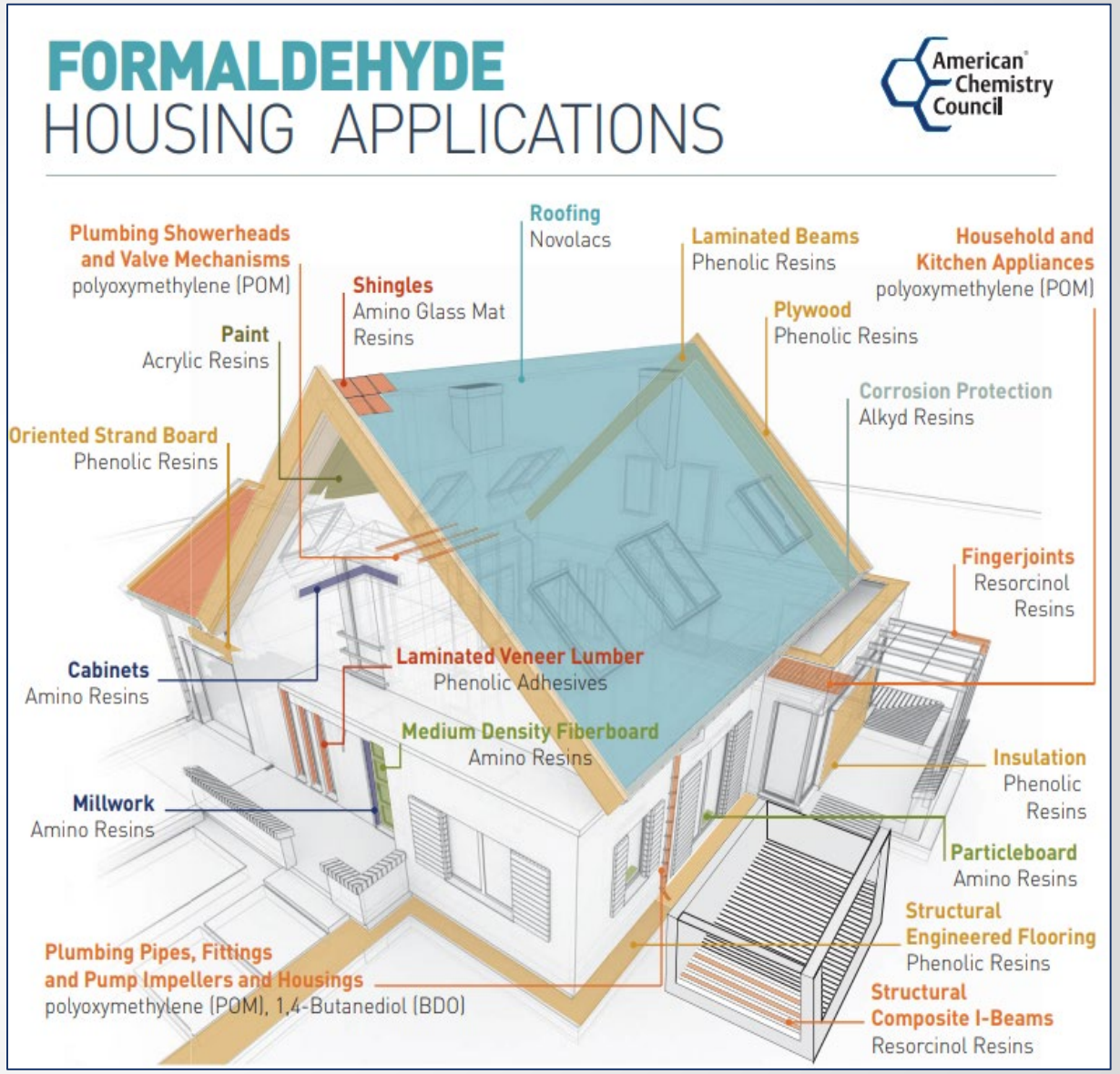
- Information is posted on the IRIS database in the form of an IRIS Summary and Supporting documents (i.e., Toxicological Reviews or IRIS Chemical Assessments).
- IRIS database provides qualitative and quantitative health effects information on over 550 substances.

Formaldehyde: An Essential Chemical Building Block



Building and Construction

Formaldehyde-based resins are used to manufacture composite and engineered wood products used extensively in cabinetry, countertops, moldings, furniture, shelving, stair systems, flooring, wall sheathing, support beams and trusses, and many other household furnishings and structures.

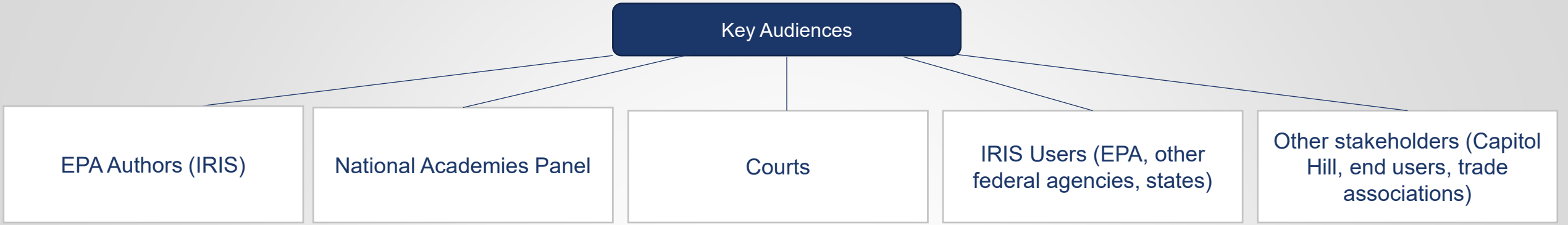


IRIS and Formaldehyde

- In 2010, EPA's Office of Research and Development released a draft IRIS (Integrated Risk Information System) assessment of formaldehyde.
- In 2011, a review by the National Academy of Sciences of EPA's last draft assessment highlighted EPA's failure to use the best available science and modern scientific methods:

  "The committee found that EPA's draft assessment was not prepared in a logically consistent fashion, lacks clear links to an underlying conceptual framework, and does not sufficiently document methods and criteria used to identify evidence for selecting and evaluating studies."
- Since 2011, more than 40 peer reviewed studies have demonstrated safe thresholds for formaldehyde.
- Trump Administration halted IRIS review for focus on TSCA review of formaldehyde. That decision was reversed by the Biden Administration.
- On April 14, 2022, EPA released an updated draft assessment with comment period deadline June 13. National Academies review followed.
- EPA's April 2022 draft assessment made the following causal conclusions:
  - "Evidence demonstrating": Nasopharyngeal cancer, myeloid leukemia, sinonasal cancer; sensory irritation
  - Evidence indicating": decreased pulmonary function; allergic conditions; asthma, reproductive toxicity
  - Lesser classifications for other cancers and nervous system effects
  - The draft assessment tees up quantification of cancer and noncancer risks at very low concentrations (between less than 1-10 parts per billion, below background levels)

EPA IRIS Assessment – Key Comments



- Of the 60 comments submitted, more than 90 percent raised fundamental concerns about the draft assessment and/or highlighted procedural concerns (including even some comments supportive of draft)
- EPA failed to follow NAS recommendations and their own policies
- EPA ignored 72 key studies and cursorily dismissed or misused dozens of others
- Draft assessment does not correctly consider role of endogenous formaldehyde exposure
- For leukemia, draft assessment continues to rely on flawed epidemiological evidence and no established biologically plausible mode of action (MOA). EPA claims of noncancer effects not supported
- EPA inappropriately discounts biologically-based dose response modeling, contrary to NAS
- EPA is out of step with international bodies, including WHO and European Chemicals Agency
- Major legal and procedural concerns include lack of independence/impartiality in peer review, failure to follow Agency policies or legal requirements, limited public participation and interagency review process, and limitations under TSCA, Federal Advisory Committee Act, Clean Air Act, and Information Quality Act

IRIS – Current vs. Proposed

Formaldehyde	1990/1991 IRIS	2022 Draft IRIS
Non-Cancer Reference Concentration (RfC)	No RfC	7 ppb
Cancer Inhalation Unit Risk (IUR)	Based only on NPC "Probable human carcinogen, based on limited evidence in humans, and sufficient evidence in animals" IUR = 1.3×10^{-2} per mg/m^3	Based on all 3 cancer types including NPC, Sinonasal Cancer, and Myeloid Leukemia* "Carcinogenic to humans" (strongest conclusion available in EPA guidelines) IUR =1.1×10^{-2} per mg/m^3

* The proposed IUR is only for NPC and not proposed for sinonasal cancer and myeloid leukemia.

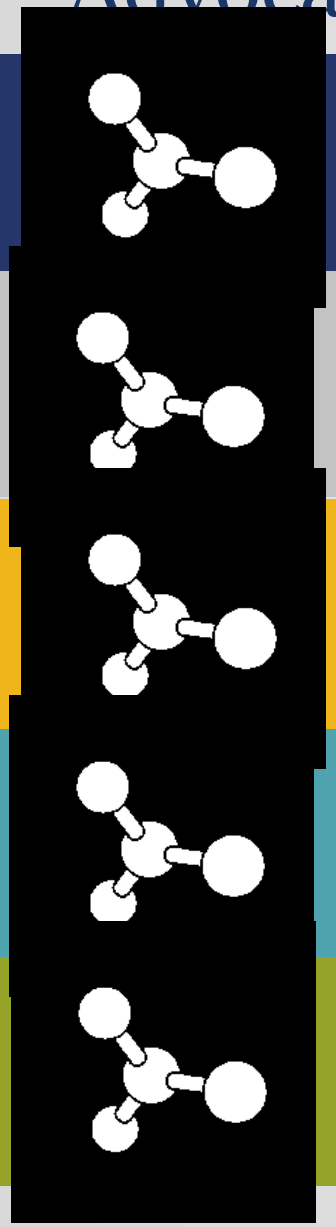
Why Is The IRIS Assessment **Important?**

- The **IRIS assessment** is being used by other EPA regulatory programs, including the Office of Pollution Prevention and Toxics' (OPPT) Toxic Substances Control Act (TSCA) risk evaluation, the Office of Pesticide Programs' (OPP) pesticide re-registration and the Office of Air and Radiation (OAR) as a **baseline for future regulation** on formaldehyde.
- IRIS has **never been authorized** by Congress, and its current approach is **at odds with** Congressional requirements for the Agency to use the **best available science** under the 2016 updates to the TSCA and other laws.
- Despite wide criticisms by the scientific community for its deficiencies and inadequate standards for scientific rigor and impartiality, **EPA is deferring to the 2022 Draft IRIS assessment for formaldehyde**
- EPA, states, and other agencies may use these conclusions to justify permitting, enforcement, monitoring, and regulatory changes for other activities. Unreasonable risk determinations may also drive product or facility litigation.

About: ACC Formaldehyde Panel

- The ACC Formaldehyde Panel represents **producers, suppliers**, and **users of formaldehyde and formaldehyde products**, as well as **trade associations** representing key formaldehyde applications.
- The Formaldehyde Panel's primary activities are **scientific research, regulatory and legislative advocacy, and outreach.**
- The Panel is also committed to **informing and educating** regulators, policymakers, the value chain, and the media on the **weight of the scientific evidence surrounding formaldehyde exposure and safety.**

Advocacy Examples



Engaged with Congressional contacts to educate on formaldehyde and chemical management issues

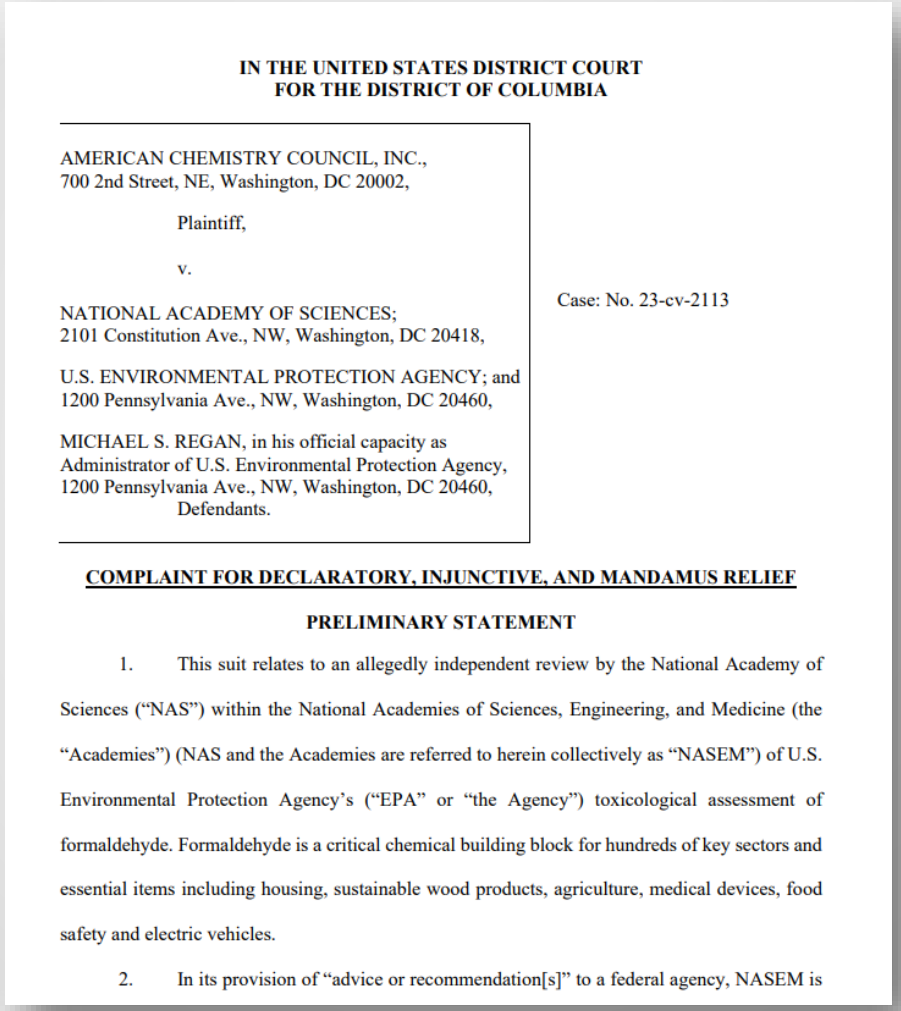
Aggregated company industrial hygiene monitoring data to inform TSCA risk evaluation

Coordinated industry comments to EPA, NAS, HSRB, SACC on their respective formaldehyde reviews

Engaged scientists to conduct research or reviews of the science used as a basis for formaldehyde assessments

Engaged with federal agencies including EPA, SBA, DOD, and FDA to inform formaldehyde assessments

ACC v. NASEM: Challenging the Review of the IRIS Assessment



IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CHEMISTRY COUNCIL, INC.,
700 2nd Street, NE, Washington, DC 20002,

Plaintiff,

v.

NATIONAL ACADEMY OF SCIENCES;
2101 Constitution Ave., NW, Washington, DC 20418,

U.S. ENVIRONMENTAL PROTECTION AGENCY; and
1200 Pennsylvania Ave., NW, Washington, DC 20460,

MICHAEL S. REGAN, in his official capacity as Administrator of U.S. Environmental Protection Agency,
1200 Pennsylvania Ave., NW, Washington, DC 20460,
Defendants.

Case: No. 23-cv-2113

COMPLAINT FOR DECLARATORY, INJUNCTIVE, AND MANDAMUS RELIEF

PRELIMINARY STATEMENT

1. This suit relates to an allegedly independent review by the National Academy of Sciences ("NAS") within the National Academies of Sciences, Engineering, and Medicine (the "Academies") (NAS and the Academies are referred to herein collectively as "NASEM") of U.S. Environmental Protection Agency's ("EPA" or "the Agency") toxicological assessment of formaldehyde. Formaldehyde is a critical chemical building block for hundreds of key sectors and essential items including housing, sustainable wood products, agriculture, medical devices, food safety and electric vehicles.

2. In its provision of "advice or recommendation[s]" to a federal agency, NASEM is

IRIS and TSCA: What We're Seeing

- TSCA requires EPA to conduct a risk evaluation to determine whether a **chemical substance** presents an unreasonable risk of injury to health or the environment, **without consideration of costs or other non-risk factors.**
- "In this draft risk evaluation, **EPA preliminarily finds that formaldehyde presents an unreasonable risk of injury to human health."**
- A final unreasonable risk determination triggers EPA to issue a proposed (1 year later) and final **risk management** rule (2 years later).
- For other chemistries, EPA has proposed **bans and unachievable workplace limits** and rare and **time-limited critical use exemptions** for narrow uses

International Formaldehyde Occupational Exposure Limits

Country	ppb (TWA)
United Kingdom	2000
Australia	1000
South Africa Mining	1000
USA – OSHA	750
Austria	300
Denmark	
European Union	
Finland	
France	
Germany (AGS)	
Germany (DFG)	
Ireland	
Italy	
Latvia	
New Zealand	
Norway	
Romania	
South Korea	
Spain	
Sweden	
Switzerland	
USA EPA Proposed OEV	**11 ppb**

Workplace Limits **Reality Check**

EPA's occupational exposure values for formaldehyde constitute unachievable workplace limits and are an unreasonable starting point for risk evaluation or risk management.

For example, **11 parts per billion** of formaldehyde is:

- Almost **70 times below** OSHA PEL (750 ppb)
- Almost **30 times below** the recently updated European Union occupational limits (300 ppb)
- **Just above** the level of formaldehyde in **exhaled human breath**
- **Below the detection limit** for OSHA-approved formaldehyde analytical methods
- **Below levels** measured in a**mbient air and below levels** seen in typical **U.S. residences**

Potential Impacts of Ongoing Regulatory Activities

- **Possible Changes or Refinements to:**
  - Chemical Composition of Consumer or Commercial Products
  - Procurement and Acquisitions Requirements
  - Product Labeling Requirements
  - Occupational Exposure Limits
  - Air Permitting Requirements
  - Environmental Clean-up Levels

Continued Sustainability and Use of Formaldehyde
What Can You Do?

- Monitor the Regulatory Process
- File Comments with EPA
- Submit Exposure Data to EPA
- Reach Out to Congressional Contacts
- Write Blog Posts, Op-eds, and Letters to the Editor
- Activate and Engage your Customers
- Promote Science-Based Regulation
- Communicate and Collaborate Regularly
- Join the Formaldehyde Panel

Thank You

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Background Slides

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Lifecycle Diagram of Formaldehyde

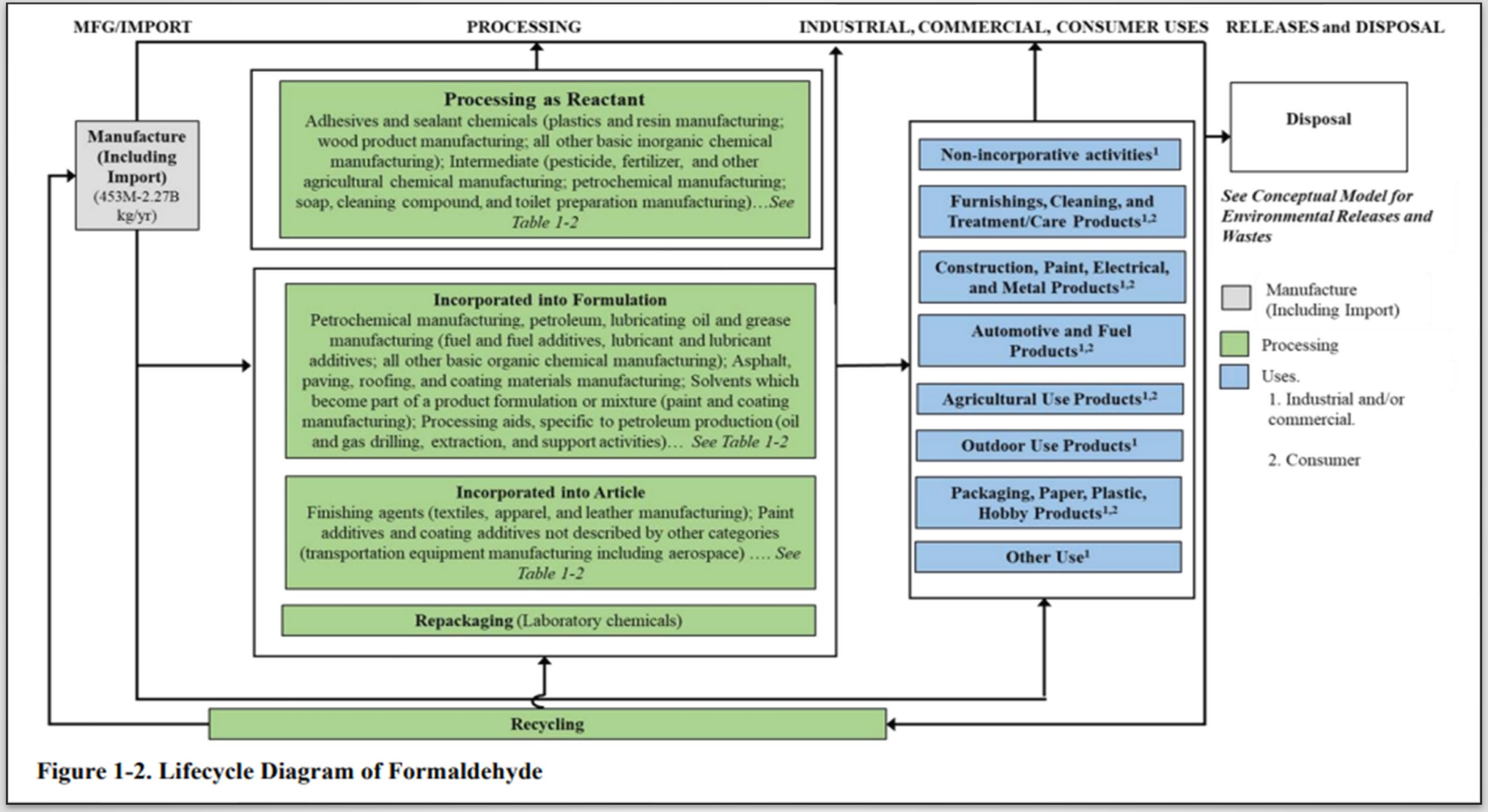

Figure 1-2. Lifecycle Diagram of Formaldehyde

Conditions of Use **In Scope**

- **62** conditions of use (COUs) of formaldehyde were determined to be within the scope of TSCA and assessed by EPA
- EPA determined the majority of these COUs contribute to unreasonable risk
- Examples of COUs considered:
  - Manufacturing of formaldehyde
  - Processing and manufacturing of articles and products
  - Composite wood products
  - Explosive materials
  - Rubber materials
  - Various adhesives and sealants
  - Agricultural chemicals in agriculture, forestry, fishing, and hunting
  - Laboratory chemicals

See *Conditions of Use for the Formaldehyde Risk Evaluation* for a comprehensive list

Not in Scope **Non-TSCA Uses**

EPA did not consider several sources that occur naturally or are regulated by other laws:

Aquaculture, Hatchery, and Animal Feeds

- Embalming and Taxidermy
- Biogenic sources of formaldehyde
- Combustion sources and secondary formation
- Personal care products

As mentioned, there are many formaldehyde sources. Not all sources are considered in the *Draft TSCA Risk Evaluation*, either because they occur naturally or because they are regulated under other statutes. These include

- forest fires;
- combustion[1];
- tail-pipe emissions from cars, trucks, and other vehicles;
- plastic products used for food storage and distribution;
- animal feed;
- biogenic sources (like trees and wood chips);
- secondary formation[2];
- drugs for fisheries and hatcheries;
- pesticides and other formaldehyde uses regulated by the Food and Drug Administration;
- pacifiers and baby bottles; and,
- embalming or as a preservative from funeral homes and taxidermy.

Not in Scope **Reality Check**

Does not ensure that there will be no impact from EPA's risk evaluation and risk management process for these uses:

- EPA still has issued a determination that formaldehyde constitutes an "unreasonable risk" which may trigger regulations under various laws overseen by EPA and other agencies.
- Excluding these uses from the scope does not provide any protection for the upstream and intermediate uses of formaldehyde, which may be subject to bans or unachievable standards, with a corresponding negative impact on cost or availability of formaldehyde-based products (including imports).
- Other bodies, including other parts of EPA and OSHA or state agencies, may use the EPA determinations and accompanying unachievable draft workplace levels (as low as 11 parts per billion) as the basis for regulatory or enforcement actions.
- EPA is required under TSCA Section 9 to work with other agencies to address risks that other agencies oversee.