What You Need to Know **About EPA's Manufacturer-**Requested Risk Evaluations of DIDP and DINP

October 9, 2024

Presented by the American Chemistry Council's High Phthalates Panel

The information in the presentation is provided for informational purposes only and does not constitute legal advice.

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Pre-Webinar Poll

1. Which industrial or commercial activity(ies) describes how you use DIDP or DINP?

2. Which consumer activity(ies) describes how you use DIDP or DINP?

Speakers

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Antitrust Compliance

Do not, in fact or appearance, discuss or exchange information on:

Prices, including:

- Individual company prices, price changes, price differentials, markups, discounts, allowances, credit terms, etc.;
- Individual company data on costs, production, capacity, inventories, sales, etc.; and
- Industry pricing policies, price levels, price changes, differentials, etc.

Production, including:

- Plans of individual companies concerning the design, production, distribution or marketing of particular products, including proposed territories or customers; and
- Changes in industry production, capacity, or inventories.

Transportation rates:

- Rates or rate policies for individual shipments, including basing point systems, zone prices, freight equalization, etc.

Market procedures, including:

- Company bids on contracts for particular products; company procedures for responding to bid invitations; and
- Matters relating to actual or potential individual suppliers or customers that might have the effect of excluding them from any market or influencing the business conduct of firms toward them.

Webinar Agenda

1. Introductions and Antitrust Compliance Reminder
2. Overview of the Manufacturer-Requested Risk Evaluations (MRREs) of DIDP and DINP
3. What Preliminary Determinations Are in the Draft MRREs of DIDP and DINP?
4. What Is Next In the Process?
5. Value Chain Engagement
6. Q+A Session

Why Did ACC File Manufacturer-Requested Risk Evaluations for DIDP and DINP?

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Why Did ACC File Manufacturer-Requested Risk Evaluations for DIDP and DINP?

Product Stewardship

We have confidence in the data and want to confirm the consensus around the safe use of DIDP and DINP as part of our product stewardship commitment.

Education

We want to reinforce that not all phthalates are the same.

Phthalates are categorized as high molecular weight or low molecular weight.

Consumer Confidence

We want to provide regulatory certainty and improve consumer confidence in the safety of high-molecular weight phthalates.

Member Companies

ACC's High Phthalates Panel member companies:

Evonik

ExxonMobil Product Solutions

Teknor Apex

We were the first manufacturers to request a risk evaluation by the EPA

Why TSCA Risk Evaluations of DINP & DIDP are Important

	European Union	Canada	United States
Risk Evaluations	✓ Rigorous assessments (2006 & 2013)	✓ Rigorous assessment (2020)	• Not conducted
Classification / Safety Determination	✓ Safe for existing uses ✓ No hazard classification (ECHA 2018)	✓ Not harmful to human health and the environment	• Not classified
Risk Management Measures	✓ None required ✓ Precautionary restriction in mouthable toys and childcare articles*	✓ None required ✓ Precautionary restriction in mouthable toys and childcare articles*	• Patchwork of State Regulations 

* Restrictions not fully supported by existing science

DIDP and DINP Applications

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DIDP and DINP Applications

DIDP and DINP

- Used primarily as a plasticizer in flexible PVC
- Also used to make:
  - Building & construction materials;
  - Automotive care and fuel products;
  - Other commercial and consumer products including adhesives and sealants, paints and coatings, electrical and electronic products

Overview of TSCA Risk Evaluation Process

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Risk Evaluations – Requirements Under TSCA

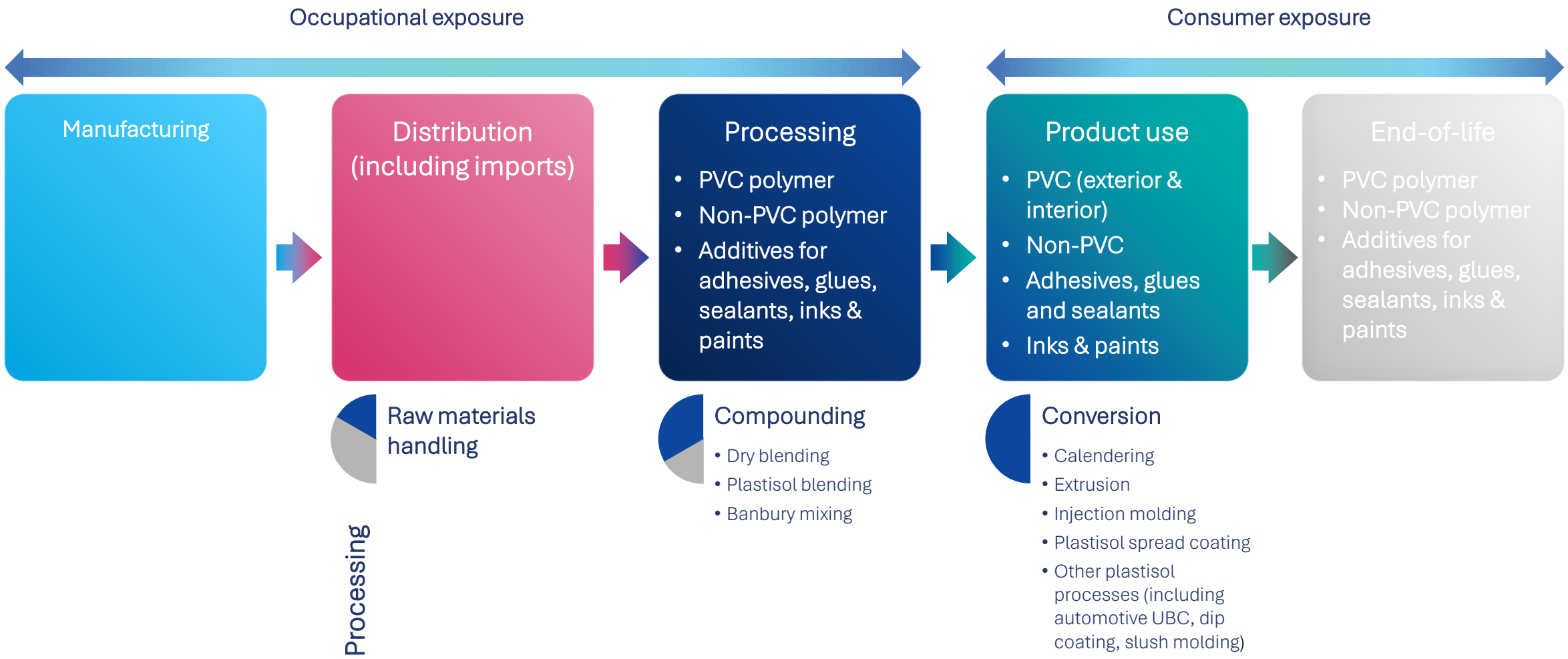
Under TSCA, EPA announces a list of candidate chemicals, initiates prioritization, and makes high-priority or low-priority substance determinations. For those substances designated high priority, EPA must:

- Determine if a chemical presents an unreasonable risk of injury to health or the environment **under the conditions of use including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation**
- Without consideration of cost or other non-risk factors
- Including unreasonable risk to potentially exposed or susceptible subpopulation(s) determined to be relevant to the evaluation

This process must be completed within 3 – 3.5 years.

Additional risk evaluations may come from manufacturer requests.

Scope of TSCA Risk Evaluation is Broad



EPA examined 47 conditions of use for **DIDP and DINP**

How Did We Get Here?

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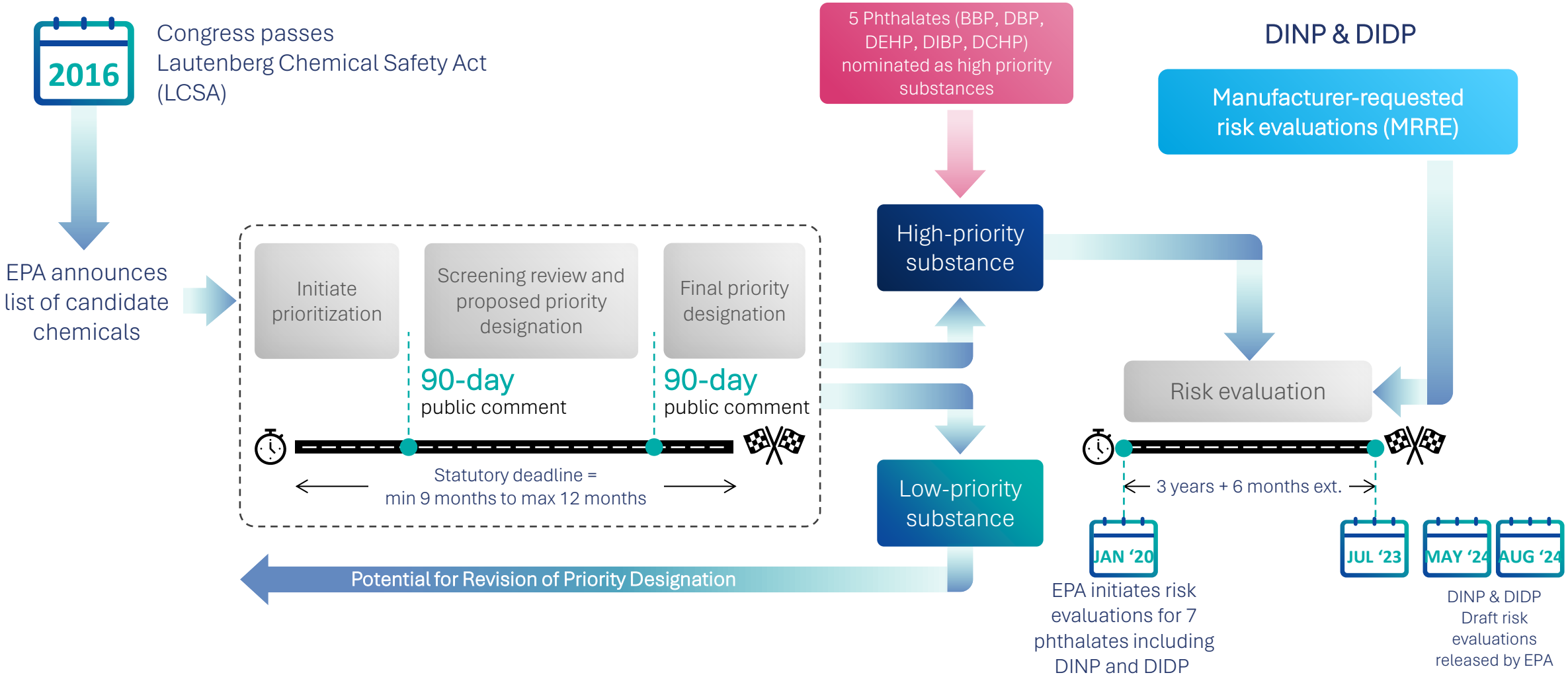
EPA-initiated and Manufacturer-requested Risk Evaluations Follow the Same Process after EPA Accepts a Manufacturer Request

- The MRRE process is not an expedited review.
- A MRRE must include all available information on relevant health and environmental hazards and exposures and exposed populations, as relevant to the circumstances identified in the request, including: the chemical substance's hazard and exposure potential; the chemical substance's persistence and bioaccumulation; any relevant potentially exposed or susceptible subpopulations; information on storage near sources of drinking water, the chemical substance's production volume or significant changes in production volume.
- After a 45-day public comment period, EPA will grant a MRRE only if it determines it has all the information needed to conduct a risk evaluation on the conditions of use that were the subject of the request. EPA will identify other conditions of use that warrant inclusion in the risk evaluation.
- Under TSCA, EPA has 3 years + 6 months extension to complete risk evaluations under both the EPA-initiated high-priority substance process or the MRRE process
- EPA may issue test orders under the High Priority Risk Evaluation process while under the MRRE process it acknowledges upon acceptance of the request that it has all the information needed to conduct the MRRE.
- EPA is required under both the EPA-initiated and manufacturer-requested risk evaluation processes to
  - 1) evaluate hazard and exposure;
  - 2) exclude consideration of costs or other non-risk factors;
  - 3) use scientific information and approaches in a manner that is consistent with the requirements in TSCA for the best available science; and
  - 4) ensure decisions are based on the weight-of-scientific-evidence.

Industry Self-selects DINP & DIDP for EPA Toxic Substances Control Act (TSCA) Risk Evaluation Process



Why Did the ACC High Phthalates Panel Sue EPA?

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Why ACC's High Phthalates Panel Sued EPA

Missing Statutory Deadline

EPA missed the statutory deadline to complete the MRREs under TSCA.

The mandatory deadline is 3 years and 6 months from the date EPA initiated the risk evaluations.

Regulatory Certainty

This assessment of safety is important for manufacturers and businesses of these important products.

Consumer Confidence

This assessment of safety is also important for consumers.

The lawsuit served to remind EPA that it is its duty to complete the risk evaluations.

Timeline of MRREs

- **January 2020**: EPA initiated risk evaluations for DIDP and DINP
- **January 2023**: 3-year statutory deadline
- **July 2023**: Statutory extension deadline (+6 months)
- **September 2023**: Notice of Intent to File Suit for EPA to complete MRREs
- **December 2023**: Suit filed
- **May 2024**: EPA releases draft risk evaluation for DIDP and draft hazard assessments for DINP
- **September 2024**: EPA releases draft risk evaluation for DINP


ACC Submits a Notice of Intent to File Suit for EPA to Complete Manufacturer-Requested Risk Evaluations

EPA Misses Statutory Deadline to Complete Reviews for DINP and DIDP


ACC's High Phthalates Panel Statement on EPA's Draft Risk Evaluation for DIDP and Draft Hazard Assessments for DINP


ACC's High Phthalates Panel Statement on EPA's Draft Risk Evaluation for DINP

EPA's Preliminary Determinations in the Draft Risk Evaluations of DINP and DIDP

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Preliminary Determinations from Draft Risk Evaluations

DIDP

46/47

Conditions of use are safe

Does not pose unreasonable risk of injury to human health for consumers, the general population, or the environment

[DIDP Draft Risk Evaluation]

DINP

44/47

Conditions of use are safe

Does not pose unreasonable risk of injury to human health for the general population or the environment

1

unreasonable risk scenario preliminarily identified for consumers

[DINP Draft Risk Evaluation]

EPA's Preliminary Determination of Unreasonable Risk for One Consumer Use of DINP Is Unfounded

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One Consumer Use of DINP

EPA preliminarily found that one consumer use of DINP contributes significantly to unreasonable risk: the use of DINP in floor coverings and construction and building materials covering large surface areas, such as vinyl flooring, in-place wallpaper and carpet backing.

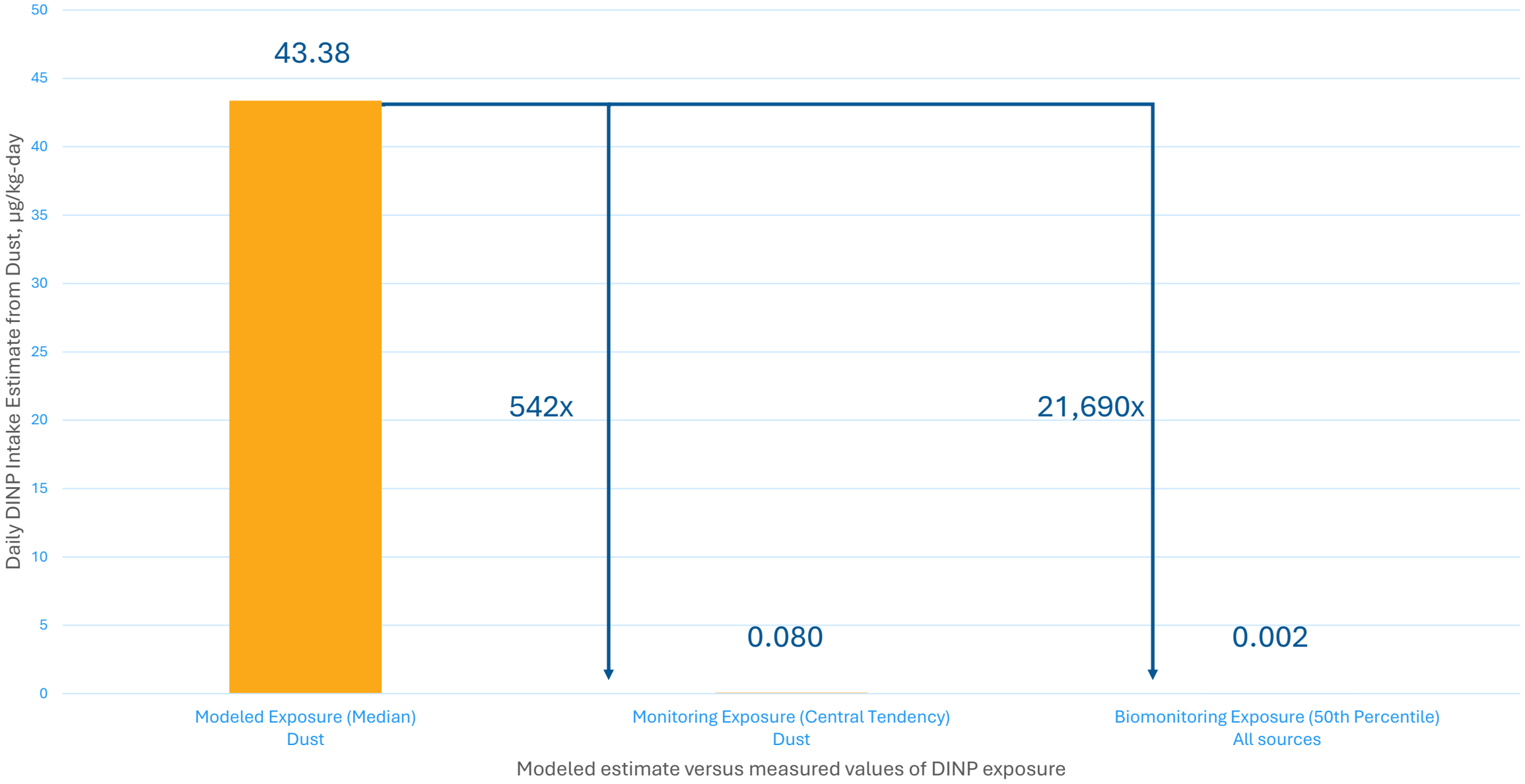
- EPA found this use is estimated to significantly contribute to the unreasonable risk of DINP to infants, toddlers and preschool children under the age of five to dust containing DINP that migrated from these materials via the air, direct contact, or both.

The EPA assumptions are overly conservative, and there are significant differences between the EPA-estimated dust exposures, published monitoring exposures, and CDC NHANES published exposures.

- The ACC High Phthalates Panel is conducting an analysis of the exposure models and inputs and will submit comments to explain why the contribution of DINP to indoor air and suspended dust is much lower than predicted by conservative models, as demonstrated in the literature.

EPA Over Estimates Exposure

EPA's modeled values over estimate dust exposures by 500 to 22,000 times measures values



EPA's Preliminary Determination of Unreasonable Risk for Two Worker Uses of DINP Is Unfounded

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Two Worker Uses of DINP

The two worker uses that EPA preliminarily determined contribute significantly to the unreasonable risk to workers involved **unprotected workers using spray adhesives and sealants or paints and coatings that contain DINP with high-pressure sprayers**.

- EPA found that using these sprayers could create high concentrations of DINP in mist that an unprotected worker could inhale.

EPA was not able to identify products containing DINP that are currently used in such high-pressure spray applications and the HPP understands **DINP is not currently used in such applications**.

- The exposure scenarios are unrealistic – no worker would perform this without PPE

EPA's Preliminary Determination of Unreasonable Risk for One Worker Use of DIDP Is Unfounded

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One Worker Use of DIDP

The one condition of use EPA determined contributes to unreasonable risk for DIDP is **if unprotected workers were to spray adhesives and sealants that contain DIDP with high-pressure sprayers**, because EPA alleges, doing so could create high concentrations of DIDP in mist that an unprotected worker could inhale.

As with the assumptions EPA makes about the use of DINP with high-pressure spray applications, **EPA was not able to identify products containing DIDP** that are currently used in high-pressure spray applications and **the HPP understands that DIDP is not currently used in such high-pressure spray applications**.

Application of adhesives and sealants (DIDP/DINP) or paints and coatings (DINP) using high pressure spray applications

EPA does not consider PPE in risk assessment

Concern is driven by assumption of high concentrations of DINP/DIDP mist in the workers' breathing space

EPA assumes exposure for 8 hours a day for nearly a year in this activity.

EPA has not Yet Incorporated Recommendations from the SACC or Public Comments (SACC Report Released October 2024)

EPA Preliminary Conclusions		Peer review / Public comments
DINP is Not Likely to be Carcinogenic to Humans at doses below levels that do not result in PPARα activation (KE1)	SACC recommendation	DINP is Not Likely to be Carcinogenic to Humans
Unreasonable risk to unprotected workers using spray adhesives and sealants (DINP/DIDP) or paints and coatings (DINP) with high-pressure sprayers	Value chain input	High pressure sprayers are not utilized by workers in these applications for DINP/DIDP containing products
Unreasonable risk to infants and children under 5 who may be exposed to dust containing DINP (e.g. from vinyl flooring, wallpaper, or carpet backings)	ACC input	Models used over-estimated concentrations of DINP in dust, and exposures calculated are several orders of magnitude greater than measured values reported in the literature

Next Steps

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Next Steps

Comment Period

The EPA draft risk evaluation for DINP was released on August 30, 2024.

The comment deadline is November 4, 2024.

Comment Submissions

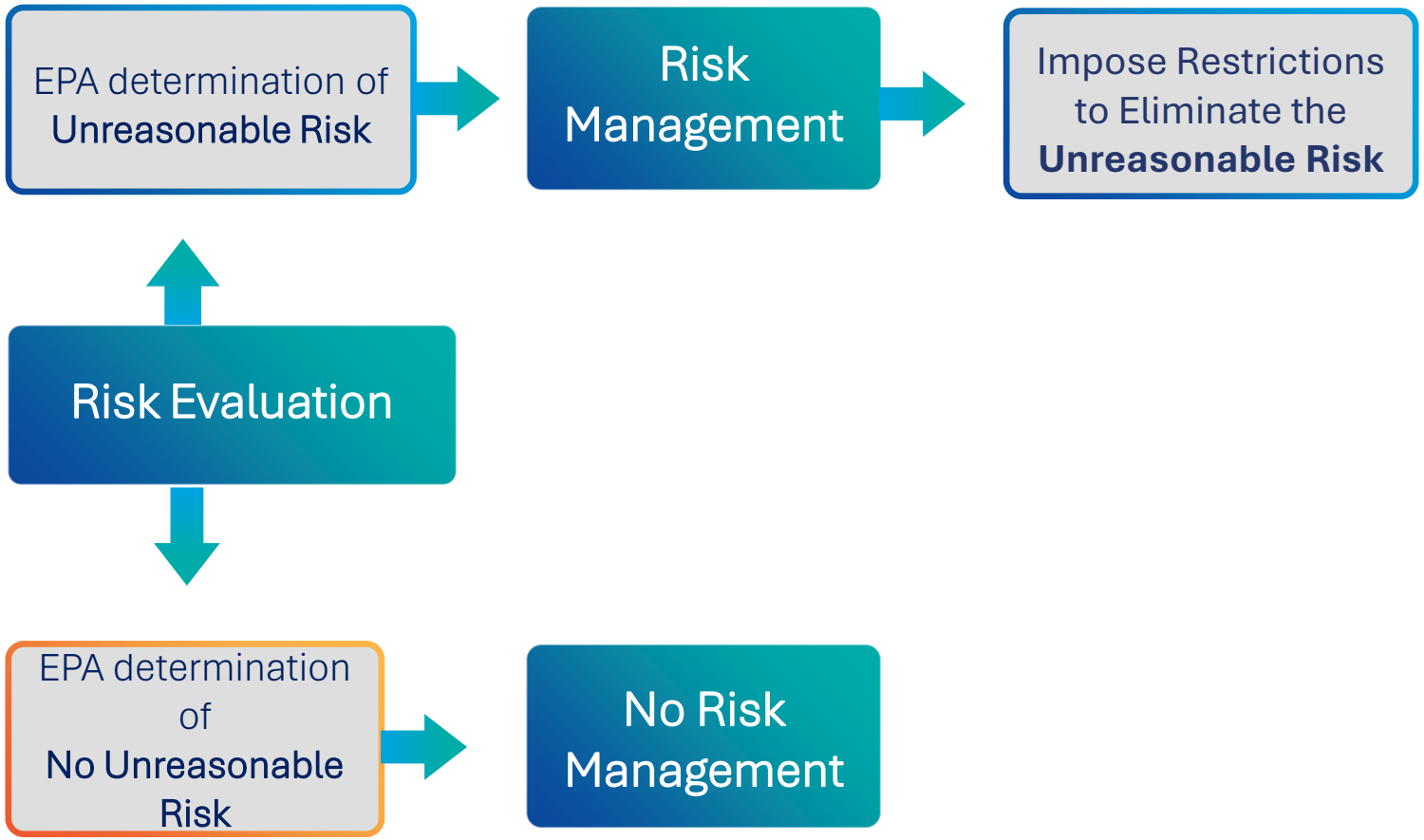
ACC's High Phthalates Panel will provide comment to EPA on exposure estimates.

Members of the value chain with information on the high-pressure spray use of paint or adhesives and sealants should consider commenting.

Final Risk Evaluations

EPA is expected to issue final risk evaluations for DIDP and DINP by December 31, 2024.

Typical Outcome of an EPA Risk Evaluation



Actions may include:

- Prohibit substance
- Concentration limits
- Require warnings and instructions
- Require recordkeeping, monitoring, or testing by manufacturers and processors.
- Prohibit or regulate manner or method of commercial use.
- Prohibit or regulate manner or method of disposal.
- Notifications

Any risk management actions would apply only to the condition(s) of use that EPA found to present an unreasonable risk in the final risk evaluation. Those that EPA found do not present an unreasonable risk will not be subject to risk management.

[Risk Management for Existing Chemicals under TSCA | US EPA]

Possible Risk Management for DINP or DIDP

EPA will initiate risk management if it determines in the final risk evaluations that any of:

- the industrial spray applications identified; or
- the consumer uses identified in building materials covering large surface areas contribute to unreasonable risk.

Risk management would likely not be a chemical-specific ban of any type but *could* result in some product use restrictions specific only to those conditions of use EPA finds contribute to unreasonable risk.

Non-TSCA Uses

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Non-TSCA Uses: Food Contact Materials

High phthalates are approved by several food safety regulatory agencies, including the U.S. Food and Drug Administration (FDA) and EU's European Food Safety Authority (EFSA), for use in some food contact products, such as conveyor belts used in food processing.

The Recent Regulatory Decisions Regarding Food Contact Have Been Positive

EFSA 2019

Exposures for all age groups are fall below the Tolerable Daily Intake (TDI) set for phthalates authorized in food contact.

Canada 2020

Analyzed all current applications including food contact and found phthalates as currently used are not harmful to the environment or to human health.

US FDA 2022

In denying two petitions seeking to revoke food contact authorizations for all phthalate plasticizers (including DINP and DIDP), the FDA stated that “based on the information currently available to FDA, we do not have a basis to conclude that dietary exposure levels from approved ortho-phthalates exceed a safe level.”

All the Food Safety Evaluations Conducted by Regulators Have Found DINP and DIDP Pose No Health Risks in Food

> 20x

below safe limit in diet

European Food Safety Authority

SAFE for use

in food contact applications

U.S. Food and Drug Administration

Value Chain Engagement

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Value Chain Engagement

- Please consider providing comments to EPA to help inform the agency on the composition of carpet tiles, floor tiles, or wallpaper.
    - For carpet tiles, for example, DINP is in the backing, not on the top.
- Comments are due to EPA **by November 4, 2024**.
- The docket number is **EPA-HQ-OPPT-2018-0436-0057** and submit a comment to https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0436-0057.

Post-Webinar Poll

1. Was the information provided today helpful? Yes or No?
2. Did the speakers answer all your questions? Yes or No?
3. Would you like someone from ACC's High Phthalates Panel to contact you with more information? Yes or No?

Thank You!

The information in the presentation is provided for informational purposes only and does not constitute legal advice.

For more information, please reach out to Eileen Conneely at Eileen_Conneely@americanchemistry.com and visit www.phthalates.org