



June 14, 2022

DINP and DIDP TSCA Risk Evaluations: Potential Impact



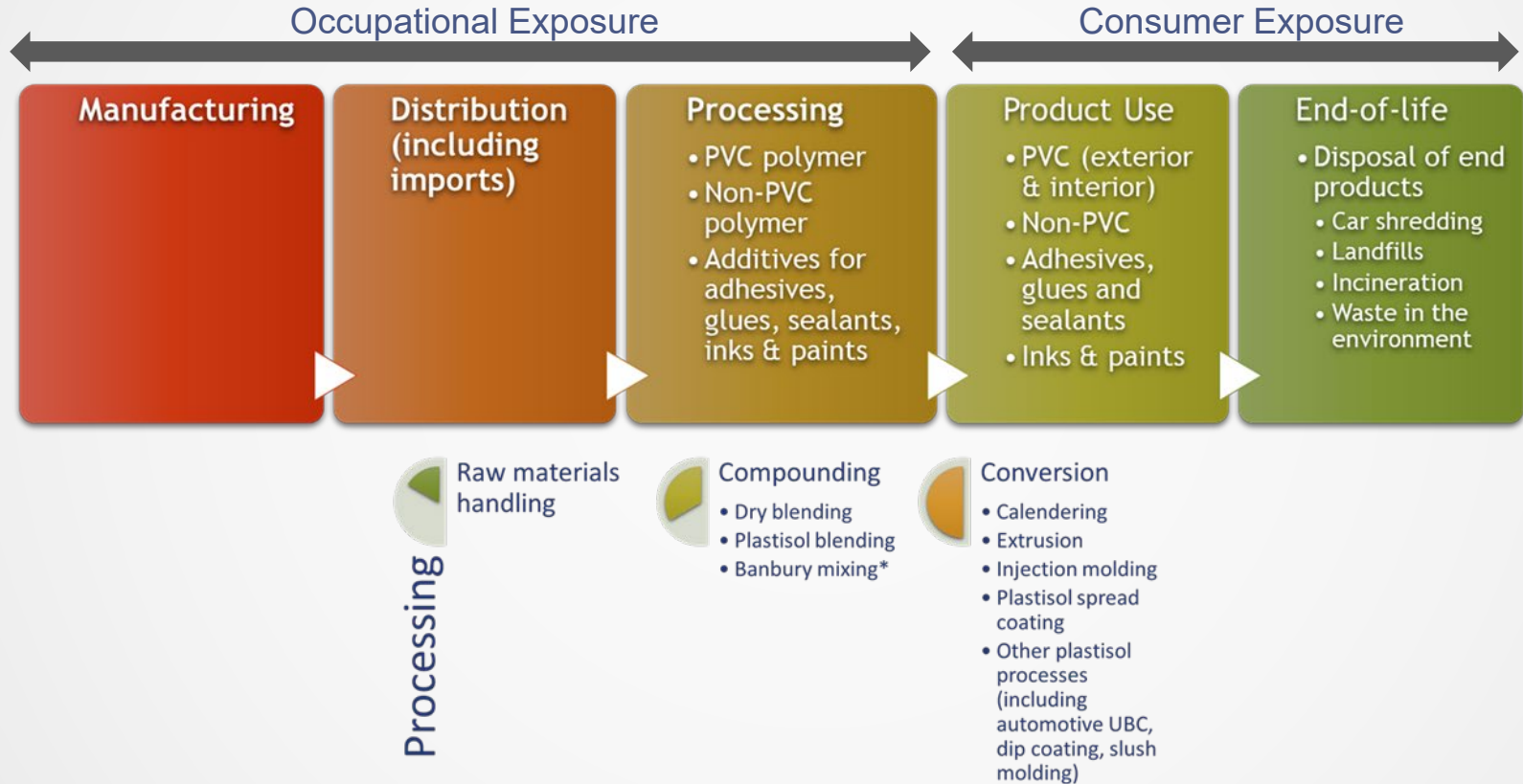
Background

History of the TSCA Risk Evaluations for DINP/DIDP



- **2016 – Congress passes Lautenberg Chemical Safety Act (LCSA)**
 - Requires risk evaluations for all chemicals on the TSCA inventory
 - EPA to designate chemicals as **high priority** for risk evaluation or **low priority**
 - Manufacturers can also directly petition EPA for a risk evaluation
- **EPA process for risk evaluation for chemicals designated high priority/manufacturer-requested risk evaluations:**
 - Determine if a chemical presents an **unreasonable risk** of injury to health or the environment under conditions of use
 - 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*
- **7 ortho-phthalates (including DINP & DIDP) on the TSCA Work Plan**
 - Since 50% of high priority chemicals must come from TSCA Work Plan list it is likely each Work Plan phthalate would eventually undergo risk evaluation
- **ACC HPP submits manufacturer requests for risk evaluation in 2019**
 - EPA grants requests **December 2, 2019**

Scope of TSCA Risk Evaluation is Broad



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 use ✓ No hazard classification (ECHA 2018)	✓ Not harmful to human health and the environment	• Not classified
Risk Management Measures	✓ None required ✓ Precautionary restricts in mouthable toys and childcare articles*	✓ None required ✓ Precautionary restricts in mouthable toys and childcare articles*	• Patchwork of State Regulations [§] 

* Restrictions not fully supported by existing science

**The Science Points to
a Positive Outcome**



ECHA 2013 Risk Evaluation

Current uses found safe



“No further risk management measures are needed to reduce the exposure of children to DINP and DIDP”

- ✓ Flooring
- ✓ Wire and cable
- ✓ Automotive interiors
- ✓ Wall coverings
- ✓ Roofing
- ✓ Adhesives





Environment & Climate Change Canada 2020 assessment

“14 substances in the original Phthalate Substance Grouping [including DINP and DIDP] are not harmful to the environment or to human health as set out in section 64 of CEPA.”



- ✓ Flooring
- ✓ Wire and cable
- ✓ Automotive interiors
- ✓ Wall coverings
- ✓ Roofing
- ✓ Toys/childcare articles
- ✓ Adhesives



A red marker is shown drawing a checkmark inside a square box on a checklist. The checklist has several other empty boxes above and below it. The background is white.

The Recent Regulatory Decisions Regarding Food Contact Have Been Positive

EFSA 2019 – exposures for all age groups are fall below the Tolerable Daily Intakes (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.”

Possible Scenarios

Risk Evaluation Scenario	Description	Estimated Probability
Scenario A	<ul style="list-style-type: none">○ No risk determination for all occupational and consumer end uses for DINP & DIDP	Medium-Low
Scenario B	<ul style="list-style-type: none">○ No risk determinations for all consumer end uses;○ Occupational uses without PPE determined to have some risk;○ Geographical impact – Limited to US	Medium-High
Scenario C (existing scenario today)	<ul style="list-style-type: none">○ No risk determinations for all DIDP consumer end uses;○ Risk determinations for legacy uses* for DINP;○ Occupational risk determination(s) remain;○ Geographical impact – Limited to US	Low-Medium

Potential Timeline

2019

2020

2023

December 2, 2019:
EPA Accepts
Manufacturer-
requested
risk evaluations
for DINP and
DIDP

January 2,
2020: Risk
evaluations
commence for
DINP and DIDP
– EPA has 3
years to
complete

January 2,
2023: Risk
evaluations
expected
to be
completed
by EPA

July 2, 2023:
Anticipated
completion
date if EPA
uses
statutorily-
granted
6 month
extension for
completion

Example TSCA Risk Summary Tables - HBCD

Table 4-27. Occupational Risk Summary Table

Life Cycle Stage/Category	Subcategory	Occupational Exposure Scenario (#)	Population	Exposure Route	Sub-Scenario Exposure Level	Risk Estimates for No PPE		Risk Estimates with PPE	
						Acute Non-Cancer (benchmark MOE = 100)	Chronic Non-Cancer (benchmark MOE = 300)	Acute Non-Cancer (benchmark MOE = 100)	Chronic Non-Cancer (benchmark MOE = 300)
Manufacture - Import	Import	Section 2.4.1.2 – Repackaging of Import Containers (1)	Workers	Inhalation	High-End	38	10	191 (APF 5)	519 (APF 50)
					Central Tendency	81	39	406 (APF 5)	394 (APF 10)
				Dermal	High-End	4	1	Exposure not expected with impervious gloves	
					Central Tendency	12	2		
Processing - Incorporated into formulation, mixture or reaction product	Flame retardants used in custom compounding of resin (e.g., compounding in XPS masterbatch) and in solder paste	Section 2.4.1.3 – Compounding of Polystyrene Resin to Produce XPS Masterbatch (2)	Workers	Inhalation	High-End	29	33	144 (APF 5)	1635 (APF 50)
					Central Tendency	58	112	289 (APF 5)	560 (APF 5)
				Dermal	High-End	4	4	Exposure not expected with impervious gloves	
					Central Tendency	12	7		
	Section 2.4.1.12 – Formulation of Flux/Solder Pastes (11)	Workers	Inhalation	High-End	29	8	144 (APF 5)	392 (APF 50)	
				Central Tendency	58	31	289 (APF 5)	1533 (APF 50)	
			Dermal	High-End	4	1	Exposure not expected with impervious gloves		
				Central Tendency	12	2			
Processing - Incorporated into articles	Flame retardants used in plastics product manufacturing (manufacture of XPS and EPS foam;	Section 2.4.1.4 – Processing of HBCD to produce XPS Foam using XPS Masterbatch (3)	Workers	Inhalation	High-End	328	1394	1642 (APF 5)	6970 (APF 5)
					Central Tendency	903	6813	4515 (APF 5)	34065 (APF 5)
				Dermal	High-End	5	22	Exposure not expected with impervious gloves	
					Central Tendency	18	39		

Example TSCA Risk Summary Tables - HBCD

Table 4-28. Highly Exposed General Population/Consumer Risk Summary Table

Life Cycle Stage/Category	Subcategory	Exposure Scenario (#)	Population	Exposure Route	Sub-Scenario Exposure Level	Risk Estimates			
						Acute Non-Cancer (benchmark MOE = 100)	Chronic Non-Cancer (benchmark MOE = 300)		
Manufacture - Import	Import	Repacking of Import Containers (1)	General Population (Highly Exposed)	Air Inhalation	Moderate	37630	>16800		
				Fish Ingestion	Highest	1307		13493	
Processing - Incorporated into formulation, mixture or reaction product	Flame retardants used in custom compounding of resin (e.g., compounding in XPS masterbatch) and in solder paste	Compounding of Polystyrene Resin to Produce XPS Masterbatch (2)	General Population (Highly Exposed)	Air Inhalation	Moderate	209835	>16800		
				Fish Ingestion	Highest	128508		42626	
		Formulation of Flux/Solder Pastes (11)	General Population (Highly Exposed)	Air Inhalation	Moderate	15033	32594	>16800	
				Fish Ingestion	Highest	1763	32594		
	Processing of HBCD to produce XPS Foam using XPS Masterbatch (3)	General Population (Highly Exposed)	Air Inhalation	Moderate	119229	>16800			
			Fish Ingestion	Highest	39092				
Processing - Incorporated into articles	Flame retardants used in plastics product manufacturing (manufacture of XPS and EPS foam; manufacture of structural insulated panels (SIPs) and automobile replacement parts from XPS and EPS foam)	Processing of HBCD to produce XPS Foam using XPS Masterbatch (3)	General Population (Highly Exposed)	Air Inhalation	Moderate	20056	>16800		
				Fish Ingestion	Highest	2743		48741	
		Processing of HBCD to produce XPS Foam using HBCD Powder (4)	General Population (Highly Exposed)	Air Inhalation	Moderate	7187	48741	>16800	
				Fish Ingestion	Highest	509	15499		
		Processing of HBCD to produce EPS Foam from Imported EPS Resin Beads (5)	General Population (Highly Exposed)	Air Inhalation	Moderate	39449	>16800		
				Fish Ingestion	Highest	2622		52951	
	Processing of HBCD to produce SIPs and Automobile Replacement Parts from XPS/EPS Foam (6)	General Population (Highly Exposed)	Air Inhalation	Moderate	14541	52951	>16800		
			Fish Ingestion	Highest	1308	27971			
	Processing - Recycling	Recycling of XPS and EPS foam, resin, panels containing HBCD	Recycling of XPS Foam and Reuse of XPS Foam (10)	General Population (Highly Exposed)	Air Inhalation	Moderate	4705	>16800	
					Fish Ingestion	Highest	680		5376
					Air Inhalation	Moderate	154878		>16800
					Fish Ingestion	Highest	139		
Air Inhalation					Moderate	14212	>16800		
Fish Ingestion					Highest	922			23422
Processing - Recycling	Recycling of XPS and EPS foam, resin, panels containing HBCD	Recycling of XPS Foam and Reuse of XPS Foam (10)	General Population (Highly Exposed)	Air Inhalation	Moderate	140770	>16800		
				Fish Ingestion	Highest	38255		34063	
Processing - Recycling	Recycling of XPS and EPS foam, resin, panels containing HBCD	Recycling of XPS Foam and Reuse of XPS Foam (10)	General Population (Highly Exposed)	Air Inhalation	Moderate	7939	20463		
				Fish Ingestion	Highest	764		20463	

Life Cycle Stage/Category	Subcategory	Exposure Scenario (#)	Population	Exposure Route	Sub-Scenario Exposure Level	Risk Estimates	
						Acute Non-Cancer (benchmark MOE = 100)	Chronic Non-Cancer (benchmark MOE = 300)
	Recycling of electronics waste containing HIPS that contain HBCD	Recycling of electronics waste containing HIPS (13)	General Population (Highly Exposed)	Air Inhalation	Relative Risk ^b	>680	>16800
Distribution - Distribution	Distribution	Activities related to distribution (e.g., loading, unloading) are considered throughout the life cycle, rather than using a single distribution scenario					
Commercial/consumer use - Building/construction materials	Plastic articles (hard: construction and building materials covering large surface areas (e.g., XPS/EPS foam insulation in residential, public and commercial buildings, and other structures) and solder paste	Installation of XPS/EPS Foam Insulation in Residential, Public, and Commercial Buildings, and Other Structures (8)	General Population (Highly Exposed)	Air Inhalation	Moderate	77282	>16800
				Fish Ingestion	Highest	62609	
	Use of Flux/Solder Pastes (12)	General Population (Highly Exposed)	Dust/Indoor air	Single Scenario	35411	22722	>16800
			Air Inhalation	Moderate	222576	221704	
Commercial/consumer use - Other	Automobile replacement parts	Installation of Automobile Replacement Parts (7)	Consumers	Dust/indoor air	Single Scenario	11259	52020
				Mouth of articles containing HBCD	Consumers	Mouth of articles	Single Scenario
	Formulated products (e.g., adhesives and coatings) and articles (e.g., textiles, electrical and electronic products)	General Population Background Exposure	General Population	Multiple	Central Tendency	N/A ^a	>42129
					High-End	N/A ^a	>9959
Disposal - Disposal	Other land disposal (e.g., construction and demolition waste)	Demolition and Disposal of XPS/EPS Foam Insulation Products in Residential, Public and Commercial Buildings, and Other Structures (9)	General Population (Highly Exposed)	Air Inhalation	Moderate	224448	>16800
				Fish Ingestion	Highest	10310	
						254	3388

^a Background general population exposures are only relevant to chronic hazards.

^b Exposure estimates were not formally calculated for this COU. Risk was estimated by comparing releases and potential MOEs relative to worst-case sub-scenarios.

^c Background general population exposures are only relevant to chronic hazards.

Any Questions?



Thank You

For more information:
eileen_conneely@americanchemistry.com

