CosPaTox (Cosmetic Packaging Toxicology Consortium)

Safety Evaluation Guidance for the Use of Post-Consumer Plastic Recyclates (PCR) in Cosmetic and Detergent packaging

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The CosPaTox guideline – Intended audience

Who is the guideline intended for?

- **Brand owners** intending to use PE or PP recyclates in packaging
- **Packaging manufacturers** intending to include PE or PP recyclates in their products for cosmetics and home care products
- **Recyclers** intending to offer PE or PP recyclates for use in cosmetics and home care product packaging applications
- **Analytical laboratories** intending to analyze recycled PE or PP
- **All other stakeholders** interested in the safety assessment of recycled PE and PP for cosmetic product and home care packaging

CosPaTox guideline download link

What did CosPaTox deliver?

Voluntary industry guideline enables the whole value chain of recyclers, converters, and brand owners to speak one language when it comes to recycled packaging safety.

It will **harmonize the market and allow for more recyclers to provide material at a high purity level**, as the guideline outlines what to test, how to test and how to assess the results.

Guideline delivers **novel test method for analyzing PCR** and state-of-the-art toxicological risk assessment principles for the whole value chain > **highly defensible if challenged by authorities**

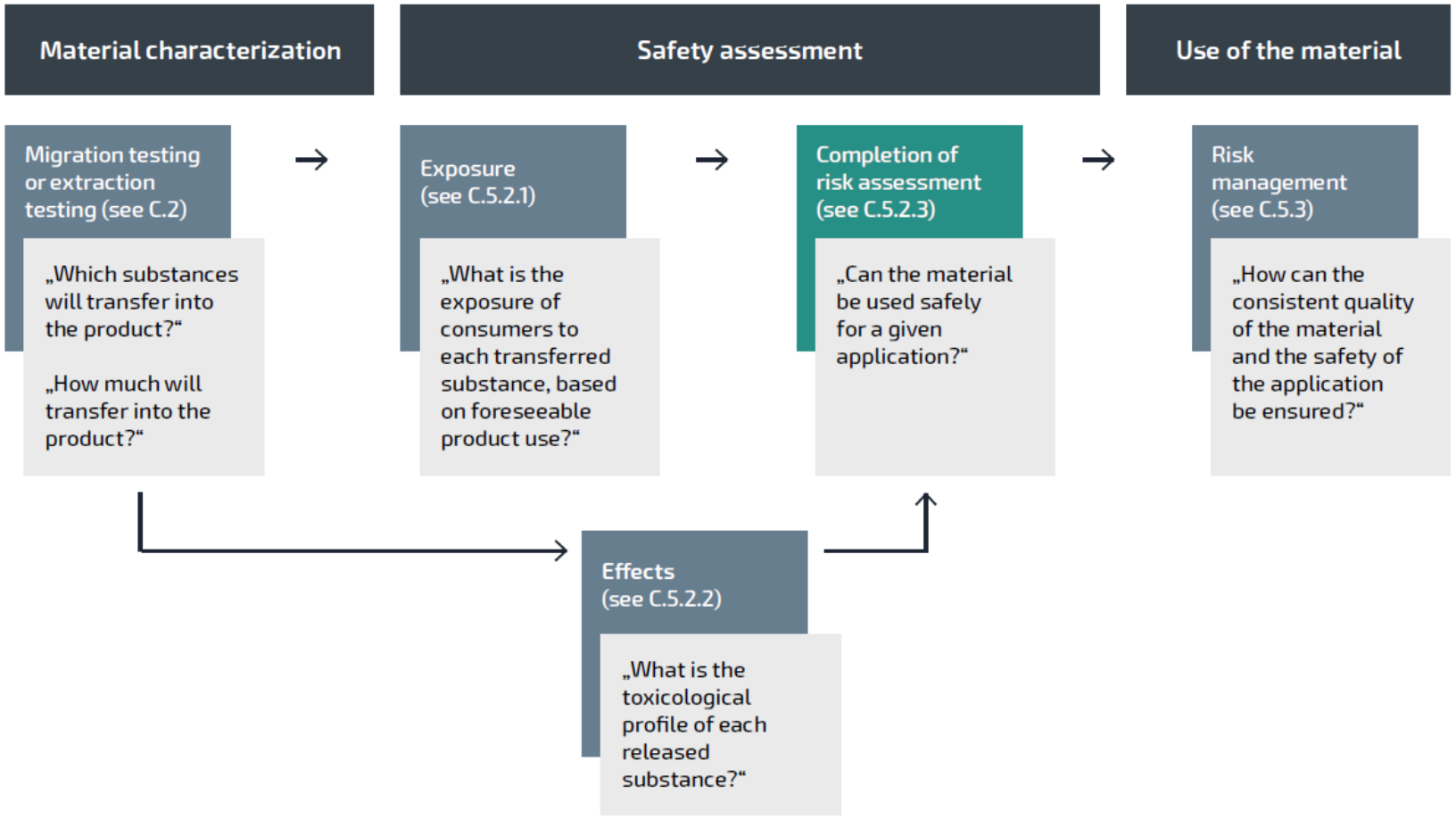
On-site qualification in a much shorter time using **pellets** is possible now

Defines basic quality management guidelines for recyclers – prerequisite to increase PCR quota to PPWR - (every lot is unique)

CosPaTox has shown that **for rinse-off and detergent grade applications mechanically recycled PCR can be safely used**.

Figure 1

Overview of the safety assessment and risk management process for recycled plastic materials.



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-Analytical Testing-

Sample preparation

HDPE

PP

LDPE

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Ring study – Experimental Design to Investigate Pellets

exp. design #	Variant „P1“	Variant „P2“	Variant „P3“	Variant „P4“
material + solvent / ratio	1g + 1ml	1g + 1ml	1g + 1ml	1g + 1ml
solvent	dichloromethane	ethanol 95%	ethanol 95	ethanol 50
extraction	./.	./.	./.	./.
concentration	./.	./.	./.	./.
incubation	3d / 40°C	3d / 60°C	10d / 60°C	3d / 60°C
injection volume	1µl	1µl	1µl	1µl
iSTD	Tridecan	Tridecan	Tridecan	Tridecan
…	BHA	BHA	BHA	BHA
…	DEHP d4	DEHP d4	DEHP d4	DEHP d4

Analytical Testing Results:

Pellets can be used for testing instead of having to blow-mold bottles saving time . Extraction testing on pellets of recycled plastic material yielded a strong overestimate of migration, while migration testing on pellets provided comparable results to testing on finished packaging articles.

A wide range of substances were detected, indicating the requirement for a nontargeted screening in addition to targeted analyses.

PCR plastic materials were found to potentially contain substances not directly related to the packaging material (for example originating from food, filling goods or nonpackaging products in the recycling input), suggesting a need for an better washing steps before using recycled plastics.

Table 2: Substance groups (excerpt) identified in extraction and migration testing of PE and PP recyclates, sorted by frequency of detection.

Substance group	Remarks	Likely major origin		
		PE/PP packaging	Product residue	Foreign sources[44]
Aliphatic compounds / Alkanes		X		
Fatty acids/esters		X	X	
Flavors/Aromas/ Fragrances			X	
Natural compounds			X	
Antioxidants	Antioxidants are used in plastics but also in filling goods (incl. some foods)	X	X	X
Salicylates	Possibly degradation products of fragrance compounds		X	
Benzoates	Possibly degradation products of fragrance compounds		X	
Plasticizers (phthalate)				X
Fatty acid derivatives (non-ester)			X	
UV filters	Likely from sunscreens or UV resistant packaging	X	X	
Plasticizers (non-phthalate)		X		X
Agricultural chemicals			X	
Photoinitiators	May originate from UV curing printing inks; UV adhesives also a possibility	X		X
Naphthalenes	Possibly degradation products of fragrance compounds		X	

Anilines	Possibly degradation products of azo dyes	X		X
Polyamide related substances	May originate from PA plastics in the input			X
Polycyclic aromatic hydrocarbons (PAH)	May originate from (certain) black pigments in plastics	X		X
PET related and polyesters	Likely related to PET plastics in the input			X
Chlorinated substances	May originate from chlorinated polymers in the recycling input or high temperature cross-reaction with salt in the input		X	X
Flame retardants				X
Pharmaceuticals			X	
Styrene-related	Likely related to PS plastics in input			X
Parabenes			X	
Acrylics		X		
Fluorinated substances				X
Food related substances			X	
Silicon compounds				
Bisphenol-A (BPA)				X
Plastic additives		X		
Cosmetic products related substances			X	
Nitriles	Potentially related to nitrile rubbers in input			X
PEG/PPG related substances			X	
Disinfectants			X	
Nitro compounds				
Pigments		X		

What does CosPaTox provide further?

- **CosPaTox has identified more than 180 unique substances through analytical testing- Most of these substances are of no concern to consumers when it comes to exposure to the product**

  - SOI (substance of interest) List that contains all chemicals regularly found, as well as the ones regulated and under scrutiny. The list contains latest risk values as published by ECHA and also explains where the TTC concept needs to be applied.

  - Example calculation tool to quickly assess if a material can be qualified. Need to develop a more sophisticated version though!
  - Worst-case exposure calculation template is provided. Gives the whole industry a common understanding of what is needed to ensure safe packaging and hence a safe product.

SUBSTANCE			ORAL, SYSTEMIC					corresponding product concentration for default quality levels		
Chemical Gr	Molecule	CAS (combined)	Source	Descript	ValueOralSystemic	Units	Date of Entry	QL 1 (mg/m	QL 2 (mg/	QL 3 (mg/
Plasticizers (phthalate)	Dibutyl phthalate	84-74-2	ECHA	DNEL	7	µg/kg bw/d	January 2024	0,18	4,48	233,32
Plasticizers (phthalate)	Tributylacetylcitrate	77-90-7	ECHA	DNEL	1,000	mg/kg bw/d	January 2024	26,07	639,84	33332,00
Salicylates	Benzylsalicylate	118-58-1	ECHA	DNEL	790	µg/kg bw/d	January 2024	20,59	505,47	26332,28

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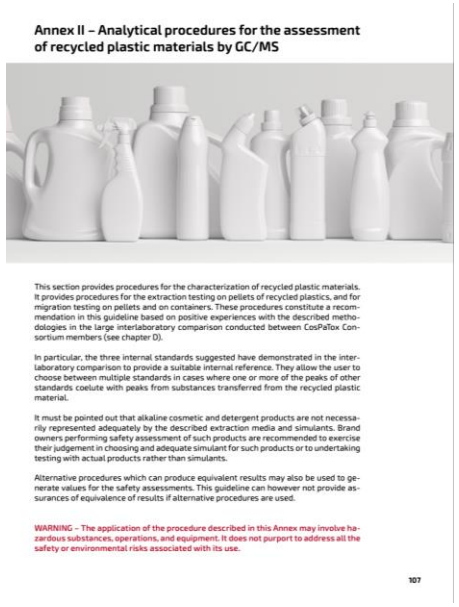
The CosPaTox guideline – Additional information and tools provided

1 Recommendations for analytical procedures for the assessment of PE and PP recyclates



Annex II – Analytical procedures for the assessment of recycled plastic materials by GC/MS

This section provides procedures for the characterization of recycled plastic materials. It provides procedures for the extraction testing on pellets of recycled plastics, and for migration testing on pellets and on containers. These procedures constitute a recommendation in this guideline based on positive experiences with the described methodologies in the large interlaboratory comparison conducted between CosPaTox Consortium members (see chapter D).

In particular, the three internal standards suggested have demonstrated in the interlaboratory comparison to provide a suitable internal reference. They allow the user to choose between multiple standards in cases where one or more of the peaks of other standards coelute with peaks from substances transferred from the recycled plastic material.

It must be pointed out that alkaline cosmetic and detergent products are not necessarily represented adequately by the described extraction media and simulants. Brand owners performing safety assessment of such products are recommended to exercise their judgement in choosing and adequate simulant for such products or to undertaking testing with actual products rather than simulants.

Alternative procedures which can produce equivalent results may also be used to generate values for the safety assessments. This guideline can however not provide assurances of equivalence of results if alternative procedures are used.

WARNING – The application of the procedure described in this Annex may involve hazardous substances, operations, and equipment. It does not purport to address all the safety or environmental risks associated with its use.

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2 Format proposal for the sharing of information on recyclates along the value chain

Annex III – Example for the sharing of information on recyclates along the value chain

Note: This example is for illustration purposes only. None of the substances or values are based on any real material.

MATERIAL DESIGNATION: RHDPE "COSMETIC PACKAGING GRADE"
MATERIAL DESCRIPTION: RHDPE PELLETS, 100% RECYCLED CONTENT
BATCH NUMBER: #AVB2352
BATCH SIZE: 15 TON
DATE OF PRODUCTION: 15.2.2024

QUALITY LEVEL: A2, MIGRATION TESTING PERFORMED WITH 95% ETHANOL

Results of non-targeted screening (GC/MS according to CosPaTox, method F.5, simulant 95% ethanol detection limit: 0.1 mg/kg pellets)

LIST OF ALL SUBSTANCES FOUND

RT (min)	RI	CAS	NAME	QUANTITY (mg/kg pellets)	CONFIDENCE
10.123	905	80-54-6	Lilial	0.312	87%
11.314	980	---	unidentified	0.101	N/A
27.414	1705	593-45-3	Octadecane	4.523	76%
28.145	1810	111-46-6	Diethylene glycol	0.235	82%
41.253	2823	3896-11-5	Bumetrizole	0.784	98%

LIST OF SUBSTANCES BANNED/RESTRICTED UNDER REG. (EC) NO 1223/2009

RT (min)	RI	CAS	NAME	QUANTITY (mg/kg pellets)	CONFIDENCE
10.123	905	80-54-6	Lilial	0.312	87%
28.145	1810	111-46-6	Diethylene glycol	0.235	82%

LIST OF SKIN SENSITIZERS UNDER REG. (EC) NO 1272/2008

RT (min)	RI	CAS	NAME	QUANTITY (mg/kg pellets)	CONFIDENCE
10.123	905	80-54-6	Lilial	0.312	87%

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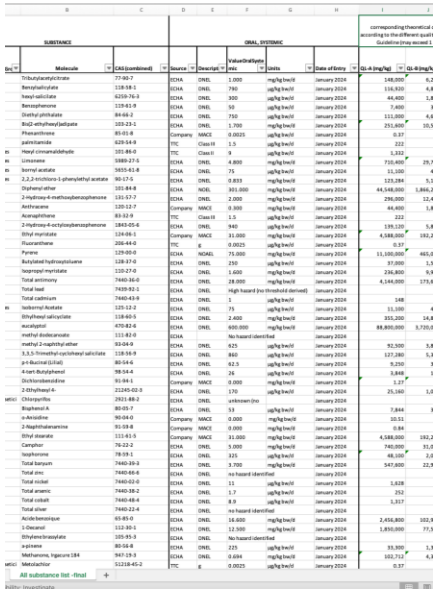
3 Curated list of toxicological information for a large number of substances of interest



4 Worst-case calculation tool in form of a spreadsheet

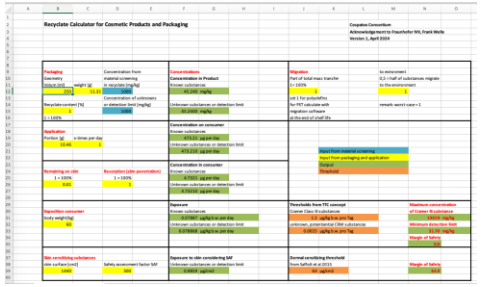
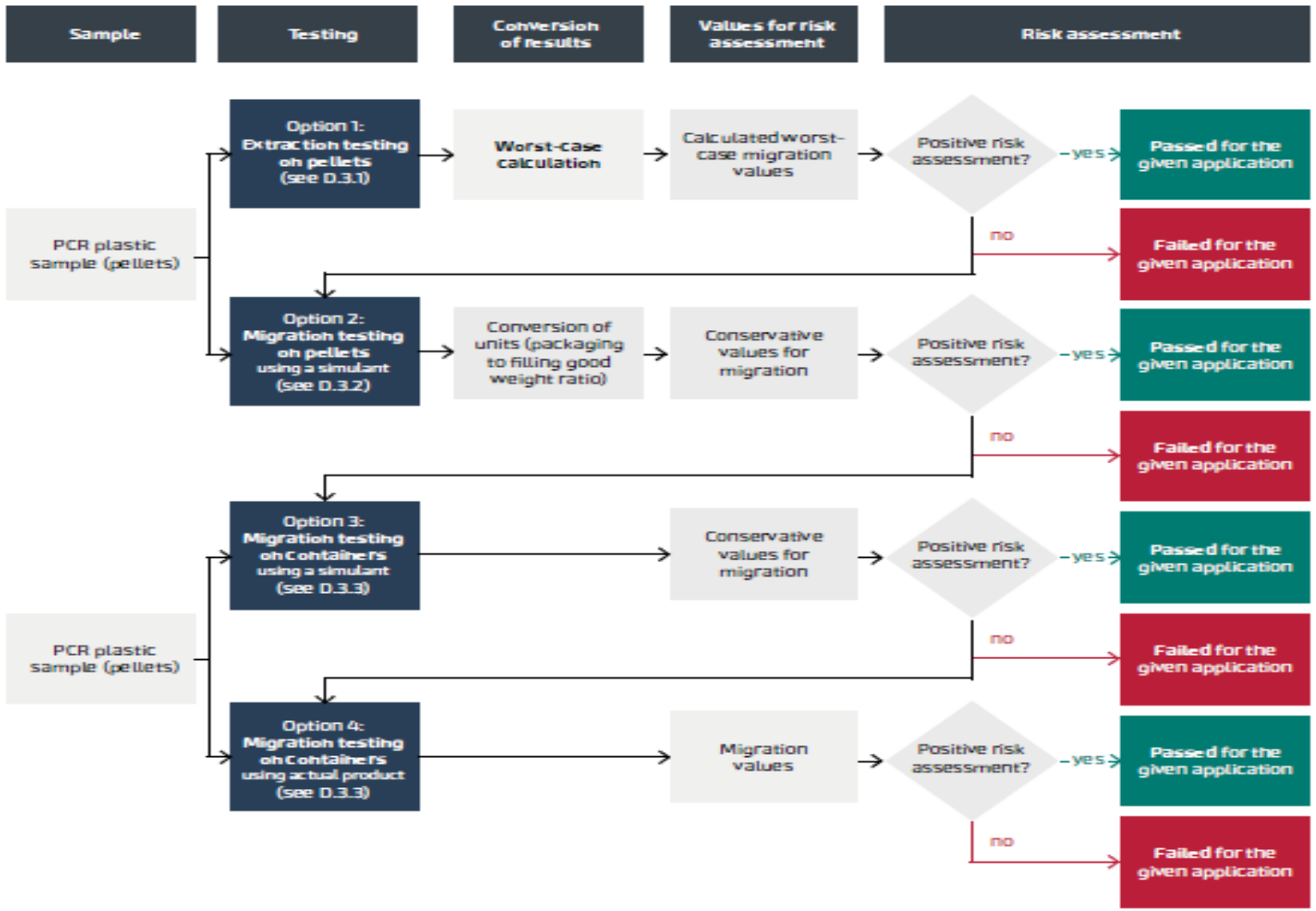
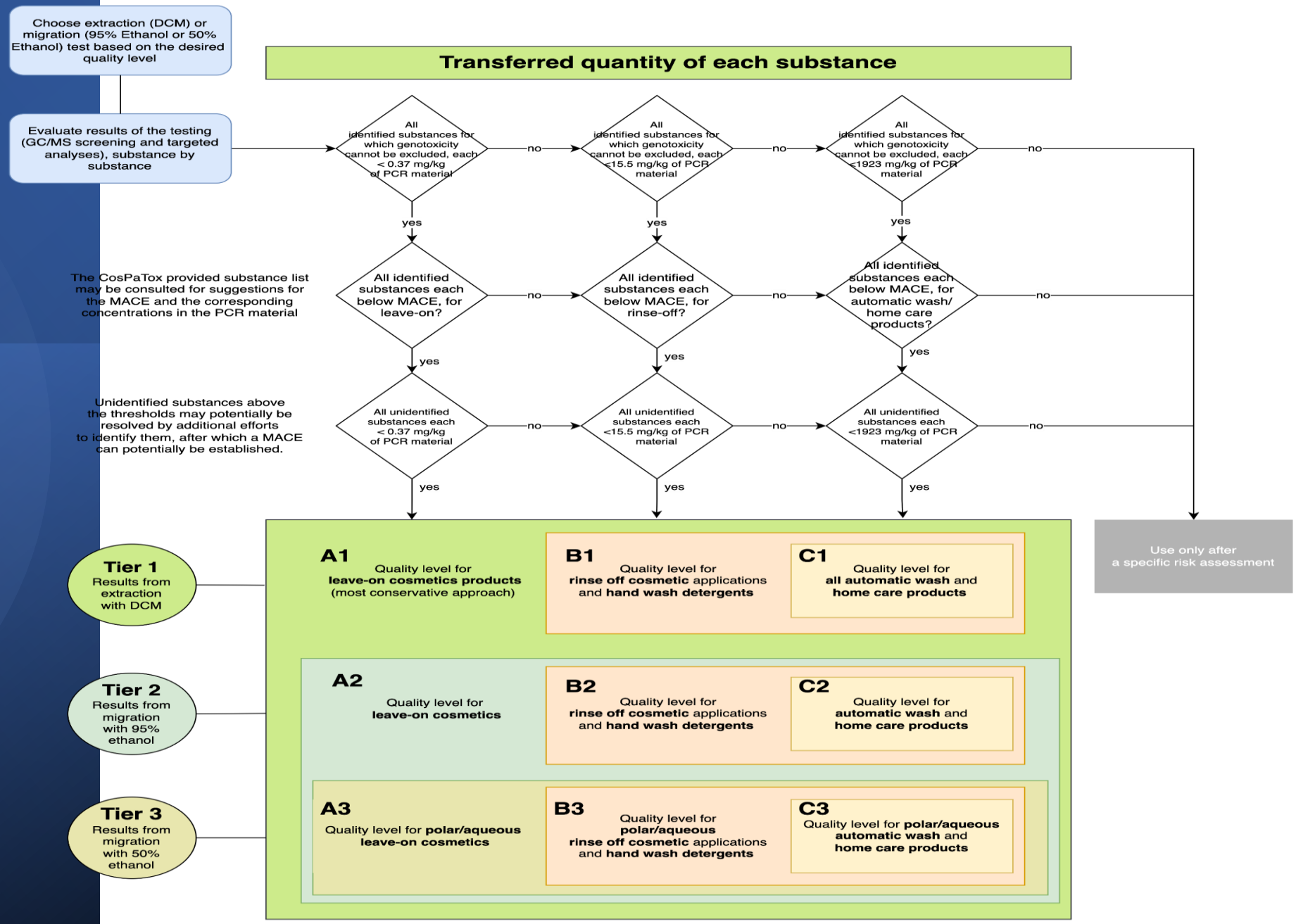


Figure 3

Flow chart for the evaluation of the transfer of substances from packaging containing recycled plastic material.



Worst case exposure assumptions: body lotion, shampoo, household cleaner



Note: These quality levels provide an indication for the most common types of products. Products which cannot be expected to be correctly represented by the testing, such as very alkaline products, should be considered specifically, and not on the basis of a quality level.

Note: 'Potentially genotoxic substances' are those substances which could be identified but for which the absence of genotoxicity

Leave-on Applications are Most Difficult to Qualify

There are many chemicals that were found through analytical testing (GCMS) via Dichloromethane and Ethanol 95% that we are unable to identify due to limitation of method and standards.

Hence, for exposure-based risk assessment we need to conservatively assume that these are potentially genotoxic (AMES test results show that this can be the case

Threshold for adult body lotion 370 ppb. But hand creme would be already 1.6 ppm

While these are conservative values they might not need to be show-stoppers the better we understand actual migration

Authorities like ECHA will likely question industry on unidentified chemicals and lean forward to a worst-case approach, due to possible presence of genotoxic chemicals.

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The CosPaTox Guideline – Summary of Key Findings

1 Groups of substances identified by GC/MS after extraction/migration testing of PE and PP recyclates

2 Results of the elemental analysis of PE and PP recyclates after digestion

3 Model use cases for common packaging types and product categories

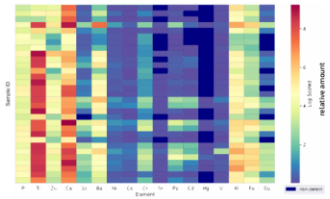
4 Example exposure scenarios based on model use cases

Table 2

Substance groups (excerpt) identified in extraction and migration testing of PE and PP recyclates, sorted by frequency of detection.

Substance group	Remarks	Likely major origin		
		PE/PP packaging	Product residue	Foreign sources[a]
Aliphatic compounds / Alkanes		x		
Fatty acids/esters		x	x	
Flavors/Aromas/Fragrances			x	
Natural compounds			x	
Antioxidants	Antioxidants are used in plastics but also in filling goods (incl. some foods)	x	x	x
Salicylates	Possibly degradation products of fragrance compounds		x	
Benzoates	Possibly degradation products of fragrance compounds		x	
Phthalates		x		x
Fatty acid derivatives (non-ester)			x	
UV filters	Likely from sunscreens or UV resistant packaging	x	x	
Plasticizers(non-phthalate)		x		x
Agricultural chemicals			x	
Photoinitiators	May originate from UV curing printing inks; UV adhesives also a possibility	x		x
Naphthalenes	Possibly degradation products of fragrance compounds		x	
Anilines	Possibly degradation products of azo dyes	x		x
Polyamide related substances	May originate from PA plastics in the input			x
Polycyclic aromatic hydrocarbons (PAH)	May originate from (certain) black pigments in plastics	x		x
PET related and polyesters	Likely related to PET plastics in the input			x
Chlorinated substances	May originate from chlorinated polymers in the recycling input or high temperature cross-reaction with salt in the input		x	x
Flame retardants				x
Pharmaceuticals			x	
Styrene-related	Likely related to PS plastics in input			x
Parabenes			x	
Acrylics		x		
Fluorinated substances				x
Food related substances			x	
Silicon compounds		?	?	?
Bisphenol-A (BPA)				x
Plastic additives		x		
Cosmetic products related substances			x	
Nitriles	Potentially related to nitrile rubbers in input			x
PEG/PPG related substances			x	
Disinfectants			x	
Nitro compounds		?	?	?
Pigments		x		

Figure 5



Comparison of the elemental analysis performed on the CosPaTox recycled plastic samples. Values are normalized to the highest result across elements and samples.

Table 3

Model use cases compiled by the CosPaTox consortium (excerpt).

Use case	Packaging type	Packaging material	Product type	Amount of content [mL][a]	Packaging weight [g]
1	tube	HDPE	shampoo	250	17.0
2	closure	PP	shampoo	250	6.2
5	bottle	HDPE	shampoo / shower gel / body lotion	250	25.8
7	pouch	PE	shampoo / shower gel	500	10.5
10	sachet	PE	shampoo / shower gel / body lotion	2	1.1
11	spray	HDPE	deodorant	100	13.0
14	tube	HDPE	creme	75	6.5
15	film	LDPE/PP	wet wipes	56 pieces	6.7
21	tube	PP	shampoo / shower gel / body lotion	30	4.78
22	bottle	PP	mascara	30	7.3
28	bottle	PP	home care product	3000	130

Table 4

Example exposure scenarios calculated based on the example use cases.

Use case (Table 3)	Packaging format	Material	Product type	Packaging weight	User	Body weight	Portion	Retention factor on skin	Absorption factor	Skin surface [cm²]	Exposure from 1g of substance transferred per kg body weight [µg/kg bw/d]	Exposure from 1g of substance transferred per kg packaging material [µg/g/d]
1a	tube	HDPE	shampoo	17.0 g	adult	60 kg	10.46 ml	1 %	50 %	1440	0.05927	0.7409
1b					infant	5 kg			100 %		1.423	
2a	closure	PP	shampoo	6.2 g	adult	60 kg	10.46 ml	1%	50 %	1440	0.0216 2	0.2702
2b					infant	5 kg			100 %		0.5188	
5a	bottle	HDPE	shampoo	17.0 g	adult	60 kg	10.46 ml	1 %	50 %	1440	0.08996	1.124
5b					infant	5 kg			100 %		2.159	
5c			shower gel	25.8 g	adult	60 kg	18.67 ml	1 %	50 %	17500	0.1606	0.3303
5d					infant	5 kg			100 %		3.8535	
5e			body lotion	25.8 g	adult	60 kg	7.82 ml	100%	50 %	15670	6.7252	15.4504
5f					infant	5 kg			100 %		161.4	
7a	pouch	PE	shampoo	10.5 g	adult	60 kg	10.46 ml	1 %	50 %	1440	0.01831	0.2288
7b					infant	5 kg			100 %		0.4393	
7c			shower gel	10.5 g	adult	60 kg	18.67 ml		50 %	17500	0.03267	0.03361
7d					infant	5 kg			100 %		0.7841	
10a	sachet	PE	shampoo	1.1 g	adult	60 kg	10.46 ml	1 %	50 %	1440	0.0794	5.993
10b					infant	5 kg			100 %		11.51	
10c			shower gel		adult	60 kg	18.67 ml		50 %	17500	0.8557	0.8802
10d					infant	5 kg			100 %		20.54	
11	spay	HDPE	deodorant	13.0 g	adult	60 kg	0.69 ml	100%	50%	200	0.7475	67.28
14a	tube	HDPE	hand creme	6.5 g	adult	60 kg	2.16 ml	100%	50 %	860	1.560	10.88
14b					infant	5 kg			100 %		37.44	
15a	wet wipes	PE/PP	wet wipes	6.7 g	infant	2 kg	16 pieces	100%	100%		9571	
15b					infant	2 kg	5 pieces				299.1	
21a	tube	PP	shampoo	4.78 g	adult	60 kg	10.46 ml	1 %	50 %	1440	0.1389	1.736
21b					infant	5 kg			100 %		3.333	
21c			shower gel		adult	60 kg	18.67 ml		50 %	17500	0.2470	0.2550
21d					infant	5 kg			100 %		5.950	
21e			body lotion		adult	60 kg	7.82 ml	100%	50 %	15670	10.38	11.93
21f					infant	5 kg			100 %		249.2	
22	bottle	PP	mascara	7.3 g	adult	60 kg	0.5 ml		50%		1.521	
28	bottle	PP	home care product	130 g	adult	60 kg	0.0018 ml	100%	100%	2085.5	0.0013	0.004

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The CosPaTox Guideline – Key Recommendations are…

1 …to apply a combination of material characterization, safety assessment and quality management

2 …to categorize PE and PP recyclates into one of three quality levels which are based on model packaging use cases

3 …to evaluate substances that may transfer from plastic into product based on the flow chart provided in the guideline

4 …to base decision making on a comparison of exposure with toxicologically derived thresholds

Figure 1 Overview of the safety assessment and risk management process for recycled plastic materials.

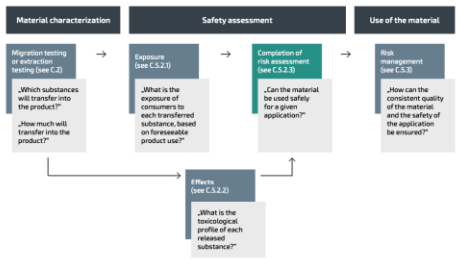


Figure 2 Decision tree for assigning recycled plastic materials into quality levels, based on the use case and example exposure scenarios for body lotion for adults 5e, shower gels for adults 5c and home care products 28 (see D.5.1 and for full details Annex I). The principles stated in D.5.2 were applied for setting the threshold values. The assessment is to be performed substance-by-substance.

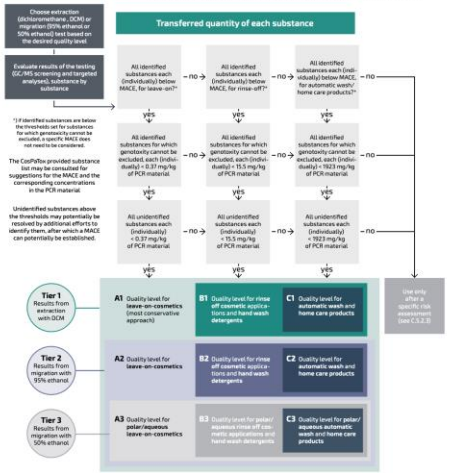


Figure 3 Flow chart for the evaluation of the transfer of substances from packaging containing recycled plastic material.

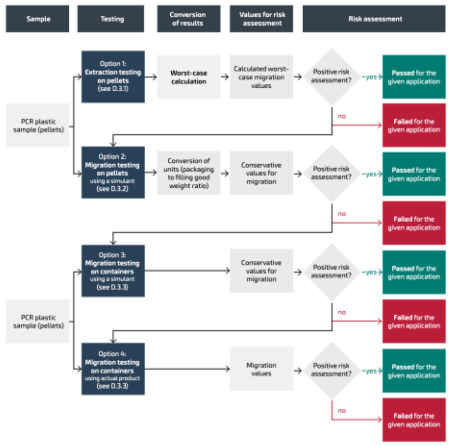
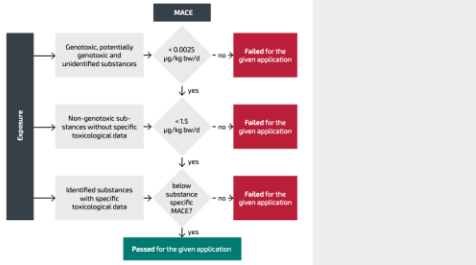


Table 2 Decision tree for the comparison of the determined exposure to chemical substances with the maximum acceptable consumer exposure (MACE). Units of exposure are micrograms per kilogram body weight per day.



CosPaTox is now a DIN Standard- DIN SPEC 91521

- DIN SPEC is a recognized specification process developed by the **German Institute for Standardization (DIN)**. It establishes **rigorous quality, safety, and performance criteria**, ensuring that products and services comply with industry-leading standards. DIN SPEC certifications are particularly critical for industries handling sensitive materials, such as healthcare, technology, and manufacturing.

Through a DIN Standard the goal of making the CosPaTox approach a CEN Standard is one step closer!

CosPaTox has submitted its risk assessment approach to ECHA

ECHA final report to Commission by **21 September 2026**

Call for Evidence for Substances in packaging and packaging waste

- ECHA launches a Call for Evidence to support the preparation of a study report under Packaging and Packaging Waste Regulation (PPWR).
- Information is sought on packaging, substances used in packaging and packaging waste, waste management and recycling technologies related to packaging.

Subject: **Request to the European Chemicals Agency (ECHA) to prepare a study report identifying substances of concern in packaging and packaging components under the Packaging and Packaging Waste Regulation.**

1. BACKGROUND

The aim of the Packaging and Packaging Waste Regulation (PPWR) is to address the impact of packaging on human health and the environment and in broader terms to achieve a better sustainability of the packaging sector. This includes circularity of the material from manufacture to use and end-of-life, including waste management, which is impacted by the presence of substances of concern (SoC). These are defined in the PPWR as substances meeting the criteria laid down in Article 2(27) of the Regulation 2024/1781(1) establishing a framework for the setting of eco-design requirements for sustainable products (2).

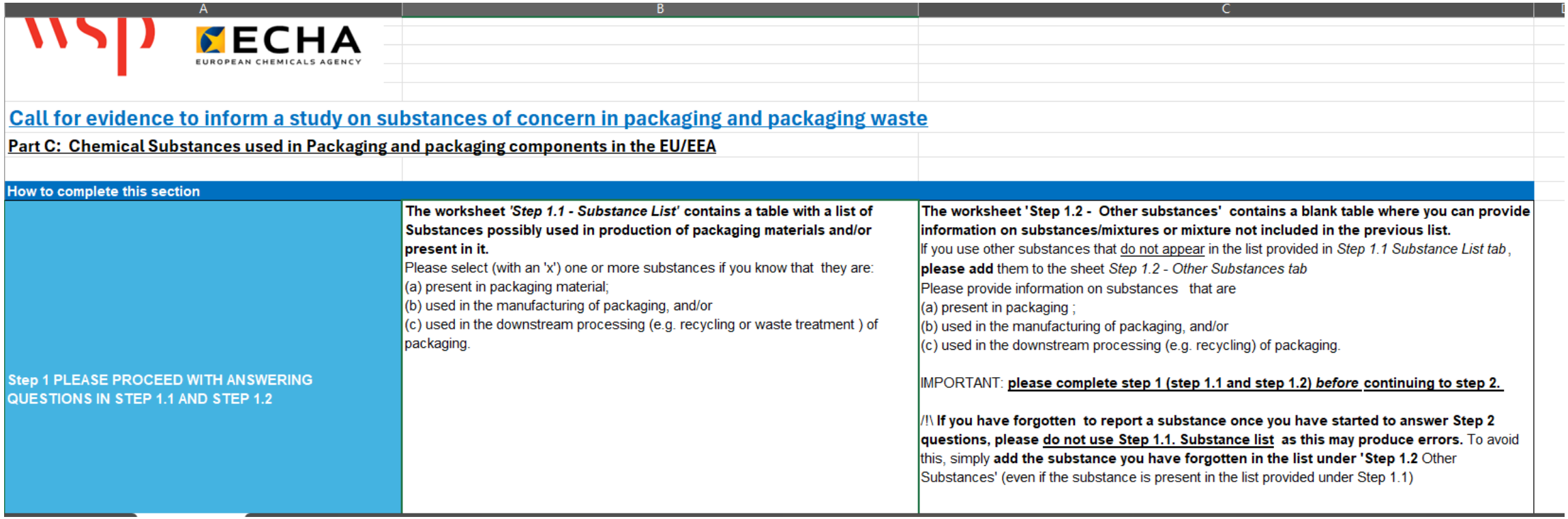
Packaging should be designed and manufactured in a way that limits the presence of certain heavy metals and other SoC in its composition. Accordingly, SoC as constituents of packaging material or of any of the packaging components should be minimised.

Art.5(2) of PPWR states that *"By 31 December 2026, the Commission, assisted by the European Chemicals Agency, shall prepare a report on the presence of substances of concern in packaging and packaging components, to determine the extent to which they negatively affect the re-use and recycling of materials or impact chemical safety"*.

2. THE MANDATE

The Commission is hereby requesting ECHA to prepare a study report identifying SoC

CosPaTox will be a powerful tool to ECHA



A	B	C
wsp ECHA EUROPEAN CHEMICALS AGENCY		
Call for evidence to inform a study on substances of concern in packaging and packaging waste		
Part C: Chemical Substances used in Packaging and packaging components in the EU/EEA		
How to complete this section		
Step 1 PLEASE PROCEED WITH ANSWERING QUESTIONS IN STEP 1.1 AND STEP 1.2	**The worksheet *'Step 1.1 - Substance List'* contains a table with a list of Substances possibly used in production of packaging materials and/or present in it.** Please select (with an 'x') one or more substances if you know that they are: (a) present in packaging material; (b) used in the manufacturing of packaging, and/or (c) used in the downstream processing (e.g. recycling or waste treatment) of packaging.	**The worksheet 'Step 1.2 - Other substances' contains a blank table where you can provide information on substances/mixtures or mixture not included in the previous list.** If you use other substances that do not appear in the list provided in *Step 1.1 Substance List tab*, **please add** them to the sheet *Step 1.2 - Other Substances tab* Please provide information on substances that are (a) present in packaging ; (b) used in the manufacturing of packaging, and/or (c) used in the downstream processing (e.g. recycling) of packaging. IMPORTANT: **please complete step 1 (step 1.1 and step 1.2) *before* continuing to step 2.** /!\ **If you have forgotten to report a substance once you have started to answer Step 2 questions, please do not use Step 1.1. Substance list as this may produce errors.** To avoid this, simply **add the substance you have forgotten in the list under 'Step 1.2** Other Substances' (even if the substance is present in the list provided under Step 1.1)

ECETOC Plastic Additives Task Force and the CosPaTox Approach

The ECETOC Plastic Additives Task Force was convened in September 2024 to respond to stakeholder concerns regarding exposure to chemical additives from plastic waste and recyclates.

While established risk assessment principles exist for certain sensitive uses, circular economy applications introduce additional complexities. Additives may degrade during processing or environmental exposure, creating new challenges for safety assessment.

This work aims to develop a practical framework that integrates existing tools and data to support risk-based decision-making across the plastic life cycle

The framework under development will:

- Distinguish between high-risk, low-risk, and uncertain scenarios.
- Support transparent decision-making by identifying data gaps and critical assumptions.
- Be applicable not only to additives but to other substances in plastic and solid polymer matrices.
- The aim is to create a scientifically sound, usable tool for regulatory and industrial stakeholders aligned with circular economy goals.

Thank you for your attention