CosPaTox

VOLUNTARY INDUSTRY **GUIDELINE**

Safety assessment of recycled plastics in packaging materials for cosmetic products and home care products

Guidance for recycled PE, PP and LDPE

Imprint

Date of publication
April 2024

Cite as

Voluntary industry guideline for the safety assessment of recycled plastics in packaging materials for cosmetic products and home care products, CosPaTox, 2024.

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The CosPaTox Consortium

CosPaTox originates from the #ForumRezyklat initiative launched by dm-Drogeriemarkt in 2018, which focuses on strategies to increase circular economy awareness, with a specific objective to sort recyclable materials by type. Over time, this approach will raise the recycling rate and the proportion of recycled materials used in packaging. In addition, the Forum is committed to reducing overall packaging amounts and ensuring new packaging is designed with recyclability in mind, so that it becomes a resource within a circular economy.

CosPaTox, a Consortium focused on the intersection of **Cos**metics, **Pa**ckaging, and **Tox**icology, is committed to formulating so-far missing specific safety assessment guidance for high-quality Post-Consumer Plastic Recyclates (PCRs) to be used in cosmetic product and detergent packaging. CosPaTox' goals also include the establishment of testing methodologies.

CosPaTox members represent the entire value chain for the packaging types in focus: brand owners, packaging producers, fillers, retailers, waste management companies, and recyclers. They have also assembled a team of external scientific experts specializing in toxicology and post-consumer packaging waste recycling.

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To deliver this guidline, CosPaTox partnered with

- Fraunhofer Institute for Process Engineering and Packaging IVV
- FH Campus Wien – University of Applied Sciences Vienna
- FABES Forschungs GmbH
- AgroParisTech and INRAE, founding members of the University of Paris-Saclay
- Dr. Dennis Bankmann, independent scientific consultant

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Siegwerk Group Holding AG & Co. KG
Valorplast S.A.
Veolia Environnement SA
Weleda AG
Werner & Mertz GmbH

A.

About this guideline

It is expected that the consumer goods industry, including producers of cosmetic products, detergents, and home care products, will increase its demand for recycled plastic for packaging applications within the next five years by five times to well over one million tons per year. A substantial increase is already expected in the EU through mandatory recycled content targets in the upcoming EU Packaging and Packaging Waste Regulation. The greatest obstacle to meeting this demand as well as to a more rapid introduction of recycled plastics in packaging is the scarcity of qualitatively acceptable recyclates.

Recycled content in plastic packaging for the cosmetic products, detergents and home care products sector is currently limited, with a few exceptions, to the use of food contact grade recyclates. The choice of such recyclates allows for a simplified safety assessment as the food contact approval ensures a comparable safety to food grade virgin plastics. Existing sources of food contact plastic recyclates are however either limited or largely exhausted across the EU. New sources for recycled plastics that can be used in the packaging of cosmetic products, detergents and home care products need to be found urgently.

It is undisputed that there is more than enough suitable post-consumer plastic waste available as input for recycling and that this waste is already collected separately and recycled in many EU countries. However, the recycled plastics made from these materials generally do not meet the legal requirements for food contact or have not received the required authorization. Therefore, established safety assessment approaches for cosmetic packaging, based on food contact approvals, cannot be applied for these materials.

CosPaTox

While the use of recycled plastics in cosmetic product, detergent, and home care product packaging materials is not legally restricted to food contact approved materials, important requirements exist for the safety of such packaging applications. For recyclates not approved for food contact applications, a dedicated safety assessment, not based on food contact approvals, is therefore required before they can be introduced in packaging.

Safety assessments are used to demonstrate safety by identifying and assessing potential *hazards* and the resulting *risks*, while *risk management* describes the implementation of organizational measures to reduce or mitigate those risks. Risk management allows for the definition of a reliable testing strategy, based on historical data on the input and output materials of recycling and on the recycling process itself, from

Cosmetic products, detergents, and home care products

When this guideline states 'cosmetic products' and/or 'detergents' and 'home care products', it refers to cosmetic products, both decorative and care, and to other consumer products for which contact with skin is part of the intentional or likely use of the product, such as in manual dishwashing and laundry, and wet wipes (both for personal care and for household use) or surface cleaning products. Industrial detergents as well as household products which should not come into contact with skin (e.g., toilet, oven and drain cleaners) are not covered in this guideline as the low level of possible accidental exposure allows for a different consideration of consumer safety.

which a statistics-based confidence is derived that the quality of the output material remains consistent.

Not all economic actors in the supply chain have been able to conduct a dedicated safety assessment or implement the required risk management processes. The CosPaTox Consortium was established to provide support to the industry based on thorough analytical studies and toxicological principles.

This guideline describes an approach that enables a wider use of recyclates by creating three *quality levels* for recycled plastics each of which sufficient to enable the safe use in packaging for most *leave-on cosmetic products (A), rinse-off cosmetic products* and *hand wash detergents*[1] *(B)*, or *home care products (C)*.

This work also aims to support the recycling industry by defining test methods that can be used on site to determine or confirm the quality of recyclates.

The focus of the CosPaTox Consortium is on *polyolefin* plastic materials (HDPE, LDPE and PP), for which food contact approved recyclates are extremely rare. The safety assessment approach developed by the CosPaTox Consortium can, in principle, also be applied to PET. However, no specific testing of PET recyclates has been conducted as for this material a much wider availability of food contact approved grades already exists.

The CosPaTox Consortium's approach is technology neutral and does not consider or require any specific collection, sorting, or recycling technology. The focus is solely only the quality of the recycled materials themselves[2]. The approach to *safety assessments* laid out in this guideline can therefore be applied to any polyolefin recyclate, be it from a mechanical, physical, or chemical recycling origin[3].

The scope of CosPaTox' studies and recommendations is primary packaging only. Secondary and tertiary packaging are not considered.

The proposed approach by CosPaTox is expected to deliver a level playing field for all market participants and reduce the effort in finding a starting point for risk assessment and risk management. The aim is that the entire cosmetic products, household detergent, and home care products industry as well as the suppliers of recycled plastics will benefit from this guideline. This includes

Note

When this guideline states 'recycled plastic material(s)', the term should be understood to include both materials with a certain recycled content as well as materials which are entirely comprised of recycled content.

The words 'recycled material' and 'recycle' are used interchangeably in this guideline.

Note

The Guideline considers the regulatory status and technical knowledge as of December 2023. Revisions of current legal frameworks or an improvement of analytical methods may require updates of the Guideline.

This guideline is accompanied by a scientific *dossier* which provides added detail and evaluations of the results of the work of the CosPaTox Consortium.

[1] Such as manual dishwashing and manual laundry detergents.

[2] For this reason, no description of collection, sorting or recycling processes is provided in this guideline.

[3] In the case of chemical recycling processes that convert plastic waste back to monomeric substances, these materials will often have the same degree of purity as virgin materials and be available in food contact approved grades. It may therefore not be necessary in these cases to apply a different approach than has already been established for virgin plastic materials.

companies that have so far refrained from using recycled plastics in their packaging due to a lack of guidance regarding the safety evaluation and recyclers that have refrained from offering recyclates for use in this sector due to a lack of quality definitions.

Cosmetic products, detergents and home care products

This guideline provides recommendations for the packaging of cosmetic products, detergents, and home care products. Where these product categories are mentioned, they refer to the following:

Cosmetic products, following the definition of Regulation (EC) No 1223/2009, refers to any substance or mixture intended to be placed in contact with the external parts of the human body [...] or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors.

Detergents and *home care* products, following the definition of detergents in Regulation (EC) No 648/2004, refers to any substance or mixture containing soaps and/or other surfactants intended for washing and cleaning processes. Detergents may be in any form [...] and marketed for or used in household, or institutional or industrial purposes. *Manual washing detergents* refers to detergents for which the intended or foreseeable use leads to a contact with skin. *Automatic washing detergents* refer to detergents for which a contact with skin in unintentional and incidental only. Both categories include the washing of clothes, textiles, and tableware.

B.

Executive summary

CosPaTox has conducted extensive studies on the safety of post-consumer recycled (PCR) plastic materials made from PE and PP for use as packaging materials in cosmetic products, detergents, and home care products. The work conducted by CosPaTox was divided into two phases: Analytical testing phase and toxicological assessment phase, which also established use cases.

In the analytical testing phase, a large interlaboratory comparison was conducted to determine the presence and amounts of chemical substances in a range of representative PCR plastic materials. The study also assessed the potential of these substances to transfer from PCR plastic materials into products using different approaches.

The toxicological assessment phase involved summarizing typical use cases of packaging and deriving model consumer exposure scenarios. Model safety assessments were conducted based on these exposure scenarios to assess potential health-related effects of chemical substances released from the packaging.

Key findings from the studies conducted by CosPaTox include:

A. Analytical Testing Results:

1. PCR plastic materials were found to potentially contain substances not directly related to the packaging material (for example originating from food, filling goods or non-packaging products in the recycling input), suggesting a need for a safety assessment before using recycled plastics.

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

3. 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.

B. Toxicological Assessment Strategy:

1. Factors influencing consumer exposure to migrated substances released from PCR packaging include packaging format, product type, and user.

2. Model safety assessments demonstrated the evaluation of recycled plastic materials and the use of toxicological principles to establish maximum acceptable consumer exposure ('MACE') values.

3. The hazard profile of a chemical does not necessarily translate into a risk for the consumer if exposure remains below the maximum acceptable consumer exposure.

CosPaTox provides ancillary information to support industry in applying the developed principles, including testing procedures, representative use cases, and a list of substances detected in recycled PE and PP materials which includes toxicological information.

Based on the analytical results and safety assessments, CosPaTox recommends recyclers implement the outlined testing procedures which support categorization of PCR materials into quality levels. The quality level is a starting point for converters and brand owners to perform safety assessment and risk management. Information transmission along the supply chain is critical for the comprehensive evaluation and implementation of toxicological principles for a robust risk assessment.

The recommendations in this guideline aim to support the safe use of recycled plastics in packaging applications and provide guidance for companies considering the use of recycled materials. By offering clear recommendations for the safe use of recycled plastic materials, CosPaTox aims to promote the adoption of recycled materials in cosmetic products and detergents packaging.

The guidance provided by CosPaTox is expected to benefit the entire cosmetic products, detergent, and home care products industry, as well as suppliers of recycled plastics, by addressing safety evaluation and standardized quality definitions for recycled materials.

How to navigate this guideline document

This guideline is structured into three parts:

Recommendations

Chapter C provides straightforward recommendations for recyclers and users of recycled plastics. It builds upon the approach and the results described in Chapter D and provides a methodology for assessing the safety of plastic recyclates for use in the packaging of cosmetic products, detergents, and home care products. It proposes quality levels for recyclates, and a matching testing methodology.

Audience

Readers who are interested in the practical implementation of recycled plastics in the packaging of cosmetic products or detergents, or in the production and trade of such materials.

Findings

Chapter D describes the core findings of the CosPaTox Consortium's analyses of post-consumer recycled plastic materials and guides the reader through the example safety assessments that were conducted during the preparation of this guideline. It describes the developed methodology for establishing safe limits for the transfer of substances from recycled plastics.

Audience

Readers interested in the methodologies and findings of the CosPaTox Consortium, and readers interested in the development of the example risk assessments.

Background

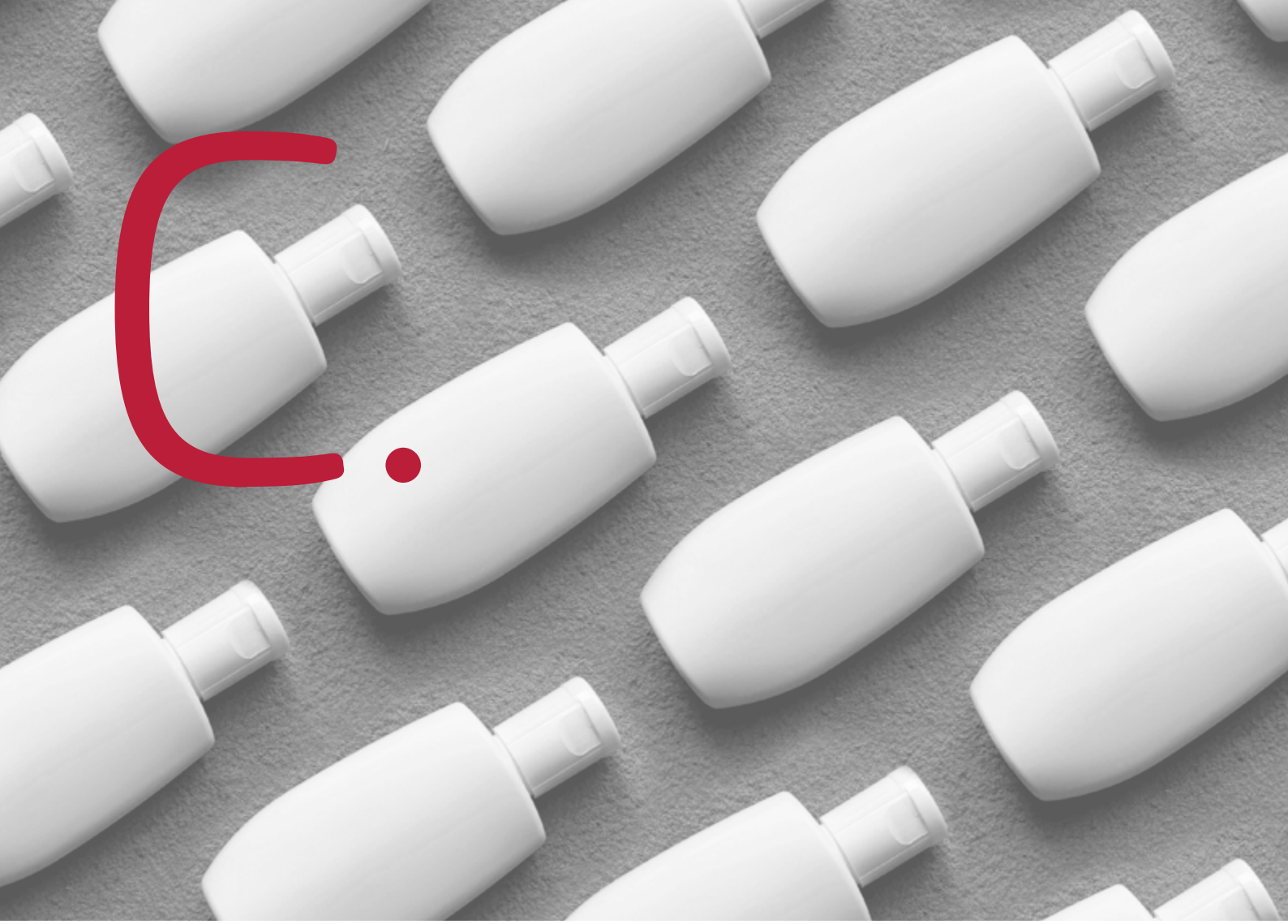
Chapter E provides background information on the products and packaging types that are in scope of this guideline, as well as information on relevant regulations and existing industry guidance related to the safety of packaging for cosmetic products, detergents, and home care products. The chapter provides a basic description of the analytical techniques that were used by the CosPaTox Consortium and a high-level summary of the concept of risk assessment and its key elements. It provides references to relevant literature for readers seeking an in-depth treatise on these subjects. This chapter is written for a wide audience seeking for additional information. A more in-depth review is provided in the accompanying CosPaTox dossier.

Audience

Readers who desire background information on the covered topics and deployed methodologies

Throughout all chapters, information boxes provide direct links to related sections.

Table of Contents



C.

Recommendations for the safety assessment of cosmetic products and detergent packaging

This section provides a concrete guidance to recyclers and users of recycled plastic materials regarding the assessment of plastic materials with recycled content for the use in the primary packaging of cosmetic products, detergents, or home care products. The aim of this guidance is to provide to industry a proposal for a harmonized approach to the assessment and qualification of recycled plastic materials, up to date with regulation and toxicological principles, and supported by solid evidence.

Audience

Readers interested in concrete recommendations.

Where to find details

CosPaTox' approach and results which underlie these recommendations are described in chapter D.

The statements and recommendations in this guideline are to be considered as steps to be performed in addition to – not instead of – ensuring compliance with regulatory requirements, both related to safety as well as other requirements.

The *safety assessment* of recycled plastic materials which have been approved for food contact is well established and may be applied as described in [1]. As packaging manufacturers and brand owners are already well versed in this process, it is not described in this guidance. Similarly, this guidance does not cover the safety assessment of recycled plastics on the basis of a US FDA food contact approval.

This guidance instead focuses on recycled HDPE, LDPE, and PP materials, which are of high importance to the cosmetic products, detergents, and home care products industries, and are typically not available in the required quantities as food contact approved grades[2]. It provides guidance for a *dedicated safety assessment* of these materials, as an alternative to the use of food contact information.

The approach described in this guideline is based on the toxicological and analytical methods described in chapter E and on the results of the CosPaTox studies and the chosen toxicological principles described in chapter D. It is furthermore also based on the detailed evaluation provided in the CosPaTox dossier. To give practical recommendations, the guidance further draws on the current practices of evaluating (virgin) plastic materials for food contact safety.

Where to find details

A *dossier* is available, detailing the results of the testing and their validation.

Where to find background information

primary, secondary, and tertiary packaging > E.1.1.2

safety assessment > E.5.2.1

cosmetic products and detergent packaging > E.2.2

toxicological principles > E.4 and D.5.2

analytical methods > E.3.4

C.1 General considerations, roles and responsibilities

Before a recycled plastic material which has not been approved for food[4] contact can be used safely for packaging of cosmetic, detergent, or home care products, a dedicated *safety assessment*, is required. This assessment must cover the potential *exposure* of consumers to substances transferred from the packaging into the product. A safety assessment is fundamentally based on a substance-by-substance comparison of the expected amounts transferred from packaging into the product with the *maximum acceptable consumer exposure* (MACE) derived for each substance from a toxicological analysis[5]. Combined with a risk management approach, a recycled material can be qualified for use. This process is illustrated in Figure 1.

Material characterization can be performed by either the manufacturer of the material (i.e., the recycler) or by its user (i.e., the packaging manufacturer or the brand owner).

The *safety assessment* of cosmetic, detergent, or home care product packaging (see C.5.2) is always performed by the brand owner as it is the final user of the packaging who must ensure ultimate safety based on the design of their packaging, the characteristics of their product, and the intended storage and usage conditions.

For *risk management*, brand owners will rely on information and *quality assurance* measures implemented by their suppliers (see C.4.3) to be confident of a consistent quality of the supplied material. Nonetheless, packaging manufacturers and brand owners are also requested by this guidance to implement suitable *risk management* processes (see C.5.3) when using recycled plastic materials for their packaging.

Where a detergent product is used to clean contacts of food contact materials (e.g., tableware, surfaces) the safety assessment methodology presented in this guidance encompasses this safety consideration.

The guidance presented in this chapter is focused solely on aspects of product safety and do not cover the technical suitability of a recycled plastic material for any given packaging application[6], nor its processability or its aesthetics.

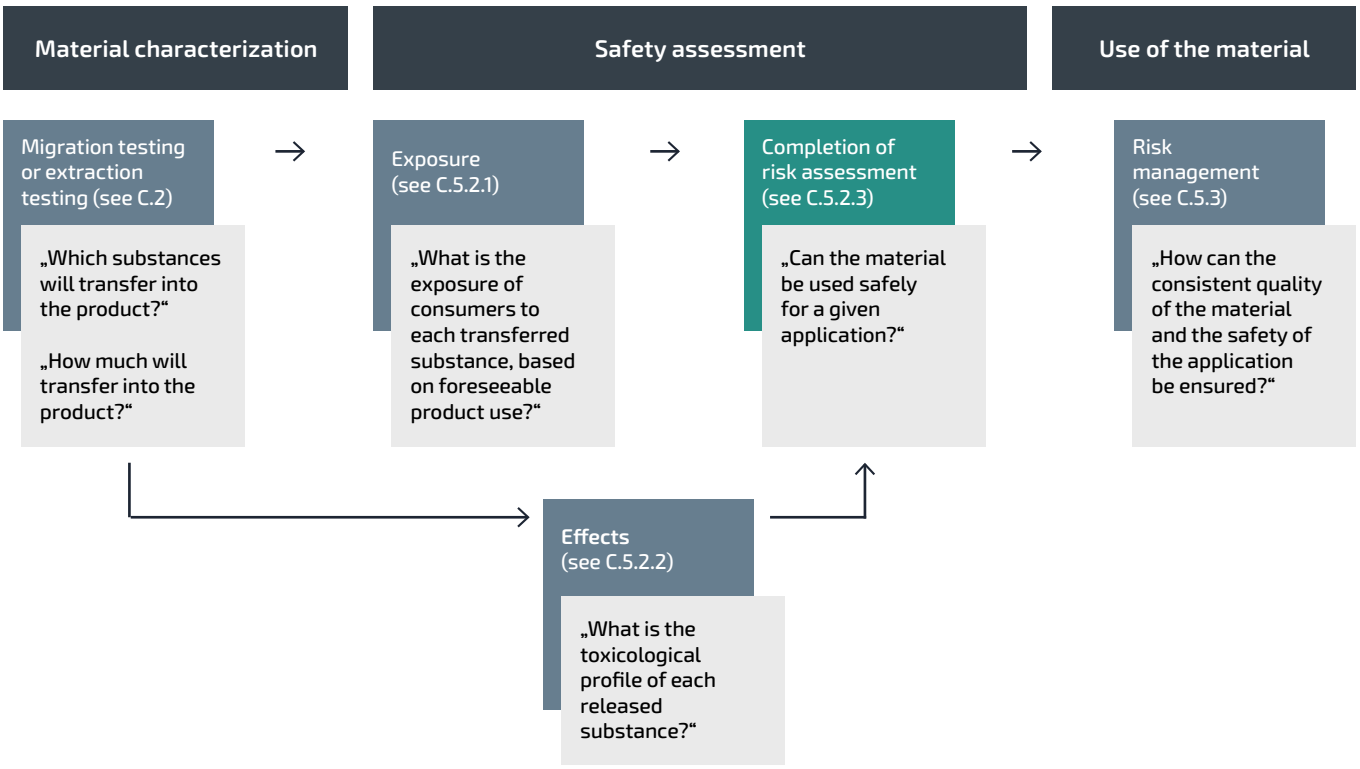
Where to find background information

food contact > E.1.3
exposure > E.4.1
MACE > E.4.3
risk management > E.4.4
material characterization > E.3

[4] Also, for food contact approved recycled plastics, as safety assessment is required. Food contact approval-based safety assessments are however outside the scope of this guidance which focuses on not food contact-approved materials (see above).
[5] This approach has also been applied in studies of other parties, e.g., [3].
[6] As such, this guideline also does not provide recommendations for the use of an overall migration limit approach to study the general inertness of recycled plastic packaging materials.

Figure 1

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



C.2 Testing procedures

Where to find background information

extraction testing > E.3.1
migration testing > E.3.2
risk assessment > E.4
risk management > E.4.4
GC/MS > E.3.4

This guideline provides two options for the testing of plastic recyclates:

1. *extraction testing on pellets* (see F.4), using dichloromethane as the solvent, for filling goods (products) of all polarities[7]

2. *migration testing on pellets* (see F.5), using either 95% ethanol or 50% ethanol as the simulant, depending on the polarity of the intended filling good[8]

[7] Dichloromethane may be used as the simulant for fatty products and for polar and aqueous products. Alkaline cosmetic and detergent products are not necessarily represented adequately by the described extraction media and simulants.

[8] This guideline uses ethanol 95% as the simulant for fatty products and ethanol 50% as the simulant for polar and aqueous products. Alkaline cosmetic and detergent products are not necessarily represented adequately by the described extraction media and simulants. This assignment of simulants to products is not to be confused with the different use cases, i.e., quality levels.

The options provided are based on and supported by the results of the CosPaTox interlaboratory comparison. Their validity for their respective uses is discussed in the CosPaTox dossier. The choice of testing approach among these options may be taken jointly between recycler and user of the recyclate[9]. The extraction testing approach with dichloromethane offers a shorter testing time, whereas the migration testing approach with ethanol provides a less overestimating result (compare E.3).

In both cases, this guideline describes the use of GC/MS as a *non-targeted screening* method to identify and quantify transferred substances (see F.7).

In special cases, where there is reason to believe that the simulants suggested by this guideline do not suitably represent the actual product, a more suitable simulant may be chosen[10]. Likewise, if the final packaging format which will use the recycled plastic material is a flexible packaging, in particular a small sachet, the validity, i.e., the representativeness of testing on pellets rather than on films shall be confirmed in each case.

In addition, specific types of *targeted analyses* need to be performed to cover substances which are not detectable in GC/MS or not with sufficient sensitivity (see Table 1).

The chosen methods need to provide a limit of detection at or below the required detection limit for genotoxic substances (see Figure 2).

Where to find details

A *dossier* is available, detailing the results of the testing and their validation.

Where to find background information

analytical techniques > E.3.4

[9] It is also possible to perform both types of testing, for example, to obtain a more comprehensive picture of the share of substances (contained in a recycled plastic material) that may migrate, or in case that specific substances of interest are expected to be not well extractable by dichloromethane.

[10] In such cases, a suitable study to prove that the simulant choice is sufficiently severe, i.e., induces at least as much migration as the actual filling good, should be performed.

Table 1

Targeted analyses for recycled plastic materials for use in cosmetic, detergent and home care product packaging[11]

Targeted analysis	Recommended methods based on total content[12]	Recommended methods based on migration
Elements, including heavy metals	EN 62321-5:2014 DIN EN 13657:2003-01	DIN EN 13130-1:2004-08; testing condition: acetic acid 3%
Carcinogenic primary aromatic amines (PAA), according to CLP	Suitable laboratory-specific method	DIN EN 13130-1:2004-08 / LC-MS
Polycyclic aromatic hydrocarbons (PAH) considered by the US Environmental Protection Agency[13]	Suitable laboratory-specific method	DIN EN 13130-1:2004-08 / GC-MS
Bisphenols: Bisphenol-A, Bisphenol-F, Bisphenol-S, Bisphenol-B, Bisphenol-AF	Adapted method, based on DIN EN ISO 11936:2023-10	DIN EN 13130-1:2004-08 / GC or LC-MS
Polychlorinated biphenyls (PCB)[14]	Adapted method based on DIN EN 16190:2019-10	DIN EN 13130-1:2004-08 / GC-MS
Phthalates according to REACH annex XIV	Suitable laboratory-specific method	DIN EN 13130-1:2004-08 / GC or LC-MS
Dioxins and furans	High resolution GC/MS based on DIN EN 16190:2019-10	DIN EN 13130-1:2004-08 / GC-MS

Note:

alkyl phenols, such as nonylphenol and its derivatives, are not mentioned in the list of analysis targets as they are readily detectable already in the GC/MS non-targeted screening method.

[11] This table does not provide a comprehensive overview of all available techniques. Additional or alternative analytical methods may be available. It is recommended that suitable established and accredited analytical methods are recommended to be chosen for targeted analysis. Established testing laboratories and institutes will be able to assist in the optimal choice of technique.

[12] Total content values may be used for a worst-case calculation of the transfer of these substances into the product. Equally, refinements as per Figure 11 may be applied.

[13] Naphthalene (NAP), acenaphthylene (ACY), acenaphthene (ACE), fluorene (FLU), phenanthrene (PHEN), anthracene (ANTH), fluoranthene (FLTH), pyrene (PYR), benzo[a]anthracene (B[a]A), chrysene (CHRY), benzo[b]fluoranthene (B[b]F), benzo[k]fluoranthene (B[k]F), benzo[a]pyrene (B[a]P), benzo[g,h,i]perylene (B[ghi]P), indeno[1,2,3-c,d]pyrene (IND), and dibenz[a,h]anthracene (D[ah]A).

[14] At least the indicative PCB: PCB 28, 52, 101, 138, 152, and 180. Additional PCB to be analyzed may be agreed between recyclers and brand owners.

Perfluoroalkyl and polyfluoroalkyl substances (PFAS)

The list of targeted analysis recommended by this guideline (Table 1) does not include PFAS, which are substances included in a recent restriction proposal[15] under REACH[16] and have recently received attention Importantly, the grouping of chemicals as 'PFAS' and the move to propose a restriction arose from their *environmental persistence* properties, and not primarily from a toxicological perspective[17]. Furthermore, as a general restriction on PFAS would affect all materials subject to regulation under REACH, it would affect all materials which a recycler produces. An end-market specific guidance, is therefore not required.

Finally, the ongoing regulatory activity, and planned restrictions on the intentional use of PFAS are assumed to reduce their use in future products.

C.3 Blending of recycled plastic materials

Common industrial practice of producing packaging materials includes using recycled plastic materials in combination with virgin materials or in combination with each other.

This guideline considers a blend of recycled plastic materials with suitable virgin material(s) to exhibit lower transfer of substances than the recycled plastic material alone. A blend of a qualified recycled plastic material with a suitable virgin material is therefore assumed to always be suitable for the same application as the pure recycled plastic material. It may also be suitable for higher exposure applications, but a separate safety assessment is required in this case. When blending two recycled plastic materials with a positive safety assessment for a given application, this guideline considers their blends, in any ratio, to be suitable as well for the same application[18].

C.4 Guidance for recyclers

This section provides guidance for recyclers regarding the *classification* of recycled plastics which are intended for use in cosmetic, detergent or home care product packaging applications. It also provides guidance on *quality assurance*. This guideline intends to

Where to find background information

safety assessessment > E.5
risk management > E.4.4

[15] 25 ppb for each individual PFAS substances and 250 ppb for the sum of all PFAS to be applied to materials under REACH (current proposal of the REACH amendment).
[16] https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term
[17] PFAS are a very wide group of substances and do not exhibit a uniform toxicological profile.
[18] This assumes that no or no significant formation of cross-reaction products occurs during blending.

harmonize the *assessment* of recycled plastics' quality by recyclers and to provide a framework for ensuring the consistency of that quality.

The guidance is defined to support but not to replace the *safety assessment* and *risk management* performed by brand owners on the finished packaging and the packaged product.

C.4.1 Quality levels

This guideline uses three distinct *quality levels*, related to the intended applications, which recycled plastics can be assigned to. The proposed quality levels support the qualification of recycled plastic materials for different packaging uses in cosmetics, detergent and household cleaner products and provide a common language between recyclers and users of recycled plastic materials[19].

The quality levels provide guidance regarding potential applications of a recyclate, but they do *not* constitute a safety assessment or replace the need for a safety assessment by the brand owner.

The quality levels provided by this guideline are based on the *example use cases* **5c**, **5e** and **28** and the corresponding *exposure scenarios* (see D.5.1). The toxicological principles for safety assessment that have been applied in their development are described in D.5.2. The quality levels represent the acceptable level of transfer of chemical substances from recycled plastic materials into packed products for a typical packaging situation of each product category[20].

The three levels represent the use of the material in packaging for

A. Leave-on cosmetic products

B. Rinse-off cosmetic products and hand wash detergents[21]

C. Home care products, including automatic wash detergents

Note

The thresholds suggested for the quality levels are based on the detailed safety assessments conducted by the CosPaTox Consortium. They are however indicative and cannot cover every packaging use case, especially not edge cases such as very high packaging to content ratios. The assignment into a quality level therefore supports but does not replace the safety assessment of the brand owner.

The provided decision tree does not explicitly list substances of specific concern, such as PCBs, but instead applies the strict limits applied to potentially genotoxic substances.

[19] Existing standards related to the quality of rHPDE, rLDPE or rPP plastics or their delivery conditions, such as EN 15344 and EN 15345, do not provide information that is sufficient for safety assessment, or to differentiate the suitability for different product use cases.

[20] The definition of these quality levels is based on the use case and example exposure scenarios **5c**, **5e** and **28** (see D.5.1). The use cases represent products used by adults; for the use of recyclates in the packaging of other products e.g., for children, corrections need to be applied. As exposures resulting from different leave-on applications may vary widely, it is possible for recycled materials that do not fulfill the requirements of the leave-on cosmetic products quality level as defined in this guideline to still be used safely in certain low exposure leave-on applications. In such cases, a more specific safety assessment may be performed on the basis on a defined application or on a more granular view of leave-on applications, for example based on the CPNP cosmetic product mapping[5]. Such a safety assessment may be performed by a recycler or their customers, or jointly.

[21] Such as manual dishwashing and manual laundry detergents.

To assign recyclates into a *quality* level, experimental data from testing (see C.2) is required. When stating a quality level, the type of testing performed to establish the quality level shall always be reported to provide suitable transparency and clarity to users of the recyclate.

The decision tree for the classification into the quality levels is shown in Figure 2, describing how every substance or element detected in the underlying testing (in both non-targeted screening by GC/MS and targeted analyses, see C.2) is to be compared with the threshold values assigned to the level in the figure. For the recycled plastic material to pass the requirements of one of the suggested quality levels, all substances and elements found in the testing must individually remain below the respective thresholds.

To assist with the quality level assignment visualized in Figure 2, this guideline is accompanied by a list of substances commonly found in recycled plastics along with a suggestion for the threshold values (*maximum acceptable consumer exposure*, MACE) to be applied. This list will be continuously updated. For substances which can be identified but which are not found in this substance list, toxicological databases (see E.4.2.1) may be consulted or other toxicological principles may be applied (see E.4.2 and D.5.2). Producers of recycled plastics can also reach out to their customers, in particular brand owners, in cases where they cannot complete the evaluation with the information provided in the substance list.

Passing the requirements of a higher quality level automatically signifies passing the requirements for lower levels. For example, a material suitable for leave-on cosmetic product packaging (A) is also considered suitable for rinse-off cosmetic product (B) and hand wash detergent[22] (C) packaging (see Figure 2). Additionally, passing the requirements for a higher tier (i.e., a more overestimating testing approach according to E.3.3) automatically signifies passing the requirements for lower tiers. For example, passing the requirements based on tier 2 testing (testing with 95% ethanol) can be considered to also pass the requirements of tier 3 (polar and aqueous products). Passing the requirements on tier 1 (testing with dichloromethane) can be considered to also pass the requirements of tier 2 and 3.

If the requirements of none of the three levels are met, the material may be blended with (more) virgin material to reduce the quantities of substances per mass of packaging materials. Alternatively, such a material shall be found to be unsuitable for any of these packaging uses and shall only be considered for other markets, unless a specific testing or safety assessment by a brand owner can demonstrate safety.

[22] Such as manual dishwashing and manual laundry detergents.

Where to find background information

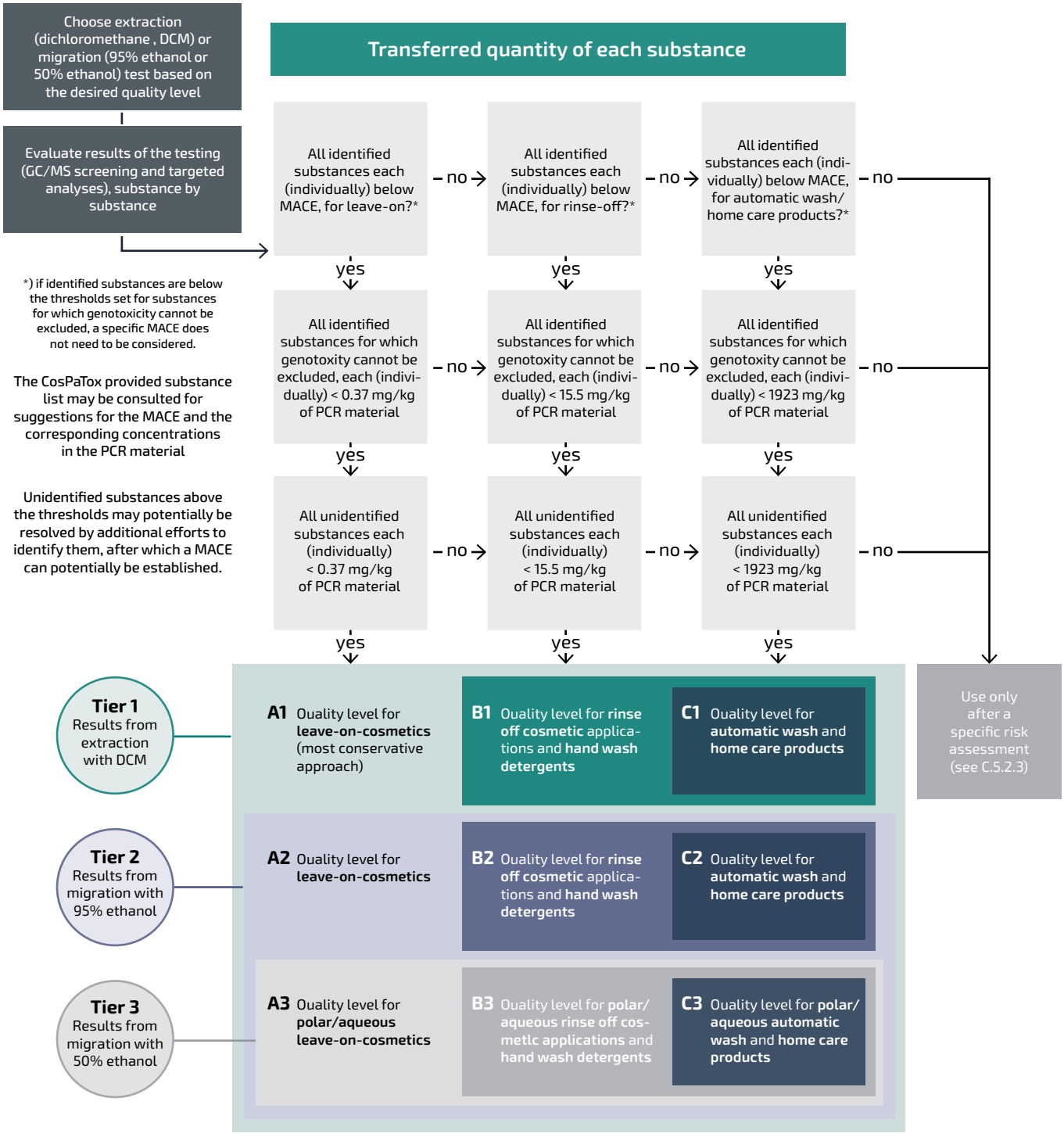
MACE > E.4.3

Where to find details

A *dossier* is available, detailing the results of the testing and their validation.

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.



For the use of the term 'unidentified substances' in this guideline, see D.5.2

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 could not be proven, e.g., based on toxicological data or testing.

C.4.2 Testing strategy

Both the suggested *quality levels* (see C.4.1) as well as the *safety assessment* of recycled plastic materials by converters and brand owners (see C.5.2) rely on testing data which characterizes the transfer of chemical substances from the recycled plastic material into the product. A successful *testing strategy* for plastic recyclates for use in cosmetic, detergent, and home care product packaging balances the need for such testing data with the operational practicalities of commercial scale plastics recycling, without creating an unacceptable compromise in safety.

The most conservative approach to testing recycled plastics is to continuously perform a full analysis and a dedicated pass/fail assessment of every production batch, before the material is released to the market of contact sensitive packaging ('100% positive batch release'). While this approach provides the highest level of control, it places substantial workload and time constraints on recyclers and recyclate users and incurs substantial additional costs throughout the supply chain, potentially restricting the availability and use of suitable recycled plastic materials in cosmetic and detergent packaging.

To avoid the need for testing and releasing every batch of recycled plastic, this guideline describes the implementation of a *testing strategy* by recyclers, combined with a *quality assurance* system (C.4.3). A reliable testing strategy is based on historical data on the input and output materials of recycling and on the recycling process itself, from which a statistics-based confidence is derived that the process is under control and the quality of the output material remains consistent.

When beginning the production or the sale of recycled plastic materials for the use in cosmetic and detergent packaging, a 100% positive batch release approach shall be applied. Transitioning to a *testing plan* becomes possible as data for multiple consecutive batches become available.

When beginning the qualification of a material, a *detailed evaluation* shall be performed for each batch of material produced for a time sufficiently long to understand all relevant variations of the process, including the consistency of the input (feedstock), production conditions, silo dimensions, batch sizes, possible homogenization processes of intermediates and/or final products, etc. This detailed evaluation shall include a non-targeted screening of extractable / migrating substances (see C.2) and the targeted analyses described in Table 1[23].

[23] Recycled plastic materials may require further testing of substances for specific markets. For example, products which are intended for sale into the United States of America, and which may be sold in California will need to comply with California Proposition 65.

This initial phase of testing serves to understand which substances can be present in a recycled plastic material and will therefore need to be considered in the *safety assessment* by the users of the material (see C.5.2). It also provides a baseline for the *testing plan* and the definition of quality assurance processes (see C.4.3 and C.5.3).

By starting out with a 100% positive batch release, material can be made available to the market immediately, i.e., even before the availability of statistical or process control data, as detailed test results are available for every production batch. This is a reasonable burden because the material can also be sold to other applications if it does not yet fit the criteria and requirements.

Once sufficient statistically robust evidence has been gathered to support the conclusion that the recycling process is stable regarding feedstock, in control and that quality across batches is consistent, both the frequency of testing as well as the level of testing may subsequently be reduced. Quality assurance principles (see C.4.3) need to be applied, similar to those used for product performance criteria (such as MFR, flexural modulus, color), but taking into account that the assessment of the chemical composition requires a more conservative and more careful approach. The exact frequency and extent of testing will depend on the specific situation of a given recycling process including the feedstock supply situation.

The guidance provided in this document includes applying at least the non-targeted screening (see C.2) to selected batches according to a *testing plan* once this stage has been reached. Recyclers shall base the frequency of testing on a statistical analysis of their process data and test result variation, in line with best practices of quality management. The sampling frequency shall be maintained at a suitable level to detect trends and/or other changes in the contamination levels of the input or output of the process.

In addition to the non-targeted screening of selected batches as per the testing plan, this guideline requests that, unless otherwise specifically agreed between recycler and their customer, at least four *detailed evaluations* (as described above for the initial qualification of a material) are performed per year for every grade of recycled plastic material sold to cosmetic and detergent packaging applications, preferably by an external independent laboratory.

The testing plan and testing results shall be made available to the costumers of the recyclates as part of the information passed along the supply chain, to support the *safety assessment* and *risk management processes* of converters and brand owners (see C.5.2 and C.5.3).

Where to find background information

safety assessment > E.5
risk management > E.4.4

C.4.3 Quality assurance

Quality assurance provides a framework to ensure the control of processes and the consistency of products and is an implementation of *risk management*.

The quality assurance system of recyclers supplying the cosmetic and detergent packaging market needs to provide adequate confidence in the capabilities and parameters of the recycling process to ensure that the recycled plastic consistently meets the requirements of the declared *quality level* (see C.4.1). This confidence forms the basis for the acceptance of a *testing plan* (see C.4.2) instead of a 100% positive batch release approach. Quality assurance and the testing strategy are subject to the agreement between recyclate supplier and user.

This guideline requests that all elements, requirements, and provisions implemented by the recycler for their quality assurance system should be aligned with the recyclate customers. They shall be documented in the form of written policy and procedures and that this documentation shall include:

- quality control plans, including for the characterization of inputs and outputs, information on sorting and washing processes[24] and on any other part of the process relevant for the quality of the recycled plastic including the choice of points which are critical for the quality control of the recycled plastic (*risk documentation*),
- procedures to monitor and control the entire recycling process, in particular including the establishment of critical limits at the points which are critical for the quality of the recycled plastic (*risk control*), and
- analytical protocols or any other scientific evidence applied before, during and after recycled plastic production, the frequency with which they will take place (i.e., the *testing plan*), and the test equipment used.

The quality assurance system needs to include an effective *change management* approach, covering potential impacts on the quality of the recycled plastics arising from changes in the input, in processes, in equipment, in product formulation or in testing. If significant variations or changes occur, it is recommended for testing to revert to a 100% positive batch release until statistical confidence in the quality of the output is again attained. Significant changes in the non-targeted screening results (obtained as per the *testing plan*) or

Where to find background information

risk documentation > E.4.4
risk control > E.4.4

[24] It is recognized that sorting and washing processes may constitute proprietary information. Due to the importance of these processes for ensuring control of the quality of the recyclate, in particular when a testing plan rather than a 100% positive batch release is used, such information will however be important for recyclate customers. Sharing of information may be conducted under appropriate confidentiality arrangements.

in the mechanical properties of recycled plastic materials may also serve as an indicator of changes in the material and as a signal to trigger reevaluation.

If a significant change occurs to the quality of a recycled material, for which the recycler has previously confirmed compliance with one of the quality levels, the recycler shall notify the user of the material without delay.

To continuously reduce consumer exposure to substances originating from packaging materials, this guideline recommends recyclers to implement programs to go beyond the monitoring of recyclate quality and strive towards a continuous improvement of recyclate purity, following the ALARA[25] principle for the presence of releasable substances in recycled plastics. Improving recyclate purity is a complex subject, connected to sorting, washing, filtration and degassing processes as well as processing parameters and providing concrete recommendations is therefore outside the scope of this guideline.

C.4.4 Information in the supply chain

Where to find background information

safety assessment > E.5
risk management > E.4.4

To support the needs of brand owners in the cosmetic products, detergents, and home care products markets, who are required to perform a *safety assessment* and *risk management* for their packaging, suitable information needs to be made available in the supply chain, i.e., to the purchasers of recyclates.

This guideline requires plastic recyclates intended for these markets to be accompanied by the following information for each delivered batch of product:

1. Designation and description of the material, including batch size
2. Declaration of the quality level as described in this guideline and of the testing employed to assign the quality level
3. Safety data sheet
4. Declaration on maximum heavy metal content 0.01 wt% meeting the requirements of the EU Packaging and Packaging Waste Directive and the expected new thresholds of a future EU Packaging and Packaging Waste Regulation
5. Confirmation of the absence of SVHC above 0.1wt% in the material[26]

[25] As Low As Reasonably Achievable.
[26] This is a general, existing requirement for recycled materials under REACH; not a specific requirement of the CosPaTox Consortium's recommendations.

6. List of substances found in the non-targeted screening of pellets, according to the testing plan, including the detection limit, the CAS numbers, and maximum test concentrations (relative to the mass of recycled plastic material), structured by:

    a. List of all substances found, including unidentified substances

    b. List of identified substances which are banned or restricted under the cosmetic products regulation annex II, annex III, CMR substances of Regulation (EC) No 1223/2009 (Cosmetic Product Regulation)

    c. List of identified substances which are skin sensitizers (based on the publicly available lists under the Regulation (EC) No 1272/2008 (CLP regulation)

7. Results of targeted analyses as described in C.2, including the detection limit

8. Testing plan and three most recent test results

9. Quality assurance documentation

10. Material characteristics as per EN 15344 or EN 15345

Annex III provides an illustration on what format such documentation may take.

C.5 Guidance for converters and brand owners

Before a recycled plastic material which has not been approved for food contact in the European market can be used safely for packaging of cosmetic, detergent, or home care products, a *dedicated safety assessment* (see C.5.2), which covers the potential *exposure* of consumers to substances transferred from the packaging into the product (see C.5.1), is required. Combined with a *risk management* (see C.5.3) approach, the recycled material can be qualified for use.

Where to find background information

risk assessment > E.4
safety assessment > E.5
exposure > E.4.1
risk management > E.4.4

C.5.1 Material characterization

If relevant data is already provided by upstream suppliers[27], e.g., in form of the accompanying documentation (see C.4.4), packaging manufacturers and brand owners may use such data directly and may not need to perform their own testing.

If such information is not available, not complete, or not sufficient, converters and brand owners themselves will need to determine the potential transfer of substances from the recycled plastic material into the product (see C.2) to be able to determine the potential *exposure*.

Additional testing may also be performed, even where supplier information is available, to obtain more refined or more realistic information on the transfer of substances into a specific type of product. This may include testing performed to assess the formation of additional substances during the process of converting recycled plastic pellets into packaging.

The different options for generating data for the risk assessment and their relationship are visualized in Figure 3, which also demonstrates how more detailed testing, such as *migration testing on containers* with a simulant or with the actual product, can be performed where the risk assessment cannot be positively completed with above approaches. Alternatively, the material needs to be rejected.

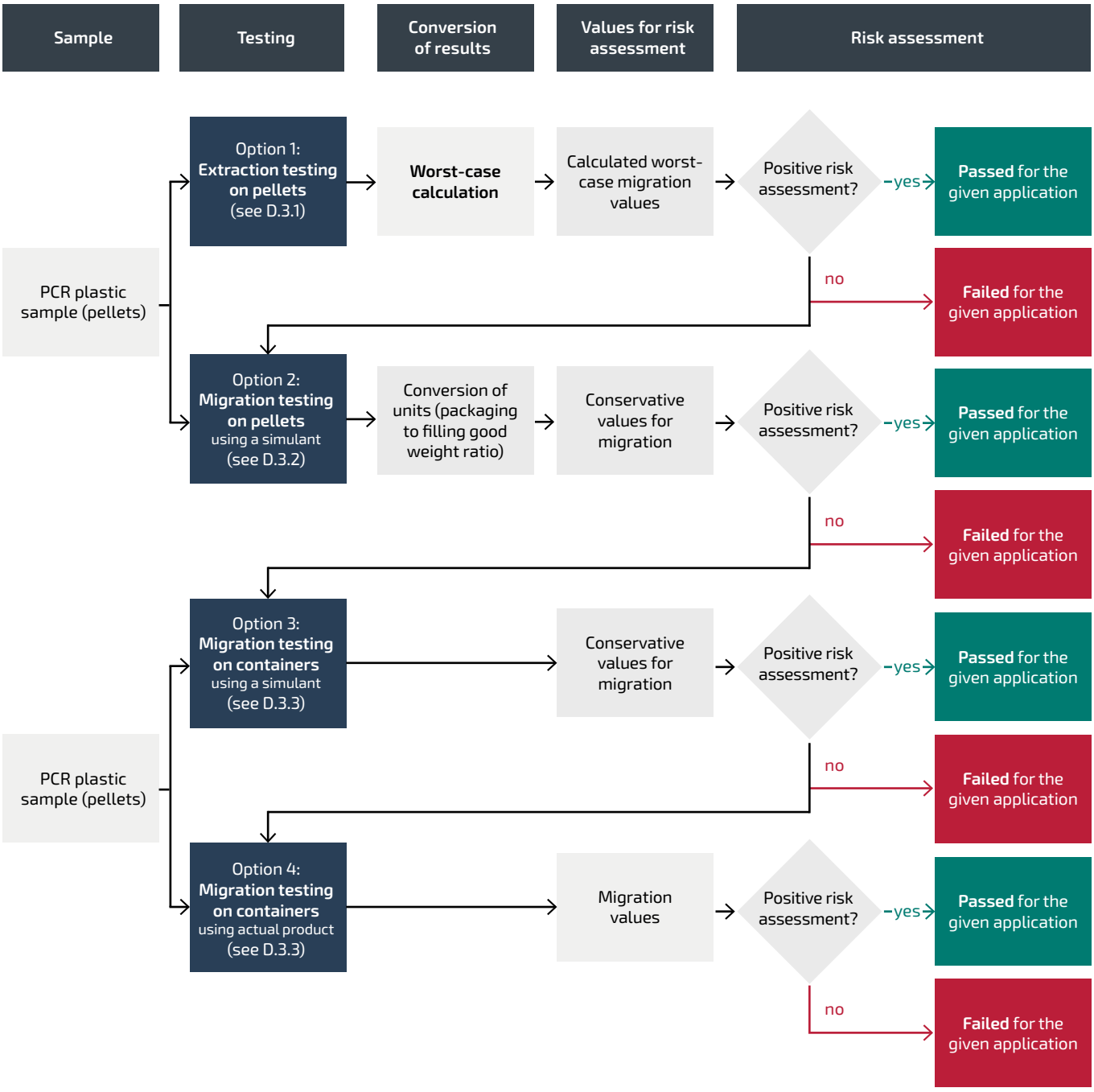
Where to find background information

extraction testing > E.3.1
worst-case calculation > E.3.1
migration testing > E.3.2

[27] Specifically, from recyclers in the case of packaging manufacturers and from packaging manufacturers in the case of brand owners.

Figure 3

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



Where to find background information

risk assessment > E.4
safety assessment > E.5
exposure > E.4.1
effects > E.4.2
MACE > E.4.3

C.5.2 Safety assessment

This guideline describes a substance-by-substance *safety assessment* approach to the use of recycled materials, based on the identification and quantification of potentially transferred substances, establishing *maximum acceptable consumer exposure* (MACE) values for each substance based on the cosmetic product, detergent, or home care product use case.

This guideline requires that the safety assessment shall be carried out by a person in possession of a formal qualification in pharmacology, toxicology, medicine or a similar discipline, or a course recognized as equivalent by an EU Member State.

To complete the safety assessment for a packaging material, its two principal inputs need to be evaluated: *exposure* and *effects*. *Exposure* is determined by the characteristics of the recycled plastic material (transfer of substances by the recycled plastic material into the product, see C.5.1) and the *use case*, i.e., the type of product, its application, and its user. *Effects* are determined by the toxicological evaluation of the substances that migrate.

C.5.2.1 Exposure assessment

In addition to the quantities of substances that can be transferred from a recycled plastic material, the use case will always influence the resulting exposure. This includes:

- the packaging geometry and weight
- the nature and weight of the contained product,
- the duration, frequency, and amount of product use, and
- the type of user (adults or infants).

As demonstrated by the *example exposure scenarios* developed by the CosPaTox Consortium (D.5.1), particular attention needs to be paid to packaging use cases where:

- the packaging to content ratio is high, such as sachets,
- the product is a leave-on cosmetic product, and
- where the intended users are infants or small children.

While each use of recycled plastic material needs to be assessed individually, the CosPaTox example exposure scenarios demonstrate that a material already qualified for a sensitive (high exposure) use may be considered safe for other applications that lead to less exposure. In such cases, existing results regarding the transfer of substances may be used and only the exposure needs to be recalculated. Alternatively, users of recycled plastic materials may pre-calculate exposure use cases for their different spe-

cific packaging formats. A qualification for a given use case can then be considered an automatic qualification for all other use cases of lower exposure.

The CosPaTox Consortium has developed a simple excel tool to calculate exposure from a known amount of transferred substance, which considers all these factors.

The use case examples in Table 3 (see D.4) can serve as a starting point for the qualification of recycled plastic materials for various applications. The exposure scenarios proposed are purposely based on several worst-case assumptions, and refinements can be applicable in a dedicated risk analysis. Where users of recycled plastic materials have already defined their own use cases, their specific values shall however be used preferentially.

Where to find tools

Calculation tool for worst-case exposure > *CosPaTox WCC calculator* (April 2024)

C.5.2.2 Effects

The exposure value obtained for each transferred substance needs to be compared to toxicologically derived thresholds that represent the limits of acceptable residual risk to complete a safety assessment. These thresholds can be expressed as a *maximum acceptable consumer exposure* (MACE).

Where to find background information

MACE > E.4.3

MACE values are derived in different ways, depending on whether the identity of a substance is known or not and what experimental toxicological data are available. Details related to the use of toxicological data and toxicological models considered good practice by the CosPaTox Consortium can be found in sections E.4 and D.5.2. The CosPaTox Consortium also provides a list of commonly found substances in the testing of PCR plastics, along with suggested MACE values. This list will be continuously updated.

Where to find tools

Calculation tool for worst-case exposure > *CosPaTox WCC calculator* (April 2024)

C.5.2.3 Completing the safety assessment

The decision process in this guideline to qualify or not ('pass' or 'fail') a packaging material containing recycled plastic for a given use case is based on a substance-by-substance comparison of the individual substances' exposure values with their *MACE* values. Figure 4 illustrates this decision tree. A packaging use case for a recyclate may be deemed suitable for applications for which exposure to all substances of interest remains below their respective MACE.

Additionally, this guideline requires confirming that the detection limit was sufficiently low to ensure that undetected substances (i.e., substances transferring at just below the limit of detection) will not lead to an exposure above the threshold for potentially genotoxic substances, which in the conservative CosPaTox approach is also applied to all unidentified substances (see D.5.2).

If a material fails the assessment for a higher exposure application, it may still be suitable for another use case which leads to lesser exposure. It may also be possible to apply mitigation options (see text box) to improve the safety assessment outcome. Safety assessments can be refined by experienced toxicologists or safety assessors by applying more appropriate, product-specific assumptions rather than the many overestimations and worst-case assumptions considered in the generic approach as detailed in this guideline.

Mitigation options in case of a negative safety assessment outcome and specific risk assessment

If the outcome of a safety assessment is negative for given application, depending on the case, mitigation options may exist which can provide a pathway to using the recycled material under investigation

Improvement in the identification of substances
If a positive safety assessment is not possible due to the presence of unidentified substances above the applicable threshold, additional effort may be directed towards the identification of these substances. This may include the use of more mass spectral databases, the creation of inhouse databases with relevant reference materials, and the manual interpretation of mass spectra to assign a structure. Where the identification is difficult due to low test concentrations of a substance in the extraction medium or simulant, improvements to the measurement and to the signal to noise ratio may be considered.

Reduction of recycled material content
If a safety assessment cannot be successfully completed for a given application at a certain recycled material content in the packaging, a reassessment at lower recycled material concentration in the plastic may be performed. If such a safety assessment provides a positive outcome, then the use of the lower amount of recycled material per packaging unit may still be considered.

Use of barrier layers
If a safety assessment cannot be successfully completed for a given application at a certain recycled material content in the packaging, it may be possible to reduce the transfer of substances from packaging into the product through the use of barrier layers in the packaging design. This approach will generally require specific migration testing on finished packaging to confirm the effectiveness of the barrier and complete the safety assessment, and is beyond the scope of this guideline.

Refinement in testing
As illustrated in Figure 3, if a safety assessment is failed on the basis of an overestimating testing method, new testing according to a less overestimating method may be performed and the safety assessment repeated with the results of that test.

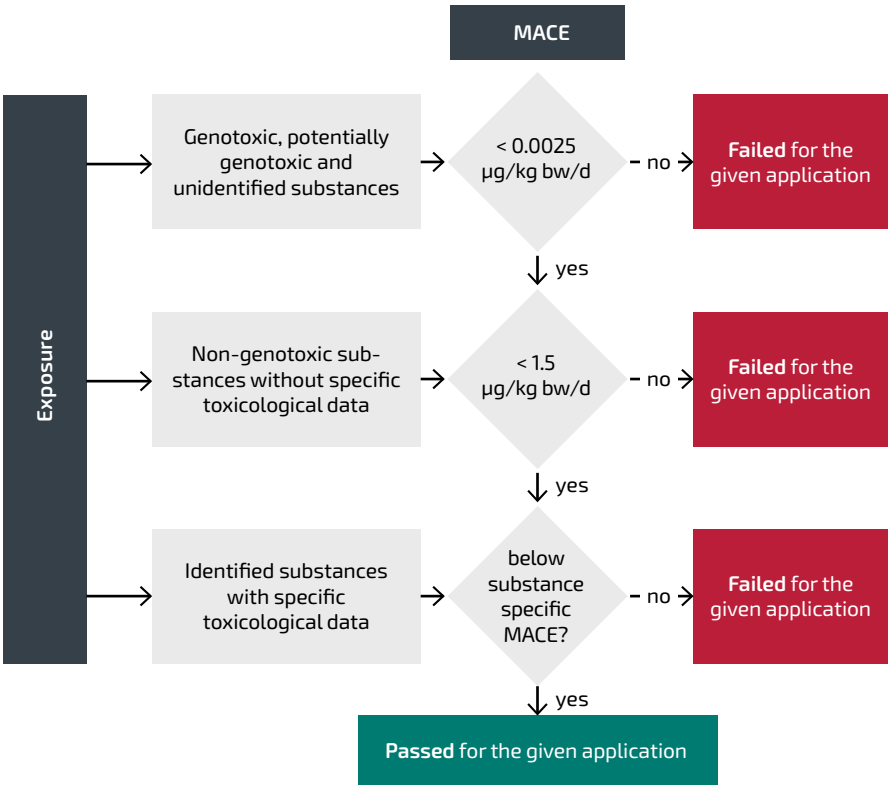
In vitro testing
Where a safety assessment cannot successfully be completed because either unidentified substances or substances of unknown genotoxic potential[28] are found in the testing and their quantities are above the TTC-derived threshold for genotoxic substances, in vitro bioassays may be considered to determine potential genotoxicity in the extraction or migration solution. If the absence of a genotoxic effect can be proven with sufficient confidence, it is possible to apply the thresholds of Cramer class III to unidentified substances and substances for which the genotoxic potential was not established before the testing.

NOTE: This guideline does not provide concrete recommendations for such testing (see E.4.2.6).

[28] Identified substances for which based on available toxicological data the existence of a genotoxic potential cannot be excluded.

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.



C.5.3 Risk management

This section describes how converters and brand owners can continue and extend their existing risk management approach for plastic packaging materials made from virgin materials, by incorporating aspects relevant for recycled plastics.

To avoid the need for testing and releasing every received batch of recycled plastic or packaging made from recycling packaging, converters and brand owners following this guideline shall also implement a *testing strategy*, combined with a *quality assurance* system.

A reliable testing strategy is based on historical data, from which a statistics-based confidence is derived that processes are under control and that the quality of the packaging remains consistent. The testing strategy may be based on reliable data received from recyclers, on own testing or a combination of both. This guideline requests to begin the production or the use of packaging containing recycled plastic materials for cosmetic and detergent packaging with a 100% positive batch release approach and transitioning to a *testing plan* as data for multiple consecutive batches becomes available.

All elements, requirements, and provisions implemented for the *quality assurance* of recycled plastic packaging shall be documented in the form of written policy and procedures and that this documentation shall include:

- quality control plans, including for the characterization of the plastic materials and/or the final packaging, information on converting processes and on any other part of the process relevant for the quality of the final packaging including the choice of points which are critical for the quality control of the final packaging, and

- analytical protocols or any other scientific evidence applied before, during and after the converting of the recycled plastic into packaging, the frequency with which they will take place (i.e., the testing plan), and the test equipment used.

The quality assurance system shall include an effective *change management* approach, covering potential changes in the quality of the recycled plastics, in the converting processes, in equipment, in product formulation or in testing. If significant variations or changes occur, testing shall revert to a higher frequency until statistical confidence in the consistency of the final packaging quality is again attained. Significant changes in the testing results (obtained as per the testing plan) or in the mechanical properties of recycled plastic materials or the final packaging may also serve as an indicator of changes in the material and as a signal to trigger reevaluation.

The risk management approach may also include the use of blends of recycled plastic material with virgin plastic material, to provide a margin of safety in the case of fluctuation of the composition of the recycled material.

D.

CosPaTox investigation of post-consumer recycled PE and PP materials and example safety assessments

Audience

Readers interested in CosPaTox' key findings and how CosPaTox' recommendations were developed.

Note

The work presented in this chapter was focused solely on aspects of product safety and did not cover the technical suitability of the studied materials for any given packaging application.

The CosPaTox Consortium has undertaken extensive studies of the presence of post-consumer contaminants in recycled plastic materials and of the transfer of chemical substances in the case that such materials are used in the packaging of cosmetic products, detergents, or home care products. This work expands upon and details out similar approaches to assessing post-consumer recycled (PCR) plastic materials which preceded it[3], [6], [7].

Based on the findings of these studies, example *safety assessments* were conducted by the CosPaTox Consortium to illustrate the overall flow of a *dedicated* safety *assessment* from an analysis of recycled plastic material to decision making.

The approach of the CosPaTox Consortium comprised the following steps:

1. Determining the *presence* (quantities and identities) of substances in a range of PCR materials[29] (section D.2)

[29] The choice of PCR materials was made based on availability and comprised a range of qualities. The selection does however not claim to be fully representative for the overall market. The focus of the interlaboratory comparison was the establishment and verification of analytical methods which this guideline recommends applying to recycled plastic materials. As this guideline recommends a testing of each grade of recycled plastic material individually, representative data was required from the interlaboratory comparison.

2. Determining the *transfer* of substances from PCR materials into products, following three approaches: *worst-case calculation* from *extraction testing on pellets* (section D.3.1), *migration testing on pellets* (section D.3.2) and *migration testing on containers* (section D.3.3)

3. Calculating *example consumer exposure scenarios* (section D.5.1) on the basis of the typical packaging designs and product use cases (section D.4)
4. Conducting *example safety assessments* based on the exposure scenarios, applying toxicological principles to the assessment of possible *effects* of substances transferred into the product (section D.5)

The CosPaTox guideline for industry provided in chapter C is based on the studies, results, and the example safety assessments presented in this chapter.

Where to find background information

exposure > E.4.1
effects > E.4.2
extraction testing > E.3.1
worst-case calculation > E.3.1
migration testing > E.3.2
risk assessment > E.4
safety assessment > D.5

D.1 Samples and methodologies

The CosPaTox Consortium conducted a large interlaboratory comparison of PCR materials in the analytical laboratories of its members, with a total of seven laboratories participating. Overall, more than 600 measurements of PCR materials were performed
This work served two principal purposes:

- investigation of different testing conditions as to their applicability, repeatability, and reliability. The testing procedures provided in C.2 and Annex II are based on these results.

- gaining an understanding of the typical properties of PE and PP recyclates, i.e., the substances that are present in PCR materials and that can be potentially transferred into packaged products.

The CosPaTox Consortium collected a total of 25 samples of rHDPE (15 pellet samples, 10 bottle samples), 19 samples of rPP (11 pellet samples, 8 jar samples) and 10 rLDPE samples (5 pellet samples, 5 films) from various sources[30]. Most materials were commercially sold post-consumer recyclates. Samples in container form were produced with 100% of recycled content. The testing, both on pellets and on containers was performed with 100% of recycled content to study the most ambitious scenario and to identify the maximum number of substances. Testing with pure recycled material goes substantially beyond current market practice as well as potential future recycled content requirements in legislation.

The testing was carried out using several conditions for each sample provided. Six different conditions, representing *extraction* and *migration* testing were applied to pellet samples and two different *migration* conditions were applied to *container* samples. The principal method of analysis of the extracted or migrated substances was a non-targeted GC/MS screening.

Additionally, all samples were analyzed for their elemental composition. This testing was not carried out as an extraction or migration but by high- microwave assisted acid digestion, followed by analysis by inductively coupled plasma – tandem mass spectrometry (ICP-MS/MS). 17 elements[31] of specific interest to the safety assessment were quantified.

The interlaboratory comparison confirmed the validity and reproducibility of GC/MS as a method to analyze recycled plastic materials, in particular to perform non-targeted screenings.

[30] Flexible PP samples were not part of the study. The CosPaTox Consortium however considers the conclusions and recommendations to be equally applicable to flexible PP packaging.

[31] Elements present in virgin packaging (calcium, titanium, zinc, phosphorus, antimony), elements associated with safety concerns (arsenic, soluble barium salts, cadmium, chromium, cobalt, mercury, nickel, lead, vanadium) and elements that occur in pigments used in plastics (aluminum, copper, iron).

Where to find details

A *dossier* is available, detailing the results of the testing and their validation.

Where to find background information

extraction testing > E.3.1
migration testing > E.3.2
GC/MS > E.3.4.2
elemental analysis > E.3.4.3

Where to find details

A *dossier* is available, detailing the results of the testing and their validation.

Where to find tools

List of identified substances > *CosPaTox Substance list* (April 2024)

Good reproducibility was found between the laboratories, considering existing differences in technical equipment and instrument settings. The results obtained for *extraction testing on pellets*, *migration testing on pellets*, and *migration testing on containers* followed the expected order (see E.3.3) and showed good correlation between and across the methodologies (see D.3.4).

Based on the experiences from the interlaboratory comparison, the CosPaTox Consortium has developed a recommendation for the testing of recycled plastic materials (see chapter C and Annex II).

D.2 Presence of post-consumer substances in PCR materials

Note

The list of substances was compiled from all testing performed. Thus, in the unlikely case that a substance was not detected during extraction testing but only while testing migration, it still is reported in the list.

The results of the interlaboratory comparison performed by the CosPaTox Consortium were combined with results of pre-studies undertaken by CosPaTox members to generate a combined list of identifiable substances found in recycled PE and PP (see Table 2 and the substance list provided online by the CosPaTox Consortium).

A variety of substances detected in the analyses were associated with plastic packaging materials themselves, either in form of substances that are known to be present in plastic packaging materials (IAS), or in form of substances that can reasonably be assumed to have formed from PE or PP packaging materials during their production, and during their use and post-use phase (NIAS). Key groups of substances attributable to packaging itself include antioxidants (including in form of their degradation products), photoinitiators (potentially from inks or certain adhesives), UV stabilizers and substances related to pigments as well as alkanes and alkenes.

Where to find background information

IAS > E.5.2
NIAS > E.5.2
packaging materials > E.2.2

A number of additional substances were detected which likely originate from *foreign materials* in the recycling input, that is, materials other than PE or PP. Several substances were identified which plausibly originate from PET, PA, PS and PVC plastic packaging materials which may have been, to a small extent, present in the recycling input. Such materials may also originate from multi-material packaging designs for example barrier layers or from packaging with multiple components. Further substances such as phthalates, bisphenol A, flame retardants, fluorinated compounds may result from non-packaging plastic items or thermographic paper being present in the recycling input. Such substances, originating from foreign materials, may be considered plausible as impurities in rPE and rPP, as recycling inputs. They always represent the present state of packaging design and collection and sorting technology (there is no 100% pure PE or PP polymer packaging waste).

The largest group by number of identified substances were however substances that are most likely related to the former *filling goods* of the packaging recycled to obtain the PCR material.

- Many substances were detected that likely originate from *food* or *cosmetic products*, such as fat-related substances (fatty acids and their esters)[32] as well as other substances with chemical structures typical for natural compounds. The fact that these particular substances were detected, and not others which are also known to be present in food or cosmetic products, may be explained by the detected substances being more difficult to remove than others in the washing processes that are established for PE and PP waste.

- A number of substances were detected that could originate from residues of *cosmetic products* and detergents contained in packaging waste, such as fragrance compounds[33], UV filters (as used in sunscreens) and preservatives.

- In addition to these substances, which plausibly originate from food and consumer products, a number of *agriculture-related chemicals*[34] were detected, suggesting that packaging containing such products may have been present in the recycling input.

- Finally, a limited number of substances that were detected appear to be related to *pharmaceuticals*, suggesting that pharmaceutical packaging, including not fully emptied packages, may have been present in the recycling input.

These findings are consistent with a comparison between PCR materials and corresponding virgin materials undertaken by the CosPaTox Consortium. This comparison demonstrated a clear increase in the amounts of fatty acid-related substances and NIAS in general in PCR materials, compared to virgin plastics.

For other groups of substances, such as various alkanes and alkenes, other aliphatic and aromatic compounds, aldehydes, ketones, carboxylic acids, alcohols, esters, ethers, and amines, and thio compounds, their origin may be either the former filling goods, the plastics, or foreign materials in the recycling input. They may have been present in these materials or, in many cases more likely, may have formed from other substances during shelf-life and recycling, e.g., as high temperature degradation products. While the formation mechanism is well known for alkanes and alkenes[3] (and they

Note

For the last two groups, it could not be firmly established whether these substances originated from food residues that contained these substances, from agricultural chemicals packaging or pharmaceutical packaging that was recycled with the other packaging, or from potential consumer misuse, i.e., storing agricultural chemicals in packaging meant for other products.

Where to find details

A *dossier* is available, detailing the results of the testing and their validation.

[32] To a certain extent, such substances are also used in the production of packaging materials. The number of substances and their elevated amounts however suggest the dominant contribution being from residual filling goods.
[33] As well as a range of naphthalene, salicylate and benzoate structures that may also be related to fragrances.
[34] Pesticides, fungicides, herbicides, insecticides.

have been risk assessed for food contact[8]), further investigation would be needed to assign other substance classes with confidence to a specific origin.

The test results also included a number of unidentifiably substances, typically at low amounts. In this regard, it is worth considering that even in the testing of virgin materials, non-targeted screenings often result in a certain number of unidentifiable peaks of low quantity, which cannot be firmly assigned.

The list of detected substances was further developed by the CosPaTox Consortium through the inclusion of relevant toxicological information, which may be used in defining *maximum acceptable consumer exposure* (MACE) values. This combined list is provided by the CosPaTox Consortium to provide an orientation, especially to recycling industry, for performing assessments of recycled plastic material, without having to resort to own toxicological review of identified substances. This list is intended to be used in conjunction with the recommendations in sections C.4.1 and C.5.2.2 and will be continuously updated.

Where to find tools

List of identified substances > *CosPaTox Substance list* (April 2024)

Where to find background information

MACE values > E.4.3
toxicological data > E.4.2

Table 2

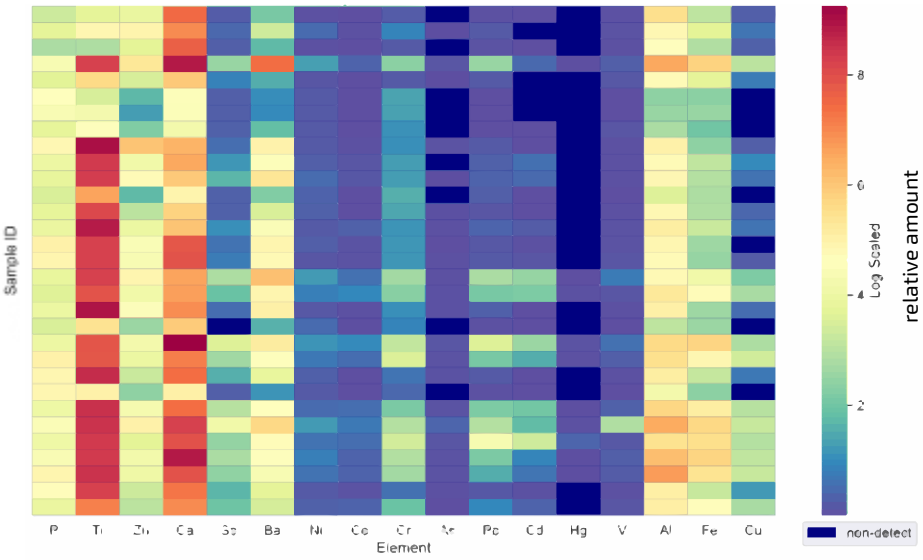
Substance groups (excerpt) identified in extraction and migration testing of PE and PP recyclates, sorted by frequency of detection.

Substance group	Remarks	Likely major origin		
		PE/PP packaging	Product residue	Foreign sources[35]
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		

[35] Such as non-packaging materials as contamination in the plastic recycling input.

In the *elemental analysis* of the CosPaTox rLDPE, rHDPE and rPP samples, clear patterns could be observed, both between the elements that were analyzed and between the recycled materials themselves. Calcium, titanium, aluminum, and iron were present in the highest amounts. Zinc, antimony, copper and phosphorus were found in intermediate amounts. Elements which are considered substances of concern were generally found at lower levels, except for barium[36]. The exact amounts of the analyzed elements varied substantially between samples (Figure 5). The results of the study, particularly the high variability of results, suggest that conducting an elemental analysis of recyclates, at least on a statistical basis, is highly advisable.

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.

[36] Packaging materials may contain insoluble barium sulfate, which is not a safety concern. Soluble barium salts may require a risk assessment. The performed analysis did not differentiate soluble and insoluble barium salts. Such a differentiation may be required in cases where elevated amounts of barium are found in an elemental analysis.

D.3 Transfer of post-consumer substances from recycled plastic materials

The results presented in this section illustrate how the transfer of substances from recycled plastic packaging materials into products can be evaluated, based on *extraction testing on pellets*, *migration testing on pellets* or *migration testing on containers* and how the results from these three methods compare to each other. The information provided is based on the data gathered in the CosPaTox interlaboratory comparison of PCR materials (see prior section) where all three methods were applied to gather as much data as possible.

> ***The testing and results described in this section cover the different methods used and evaluated during the CosPaTox interlaboratory study. For the recommendations in chapter C, a selection among these options was made based on the experiences gathered during the CosPaTox studies.***

Where to find background information

extraction testing > E.3.1
migration testing > E.3.2

D.3.1 Extraction testing on recycled plastic pellets

The CosPaTox extraction studies on pellets of recycled plastic materials were conducted according to the procedure described in section F.4.

When recycled plastic pellets are analyzed in form of an extraction, a conversion from the *extraction results* (test concentrations, per mass of pellets) to the corresponding concentrations in the product (filling good) is required (see section E.3.1). The CosPaTox Consortium applied a *worst-case calculation* to the extraction results before translating the results to be relative to the mass of product.

Where to find background information

worst-case calculation > E.3.1

D.3.2 Migration testing on recycled plastic pellets

The CosPaTox study of pellets of recycled plastic materials was also conducted according to the procedure described in section F.5, in two series, using 95% ethanol and 50% ethanol, respectively, as the simulant. These two simulants were chosen to approximate the properties of either lipophilic (hydrophobic) cosmetic products (use of 95% ethanol) or of hydrophilic (polar) cosmetic products, detergents, and home care products (use of 50% ethanol).

When recycled plastic pellets are analyzed in form of a *migration test*, a conversion of the results is required (see section E.3.2.1) to obtain values relative to the amount of product (filling good). The CosPaTox Consortium did not apply any correction factors to the migration testing results; only a conversion of the results to be relative to the mass of product was performed.

Where to find details

A *dossier* is available, detailing the results of the testing and their validation.

D.3.3 Migration testing on bottles made from recycled plastic

The CosPaTox migration testing on containers made from recycled plastic materials was conducted using 200 mL blow molded bottles, containing 100% recycled plastic content and in two series,

using either 95% ethanol or 50% ethanol, respectively, as the simulant, according to the procedure described in section F.6.

The purpose of this testing was to demonstrate that results obtained from *migration testing on pellets* are suitably correlated with the results from *migration testing on containers*.

The chosen setup of migration testing directly provides values for the migration of substances relative to the amount of product (filling good). No conversion of the results was required or performed.

D.3.4 Comparison of results between the different testing approaches

The results of the *extraction tests* (applying a *worst-case calculation*) uniformly led to higher quantities of transferred substances than either the *migration testing on pellets* or *migration testing on containers*. Extraction testing typically yielded at least double the values found in either of the other two methods. These results confirm the expected overestimation of extraction testing.

At the same time, the number of substances detected in the *extraction tests* was comparable to that of *migration testing on pellets* and *migration testing on containers*, both with 95% ethanol as the simulant. The difference between these two sets of results were therefore seen mainly in the quantities of substances detected, not in the number of substances detected.

Considering the overestimation inherent in the method, the CosPaTox Consortium considers *extraction testing* relevant especially for low exposure use cases such as home care products or for plastic materials with a low recycled content. In cases where a worst-case calculation from *extraction testing on pellets* demonstrates that an application can be considered safe for consumers, *migration modelling* or *migration testing* may not be necessary. If, however, a worst-case calculation from extraction testing results fails to demonstrate safety, the latter two approaches can still be followed to potentially complete the safety assessment of a recycled plastic material (see also E.3.3). This is possible due to the generally highly overestimating nature of coupling an extraction testing with a worst-case calculation.

CosPaTox' results demonstrate that results obtained from *migration testing on pellets* with 95% ethanol correlate very well with results obtained from *migration testing on containers* (bottles), also with 95% ethanol, made from the same PCR material.[37, 38] ‚CosPaTox'

Where to find details

A *dossier* is available, detailing the results of the testing and their validation.

Where to find background information

migration modelling > E.3.1

[37] The comparative testing of PCR pellets demonstrated also that *migration testing on pellets* is less overestimating than an equally simple *extraction test on pellets*.

[38] It is noted that this statement is made for bottles and comparable rigid containers. This correlation may not hold in general for flexible packaging, in particular not for small sachets.

findings thereby expand upon prior studies performed by other parties on pellets only[3]. The comparison between the various conditions and samples in the study allowed to demonstrate that the described *migration testing on pellets* is generally most severe and tends to overestimate the migration, compared to the *migration testing on containers*[39]. This finding is in line with an experimental comparison of the surface area of pellet samples and the bottles produced from those pellets conducted by the CosPaTox Consortium. This comparison, conducted by a computer tomography analysis, demonstrated that commonly sized pellets of recycled plastic exhibit a 50 to 100 % larger surface area than a bottle of the same mass. A higher surface area for the pellets is conducive to increased migration and therefore, *migration testing on pellets* may be expected to yield overestimating results.

One exception of the overestimating nature of the testing on pellets compared to bottles was found in some of the detected quantities of alkanes. As alkanes and alkenes (polyolefin oligomers in general) have been risk assessed[8] and generally found to be of low concern, this guideline considers this potential underestimation as acceptable for the purposes of safety assessment.

The *migration testing on pellets* was concluded by the CosPaTox Consortium to be a validated, sufficiently severe and at the same time simplified approach for the generation of data for the purposes of safety assessment of recycled plastic materials to be used as packaging of cosmetic products and detergents.

[39] If the final packaging format which will use the recycled plastic material is a flexible packaging, in particular a small sachet, the validity, i.e., the representativeness, of testing on pellets rather than films should be confirmed in each case.

D.4 Example packaging use cases

Migration testing on pellets rather than on containers means that the testing results have to be converted for the use in *safety assessments*. Specifically, the amounts of migrated substances must be converted from being expressed relative to a certain amount of recycled plastic material (the mass of the pellets) to being expressed relative to the amount of product into which the substance would migrate (mass of the filling good in actual packaging designs). This conversion is performed by multiplying the concentration of a substance relative to recycled plastic material with the packaging weight and then dividing by the product weight[40]. As such, this calculation requires knowledge of the packaging *use case*, in particularly the weight of the packaging, the product type, and the filling amount.

This section provides data for packaging *example use cases* that can be useful for performing the conversion and is provided for orientation to users of this guideline that do not (yet) have a specific packaging design in mind.

Required information such as the weight of each packaging, the volume of the product as well additional information such as the shelf life of the product was provided by CosPaTox Consortium members. Overall, 28 use cases were created (Table 3), which can serve as a reference for generalized safety assessments, i.e., cases where the safety assessment is not performed for a specific packaging/ product combination.

[40] This calculation is just a conversion of base/reference quantity, from packaging weight to filling good weight. It does not (need to) introduce assumptions or models regarding the migration behavior of substances as is the case in worst case calculations or migration modeling.

Table 3

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

Use case	Packaging type	Packaging material	Product type	Amount of content [mL][41]	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

The CosPaTox Consortium has developed an excel calculation tool for the conversion of *extraction testing* derived data and data from migration testing on pellets to obtain amounts relative to the product, as would be obtained by the more effort-intensive *migration testing on containers*. For extraction testing derived data, this tool implements a *worst-case calculation*, by applying the full mass transfer assumption.

Where to find tools

Calculation tool for worst-case exposure > *CosPaTox WCC calculator* (April 2024)

[41] For a generalized calculation, where the exact density of the product is not known, a density of 1 g / dm^3 is typically assumed for the calculation.

D.5 Safety assessment

Where to find details

Annex I – Example safety assessment results

Where to find background information

exposure > E.4.1
exposure scenarios > E.4.1
risk assessment > E.4 safety assessment > E.5
MACE > E.4.3

This section describes how example use cases (see D.4) were combined by the CosPaTox Consortium with *exposure scenarios* (see D.5.1) to perform *example safety assessments* (see D.5.3 and Annex I). In total, 28 use cases were evaluated with this methodology, accounting for different products, packaging weights, product use amounts and for different body weights (adults and infants)[42].

The results also demonstrate how to derive *maximum acceptable consumer exposure* (MACE) thresholds for the safety assessment and how to set the required *detection limit* when analyzing recycled plastic material for use in different types of packaging and product combinations.

D.5.1 Model exposure scenarios and exposure calculation

Since different types of products and applications imply very different levels of consumer contact with the product, exposure calculations were performed by the CosPaTox Consortium separately for several examples of each of the three product categories rinse-off cosmetic products, leave-on cosmetic products, and detergents (Table 4). The last two columns contain the exposure to a substance which would result for the given use case assuming that the packaging material transfers one gram of that substance into the product[43].

The results provide a useful illustration of the relative exposures resulting from different packaging formats and products, under the assumption that the transfer of substances is identical in all cases.

[42] Body weight values were based on [9].
[43] This value is an exposure (in units of µg/kg bw per day). Not to be confused with the analytical result, i.e., the amount of substance transferred (in units of mg/kg pellets or mg/kg product).

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 (adult) / cm^2	Exposure from 1g of substance transferred per kg packaging material [µg/kg bw per d]	Exposure from 1g of substance transferred per kg packaging material [µg/cm^2]
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	0.02162	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	0.4794	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%		957.1	
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

When comparing the exposure calculation results for the different example use-cases (Table 4, and Annex I), three key factors were found to influence the level of exposure:

- the *packaging format*: packaging formats with low filling weight, such as small sachets, exhibit a higher quantity of transferred substances relative to the product; higher concentrations of transferable substances in the product lead to higher exposure to these substances, all other factors being equal;

- the *product type*: leave-on cosmetic products typically lead to substantially higher exposure than rinse-off cosmetic products and hand wash detergents[44], assuming the quantities of substances transferred into the product are equal. Home care products can be seen to result in exposures that are orders of magnitude lower than even rinse-off cosmetic products; and

- the *user*: given a specific application and packaging type, i.e., a fixed absolute substance exposure, the relative substance exposure per kilogram of body weight is highest for infants, due to their lower body weight. As such, all other aspects being equal, products intended for small children and infants will require highest levels of packaging material purity.

Each product, which will be a specific combination of above factors, in principle needs to be assessed individually in a case-by-case evaluation. However, the results presented in this section show that for the purposes of classifying recycled plastics, it is possible to group the use cases into the following three categories[45]:

A. Leave on cosmetic products
B. Rinse-off cosmetic products and hand wash detergents[46]
C. Home care products, including automatic wash applications

The results of the example exposure scenarios suggest that it can then generally be assumed that a material suitable for leave-on cosmetic products is also suitable for a rinse-off product or a hand wash detergent product. In addition, a material suitable for rinse-off products is also suitable for home care products. In both cases this is not valid, if very large packaging-to-product ratio differences exist between the applications.

[44] Such as manual dishwashing and manual laundry detergents.

[45] The following use-cases were considered as indicative default scenarios for each category. The scenarios do cover the average but not worst-case application and must be confirmed for the envisaged product application; adjustments in terms of packaging format or use group (e.g. children) needs to be considered in the final safety assessment. Leave-on cosmetic products: body lotion, adult use, use case 5e; rinse-off cosmetic products and hand wash detergents (such as manual dishwashing and manual laundry detergents): shower gel, adult use, use case 5c; home care products: adult use, use case 28. See Annex I for the listing of use cases and calculation results.

[46] Such as manual dishwashing and manual laundry detergents.

Where it is required to define a single scenario that shall be applicable to multiple types of product applications, the scenario with the highest exposure needs to be chosen. A potential consequence of following this approach is that recycled plastic materials may fail the safety assessment, even though they would comply with a lower exposure application like the use for detergent packaging.

The CosPaTox Consortium has developed an excel spreadsheet which allows easy calculation of exposure based on a defined concentration of a substance in a packaging material, applying the full mass transfer assumption

D.5.2 Safety assessment principles and assumptions applied by the CosPaTox Consortium

The example safety assessments provided in this guideline focus on the dominant exposure route *of skin contact with the product* (relevant for all products in the scope of this guideline).

The safety assessments do not specifically consider exposure from *skin contact with the packaging* itself, *inhalation* exposure for products applied in aerosol form or which may be converted to an aerosol during use (e.g., hair spray, deodorant, products used in the shower), nor *ocular* exposure. The exposure by routes not covered were considered to be substantially lower than the main exposure route of skin contact. For the use cases assessed by the CosPaTox Consortium, contact with the packaging, inhalation of the product and ocular exposure was therefore concluded to be covered within the safety assessment performed for the two dominant exposure route, skin contact.

However, if a packaging were to be assessed for a product type that leads to a significant inhalation exposure, this exposure route requires a dedicated assessment, including the evaluation of suitable toxicological reference values. Equally, if a packaging is to be assessed for a product type that leads to a significant exposure by *ingestion* (relevant e.g., for mouth wash and lipstick), a dedicated safety assessment is required.

Where to find tools

Calculation tool for worst-case exposure > *CosPaTox WCC calculator* (April 2024)

Note

The CosPaTox approach is technology neutral and does not consider any specific recycling technology, but only the quality of the recycled materials. It follows that the safety assessment described in this section is not based on determining and assessing the purity of plastic waste input materials and the decontamination efficiencies of different recycling processes but only the chemical composition of the recycled materials themselves. As such, the methodology described here is independent of the nature of recycling processes and can be applied to recycled plastics from any source.

Where to find background information

TTC > E.4.2.4

Note

Where this guideline states 'unidentified substances', it refers to substances for which no chemical structure can be assigned with confidence.

This is to be differentiated from cases where the chemical structure of a substance can be approximated, which allows to understand the toxicology of the substance and apply a different threshold.

For the evaluation of effects, it was assumed that toxicological data or models for the exposure by ingestion[47] could also be used to assess dermal exposure, e.g. by route-to-route extrapolation, except for skin sensitization effects which were assessed separately. Aggregate effects of exposure to multiple chemical substances have not been considered in this work[48]. The assessment assumes that exposure to a specific dose of an individual substances occurs constantly for a whole life-time, which is a considerable overestimation, considering the variability in the presence of individual, potentially hazardous substances in a PCR material.

In the example safety assessments, no substance-specific information regarding safe thresholds (e.g., ADI, DNEL, SML) were considered[49]. Instead, the Threshold of Toxicological Concern (TTC) approach was applied to define safe exposure thresholds for systemically toxic substances, including potentially genotoxic and endocrine active substances[50]. For substances with (potential) genotoxic properties, the TTC threshold value of 0.0025 µg/kg bw/d[51] was used[52]. Following the precautionary principle the members of the CosPaTox Consortium agreed that this threshold value should also apply to substances with known endocrine disruptive properties if no substance-specific threshold for adverse endocrine activity is known. Additionally, the CosPaTox Consortium conservatively considered all *unidentified substances* as potentially genotoxic even though experience shows that only a fraction of such substances exhibits genotoxic potential. For substances for which genotoxicity and endocrine activity can be excluded, exposure assessment was performed using the highest Cramer class (Class III). The corresponding threshold value is 1.5 µg/kg bw/d[53]. This approach is more conservative than the general TTC concept by not considering Cramer classes I and II with their higher respective thresholds. It should be borne in mind that in a practical safety assessment, where substance-specific toxicological information exists, specific threshold values (see E.4.2) may be used instead of TTC limits to calculate acceptable concentration levels for these specific substance in products.

[47] This refers to toxicological data generated in studies focusing on the exposure by ingestion, a very common type of study. This does not refer to considering ingestion exposure in the safety assessments described in this guideline (see above).
[48] See the CosPaTox dossier for details.
[49] In the practical application of the described concepts to actual recycled materials, substance-specific data will generally be used (see E.4.2).
[50] This approach has also been applied in studies of other parties, e.g., [3].
[51] Corresponds to 0.15 µg/person/day for a person of 60 kg, see E.4.2.4.
[52] It should be noted that certain substances classes are excluded from the application of the TTC concept (see E.4.2.4). Such substances were not considered in the example risk assessments.
[53] Corresponds to 90 µg/person/day for a person of 60 kg.

For skin contact, the DST approach was applied. In order to calculate skin exposure for the different use cases, the average skin surface area that comes into contact with the product must be taken into account. The skin surface areas and safety factors for the different use cases considered by the CosPaTox Consortium were taken from the AISE REACT tool[10], SCCS[11] (Table 4) and QRA II[12][54]. According to [13], the exposure to skin should remain below of 64 µg/cm^2 for substances for which skin sensitization cannot be excluded[55]. It should be borne in mind that in practical safety assessment, where substance-specific information exists, specific threshold values (see E.4.2) may be used instead of DST limits to calculate acceptable concentration levels for these specific substance in products.

Where to find background information

DST > E.4.2.5

[54] See E.4.2.5 for more information on the DST approach.
[55] See E.4.2.5 regarding restrictions to the applicability of the DST approach to certain groups of substances.

Residual uncertainties in the described approach and results

While the investigations and safety assessment approaches described in this guideline have been conducted and assembled with utmost care and to the most up-to-date principles of risk assessment, intrinsically, any such assessment contains residual uncertainties.

Out of these uncertainties, which are discussed in detail in the CosPaTox dossier, the most significant one is the measurement uncertainty, that is the potential for the measured quantities of a substance to deviate from the true quantities, due to inherent limits in the analytical techniques. Such uncertainty (including due to different lab standards) will differ from technique to technique. This guideline describes, following good practice, to determine the uncertainty for each method used and to factor this into the safety assessment, for example in the comparison of experimental results with maximum acceptable consumer exposure (MACE) values.

Where to find tools

Calculation tool for worst-case exposure > *CosPaTox WCC calculator* (April 2024)

D.5.3 Illustrative example

The applied methodology can be illustrated using use-case **1a** as an example. In this example, the use-case of the recycled plastic material is a HDPE tube for shampoo with a content volume of 250 mL and an assumed density of the product of 1 g/dm^3. The tube weight is 17 g. Assuming a transfer of a post-consumer substance of 1000 mg per kg of recycled packaging material from the HDPE tube manufactured with 100 % recycled plastic content[56] results in a concentration of 68 mg/kg in the shampoo.

In the use case **1a**, a portion typical for an adult person of 10.46 g of shampoo once per day will then contain 711 µg of the post-consumer substance. With the retention factor specifying that 99 % of the shampoo is rinsed off with water and only 1 % of the product remains on the skin, an amount of 7.11 µg of the substance is available for dermal absorption. The skin penetration in this scenario is assumed to be 50 % (section D.5.1). For an adult person with 60 kg body weight (bw), the systemic exposure will therefore be 0.05927 µg/kg bw/d. This value is far below the safe threshold of 1.5 µg/kg bw/d for Cramer Class III substances, but it exceeds the acceptable TTC level of 0.0025 µg/kg bw/day for genotoxic substances. In this case, the amount of this substance could only be considered safe, if there is clear evidence of absence of genotoxic potential. If potential genotoxic properties cannot be excluded, which in the conservative approach applied in this guideline includes all unidentified substances, the amount of the substance transferred from the packaging in example use-case **1a** must not exceed 42.18 mg/

[56] 100% recycled content chosen for illustrative purposes and to describe the most ambitious scenario. A reduction in recycled material content will lead to a reduction of substances transferred into the product.

kg packaging material. If, as in the example above, this cannot be achieved with 100% recycled content, or at any other given content, one option is to reduce the recycled content to meet the threshold.

For more examples, see Annex I. Additionally, an excel spreadsheet has been developed by the CosPaTox Consortium which allows easy calculation of exposure based on a given transfer of a substance or the concentration of a substance in a packaging material, applying the full mass transfer assumption.

D.5.4 Setting required detection limits for analytical techniques

Example use case **1** can also be used to explain how to assess the appropriateness of the analytical *limit of detection*. Recycled plastic materials will contain a number of substances at concentrations below any given detection limit. As the identity of such substances can principally not be established (being below the detection limit), the CosPaTox Consortium took a conservative approach in which all such unidentified substances are considered potentially genotoxic. The maximum acceptable transfer of a (potentially) genotoxic substance from a packaging material in the CosPaTox example safety assessments corresponds to an exposure of 0.0025 µg/kg bw/d, which is the TTC threshold for genotoxic compounds. The corresponding maximum amount of substance transfer can be set as the required detection limit of the analytical method. This approach ensures that substances that are not detected but may transfer undetectably in amounts just under the detection limit do not need to be separately considered in a safety assessment[57].

For example, if the resulting maximum acceptable transfer of unidentified and potentially genotoxic substances from the packaging material is 5 mg/kg of plastic material for a given use case, the detection limit would have to be at or below 5 mg of substance per kg of plastic material, to allow confirming the safety of the material for the respective application. The higher the maximum acceptable test concentration, the lower are the requirements regarding the analytical detection limit.

Assuming a detection limit of 5 mg of substance per kg of pellets, i.e., an amount of 5 mg substance per 1 kg recycled plastic material, under the conditions of use case **1a**, 0.34 mg of the substance may be present in the product in case of full transfer and may be available for dermal absorption. An adult person with 60 kg body weight will have an internal exposure of 0.000296 µg/kg bw/d. This value is below the TTC threshold value of 0.0025 µg/kg bw/d for genotoxic substances, with a margin of safety of 8.5. A margin of safety of

[57] If the detection limit is not sufficiently low, additional assessments, e.g., in vitro assessments (see E.4.2.6), will be required.

1 is achieved at a detection limit of 42.18 mg/kg packaging material. Therefore, 42.18 mg/kg packaging material is the highest detection limit that can still be accepted for confirming the safety of the material[58].

Assuming the same detection limit of 5 mg/kg of packaging material, but for a baby shampoo application (use case **1b**), the results will be different due to the lower body weight of an infant (5 kg), resulting in an exposure of 0.00473 µg/kg bw/d. This is above the threshold value of 0.0025 µg/kg bw/d for genotoxic substances. Therefore, use-case **1b** cannot be considered safe based on the given detection limit, which is not sufficiently low to detect substances at a level which corresponds to the threshold given by TTC. Only with a detection limit better than 2.64 mg/kg of packaging material, would it be possible to confirm the safety of the material for this specific application. The calculation assumes the use of 100% recycled plastic in the packaging. Exposure levels can be reduced by reducing the proportion of recycled plastic in the overall packaging. If the recycled plastic content of the HDPE tube were reduced to levels below of 52.8%, the detection limit of 5 mg of substance per kg of packaging material would be appropriate, and the example may be considered as safe.

[58] The thresholds values referenced in this guideline, in particular the TTC thresholds and the MACE, represent the maximum acceptable consumer exposure level and already contain safety factors. When the margin of safety approach is applied to these values, the estimated exposure is compared to the TTC threshold or MACE to confirm that a margin of safety of at least 1 is achieved. A margin of safety of 1 or greater signifies that the level of exposure is acceptable.

E.

Background

Audience

All readers who desire more information on the covered topics.

This chapter is intended to serve as background and reference for chapters C and D for readers not yet familiar with the described concepts.

This chapter summarizes the regulatory basis for the safety assessment of cosmetics, detergents and home care packaging. In addition, it provides a short description of the packaging materials and formats involved. Fundamentals of *risk assessment* and of *analytical techniques which supply data to be assessed*, are also described.

E.1 Regulatory framework for cosmetic product, detergent, and home care product packaging

A growing number of EU legal measures requires a safety evaluation of primary packaging materials. These measures aim to further improve the protection of both human health and the environment.

This section provides a short overview of legislation which is applicable to or relevant for cosmetic products, detergents, and home care products. Figure 6 provides an overview of the legal framework described in this section.

Cosmetic products, detergents and home care products

When this guideline states 'cosmetic products' and/or 'detergents' and 'home care products', it refers to cosmetic products, both decorative and care, and to other consumer products for which contact with skin is part of the intentional or likely use of the product, such as in manual dishwashing and laundry, and wet wipes or surface cleaning products. Industrial detergents as well as household products which should not come into contact with skin (e.g., toilet, oven and drain cleaners) are not covered in this guideline as the low level of possible accidental exposure allows for a different consideration of consumer safety.

Figure 6

Overview of EU regulations and directives relevant for the safety assessment of cosmetic products, detergents, and home care products packaging[59].

Direct legal requirements on the safe use of packaging materials	Indirect legal requirements on the safe use of packaging materials	Regulations for food contact materials and articles used as references
Cosmetic Product Regulation Regulation (EC) No 1223/2009	**General product safety regulation** Regulation (EU) 2023/988	**Framework regulation** Regulation (EC) No 1935/2004
Packaging and packaging waste directive | Directive 94/62/EC	**EU Detergent Regulation** Regulation (EC) No 648/2004	**Plastic regulations** Regulation (EU) No 10/2011
	CLP regulation Regulation (EC) No 1272/2008	**Recycled plastics regulation** Regulation (EU) No 2022/1616
	REACH regulation Regulation (EC) No 1907/2006	**GMP regulations** Regulation (EC) No 2023/2006

[59] As of March 2024.

E.1.1 Direct legal requirements regarding the safe use of packaging materials

Several EU legal instruments apply directly to cosmetic products, including their packaging, and to packaging in general and therefore need to be respected when considering the use of recycled plastics as packaging materials.

E.1.1.1 Cosmetic Product Regulation (Regulation (EC) No 1223/2009)

Cosmetics are regulated by a dedicated legal framework, the EU Cosmetic Product Regulation[60]. It requires that all cosmetic products to be placed on the market in the EU shall be safe for human health (article 3).

The regulation requires a defined documentation to prove the safety of cosmetic products. This documentation also needs to cover the packaging material and its potential impurities, i.e., chemicals which are not intentionally added to the packaging material, and which may transfer from the packaging into the product.

In distinction to the prohibition of certain intentionally added substances (listed in Annex II of the regulation), article 17 states that "the non-intended presence of a small quantity of a prohibited substance, stemming from [...] migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3". Certain substances listed in Annex II of the regulation, when appearing only as impurities, have been further regulated by the implementation of concentration limits.

All substances which transfer from packaging into the product, whether specifically regulated or not, are to be assessed by a safety assessor regarding a possible impact on consumer safety.

Commission Implementing Decision 2013/674/EU provides more details on the safety assessment of packaging materials by stating that migration tests are to be performed under specific and relevant test conditions. It further states that at the time of publication, no standardized procedures for migration testing of cosmetic products packaging were available. Instead, the EU food contact Framework Regulation (EC) No 1935/2004 is mentioned as a reference together with the indication that for materials developed for the packaging of food, additional testing may not be required.

> ***The aim of this guideline is to provide clear recommendations (see chapter C) for addressing the requirements of the Cosmetic Product Regulation in the case that a food contact approval is not available for a recycled plastic material.***

[60] This document considers amendments to the regulation up to November 10th, 2022.

Note

The focus of this description is, as is the work of the CosPaTox Consortium overall, on polyolefin materials as they are the mode widely and most diversely used materials and as recycled materials, they are not available in food contact approved quality. The description of the regulatory framework focuses on regulations directly relevant to the packaging of cosmetic products, detergents, and home care products or used as a reference in the work of CosPaTox.

Where to find background information

non-intentionally added substances > E.5.2

Where to find background information

migration testing > E.3.2
food contact regulations > E.1.3

E.1.1.2 Packaging and packaging waste directive (Directive 94/62/EC)

The EU Packaging and Packaging Waste Directive[61] contains provisions that apply to all packaging (primary, secondary, tertiary) and to all product types on the European market, including cosmetic products, detergents, and home care products.

Article 11 of the directive prescribes a maximum content of 100 ppm of the *heavy metals* lead, cadmium, mercury, and hexavalent chromium in all types of packaging materials. While this provision addresses primarily an environmental concern, the presence of these materials can be considered undesirable from a human health perspective as well.

Safety is explicitly covered only in the recitals of the directive, stating that "[…] inclusion of recycled material in packaging should not contradict relevant provisions on hygiene, health and consumer safety".

> *The recommendations (see chapter C) include the consideration of heavy metals in recycled plastic materials (see C.2 and C.4.4).*

[61] This document considers amendments to the directive up to July 4th, 2018.

Primary, secondary, and tertiary packaging

This guideline follows the definitions of EU Directive 94/62/EC and differentiates

- sales packaging or **primary packaging**, i.e., packaging conceived so as to constitute a sales unit to the final user or consumer at the point of purchase
- grouped packaging or **secondary packaging**, i.e., packaging conceived so as to constitute at the point of purchase a grouping of a certain number of sales units whether the latter is sold as such to the final user or consumer or whether it serves only as a means to replenish the shelves at the point of sale; it can be removed from the product without affecting its characteristics
- transport packaging or **tertiary packaging**, i.e., packaging conceived so as to facilitate handling and transport of a number of sales units or grouped packaging in order to prevent physical handling and transport damage. Transport packaging does not include road, rail, ship, and air containers.

E.1.2 Indirect legal requirements on the safe use of packaging materials

In addition to direct legal requirements for the packaging of cosmetic products, and consumer packaging in general, other legislation creates further requirements for the safe use of packaging materials for cosmetic products and also for detergents.

E.1.2.1 General product safety Regulation (EU) 2023/988 and former directive (Directive 2001/95/EC)

The General Product Safety Regulation (2023/988/EC) requires every product made available on the EU market to be the safe for use when applied as intended and under all reasonably foreseeable conditions of use. This requirement implies an assessment of product characteristics such as its composition and its packaging.

The General Product Safety Regulation is typically considered as a basis for the assessment of detergent and home care product safety, as for cosmetic products, a specific measure existed in the form of the Cosmetic Product Regulation, which also provides more detailed safety assessment requirements than the General Product Safety Regulation.

> *The example uses cases studied by the CosPaTox Consortium (see D.5.1) demonstrate how the principles in this guideline can be applied to detergent and home care products. The recommendations (see chapter C) provided in this guideline cover assessments not only for cosmetic products but also for detergent and home care products packaging.*

E.1.2.2 CLP regulation (Regulation (EC) No 1272/2008)

While cosmetic products are exempt, detergents and home care products are subject to the EU regulation on classification, labelling and packaging of substances and mixtures (CLP), which translates the UN GHS system for the classification and labelling of chemicals and mixtures to the EU level[62]. The CLP regulation may require tracking of e.g., fragrance substances to prove compliance with labelling requirements. The CLP regulation is closely linked to the REACH regulation.

Where to find background information

REACH > E.1.2.4

E.1.2.3 EU Detergent Regulation (Regulation (EC) No 648/2004)

The EU Detergent regulation contains multiple provisions related to detergents and home care products, such as their labeling, but does not make specific requirements related to their safety.

> *This regulation is not described in further detail in this guideline.*

[62] The CLP regulation is the EU implementation of the Globally Harmonized System (GHS).

E.1.2.4 REACH regulation (Regulation (EC) No 1907/2006)

Regulation (EC) No 1907/2006 is the fundamental EU regulation governing chemicals. It is typically referred to as the 'REACH regulation' and is a framework for the hazard assessment of chemicals. The acronym stands for *Registration*, *Evaluation*, *Authorization* and *Restriction* of *Chemicals* and describes the key facets of this regulation.

Authorization applies to *substances of very high concern* ('SVHC', Annex XIV), which are to be progressively replaced by less hazardous substances by removing them from free circulation and instead allowing their use only by specifically authorized economic operators[63].

Economic operators who produce or import into the EU chemical products which contain SVHC at concentrations of above 0.1wt% are required to inform their customers about the presence of these substances and provide guidance for the safe handling of the product (article 33).

Whilst REACH does not apply to waste, it does apply to the output of recycling, the recyclates[64]. Consequently, plastic recyclers are manufacturers[65] under REACH. They are subject to the requirement of producing safety data sheets for dangerous goods[66] and are required to inform their customers about the presence of substances of very high concern (SVHC) above a concentration of 0.1 weight% in a material.

To confirm the absence of SVHC in recycled materials, recyclers may apply chemical analysis, or knowledge about the composition of the input waste material, or a combination thereof. These quality management measures may be further augmented by routine analysis of the output product.

> ***The recommendations of this guideline (see chapter C) include the consideration of substances of very high concern in recycled plastic materials (see C.2 and C.4.4).***

Where to find background information

analytical techniques > E.3.4 and E.3

[63] Additionally, substances may also be 'restricted' under REACH, i.e., limited to specific uses or conditions (Annex XVII to REACH).

[64] As the approach of the CosPaTox Consortium focuses on the evaluation of the safety of recycled plastic materials for the use in packaging, it considers only the plastic recyclate as a product, not the process that led to its creation. As such, REACH-related questions such as end-of-waste criteria are out of scope for this guideline. Readers interested in specific aspects of REACH related to waste materials are directed to relevant literature[14], [15].

[65] In recognition of the distinct differences between primary manufacturing and recycling, recyclers enjoy special exemptions from registration requirements that are placed on the manufacturers of virgin materials ('recycling privilege', Article 2(7d)).

[66] Which, in the case of polymers, may apply if hazardous additives or impurities are present at above 0.1wt% or 1wt%, depending on the substances' hazard profiles.

The EU Chemicals Strategy for Sustainability

The 2020 EU Chemicals Strategy for Sustainability is part of the wider EU Green Deal and aims to provide increased protection of citizens and the environment while boosting the use of safe and sustainable chemicals.

The strategy includes specific actions to restrict or ban the use of certain harmful chemicals, to decontaminate waste streams and to revise e.g. the REACH and food contact legislation with updated toxicological models.

E.1.3 Regulations for food contact materials and articles used as references

All legal frameworks described in preceding sections contain provisions relevant to packaging materials in direct contact with cosmetic products, detergents, or home care products. However, none of these legal texts provides details on the testing or *safety assessment* strategy for packaging materials. As such, for the safety assessment for cosmetic product, detergent, or home care product packaging, the regulatory framework for food contact materials and articles is often used as a reference. This approach follows the recommendation made by the EU Commission in the Implementing Decision 2013/674/EC to Regulation (EC) No 1223/2009.

> ***The recommendations in this guideline (see chapter C) build upon best practices for the safety assessment of food contact materials but have been developed specifically for the safety assessment of recycled plastics materials for which no food contact approval is available.***

E.1.3.1 Framework regulation (Regulation (EC) No 1935/2004)

The Framework Regulation[67] is the fundamental legal text in the EU for materials that come into contact with food. It requires that food contact materials and articles, including packaging, shall be safe for consumers. Article 3 requires that all food contact materials shall not transfer their constituents into food in amounts that could:

a) endanger human health,
b) bring about an unacceptable change in the composition of the food,
c) bring about a deterioration in the organoleptic characteristics of the food.

Where to find background information

safety assessment > E.4

[67] This document considers amendments to the regulation up to June 20th, 2019.

The regulation furthermore requires that food contact articles and materials are produced under *Good Manufacturing Practice* (GMP). Detailed requirements on GMP are provided in Regulation (EC) No 2023/2006.

For detailed guidance, the framework regulation foresees the creation of *material-specific measures* under its framework.

E.1.3.2 Plastics regulation (Regulation (EU) No 10/2011)

The Plastics Regulation[68], which is a *material-specific measure* under Regulation (EC) No 1935/2004, is a useful reference for the safety assessment of plastic packaging. The concept of *migration*, as defined in the framework regulation, is detailed out in this regulation.

Where to find background information

safety assessment > E.4
risk assessment > E.4
migration testing > E.3.2.2
migration modelling > E.3.1
worst case calculation > E.3.1

The legal text defines an *overall migration limit*, as an expression of overall inertness, and *specific migration limits* for individual chemical substances as a basis for the *safety assessment*. Demonstrating safety is typically achieved by way of *migration testing*, but the regulation also allows for alternative approaches such as *migration modelling*, and *calculation of migration* from known quantities of substances in the food contact material.

Analyzing migration, especially down to the required detection and quantification limits, is challenging in a complex matrix such as food. Hence, the regulation describes *food simulants*, which can be used for migration testing instead of actual food[69]. The simulants provided in the annex of the regulation represent specific food groups, based on their physical and chemical properties. They are overestimating the migration which occurs into real food[16]. As many cosmetic products and detergents possess similar physical and chemical properties, the listed food simulants are also regularly used for the testing of cosmetic product, detergent, and home care product packaging materials.

> ***The recommendations in this guideline (see chapter C) build upon the approaches described for food contact materials. The testing conducted as part of the CosPaTox studies (see chapter D) borrows from techniques established for food contact materials. As this guideline focuses solely on safety, it does not provide recommendations for the use of an overall migration limit approach to study the general inertness of recycled plastic packaging materials.***

[68] This document considers amendments to the regulation up to August 10th, 2023.
[69] The simulants are assumed to be at least as conducive to the migration of substances from plastic materials as all real foods they represent. Today, nearly all migration testing in the context of food contact is performed with simulants.

E.1.3.3 Recycled plastics regulation (Regulation (EU) No 2022/1616)

The Recycled Plastics Regulation requires that recycling technologies used to produce food contact plastic recyclates must be suitable to create materials that 1.) can comply with article 3 of the framework regulation (EC) No 1395/2004 and that 2.) are microbiologically safe. Suitable recycling technologies are those technologies which have been authorized by EFSA, the European Food Safety Authority.

For recycled PET, a scheme for the safety evaluation has been developed by EFSA[17]. The full list of approvals granted to date by EFSA can be consulted online[18],[19].

The current Recycled Plastics Regulation provided an update of a prior regulation it replaced[70], defining new rules which cover all existing and future plastic recycling technologies. It also contains rules for the introduction of 'novel technologies'. The requirements include a certified quality assurance system to ensure the quality and traceability of the plastic waste input and that the plastic waste input must originate from food packaging. The regulation obliges recyclers to monitor the average contamination level on a batch-to-batch basis and to provide instructions regarding the use of a recyclate to converters.

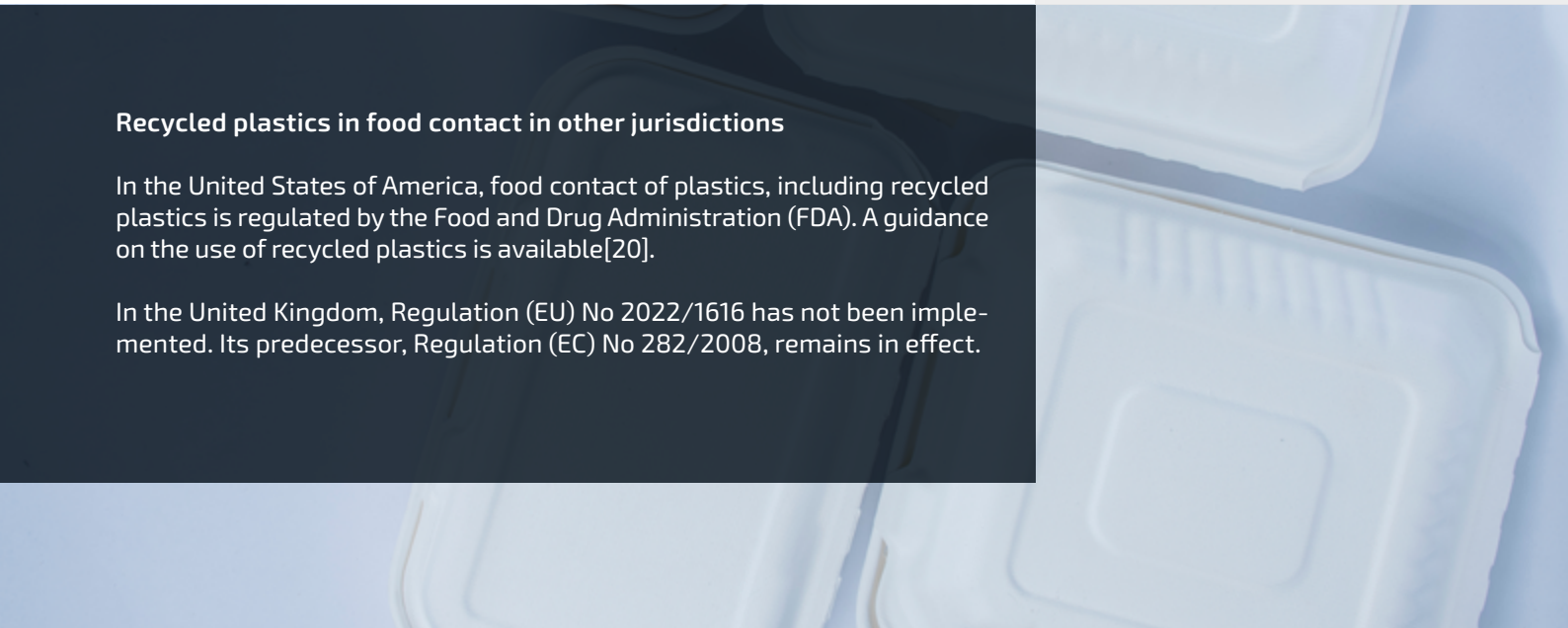
> ***The focus of this guideline is to provide an alternative approach to the use of food contact approvals for recycled plastics to be used in the packaging of cosmetic products, detergents, and home care products. At the same time, the recommendations of this guideline (see chapter C) include key principles of the Recycled Plastics Regulation, especially related to quality control.***

[70] Regulation (EC) No 282/2008.

Recycled plastics in food contact in other jurisdictions

In the United States of America, food contact of plastics, including recycled plastics is regulated by the Food and Drug Administration (FDA). A guidance on the use of recycled plastics is available[20].

In the United Kingdom, Regulation (EU) No 2022/1616 has not been implemented. Its predecessor, Regulation (EC) No 282/2008, remains in effect.



E.2 Cosmetic products and detergent products and their packaging

Where to find background information

risk assessment > E.4
EU Cosmetic Product Regulation > E.1.1
exposure > E.4.1

Where to find results

example exposure scenarios > D.5.1
contact time > D.5.1
absorption rate > D.5.1
retention rate > D.5.1

Cosmetic products, detergents, and home care products themselves as well as their packaging formats can be assigned into distinct groups. Such a grouping can serve not only an explanatory function but is also useful for the *safety assessment*.

E.2.1 Categories of cosmetic products, detergents, and home care products

The product categories defined in the Notes of Guidance of the Scientific Committee on Consumers[11] are expanded in this guideline by detergents and home care products, resulting in a set of three product groups. As is demonstrated in D.5, each group represents a different consumer *exposure* based on the products' intended or reasonably foreseeable uses.

> ***The categorization described in this chapter was confirmed by the example use cases described in D.4 and D.5.1. The groups form the basis of the quality levels for recycled plastics described in this guideline (see chapter C).***

E.2.1.1 Leave-on cosmetic products

Leave-on cosmetic products comprise those cosmetic products that are 'intended to stay in prolonged contact with skin, hair or mucous membranes'[21]. These products remain in place for a given *contact time* after which they are either fully removed, or they are partially or completely absorbed into the body during this time (*'absorption rate'*). Typical examples include skin creams and oils and decorative cosmetic products.

The category of leave-on cosmetic products is characterized by potentially large differences in the resulting *exposure* between different applications, for example between a sun lotion used applied to the whole body, a facial cream and a leave-on product for hair[11].

E.2.1.2 Rinse-off cosmetic products

Rinse-off cosmetic products comprise those products that are 'intended to be removed after application on the skin, the hair or the mucous membranes'[21]. Typical examples include soap, shower gels, shampoo, conditioner, and shaving gels.

While most of the applied amount of product in this category is removed after a short *contact time*, in the order of seconds to a few minutes, a certain residue may remain on the body. This is reflected by the so-called retention factor, introduced into the SCCS Notes of Guidance[11] some years ago.

E.2.1.3 Detergents and home care products

Detergents and home care products comprise a wide range of products which are used in households to clean for example floors, windows, bathroom surfaces, furniture, and appliances as well as for movable items such as clothes, tableware, textiles, smaller furniture, and decorations.

As with cosmetic products, different *exposure scenarios* can be distinguished for different types of detergents and home care products. This guideline focuses on detergent products and home care products for which intentional contact with skin or food occurs.

As such, this guideline distinguishes two categories:

1. *hand wash detergents* such as manual dishwashing and manual laundry detergents

2. *home care products*, including automatic washing products, for which skin contact may occur as part of intended or foreseeable use[71]

E.2.2 Common plastic packaging formats for cosmetic products and detergents

Cosmetic products, detergents and home care products are sold in a variety of *packaging formats*, with a wide range of materials, from plastics to paper to glass and metals. The CosPaTox Consortium focuses on plastic packaging materials and categorizes packaging types by the format and by the type of plastic (polymer) that is used[72].

E.2.2.1 HDPE and PP bottles and tubes

Many rigid packaging formats for consumer goods are made from one of the two polyolefin materials *high density polyethylene* (HDPE) and *rigid polypropylene* (PP).

HDPE and PP are polymers that are resistant to many filling goods and are therefore used for a wide range of products. They are however relatively readily penetrated by chemical substances contained in the filling good and provide a weak barrier to the migration of substances. As such, post-consumer recycled HDPE and PP materials (rHDPE, rPP) must be assumed to have absorbed certain

Where to find results

ratio of packaging to content
> D.5.1

Where to find details

A *dossier* is available, detailing the results of the testing and their validation.

[71] Household products which should not come into contact with skin (e.g., toilet, oven and drain cleaners) are not covered in this guideline as the low level of possible accidental exposure allows for a different consideration of consumer safety.

[72] This section describes the three polymer types that are in widest use for the packaging of cosmetic products and detergents and already widely recycled. It is acknowledged that further types of plastics are used for more specialized packaging types. Both due to the lesser usage volumes in the market as well as the substantially more limited availability of recycled materials for other polymer types, they are not covered in this guideline.

amounts of substances from their previous filling goods as well as potentially having picked up contaminants from misuse, or during waste collection and handling. The cleaning of post-consumer HDPE and PP is therefore more difficult than for example for PET, which is a more inert material[22], [23], [24].

Figure 7: Examples of HDPE and rigid PP bottles and tubes used for the packaging of cosmetic products and detergents.

E.2.2.2 LDPE and PP films, pouches, and sachets

The vast majority of flexible packaging is produced with low *density polyethylene* (LDPE) or flexible *polypropylene* (PP) films as the main material.

LDPE and flexible PP are materials that are resistant to many filling goods and therefore used for a wide range of products. Similar to HDPE and rigid PP, both materials are readily penetrated by chemical substances contained in the filling good and provide a weak barrier to the migration of substances. As such, post-consumer LDPE and flexible PP materials must be assumed to have absorbed certain amounts of substances from their filling goods as well as potentially having picked up contaminants from misuse, or during waste collection and handling. The cleaning of post-consumer LDPE and flexible PP is more difficult than for example for PET, which is a more inert material[22], [23], [24].

Figure 8: Examples of flexible packaging made from LDPE or flexible PP used for the packaging of cosmetic products and detergents.

E.2.2.3 PET bottles

Bottles made from *polyethylene terephthalate* (PET) are very common both for beverages and are also used in consumer goods packaging. In the latter case, this category includes 'conventional' bottles as well as containers in more complex shapes and with added functionality, such as triggers and spray nozzles.

PET is a glassy polymer that is characterized by its high resistance to penetration by chemical substances. As such, post-consumer PET material can generally be assumed to have absorbed lower amounts of substances from filling goods or other contamination than most other plastic materials. Contaminations will mainly be present on the surface rather than deep within the polymer matrix. Consequently, they can typically be removed more efficiently before and during recycling processes.

> ***As many food contact approvals exist for recycled PET under the Recycled Plastics Regulation (see E.5.2.1), the focus of this guideline is on PE and PP.***

Figure 9: Examples of flexible packaging made from LDPE or flexible PP used for the packaging of cosmetic products and detergents.

E.3 Characterization of PCR materials with regard to their ability to transfer substances into products

Where to find background information

safety assessment > E.4
risk assessment > E.4
analytical techniques > E.3.4

The legal framework governing the packaging of cosmetic products, detergents, and home care products (section E.1) requires a *safety assessment* of primary packaging. This assessment is based on identifying chemical substances which may transfer from the packaging material into the product and applying principles of *risk assessment* to the results. *Analytical techniques* exist to determine such transfer from plastic packaging materials in the form of *extractable* and *migratable* substances. Figure 10 provides an overview and comparison of the available options, which are described in further detail below.

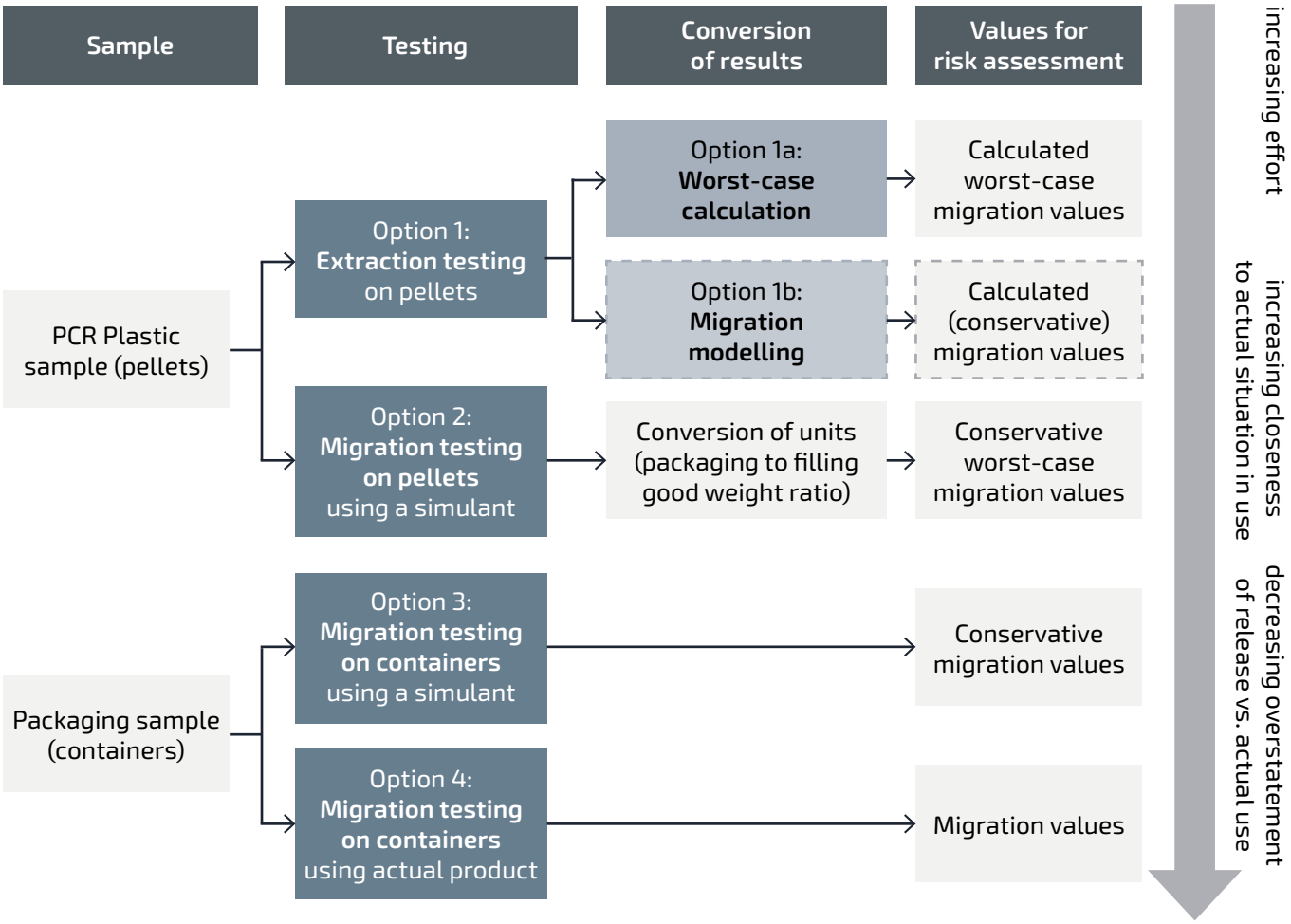


Figure 10: Comparison of different options to determine the transfer of substances from plastic packaging materials into products.

Plastic packaging materials are composed of a variety of chemicals, intentionally incorporated throughout the manufacturing process. These intentionally added substances (IAS) include the principal building blocks of plastics ('monomers'), additives designed to enhance the properties of plastics or the performance of the packaging as well as solvents, polymer production aids and aids to polymerization. Further materials, such as inks, coatings, and adhesives are intentionally added along the converting process from plastic granule to finished packaging.

In addition to intentionally added substances, plastic materials and articles generally also contain additional substances that are non-intentionally added (NIAS). The origin of these substances may not always be fully traceable, but they typically arise from impurities that are present in IAS, as by-products during production steps, or by degradation processes acting upon IAS. For an exhaustive discussion of NIAS and their management, readers are directed to relevant literature and sectorial guidance[25], [26], [27], [28].

For the purposes of this guideline, NIAS must be considered with a wider view than in the production of packaging from virgin materials. Formation of NIAS from IAS in recycling processes, as well as the introduction of NIAS that are not found in virgin materials, must be considered. This includes cross-contamination from filling goods and foreign materials that are collected, sorted, and recycled together with plastic packaging waste.

> ***Section D.2 provides and overview and a discussion of IAS and NIAS found as part of the large CosPaTox interlaboratory comparison on recycled plastics.***

Terms used in this guideline

Extraction testing

Testing performed with the intention to transfer all substances from a test material into a liquid for further analysis. The aim of this analysis is a characterization of substances and their amounts in a sample.

The conditions of this testing are chosen to transfer all substances in a material as completely ('quantitatively') as possible into a liquid, which is generally a strong solvent, and which may also accelerate the transfer of substances by swelling the plastic. Extraction testing is commonly used for determining the *composition* of a test material[73]. As extraction testing aims at a full transfer of all substances contained in the test material, its results are independent of the intended use of the tested material, in particular in the case of packaging, of the packaging geometry, the nature (e.g., polarity) of the filling good, the shelf life and the storage conditions.

A typical medium to perform extraction testing is the solvent dichloromethane. Typical contact conditions are 3 days at 40°C.

Migration testing

Testing performed to simulate the transfer (desorption) of substances from a test material into a product under realistic or slightly overestimating conditions.

The aim of this analysis is to understand the capacity for migration of the substances present in a sample.

The conditions of this testing are chosen to approximate the actual transfer of substances from the test material into a product. Migration testing is commonly used for safety assessment purposes and compliance work, especially in the case of food packaging[74]. As migration testing aims at realistically approximating the real-world situation, its conditions and its results for packaging are bound to the nature of the packed product, the packaging geometry, the shelf life and the storage conditions.

Migration testing is typically performed using a simulant, which should suitably represent the properties of the actual filling good, instead of using an extraction solvent[75]. For food contact materials and articles, where migration testing is widely used in safety assessments[76], standardized simulants have been established. Commonly used simulants are ethanol 95% (for fatty foods) and ethanol 50% (e.g., for dairy products). Typical contact conditions for product with a shelf life of one year or longer are then days at 60°C. The use of simulants is intended to simplify the analytical effort[77], to improve the analytical sensitivity and as a way of reducing the amount of required testing, by allowing to obtain results for an entire group of products. To achieve the latter, simulants are generally chosen to be more severe than actual products and to provide overestimating (i.e., higher) migration results compared to any real product (food) they simulate.

Testing on pellets

Testing performed on pellets (granules) of a test material

Both extraction and migration testing can be conducted on pellets. The results of testing on pellets are expressed as mg of substance per kg of pellets.

Testing on containers

Testing performed on ready-to-fill packaging articles, such as bottles, tubes, or pouches

Both extraction and migration testing are in principle possible on containers, but only migration testing is commonly performed[78]. The results of testing on containers are expressed as mg of substance per kg of packed product (filling good)[79].

[73] Example of an extraction testing: EN 13130-8:2004 – Materials and articles in contact with foodstuffs - Plastics substances subject to limitation - Part 8: Determination of isocyanates in plastics.

[74] Example of migration testing: EN 13130-1:2004 – Materials and articles in contact with foodstuffs – Plastics substances subject to limitation - Part 1: Guide to test methods for the specific migration of substances from plastics to foods and food simulants and the determination of substances in plastics and the selection of conditions of exposure to food simulants.

[75] For example, state of matter (solid, liquid), polarity, and ability to influence the properties of the packaging material (e.g., swelling of plastics).

[76] The wide use of migration testing for food contact plastics results from the fact that the safety of food contact plastics, including virgin materials, can often not be demonstrated on the basis of extraction data, which typically proves too strong an exaggeration of the transfer of substances compared to reality.

[77] Determining migration in a complex matrix such as food is analytically much more challenging than determining the migration into a simulant of simple and defined composition.

E.3.1 Extraction testing on pellets of plastic materials

The typical approach for the extraction testing of recycled plastic materials is to perform *extraction testing on pellets* using a strong solvent such as dichloromethane.

In some cases, extraction testing can be used instead of migration testing for assessing packaging safety. Specifically, if safety can be demonstrated using a *worst-case calculation result* (see below) based on extraction testing data, safety can be assumed under all different types of packaging geometries, shelf lives and for all product types. This approach is particularly relevant for home care product packaging, which may in many cases be demonstrated to be safe based on a worst-case calculation, due to the lower associated *exposure*. Where safety cannot be demonstrated using worst-case calculation, *migration modelling* (see below can be employed, or the transfer of substances can be tested under conditions that more closely reflect the real use, such as *migration testing* as described below (see E.3.2).

The results of extraction testing, before applying a worst-case calculation or migration modelling, are expressed in units of mg of extracted substance per kg of pellets.

> ***The recommendations of this guideline (see chapter C) include the option of applying extraction testing on pellets of recycled materials as a rapid testing approach.***

Worst-case calculation from results of extraction testing on pellets

Once the amounts of extractable substances are known for a material, a *worst-case calculation* can be performed, by assuming that all substances extracted from the pellets would completely be transferred into a product if the material were to be used as packaging. In this *'full mass transfer'* calculation, only the relative masses of packaging material and product are needed; neither the geometry of the packaging, the shelf life, the storage conditions, nor the chemical properties of the product need to be specified.

Worst case calculations do not consider the *diffusion* behavior of substances, especially higher molecular mass substances, which may be limited in their mobility, and it does not consider the *partiti-*

Where to find background information

analytical techniques > E.3.4
exposure > E.4.1

Where to find background information

More information on diffusion behavior and partition coefficients can be found in the CosPaTox *dossier*.

[78] Extraction testing may not be possible in certain cases, in particular when the extraction medium is aggressive enough (due to its swelling behavior) to damage or destroy the container that is being tested.

[79] Test results may also be obtained in units of mg per dm2 of contact surface. In such case, conversion into units related to kg of packed product can be performed mathematically.

on coefficient[80] between packaging and product. Worst-case calculations provide therefore the greatest possible overestimate of the real transfer for substances from packaging into product, compared to *migration testing* (see E.3.2) and also compared to *migration modelling (see below)*.

The results of a worst-case calculation are expressed in the same units as for the testing on containers, as mg of transferred substance per kg of packed product (filling good).

> ***Examples of worst-case calculations are provided in D.5.1. The recommendations of this guideline (see chapter C) include the option of applying a worst-case calculation as a conservative approach.***

Modelling migration from results of extraction testing on pellets

Where a worst-case calculation fails to demonstrate safety, *migration modelling* can be employed as a refinement. To model the migration of substances into the product requires modelling their movement, first within the packaging material and then into the product. Different to a worst-case calculation, migration modelling does consider the *diffusion* behavior and the *partition coefficient*, the contact / storage conditions, and the shelf life. It therefore provides a more realistic, that is, less overestimating, result than worst-case calculation. Migration modelling is typically performed with the aid of computer-based tools. An introduction to migration modelling is provided in [29].

The results of migration modelling are expressed in the same units as for the testing on containers, as mg of transferred substance per kg of packed product (filling good).

> ***The CosPaTox Consortium did not perform migration modelling as part of the development of this guideline. The option to use migration modelling to refine worst-case calculation results is however provided in the recommendations (see chapter C).***

E.3.2 Migration testing in accelerated conditions

Migration testing may be performed as the initial analysis of a plastic material, or in sequence after extraction testing[81].

Note

As there is no clear and binding definition of 'migration testing' outside of the context of food contact articles and materials, the CosPaTox Consortium has chosen the practical definition of migration testing provided in the beginning this section.

[80] The partition coefficient describes the relative amounts of a substance that will be found in the packaging compared to the amounts in the filling good (product), after migration has reached an equilibrium.

[81] In many cases, the use of results derived from extraction testing (see E.3.1) will not be suitable for the purposes of safety assessment as the overestimation is too severe. In these cases, migration testing as a less severe (but still overestimating) testing approaches can be employed.

For the results of migration testing to adequately reflect the migration that occurs in real use, the *simulant* used for the testing as well as the temperature and contact time must be chosen appropriately.

Where testing migration with simulants, which provide, by design, overestimating results, cannot demonstrate safety, testing with the actual product may be performed as a last resort. Results obtained with the actual product are the closest to the actual use case, but often the hardest to obtain experimentally[82].

> ***The recommendations of this guideline (see chapter C) include the option of conducting migration testing with simulants. This option is provided as a more representative test, compared to extraction testing, especially when the latter is combined with worst-case calculation.***

Where to find background information

simulant > E.1.3.2

E.3.2.1 Migration testing on pellets of packaging material

Migration testing on pellets of the packaging material (i.e., before conversion of the material into a packaging form) retains the simplicity of pellet testing while introducing the use of *simulants* to obtain more realistic, that is, less overestimating, results, compared to extraction testing on pellets. This relatively new approach has been extensively evaluated by the CosPaTox Consortium (section D.3.4) and has also been applied in studies conducted by other parties[3].

Where to find background information

simulant > E.1.3.2

The results of migration testing on pellets of packaging material are expressed in form of the mass of transferred substances relative to the mass of the packaging material sample (mg transferred substance / kg of packaging material).

> ***The interlaboratory comparison performed by the CosPaTox consortium (see D.2) demonstrated that the migration testing on pellets provides results which are comparable to the migration testing on containers. The recommendations for testing (see C.2) therefore include the option of migration testing on pellets.***

E.3.2.2 Migration testing on containers

Migration testing on containers (bottles, tubes, pouches, …) provides the most realistic results of the real-world transfer of substances from packaging into products, because the test sample in this form of testing is closest to the actual geometry and composition of the final packaging. However, it requires a substantially increased effort compared to testing on pellets, as finished packaging samples such as bottles, tubes, or pouches need to be produced before the testing can occur.

[82] In addition, the chemical complexity of actual products often makes non-targeted screening impossible and only targeted analyses may be possible.

The results of migration testing on containers are generally expressed in form of the mass of migrated substances relative to the packed product (filling good).

As an intermediate, simplified option between the testing on pellets and the testing on (complete) containers, it may in some cases be possible to test on semi-finished packaging materials. For example, in the case of flexible packaging, it is possible to test the packaging film itself, rather than a formed pouch made from that film. Such testing will, like the testing on pellets, require a numerical conversion of the results to actual packaging geometries. A detailed description or complete list of such simplified testing options is however beyond the scope of this document.

> ***The interlaboratory comparison performed by the CosPaTox consortium (see D.2) demonstrated that the migration testing on pellets provides results which are comparable to the migration testing on containers. The recommendations (see chapter C) are therefore focused on the testing of pellets, rather than containers.***

E.3.3 Hierarchy of results obtained from different methods

The methods described in the preceding sections all provide information on the transfer of substances for a given packaging/product combination. As Figure 10 describes, it is possible to begin evaluations with any of these methods. Their results are however not equal in weight as they differ in their degree of overestimation and, conversely, in closeness to the real application. As such, results obtained from a methodology closer to the real use should be considered to prevail over results from a more coarsely approximated and more overestimating approach (but not vice versa). It is therefore possible to reevaluate, if desired, a risk assessment result with a method that is closer to the real use and less overestimating. At the same time, such an assessment however becomes more specific and less applicable to other packaging designs or use cases. Figure 11 visualizes the options described above.

Where to find details

A *dossier* is available, detailing the results of the testing and their validation.

Where to find background information

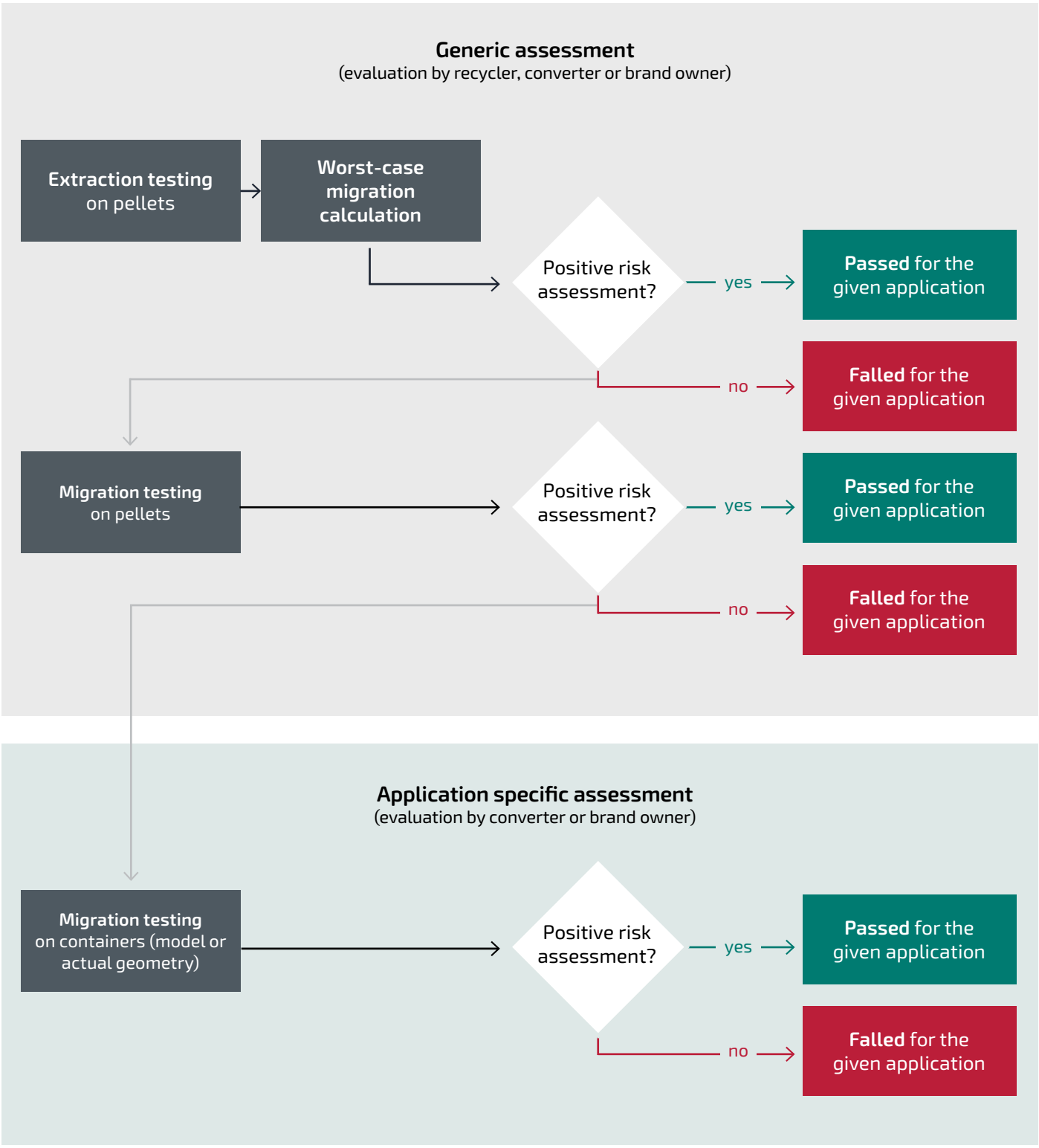
risk assessment > E.4

Where to find results

Testing performed by CosPaTox > D.1

Figure 11

Hierarchy of testing approaches for determining the transfer of substances from packaging into products.



> ***The recommendations provided in this guideline (see chapter C) reflect this hierarchy and the resulting options of refining testing results.***

E.3.4 Analytical techniques

Where to find background information

Testing performed by CosPaTox > D.1
Recommendations for testing procedures > C.2

Both approaches described above, *extraction testing* and *migration testing*, result in a liquid (extraction solvent or simulant) that needs to be subjected to analytical techniques to *identify* and *quantify* the substances that were extracted or that migrated.

Modern analytical devices allow for the separation of very complex substance mixtures. The different contained substances reach the *detector* of the device, allowing for substance-by-substance *identification* (via a 'fingerprint' obtained from the detector, by knowledge of the time at which a specific substance will reach the detector, or by a combination of both) and *quantification* (from the strength of the signal at the detector).

This section provides a simplified description of key analytical techniques.

> ***The specific analytical techniques recommended in this guideline are described in C.2.***

E.3.4.1 Non-targeted screenings and targeted analyses

Two basic types of analyses are used in the determination of the transfer of substances from packaging materials into products.

Where to find background information

NIAS > E.3

Non-targeted analyses, also referred to as *non-targeted screenings* utilize analytical technical that allow for the detection, identification, and quantification of a wide range of substances. For this type of analysis, no knowledge of the expected substances is required, nor is a list of substances to search for required. Non-targeted screenings are therefore a useful tool for an initial analysis of a material and to analyze materials, for which the composition is not (fully) known. For the same reasons, they are the dominant technology to study the presence and quantities of NIAS in a sample.

Targeted analyses typically offer a more precise quantification and/or a better limit of detection than non-targeted screenings. By their nature, targeted analyses can only be performed if the target, i.e., the *analyte*, is defined. Targeted analyses are typically used for three cases related to the study of the transfer of substances from packaging materials into products: 1) for the quantification of elements and other substances which are not volatile enough to be detected in a typical non-targeted screening 2) for

the targeted analysis of defined substances or classes of substances, often due to regulatory limits and 3) for a refined quantification of substances detected in non-targeted screenings.

E.3.4.2 Chromatography

The term chromatography summarizes techniques that allow a complex mixture of chemical substances to be separated into individual substances, so that these substances can be separately identified and quantified. The fundamental principle of chromatography is that when different substances contained in a flowing liquid or gas (a 'mobile phase') are in contact with a solid material ('stationary phase'), they will travel at different speeds, due to their different affinities to the stationary phase.

The two main chromatographic techniques in use today for the characterization of extractable and migrating substances are *liquid chromatography* (LC) and *gas chromatography* (GC). These techniques can each be fitted with different detectors that provide unique information about the substances contained in a sample. The typical combinations and their uses are shown in Table 5.

> ***The interlaboratory comparison performed by the CosPaTox Consortium (see D.2) applied GS-MS analysis to a large set of samples. D.2 also describes the substances that were detected in recycled plastic samples using this method. The test method recommendations in this guideline (see C.2) are based on the positive results obtained for this method. GC-MS is recommended as the primary non-targeted screening methodology in chapter C.***

Table 5

Overview of common chromatographic techniques

Technique	Description	Provided information	Typical uses
GC-MS	Gas chromatography with (electron impact) mass spectrometry as detection method	**Quantity** (strength of mass spectral signals) **Identity** (mass spectral 'fingerprint' of substances and retention index)	Non-targeted screening of extractables or migration Quantification of extraction or migration of specific substances (e.g., PAH)
GC-FID	Gas chromatography with flame ionization detector	**Quantity** (strength of FID signal) **Identity**, for substances that have been referenced beforehand (retention index)	Quantification of extraction or migration of specific substances
LC-MS	Liquid chromatography with (electrospray) mass spectrometry as detection method	**Quantity** (strength of mass spectral signal) **Identity**, for substances that have been referenced beforehand (retention index)	Quantification of extraction or migration of specific substances (e.g., PAA) Quantification in non-targeted screening of extractables or migration, always in combination with identification via MS
LC-UV-VIS	Liquid chromatography with UV and visible light detectors	**Quantity** (strength of the UV or visible light detector signal) **Identity**, for substances that have been referenced beforehand (retention index)	Quantification of extraction or migration of specific substances (e.g., antioxi-dants and UV stabilizers)

E.3.4.3 Elemental analysis

Dedicated analytical techniques exist to provide an elemental analysis of a sample. This type of analysis can be used to determine the amount of (heavy) metals contained in a plastic material sample.

The most common elemental analysis techniques are inductively coupled plasma atomic emission spectroscopy (ICP-AES), and inductively coupled plasma mass spectrometry (ICP-MS). Both are capable of matching the required detection limits for multiple elements. Flame atomic absorption spectrometry (F-AAS) and graphite furnace atomic absorption spectrometry (GF-AAS) may also be used but are typically only capable of analyzing a small number of elements in each analysis. X-ray fluorescence spectroscopy (XRF) is another elemental analysis technique. However, the detection limit of this technique is typically not low enough to assess elements in plastics. Analytical laboratories will decide on the most suitable technique based on the nature of the sample and the elements to be quantified.

For ICP-AES, ICP-MS, and AAS, plastic samples need to be 'digested' (dissolved) or extracted to obtain the sample for analysis. Microwave assisted acid digestion of the samples using concentrated acid (following EPA SW849 3052 or a variation thereof) yielding a clear sample allows for the most conservative assessment of elements, in particular heavy metals, present in a PCR plastic material as it captures all the metals present in the sample. Alternatively, an extraction can be conducted either by using dilute acid[83]. A migration testing approach, using a product simulant, can also be applied. Particular attention should be paid to the pH of the product when assessing the migration of elements from a PCR plastic material.

> ***The interlaboratory comparison performed by the CosPaTox Consortium (see D.2) applied elemental analysis to a large set of samples. D.2 also describes the elements that were detected in recycled plastic samples using this method. The test method recommendations in this guideline (see C.2) contain a selection of suitable techniques.***

[83] Dichloromethane, ethanol, and ethanol/water mixtures as used for non-targeted screening of organic substances are not appropriate to extract elements from plastic materials.

E.3.4.4 Detection limit and quantification limit

Every analytical technique exhibits a specific and finite sensitivity, which leads to a lower limit on the amount or test concentration at which a substance or element can be detected by the technique.

This so-called *detection limit* or *limit of detection* (LoD) depends on several factors, such as the instrumentation, the sample preparation, and the nature of the sample. It is important to recognize that below the detection limit, an analytical technique cannot prove the absence or presence of a substance or element. As such, in a conservative approach, it must be assumed that any given substance or element in a sample may be present in an amount or concentration just below the detection limit.

The detection limit is formally defined as the lowest quantity of a substance that can be analytically distinguished with more than 50% confidence from the absence of that substance. The LoD may be calculated from baseline noise by applying a signal-to-noise ratio of 3. The detection limit of a given analytical technique and testing protocol can also be determined according to established methodologies, such as DIN 32645.

> ***In the studies performed by the CosPaTox Consortium, for organic substances determined by liquid chromatography (LC) or gas chromatography (GC) this limit was defined conventionally as 1% of the amount or concentration of the used internal standard. For elements, a signal-to-noise ratio of 3 was used in addition to an external calibration curve for each element reported. The detection limit is considered in the safety assessment approach which this guideline recommends. Details regarding the required detection limit can be found in D.5.4. The recommendations (chapter C) also rely on the detection limit being suitable for the safety assessment.***

In addition to the limit of detection, another threshold can be defined, namely the *limit of quantification* (LoQ), which represents the lowest amount or test concentration of a substance that can reliably be quantified. The LoQ may be calculated from baseline noise by applying a signal-to-noise ratio of 10. This guideline focuses on the use of the limit of detection.

E.4 Risk assessment and risk management

Analytical data as described in the previous section alone does not provide an answer whether a recycled plastic material can or cannot be used safely for a given application. This section describes the fundamentals of *risk assessment* and *risk management* whereas section E.5 describes the application of these concepts to packaging.

Risk assessment and risk management are closely related concepts that are applied to ensure human safety in many fields. While these concepts can be applied to any situation in which there may be a risk, this guideline applies them to risks originating from the exposure to *chemical substances*[84].

Risk assessments are used to identify and assess potential hazards and the resulting *risks*, while *risk management* describes the implementation of organizational measures to reduce or mitigate those risks. This section provides an overview of these concepts and their interrelation.

The United States EPA frame for human health risk assessment[30] illustrates a process for undertaking risk assessments. As shown in Figure 12, the risk assessment step in this process is based on the combination of the two principal components of risk, *exposure assessment* and *effects (hazard) assessment*.

Where to find details

risk assessment > D
exposure assessment
> D.3 and D.5.1
effects assessment and
risk characterisation > D.5.2
decision-making > D.5
and recommendations in C

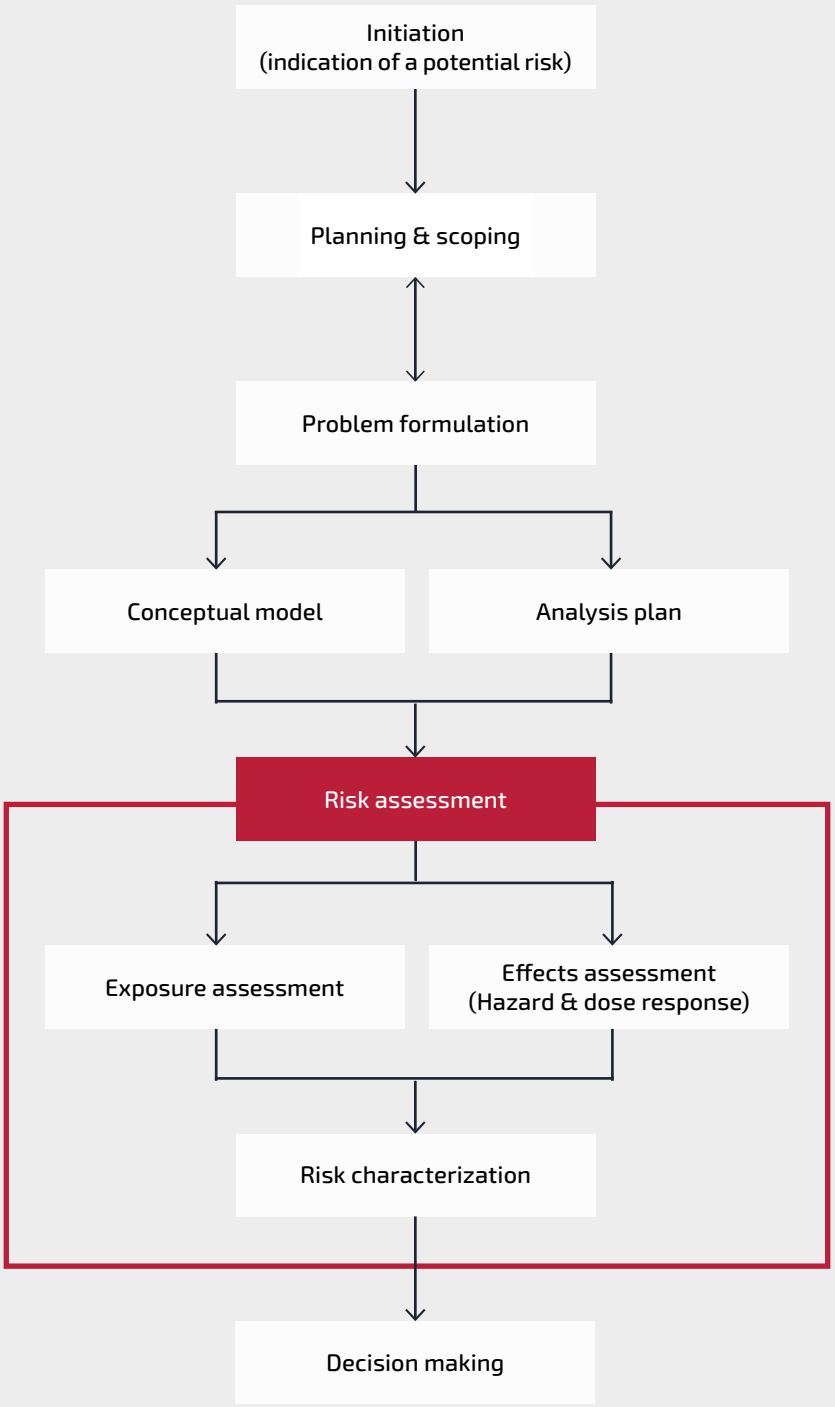
Note

The use of terms 'effects assessment' and 'hazard assessment' varies between different publications. The two terms can be used interchangeably. For this guideline, the CosPaTox Consortium chose the term 'effects assessment' to be used throughout the guideline. Readers more accustomed to 'hazard assessment' may consider the term 'effects assessment', when used in this guideline, to refer to the same concept.

[84] Other risks, for example, physical risks (such as risks of cuts or bruises, risks of burns), biological risks (such as risk of infection) are not in scope of this guidance.

Figure 12

Visualization of the risk assessment approach, based on [30].



E.4.1 Exposure assessment

Exposure describes the concentrations (doses) and the pathways of human contact with *hazards*, such as chemical substances. It includes for example the routes, magnitude, skin surface area, duration, and frequency of exposure. Exposure can be assessed by direct measurement (biomonitoring), but this approach is rarely used. Most commonly, exposure is estimated with an *exposure model*[31].

For the safety assessment of cosmetic, detergent or home care products and their packaging, the exposure of consumers to the product itself and thereby to substances contained in that product needs to be determined. This can be achieved by applying an exposure scenario, i.e., a model that considers the typical use of a product and how much product the customer is exposed to. To determine the exposure of a consumer to a certain substance, the exposure scenario is combined with knowledge of the concentration of the substance in the product.

> ***Examples of exposure assessments performed by the CosPaTox Consortium are described in D.5.1.***

Where to find details

example exposure scenarios > D.5.1
example exposure calculations > D.5.3

Where to find background information

determining substance concentration in a product > E.3

E.4.2 Effects assessment

Effects, i.e., impacts on human health, can be described as a combination of *hazard*, (the intrinsic toxicological properties of substances) and a *dose response* (the materialization of hazards at different levels of exposure). For an effects assessment, either data or acceptable assumptions regarding the toxicological properties of a substance are required.

The following sections provide a brief overview of the different possible approaches to assessing effects.

> ***The presentation of multiple possible approaches is particularly relevant for NIAS. While some NIAS are also commercial chemical products with available toxicological data, many NIAS are structures that are not commercially produced and for which no experimental toxicological data is available. The effects assessment approach chosen by the CosPaTox Consortium is described in D.5.2.***

Where to find background information

NIAS > E.3

E.4.2.1 Use of toxicological data

For many substances, effects can be understood based on *toxicological data* obtained from studies, which can be found in searchable databases. The most commonly used public databases are hosted by the European Chemicals Agency (ECHA), especially the REACH database, and by the US Environmental Protection Agency which

provides the EPA CompTox Chemicals Dashboard. The meta-database eChemPortal also provides a starting point which offers links to further databases that contain information about a substance of interest. Toxicological information can also be retrieved from literature research, e.g. in PubMed or Scopus.

When working with toxicological data, it is generally recommended that focus be placed on the types of studies and the *toxicological endpoints* that are most relevant for a product category. For the purposes of the risk assessment of the exposure to small amounts of chemical substances, as is potentially the case for contaminants from packaging materials, information from studies on *chronic effects* and information on *carcinogenicity*, *mutagenicity* and *reproductive toxicity* are generally more relevant than data from *acute toxicity* studies.

Information on safe levels of exposure to chemical substances can also be obtained from opinions published by the SCCS and from *specific migration limits* provided in food contact regulations, which are convertible to appropriate thresholds.

Data from toxicological studies and the derived safe exposure thresholds for specific substances can be conflicting, as the design and quality of the studies as well as the approach to translate the study results into a safe exposure threshold may vary. A trained toxicologist or safety assessor can convert between different types of thresholds, apply a weight-of-evidence approach between different or conflicting threshold values and derive a single value to be used in risk assessment[32].

> ***A list of substances potentially present in recycled plastic materials and the available toxicological date for these substances is described in D.2.***

Note

Typical limits found in studies include:

DNEL: Derived No-Effect Limit, defined in REACH as the level of exposure 'above which humans should not be exposed'. Expressed in mg/kg bw/day.

SML: Specific Migration Limit, the 'maximum permitted amount of a given substance released from a material or article into food or food simulants' according to the Plastics Regulation. Expressed in mg/kg food.

ADI: Acceptable Daily Intake, the amount of a specific substance that can be ingested daily over a lifetime without an appreciable health risk. Expressed in mg/kg bw/day.

E.4.2.2 Use of a read-across approach

In practice, the toxicological profile of many substances is incomplete. In such cases, a *read-across* approach may be applied by a trained toxicologist. A detailed description of the ECHA read-across framework for the assessment of chemicals under REACH can be found in [33]. ECHA also provides guidance on the application of quantitative structure-activity relationship (QSAR) principles for the grouping of chemicals of comparable toxicological profile[34].

Note

When employing toxicological data in the course of risk assessments, the CosPaTox Consortium reminds that regulatory limits may exist which are stricter than toxicologically derived limits.

E.4.2.3 Use of in silico prediction of toxicological properties

Where no information about the toxicity, including genotoxicity[35], of a substance is available from studies, the use of prediction models can be considered. This approach is applied for food contact

materials and articles[36]. Prediction models classify chemical substances by defining a set of rules that are applied to their chemical structure. The classification may be in the form of assigning the substance to a defined level of risk or in the form of producing 'structural alerts' that the substance may exhibit certain toxicological properties. Being based on the chemical structure of a substance, prediction models cannot be applied to substances whose structure is not known.

Where such models are computer-based, they are referred to as *'in silico'* prediction. Software for performing in silico prediction is available both in the public domain and as commercial products, with e.g. 'ToxTree'[37] and the OECD 'QSAR toolbox'[38] being well-known, publicly available tools.

Due to different possible choices for the ruleset and its variants, a detailed assessment of the prediction quality, for example by combining multiple tools, and a documentation of the parameters used for an in-silico prediction is essential. In silico prediction tools must be considered 'supervised' tools which should only be applied with the involvement of a toxicologist or subject matter expert, who is able to adequately assess the inputs and the outputs of the process. A detailed guidance can be found in [34].

> ***As this guideline describes the general approach to safety assessment rather than the safety assessment of a specific material, no concrete examples of in silico prediction of properties are described.***

E.4.2.4 Use of the toxicological threshold of concern (TTC) approach

A common ruleset for classifying chemicals, for which no toxicological data is available, has been created by Cramer et al.[39], defining the so-called 'Cramer classes':

- Class I: substances with a simple chemical structure and for which efficient modes of metabolism exist, suggesting a low order of oral toxicity
- Class II: substances which possess structures that are less innocuous than Class I substances but do not contain structural features suggestive of toxicity
- Class III: substances with chemical structures that permit no strong initial presumption of safety or may even suggest significant toxicity or have reactive functional groups

Note

In practice, Cramer class II is not always used and substances falling into this class treated also as class III substances. This is in particular the case in the work and opinions of the SCCS.

Cramer class system has been developed further over the years and adopted widely, including in the *toxicological threshold of concern* (TTC) approach used in the safety assessment of food contact materials in the EU[36][85] and has been reviewed by the SCCS[11]. In this approach, a TTC is assigned to groups of substances, including each Cramer class[86].

The toxicological threshold of concern (TTC) concept is an approach to the evaluation of risks which acknowledges the view that a threshold of *exposure* to chemicals exists below which there is no significant risk from systemic toxicity to human health[40], [41]. It is therefore a useful approach where a low exposure to substances of unknown toxicological profile occurs.

The TTC concept is widely applied for the safety evaluation of packaging materials[36], [42], [43], [44] and also for the evaluation of post-consumer recycled plastics used in packaging materials[45], [46]. In addition, TTC has been incorporated into the evaluation of flavoring substances[41], [42]. Based on the work of Kroes et al.[47], EFSA promotes a more conservative TTC approach with regard to potentially DNA-reactive mutagens and/or carcinogens with a threshold of 0.15 µg/person/day for substances found in food[36], an approach also found in the SCCS Notes for Guidance.

The evaluation of the TTC concept over time has demonstrated that, for the substance classes to which it can be applied, none of the evaluated specific non-cancer endpoints (e.g., reproductive, and developmental toxicity) were more sensitive than the cancer endpoint. Therefore, the use of the TTC value of 0.15 µg/person/day provides an adequate margin of safety for all toxicological endpoints, meaning that at exposures below this value, the exact chemical identity of a substance is not required to be known. TTC therefore provides an important framework for dealing with substances that are detected in analytical screenings but cannot be (fully) identified and therefore not be covered through existing toxicological data or in-silico techniques. It also allows for ignoring the presence of substances below the limit of detection of analytical techniques if that limit lies at or below the equivalent of the TTC value of 0.15 µg/person/day.

> ***The TTC approach has been applied in the example safety assessments described in D.5 and is part of the guidance provided in chapter C.***

[85] In the evaluation by EFSA, it was noted that TTC should not be used when actual toxicological data is available, and that it does not cover certain classes of substances. A trained toxicologist may exercise their own judgement on how to approach the assessment of such substances.

[86] See for example Table 2 in [36].

E.4.2.5 Use of the dermal sensitization threshold approach

Information and data generated from investigating systemic toxicity does not allow for the evaluation of *skin sensitization*. While for some substances migrating from packaging, information about their skin sensitizing property/potency may be available and may inform a (quantitative) risk assessment, it is expected that for a significant number of migrating substances such information will be missing.

Similar to the use of the TTC concept for toxicity, the Dermal Sensitization Threshold (DST) [13] approach can be used in the risk assessment for skin sensitizing substances in cases where human exposure is low.

The authors of the DST approach derived a safe threshold of 64 µg/cm² to which safety factors are applied according to the QRA II approach developed by IFRA[48]. These safety factors are application-specific and suggested to be set 100 or 300 by IFRA, resulting in a threshold-of-safety of 0.64 µg/cm² and 0.21 µg/cm², respectively, for skin sensitizing substances and for substances for which absence of sensitization is not proven.

> ***The DST approach has been applied in the example safety assessments described in D.5.***

Note

Different to the TTC concept, which uses exposure in units of weight per body weight, the relevant dose descriptor for skin sensitization is an area dose, i.e., the dose of substance per area of skin.

E.4.2.6 Use of in vitro test methods for toxicological properties

Where existing toxicological data, prediction models or the TTC concept are not sufficient to complete a risk assessment, practical testing may be conducted. Such testing will generally be performed *in vitro*, meaning on artificial samples rather than on animal or humans,

Bacterial reverse mutation test

The bacterial reverse mutation test or 'Ames' test (OECD TG 471, 1997) is used across industries to identify DNA-reactive *mutagens* as a first step within testing strategies for *genotoxicity* (e.g., as part of REACH and CLP regulations)[49]. Mutations are measured as reversion to amino acid dependency for bacterial growth. The results of six different strains in total, identifying different types of mutations, are recommended in OECD TG 471 to conclude on the mutagenic potential of a chemical substance.

> ***The CosPaTox Consortium intended to investigate whether the Ames methodology would be sufficiently predictive for excluding the genotoxic hazard in extraction or migration solutions. It was thought that in particular the assessment of unidentified substances[87] could profit from this approach, as for these cases***

Where to find background information

REACH > E.1.2.4
CLP > E.1.2.2

[87] For whose peaks in the GC-MS screening no chemical structure could be allocated.

neither a reference to databases nor in silico prediction of genotoxicity is possible[50]. For the experimental phase of CosPaTox, a miniaturized version of the Ames was chosen which had recently been proposed to inform the safety assessment of food packaging[51]. Available time in the CosPaTox project did not allow to further investigate the general relevance of the miniaturized Ames test for the intended purpose, including whether the only two bacterial strains it uses sufficiently predict DNA-reactive mutagens or whether the methodology is sufficiently sensitive to identify mutagens at relevant levels.

In vitro skin sensitization test methods

Several in vitro skin sensitization assays have gained regulatory acceptance in recent years[88].

> *Considering the difference in magnitude between skin sensitization threshold levels derived from the DST model and the toxicological thresholds derived from the TTC model, the CosPaTox Consortium has decided to not conduct in vitro skin sensitization tests. It was not expected that substances will transfer from recycled materials into the product which exhibit an unknown skin sensitization potential but for which enough toxicological data is available that would allow deriving a maximum acceptable consumer exposure (MACE) which lies above the threshold resulting from the DST model.*

Where to find background information

TTC > E.4.2.4
MACE > E.4.3

E.4.3 Risk assessment and decision-making

Even though substances that present *hazards* can potentially pose a *risk* to consumers even at low exposure levels, *exposure limits* can still be defined that prevent an unacceptable risk and ensure products that are safe for consumers. In this approach, based on the assessment of possible *effects* (which cannot be influenced), a *level of exposure* (which can be influenced) is determined at which the residual risk can be considered acceptable. In this way, a *maximum acceptable consumer exposure* (MACE) value can be derived.

Where to find details

exposure assessment > D.3 and D.5.1
effects assessment and risk characterisation > D.5.2
decision-making > D.5.3
and recommendations in C

The MACE can further be converted into a maximum acceptable concentration of a substance in a product by considering how the product is used by consumers and what exposure results from this use (exposure scenario). The MACE can also be converted to a maximum acceptable concentration of a substance in packaging and to the maximum acceptable concentration in recycled plastic materials themselves[89]. This conversion is visualized in Figure 13. Concrete examples are provided in sections D.4, D.5.1 and D.5.3.

[88] For example, through the REACH regulation (Regulation (EC) No 1272/2008), and OECD TG 442 D, OECD TG 442 E, OECD TG 497 (defined approach), OECD 442C DPRA and [52], [53], [54], [55].

[89] This differentiation considers that packaging does not necessarily contain only recycled plastic but may also contain a share of virgin material. Furthermore, packaging may contain multiple types of recycled plastic, including of different purity.

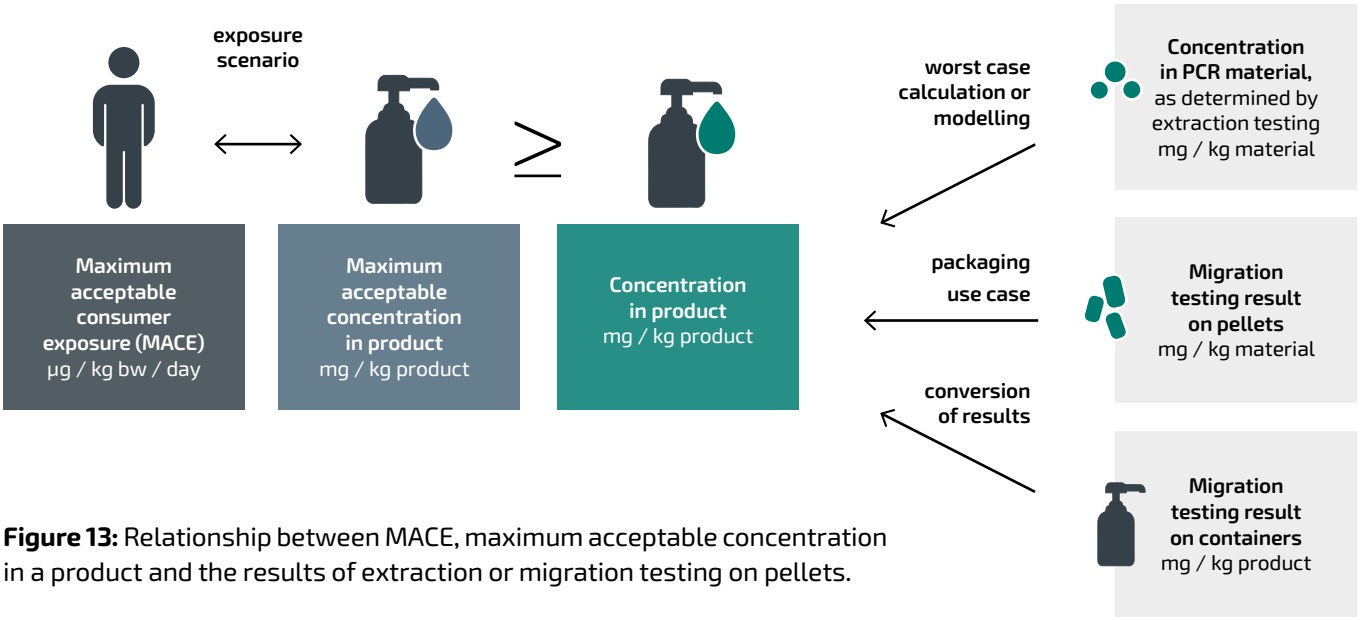


Figure 13: Relationship between MACE, maximum acceptable concentration in a product and the results of extraction or migration testing on pellets.

> ***The CosPaTox Consortium has performed this form of assessment for illustrative examples, see D.5.3 for a description. For the list of substances described in D.2, the CosPaTox Consortium has compiled suggestions for the MACE values to be applied to each substance.***

E.4.4 Risk management

Risk assessment is generally combined with the wider process of *risk management*. The two can be differentiated as follows: the aim of risk assessment is to characterize a risk and its acceptability. As such, risk assessment supports organizational decision making but it is not the process of that decision making. The decisions regarding which applications of a recycled plastic material will be implemented, the decision to conduct more detailed migration studies or to work towards an optimization in the recycling process instead are part of *risk management*.

The key aspects of risk management are:

- *Risk identification and analysis* (i.e., *risk assessment*)
- *Risk documentation*
- *Risk control*
- Evaluation of overall *residual risk acceptability*

> ***See C.5.3 for the concrete guidance that was developed by the CosPaTox Consortium regarding risk management.***

E.5 Safety assessment of packaging for cosmetic products and detergents

Where to find background information

regulatory background > E.1
risk assessment > E.4

Using the principles of *risk assessment* to determine the safety of a given product or its packaging is generally referred to as *safety assessment*. For the safety assessment of cosmetic products in the EU, it is legally required to include a consideration of its packaging in direct contact with the product (primary packaging), with a view to its ability to transfer substances into the cosmetic product[90].

This section begins with an overview of the established approaches for the safety assessment of cosmetic product packaging made of virgin plastic materials. This information is provided only for reference and to provide a comparison with the assessment of recycled plastic materials, which is the focus of this guideline.

The same approaches used for cosmetic product packaging can also be applied to perform a safety assessment for other product types that can come into contact with skin such as detergents and home care products.

The second part of this section provides an overview of previous approaches to the safety assessment of recycled plastic materials for use in the packaging of cosmetic products, detergents, and household products which have been published prior to the work of the CosPaTox Consortium.

E.5.1 Safety assessment of cosmetic packaging made from virgin plastics

Where to find background information

food contact regulations > E.1.2
substances of concern > E.1.1
SVHC > E.1.2.4
heavy metals > E.1.1.2

For cosmetic products, a key guidance document related to the safety assessment of packaging materials has been published by Cosmetics Europe[1]. This document was written with virgin materials in mind and describes which information related to packaging needs to be made available to the safety assessor who is evaluating a packaging material.

A key approach of the Cosmetics Europe guidance is the use of *food contact information*, which is available for many virgin packaging materials, as the main source of information for the safety assessment[91], and to additionally consider specific *substances of concern* in the Cosmetic Products Regulation.

The Cosmetics Europe guidance further requires that *good manufacturing practice* (GMP) is implemented. This may be assured implicitly through compliance of the material with food contact

[90] This consideration needs to include, as applicable to the given application, the possibility that a substance may be both contained in the product itself as well as transfer into the product from the packaging. In such cases, even if the (initial) concentration of substance the product itself as well as the transfer of the substance from packaging into product are individually below the maximum acceptable consumer exposure or regulatory thresholds, their sum may exceed this value.

[91] This is in line with regulation; see section E.1.1.

regulations, or be confirmed by other means, e.g., through quality management systems such as ISO 9001.

The Cosmetics Europe guidance acknowledges the complexity of packaging materials, stating that "[…] A full breakdown of compositional detail would create a disproportionate administrative burden along the supply chain without being necessary for an adequate safety assessment by the cosmetic product safety assessor. […]". Instead, it suggests that the following information is made available for safety assessments:

1. Information on the presence of substances on the candidate list for *substances of very high concern* (SVHC), if present above 0.1wt%
2. Information on the presence of *heavy metals*
3. Information of substances that are capable of transferring into the product
4. Declaration of compliance with food contact regulations or relevant information for the safety evaluation of the packaging by other means
5. Information on substances of specific concern under the cosmetic products regulation (especially Annex II, Annex III, CMR substances and skin sensitizers), taking into account the reporting threshold for these substances as defined in [1].

6. Information on good manufacturing practice

> ***The recommendations in chapter C for recycled plastics are closely aligned with the content of the Cosmetics Europe guidance for virgin materials. In particular, the recommendations for information to be transmitted along the supply chain (see C.4.4) and on good manufacturing practice (see C.4.3 and C.5.3) are closely aligned.***

E.5.2 Safety assessment of packaging made from recycled plastics

When using recycled plastics for the packaging of cosmetic products, detergents, and home care products, different to virgin materials, the presence of potential contaminants in these materials needs to be considered.

In addition, substances that are present in any plastic, whether virgin or recycled material, comprise not only intentionally added substances (IAS), but also non-intentionally added substances (NIAS). For an exhaustive discussion of NIAS and their management, readers are directed to relevant literature and sectorial guidance[25], [26], [27], [28], [56], [57]. While a certain amount of NIAS is also present in virgin plastic materials[58], in the case of recycled plastic

Where to find background information

NIAS > E.3

materials, additional substances may have formed during the product shelf life[92], during the recycling process or have been transferred as (cross-) contamination[46]. This includes, based on [46]:

- contaminants from possible misuse,
- contaminants from non-food contact applications (non-authorized monomers and additives, chemicals from non-food consumer products)
- chemicals from material other than the plastic being recycled,
- chemicals used in the recycling process,
- degradation products of the plastic (and other packaging components such as inks, adhesives, coatings, and additives), and
- components of the food or other products packaged in packaging that is being recycled.

The presence of such substances cannot fully be controlled if the plastic packaging waste is not obtained from a controlled loop[93]. Recycled materials consequently often contain a substantially higher number of unknown or unexpected substances than virgin materials because for technical, ecological, or economic reasons, recycling processes cannot completely remove all possible contaminants. Limiting the composition of recycled plastic materials to a select number of positively listed intentionally added substances and fully evaluated NIAS as is practiced for virgin materials, is therefore not viable.

Certain substances can pose a health risk to consumers already at a low level of *exposure*. Therefore, even when high quality post-consumer recycled plastics are used, a safety assessment is required.

Two fundamental approaches to assess recyclates to be used in packaging have been considered prior to the work of the CosPaTox Consortium. One approach is to base the safety assessment on existing or expected food contact approvals, in which case, the process can follow the Cosmetics Europe guidance[1] which was developed for virgin materials (see E.5.1). Where food contact approvals are not available, a *dedicated* safety *assessment*, based on knowledge of the substances that are present in the recyclates and which could migrate into the product is required.

> ***The focus of CosPaTox is on the second case, for which no clear guidance is yet available. However, for the sake of completeness, both approaches are described in the following sections.***

[92] For example, degradation products of antioxidants or oxygen scavengers, decomposition products generated when heating ready meal packaging in an oven or microwave, degradation products due to exposure to sunlight.

[93] A typical example of a controlled loop for PE and PP are plastic crates for produce which are kept in a pool system. Such crates are produced, issued to the food supply chain, and used multiple times. Broken crates are collected selectively from the supply chain with 100% positive identification and are recycled back into new crates for the same application. Note that the presence of residual product is not guaranteed to be excluded by controlled loop systems.

Where to find background information

exposure > E.4.1
availability of food contact PCR plastics > E.2.2 and E.1.3.3

E.5.2.1 Safety assessment using food contact information

The use of food contact approvals is a commonly used approach to the safety of virgin plastic packaging materials and can be applied also for recycled plastics, including post-consumer recyclates (PCR). It is however limited in practice by the availability of food contact approved PCR materials [2].

For recycled PET, a scheme for the safety evaluation has been developed by EFSA[17]. Numerous approvals have been given by EFSA for the recycling of post-consumer PET packaging into material for food-contact applications[18]. A substantial quantity of recycled PET (rPET) is therefore available in food-contact quality.

The availability of food contact approved mechanically recycled PE and PP for rigid packaging applications, is however extremely limited and, different to PET, no uniform scheme for their assessment has been published by EFSA[94]. To date, only a limited number of approvals has been provided by EFSA for food contact of recycled HDPE and PP[18]. The approved cases[95] can all be characterized as being *controlled loop*[96] systems or based on highly controlled feedstocks. The availability of 'general use' food contact grade recycled HDPE and PP remains extremely limited today[97]. At time of writing, there is an absence of approvals for the use of mechanically recycled LDPE and flexible PP films in food contact film applications[18][98,99].

> ***Where no food contact approval is available for PE and PP PCR materials[2], the safety assessment of their use in cosmetic products and detergent packaging needs to be based on a specific investigation and a dedicated safety assessment of each material. This is the motivation and focus for this guideline.***

[94] It follows that if HDPE or PP packaging includes recycled content, it is uncommon for such packaging to fulfill food contact requirements since the recycled part of the packaging is unlikely to be food-contact approved.

[95] As of March 2024.

[96] A system in which the circulation of materials is controlled and limited to system-compatible items, whose identity is established for every item before recycling. A typical example are crates and palettes for produce. These items remain in a controlled circulation (agriculture, retail). No mixing with other items occurs during use or during recycling. Only positively identified broken crates or palettes from the system are allowed as recycling input.

[97] Except for PE and PP produced from feedstocks that originate from chemical recycling.

[98] It follows that if LDPE or PP flexible packaging includes recycled content, it is unlikely that the packaging fulfills food contact requirements since the recycled part of the packaging is unlikely to be food-contact approved.

[99] As of March 2024. Individual examples for recycled polyolefin films in food contact exist which are based on an exemption from pre-market approval of recycled plastics when used behind a barrier that was provided by Regulation (EC) No 282/2008. These use cases were characterized by being limited to dry foodstuff and storage below room temperature such as frozen foods. Regulation (EC) No 282/2008 has however been repealed and replaced and the exemption no longer applies. See section E.1.3.3.

E.5.2.2 Dedicated safety assessment of not food contact approved recycled plastic materials

Where a food contact approval is not available for a recycled plastic material, a dedicated safety assessment is required before the use of the material in cosmetic or detergent packaging.

Such safety assessments are based on knowledge of chemical substances present in the plastic materials and the potential exposure of consumers to these substances when used as a packaging material.

The composition of PCR materials and their safety assessment have already been the subject of studies before the work of the CosPaTox Consortium[3], [7], [59].

> *The work of the CosPaTox Consortium builds and expands upon this prior work, to provide comprehensive findings and clear recommendations to industry (see chapter C) for conducting recycled plastic material characterization and performing dedicated safety assessments for recycled plastic materials in the absence of food contact approvals.*

Where to find details

characterization of recycled plastics > D.2
safety assessment > D.5

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Glossary & list of abbreviations

Term	Explanation
ADI	Acceptable Daily Intake
CMR substance	Substance listed as Carcinogenic, Mutagenic, or toxic to Reproduction Category 1A, 1B or 2 in Regulation (EC) No 1272/2008 Annex VI table 3.1
DNEL	Derived No-Effect Limit
DST	Dermal sensitization threshold
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
FDA	(United States) Food and Drug Administration
GC/MS	Gas chromatography coupled with mass spectrometry
IAS	Intentionally Added Substance
ICP-MS	Inductively Coupled Plasma Mass Spectrometry
LC/MS	Liquid chromatography coupled with mass spectrometry
MACE	Maximum acceptable consumer exposure
NIAS	Non-Intentionally Added Substance
OML	Overall Migration Limit
PCR	Post-consumer recycled
PE	Polyethylene polymer or plastic
PET	Polyethylene terephthalate
PP	Polypropylene polymer or plastic
rPE	Recycled polyethylene
rPET	Recycled polyethylene terephthalate
rPP	Recycled polypropylene
SCCS	Scientific Committee on Consumer Safety
Skin sensitizer	Substance classified as a skin sensitizer in Regulation (EC) No 1272/2008 Annex VI table 3.1 (hazard statement code H317)
SML	Specific Migration Limit
SVHC	Substances of Very High Concern (as per REACH)
TTC	Toxicological Threshold of Concern
XRF	X-ray fluorescence
µg/kg bw/d	Microgram per kilogram body weight per day

Annex I – Example safety assessment results

How were the use-cases calculated?

For the same use cases that were used for migration calculations (section D.4), example exposure scenarios were applied. For cosmetic products, the most relevant exposure scenarios are described in [11]. Different collections of exposure scenarios exist for laundry and home care products. The exposure models and parameters provided in the AISE REACT tool[10] were considered appropriate for establishing use-cases for detergent products within the scope of this work. For the dermal absorption of cosmetic products, a default rate of 50% for adults and 100% for children and newborns was used in accordance with [11]. For detergents and hand dishwashing products, a default value of 100% dermal absorption was applied for both adults and children/newborns according to the parameters applied in the standard exposure scenarios[10]. For wet wipes, the assumption was made that a complete and uniform transfer of substances occurs from the packaging to the wipes and that in use, the entire liquid present on the wipes transfers onto the skin. Both assumptions are seen as highly conservative. For wet wipes, the concentration in the product is to be understood as the concentration per wipe.

Body weights of 60 kg for adults, 5 kg for infants, and 2 kg for newborns were used throughout[9].

In general, the *systemic exposure* to a substance is calculated based on the amount of daily contact with a cosmetic or detergent product, the *retention factor*, which describes the amount of product expected to remain on the skin (or mucosa) after product use, the degree of (dermal or oral) *absorption*, and the body weight of the person using the product.

A	B	C	D	E	F	G	H	I	J	K	L	M		N	O	P		Q	R
	Input													**Output:**					
														Transfer from packaging				Conc. in content	
result file	packaging	material	content volume [mL]	packaging weight [g]	shelf life [years]	product	portion [mL]	recyclate content [%]	on skin [%]	resorption [%]	body weight [kg]	skin surface [cm²]		maximum quantit				maximum conc.	
														genotoxic [mg/kg plastic]	Cramer III [mg/kg plastic]	DST [mg/kg plastic]		gentoxic [µg/ml product]	Cramer III [µg/ml product]
1a	tube	HDPE	250	17.0	3	shampoo	10.46	100	1	50	60	1440		42.180	25310.0	141.72		2.8682	1721.08
1b										100	5			1.757	1054.0			0.1195	71.67
2a	closure	PP	250	6.2	3	shampoo	10.46	100	1	50	60	1440		115.600	69390.0	388.60		2.8669	1720.87
2b										100	5			4.819	2891.0			0.1195	71.70
3a	bottle	HDPE	300	20	2,5	shampoo	10.46	100	1	50	60	1440		43.020	25810.0	144.53		2.8680	1720.67
3b										100	5			1.793	1076.0			0.1195	71.73
4a	bottle	HDPE	500	36.0	3	shampoo	10.46	100	1	50	60	1440		39.830	23900.0	133.84		2.8678	1720.80
4b										100	5			1.660	995.9			0.1195	71.70
5a	bottle	HDPE	250	25.8	3	shampoo	10.46	100	1	50	60	1440		27.790	16680.0	186.83		2.8679	1721.38
5b										100	5			1.158	694.8			0.1195	71.70
5c						shower gel	18.67			50	60	17500		15.500	9342.0	635.78		1.5996	964.09
5d										100	5			0.650	389.0			0.0671	40.14
5e						body lotion	7.82		100	50	60	15670		0.370	223.0	13.59		0.0382	23.01
5f										100	5			0.020	9.0			0.0021	0.93
6a	bottle	HDPE	300	23.0	3	shampoo	10.46	100	1	50	60	1440		37.410	22450.0	125.67		2.8681	1721.17
6b										100	5			1.559	935.2			0.1195	71.70
7a	pouch	PE	500	10.5	3	shampoo	10.46	100	1	50	60	1440		136.600	81950.0	458.92		2.8686	1720.95
7b										100	5			5.691	3414.0			0.1195	71.69
7c						shower gel	18.67			50	60	17500		76.520	45910.0	3124.54		1.6069	964.11
7d										100	5			3.188	1913.0			0.0669	40.17
8a	pouch	PE	1000	18.7	3	shampoo	10.46	100	1	50	60	1440		153.400	92020.0	515.34		2.8686	1720.77
8b										100	5			6.391	3834.0			0.1195	71.70
8c						shower gel	18.67			50	60	17500		85.930	51560.0	3508.77		1.6069	964.17

A	B	C	D	E	F	G	H	I	J	K	L	M		N	O	P		Q	R
	Input													**Output:**					
														Transfer from packaging				Conc. in content	
result file	packaging	material	content volume [mL]	packaging weight [g]	shelf life [years]	product	portion [mL]	recyclate content [%]	on skin [%]	resorption [%]	body weight [kg]	skin surface [cm²]		maximum quantity				maximum conc.	
														genotoxic [mg/kg plastic]	Cramer III [mg/kg plastic]	DST [mg/kg plastic]		gentoxic [µg/ml product]	Cramer III [µg/ml product]
8d										100	5			3.580	2148.0			0.0669	40.17
9a	pouch	PE	15	5.0	3	shampoo	10.46	100	1	50	60	1440		8.604	5163.0	28.91		2.8680	1721.00
9b										100	5			0.359	215.1			0.1195	71.70
9c						shower gel	18.67			50	60	17500		4.821	2892.0	196.81		1.6070	964.00
9d										100	5			0.201	120.5			0.0670	40.17
9e						body lotion	7.82		100	50	60	15670		0.115	69.1	4.21		0.0384	23.02
9f										100	5			0.005	2.9			0.0016	0.96
10a	sachet	PE	2	0.8	3	shampoo	10.46	100	1	50	60	1440		7.188	4313.0	24.15		3.9534	2372.15
10b										100	5			0.300	179.7			0.1647	98.84
10c						shower gel	18.67			50	60	17500		4.027	2416.0	164.45		2.2149	1328.80
10d										100	5			0.168	100.7			0.0923	55.39
10e						body lotion	7.82		100	50	60	15670		0.096	57.7	3.52		0.0529	31.72
10f										100	5			0.004	2.4			0.0022	1.32
11a	spray	HDPE	100	13.0	3	deodorant	0.69	100	100	50	60	200		3.344	2007	1.56		0.4347	260.91
12a	spray	HDPE	150	15.0	3	deodorant	0.69	100	100	50	60	200		4.348	2609	2.02		0.4348	260.90
13a	spray	HDPE	200	22.0	3	deodorant	0.69	100	100	50	60	200		3.953	2372	1.84		0.4348	260.92
14a	tube	HDPE	75	6.5	2,5	hand creme	2.16	100	100	50	60	860		1.603	961.5	9.65		0.1389	83.33
14b										100	5			0.066	40.1			0.0058	3.48
15a	wet wipes	PE/PP	56 pieces	6.7	2,5	wet wipes	16 pieces	100	100	100	2			0.003	1.6			0.0003	0.19
15b							5 pieces				2			0.008	5.0			0.0010	0.60
16a	wet wipes	PE/PP	80 pieces	7.8	2,5	wet wipes	16 pieces	100	100	100	2			0.003	1.9			0.0003	0.19
16b							5 pieces				2			0.010	6.2			0.0010	0.60
17a	wet wipes	PE/PP	48 pieces	5.6	2,5	wet wipes	16 pieces	100	100	100	2			0.003	1.6			0.0003	0.19

A	B	C	D	E	F	G	H	I	J	K	L	M		N	O	P		Q	R
	Input													**Output:**					
														Transfer from packaging				Conc. in content	
result file	packaging	material	content volume [mL]	packaging weight [g]	shelf life [years]	product	portion [mL]	recyclate content [%]	on skin [%]	resorption [%]	body weight [kg]	skin surface [cm²]		maximum quantity				maximum conc.	
														genotoxic [mg/kg plastic]	Cramer III [mg/kg plastic]	DST [mg/kg plastic]		gentoxic [µg/ml product]	Cramer III [µg/ml product]
17b							5 pieces				2			0.009	5.1			0.0010	0.60
18a	wet wipes	PE/PP	56 pieces	7.9	2,5	wet wipes	16 pieces	100	100	100	2			0.002	1.3			0.0003	0.19
18b							5 pieces				2			0.007	4.3			0.0010	0.60
19a	wet wipes	PE/PP	80 pieces	7.8	2,5	wet wipes	16 pieces	100	100	100	2			0.003	1.9			0.0003	0.19
19b							5 pieces				2			0.010	6.2			0.0010	0.60
21a	tube	PP	30	4.78	3	shampoo	10.46	100	1	50	60	1440		18.000	10800.0	60.48		2.8680	1720.80
21b										100	5			0.750	450.0			0.1195	71.70
21c						shower gel	18.67			50	60	17500		10.080	6051.0	411.76		1.6061	964.13
21d										100	5			0.420	252.1			0.0670	40.17
21e						body lotion	7.82		100	50	60	15670		0.241	144.5	8.80		0.0384	23.02
21f										100	5			0.010	6.0			0.0016	0.96
22	bottle	PP	20	7.3	3	mascara	0.5	100		50	60			1.644	986.3			0.6001	360.00
26	bottle	HDPE	3000	120		special detergent (with hand wash)	0.5418 g	100	100	100	60	2085.5		6.920	4153.0	615.85		0.2768	166.08
27	bottle	PP	3000	130		heavy duty detergent (with hand wash)	0.5418 g	100	100	100	60	2085.5		6.390	3833.0	568.48		0.2769	166.14
28	bottle	PP	3000	130		home care product	0.0018 g	100	100	100	60	2085.5		1923.000	>100000	>100000		83.3300	49998.00

In the following, the columns in the result sheet are explained:

Column	Input/ Output	Explanation
A	Input	Use-case number (see section D.4)
B	Input	Packaging type (individual component, e.g. bottle without closure)
C	Input	Type of plastic
D	Input	Filling good weight or volume in g or ml; used to calculate the concentration of transferred substances in the product
E	Input	Packaging (material) weight of the individual component, see B
F	Input	Shelf life of the product. The shelf life was not used for the calculations.
G	Input	Product description
H	Input	Daily applied volume of the product
I	Input	Recyclate content in the packaging material. 100% recyclate content was used as default value for the calculations (worst-case)
J	Input	Retention factor: percentage of the daily applied portion given in column H, which remains on the skin
K	Input	Absorption factor: percentage of absorption of the amount that is retained on skin (column J). 50% for adults and 100% for children was set as default value (worst-case) for cosmetic products. For household products, generally an absorption of 100% was applied
L	Input	Body weight of the consumer. Default values for adults (60 kg), infants (5 kg) and newborns (2 kg)[46] were used
M	Input	Exposed adult skin surface area in cm^2 for a specific product application (e.g., shampoo, shower gel or hand cream); used to determine the area dose related to dermal sensitization (column Q)
N	Output	Maximum transfer of an unidentified or potentially genotoxic substance from the packaging material into the product, corresponding with an exposure of 0.0025 µg/kg bw/d (TTC threshold for genotoxic substances). This value can be correlated to the required lower detection limit of the applied analytical method.
O	Output	Maximum transfer of a substance from the packaging material into the product corresponding with an exposure of 1.5 µg/kg bw/d (TTC threshold for Cramer class III substances)
P	Output	Maximum concentration of a substance in the packaging material corresponding with an skin exposure of 0.21 $µg/cm^2$ and 0.62 $µg/cm^2$ (for detergents), respectively, according to the DST approach. Values are only given for adults for which also the skin area of exposure is given.
Q	Output	Concentration of a substance in the packed content resulting in an exposure of 0.0025 µg per kg bw per day (TTC threshold for genotoxic compounds).
R	Output	Concentration of a substances in the packed content resulting in an exposure of 1.5 µg per kg bw per day (TTC threshold for Cramer Class III compounds).

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.

F.1 Equipment

Aside from common laboratory equipment and tools, the following equipment is recommended for conducting the testing described in this procedure. Alternative equipment which can produce equivalent results may be used to conduct the recommended testing; no assurances of the equivalence of the results are provided, however, if alternative equipment is used.

- **Gas chromatography system with mass spectrometry detector (GC/MS), with helium carrier gas**, including standard consumables such as vials, liners etc.
- **Chromatographic column**, e.g., Restek Rxi-5Sil MS, 30 m x 0.25 mm id, 0.5 µm df
- **10mL pipette**, for adding internal standards

Additionally, for the extraction and migration testing on recycled plastic pellet samples:

- **16 x 100 mm Duran glass test tubes**, for immersing the pellet samples in the simulant (e.g., VWR art. 391-0145)
- **Red screw caps GL18 made of PBT with PTFE coated seals**, for closing the test tubes (e.g., VWR art. 201-0001)
- **Heating block for test tubes**, e.g., Liebisch Thermobil type TM-130-56 equipped with a monoblock MHB-S-26-16, for temperature control during extraction/migration testing

Additionally, for the migration testing on bottles made with recycled plastic material:

- **Blow molding equipment to produce bottles**, of a brimful volume of ca. 225mL (incl. neck) and dimensions of approximately 60 mm x 132 mm x 36 mm (width x height from bottom to neck x depth) and with a neck that allows closing during testing
- **Temperature controlled cabinet or room, suitable to reach 60 °C and suitable for flammable material storage**, for the temperature control of bottle samples containing simulant during the migration testing

F.2 Chemicals and materials

The following chemicals and materials are recommended to conduct the testing described in this procedure. Alternative chemicals and materials which can produce equivalent results may be used to conduct the recommended testing; this guideline can however not provide assurances of equivalence of results if alternative chemicals and materials are used.

Internal standards, to be added to the extraction medium/simulant before the GC/MS analysis:

- **4,4'-difluorobiphenyl** (DFBP)[100]
- **3-tert-Butyl-4-hydroxyanisole** (BHA)[101]
- **Tridecane**[102]

For the extraction testing on recycled plastic pellets:

- **Dichloromethane** (<0.02% water)[103], as extraction medium

For the migration testing on recycled plastic pellets and bottles made with recycled plastic material:

- **Ethanol** (absolute)[104], as simulant
- **Purified water**, for diluting absolute ethanol to the target concentration

F.2.1 Preparation of the simulant Ethanol 95%

Prepare the simulant by diluting absolute ethanol (used as purchased) to 95% (v/v) with purified water.

F.2.2 Preparation of the simulant Ethanol 50%

Prepare the simulant by diluting absolute ethanol (used as purchased) to 50% (v/v) with purified water.

[100] For example, Sigma-Aldrich D102407.
[101] For example, Supelco PHR1306.
[102] For example, Sigma-Aldrich T57401.
[103] For example, VWR 83665.320.
[104] For example, Merck article 1.00983.2511.

F.3 Samples

For the migration testing of recycled plastic pellets:

- **25 g of recycled plastic material pellets**, collected from a batch of recycled plastic material[105]

For the migration testing of bottles made with recycled plastic material:

- **Three 200 mL bottles produced with recycled plastic material**, produced from pellets randomly collected from a batch of recycled plastic material. Produce the bottles by injection molding, avoiding the use processing aids[106]. The weight of the bottle should be approximately 19 g.

F.4 Procedure for the extraction testing on pellets of recycled plastic material

Weigh 3.0 g ± 0.1 g of recycled plastic material sample in the form of pellets into a screw cap glass tube and add 3.00 mL ± 0.07 mL of extraction medium. Close the tube with a screw cap and place it in a metal block thermostat for three days at a set temperature of 40 °C ± 2 °C. After this time, remove the tube from the block and allow it to cool to room temperature. After a short shaking of the tube, transfer 1.00 mL ± 0.07 mL of the extraction medium into a GC sample vial. Analyze the sample by GC/MS a per section F.7.

Test each recycled plastic material sample in full triplicate, i.e., bring three different pellet samples from each recycled plastic material in contact with extraction medium as described above and analyze the extraction medium of each replicate separately by GC/MS.

F.5 Procedure for the migration testing on pellets of recycled plastic material

Weigh 3.0 g ± 0.1 g of recycled plastic material sample in form of pellets into a screw cap glass tube and add 3.00 mL ± 0.07 mL of simulant. Close the tube with a screw cap and place it in a metal block thermostat for seven days at a set temperature of 60 °C ± 2 °C. After this time, remove the tube from the block and allow it to cool to room temperature. After a short shaking of the tube, transfer 1.00 mL ± 0.07 mL of the simulant into a GC sample vial. Analyze the sample by GC/MS a per section F.7.

Test each recycled plastic material sample in full triplicate, i.e., bring three different pellet samples from each recycled plastic material in contact with simulant as described above and analyze the simulant of each replicate separately by GC/MS.

[105] To obtain a sample as representative as possible of a production batch, common practice is to regularly take pellet samples over the course of the production run and mix them to prepare a sample for testing.
[106] Processing aids, including mould release agents may influence the test results by transferring into the simulant.

F.6 Procedure for the migration testing on bottles made from recycled plastic material

Fill the bottle with 200 mL of simulant and close with a suitable cap. Place the bottle in a temperature test cabinet / climate test chamber for seven days at a set temperature of 60 °C ± 2 °C. After this time, remove the bottle from the temperature test cabinet / climate test chamber and allow it to cool to room temperature. After a short shaking of the bottle, transfer the simulant into a glass round-bottom flask and reduce the volume of simulant by a factor of 10 using a rotary evaporator. Transfer 1.00 mL ± 0.07 mL of concentrated sample of simulant into a GC sample vial. Analyze the sample by GC/MS a per section F.7.

Test each sample of recycled plastic material in full triplicate, i.e., bring three different bottles from each recycled plastic material sample in contact with simulant as described above and analyze the simulant of each replicate separately by GC/MS.

F.7 Non-targeted screening by GC/MS

Gas chromatography combined with mass spectrometry allows for a non-targeted screening of (organic) substances transferred from recycled plastic materials into an extraction medium or simulant as described in sections F.4, F.5 and F.6.

Before performing the GC/MS analysis, add the internal standards described in F.2 to the extraction medium or simulant, with a target concentration for each internal standard of about 10 ppm.

F.7.1 GC/MS equipment settings

This guidance recommends the GC/MS equipment settings described below, based on positive experiences during the interlaboratory comparison (section D.1). When deviating from these recommendations, ensure that the system can sufficiently separate substances of retention indices between 1000 and 3000[107].

Injector:	40 °C, hold for 0.1 min 12 °C/s – 280 °C, hold for 5 min Split: 10 mL/min
Carrier gas:	Helium, 1.0 mL/min
Oven:	40 °C, hold for 2 min 5 °C/min – 100 °C 7 °C/min – 150 °C 10 °C/min – 280 °C, hold for 12 min 80 °C/min – 320 °C, hold for 15 min
Transfer line:	270 °C
MS:	scanning mode, 35 – 550 amu

[107] The CosPaTox interlaboratory comparison showed that nearly all substances exhibited a retention index in between these values..

F.7.2 Minimum requirements on quality control

The GC/MS equipment is recommended to be covered by a quality assurance system. This guideline recommends the use of a suitable alkane standard to ensure that the chromatography equipment produces stable retention index (RI) values and a suitable quality control standard to ensure that the mass detector produces stable (semi-) quantitative results.

F.7.3 Identification of transferred substances

Evaluate the chromatograms qualitatively (identification of substances using the retention index and the mass spectrum) and semi quantitatively (by single-point calibration using one of the internal standards). Report peaks for which the chemical structure could not be identified unambiguously as "unidentified". Generate a report for each sample, listing each peak/substance with its retention time, retention index, the identified structure (where possible), the corresponding CAS number, the quantity (test concentration) and the level of confidence of the structural assignment. Express the quantity as mg per kg of pellets for the testing of pellets and as mg per kg of product for the testing on bottles. Provide a sum of the total amount of identified and unidentified substances.

For all samples and references, evaluate each replicate separately.

This guideline recommends the use of both retention index (RI) and mass spectrum for the identification of substances. A 50% threshold setting for the level of confidence of these assignments is recommended. Operators are recommended to use and maintain commercial as well as material-specific inhouse mass spectral databases and to review or augment automatic structural assignments obtained from GC/MS software by manual review.

F.7.4 Detection limit

The detection limit is conventionally defined as 1% of the amount or concentration of the used internal standard.

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%

RESULTS OF TARGETED ANALYSES:

Elements (EN 62321-5:2014, detection limit: 0.1 mg/kg pellets)

Cd:	<0.1 mg/kg
Pb:	<0.1 mg/kg
Cr:	<0.1 mg/kg

Elements (DIN EN 13657:2003-01, detection limit: 0.1 mg/kg pellets)

P:	5.2 mg/kg pellets
Ti:	6.0 mg/kg pellets
Zn:	9.5 mg/kg pellets
Ca:	12.1 mg/kg pellets
Sb:	0.2 mg/kg pellets
Ba:	0.8 mg/kg pellets
Ni:	0.2 mg/kg pellets
Co:	0.2 mg/kg pellets
As:	<0.1 mg/kg pellets
Hg:	<0.1 mg/kg pellets
V:	<0.1 mg/kg pellets
Al:	0.7 mg/kg pellets
Fe:	1.3 mg/kg pellets
Cu:	0.2 mg/kg pellets

PAA(LC-MS, detection limit 0.1 mg/kg pellets)

4,4‘-Diaminodiphenylmethane:	<0.1 mg/kg pellets
2,2‘-Diaminodiphenylmethane:	<0.1 mg/kg pellets
2,4‘-Diaminodiphenylmethane:	<0.1 mg/kg pellets
4,4‘-Oxydianiline:	<0.1 mg/kg pellets
2,4-Diaminotoluene:	<0.1 mg/kg pellets
2,6-Diaminotoluene:	<0.1 mg/kg pellets
Benzidine:	<0.1 mg/kg pellets
4,4‘-Methylene-bis-(2-Methylaniline):	<0.1 mg/kg pellets
Aniline:	<0.1 mg/kg pellets
3,3‘-Dimethylbenzidine:	<0.1 mg/kg pellets
o-Dianisidine:	<0.1 mg/kg pellets
o-Anisidine:	<0.1 mg/kg pellets
o-Toluidine:	<0.1 mg/kg pellets
2-Methoxy-5-Methylaniline:	<0.1 mg/kg pellets
2,6-Diaminotoluene:	<0.1 mg/kg pellets
4,4‘-Diaminodiphenyl Sulfide:	<0.1 mg/kg pellets
2-Naphthylamine:	<0.1 mg/kg pellets
2,6-Dimethylaniline:	<0.1 mg/kg pellets
4-Chloroaniline:	<0.1 mg/kg pellets
4-Aminobiphenyl:	<0.1 mg/kg pellets
4-Aminoazobenzene:	<0.1 mg/kg pellets

PAH (DIN EN 17937:2023-02, detection limit: 0.1 mg/kg pellets)

NAP:	<0.1 mg/kg pellets
ACY:	<0.1 mg/kg pellets
ACE:	<0.1 mg/kg pellets
FLU:	<0.1 mg/kg pellets
PHEN:	<0.1 mg/kg pellets
ANTH:	<0.1 mg/kg pellets
FLTH:	<0.1 mg/kg pellets
PYR:	<0.1 mg/kg pellets
CHRY:	<0.1 mg/kg pellets
B[b]F:	<0.1 mg/kg pellets
B[k]F:	<0.1 mg/kg pellets
B[a]P:	<0.1 mg/kg pellets
B[ghi]P:	<0.1 mg/kg pellets
IND:	<0.1 mg/kg pellets
D[ah]A:	<0.1 mg/kg pellets

PCB (based on DIN EN 16190:2019-10, detection limit: 0.1 mg/kg pellets)

PCB28:	<0.1 mg/kg pellets
PCB52:	<0.1 mg/kg pellets
PCB101:	<0.1 mg/kg pellets
PCB138:	<0.1 mg/kg pellets
PCB152:	<0.1 mg/kg pellets
PCB180:	<0.1 mg/kg pellets

Bisphenols (based on DIN EN ISO 11936:2023-10, detection limit: 0.1 mg/kg pellets)

Bis-A:	<0.1 mg/kg pellets
Bis-F:	<0.1 mg/kg pellets
Bis-S:	<0.1 mg/kg pellets
Bis-B:	<0.1 mg/kg pellets
Bis-AF:	<0.1 mg/kg pellets

Phthalates (GC/MS, detection limit
0.1 mg/kg pellets)

DEHP:	<0.1 mg/kg pellets
DBP:	<0.1 mg/kg pellets
BBP:	<0.1 mg/kg pellets
DIBP:	<0.1 mg/kg pellets

Dioxins and furans (GC/MS, detection limit
10 ng/kg pellets)

2,3,7,8-TCDD:	< 10 ng/kg pellets
1,2,3,7,8-PeCDD:	< 10 ng/kg pellets
1,2,3,4,7,8-HxCDD:	< 10 ng/kg pellets
1,2,3,6,7,8-HxCDD:	< 10 ng/kg pellets
1,2,3,7,8,9-HxCDD:	< 10 ng/kg pellets
1,2,3,4,6,7,8-HpCDD:	< 10 ng/kg pellets
OCDD:	< 10 ng/kg pellets
2,3,7,8-TCDF:	< 10 ng/kg pellets
1,2,3,7,8-PeCDF:	< 10 ng/kg pellets
2,3,4,7,8-PeCDF:	< 10 ng/kg pellets
1,2,3,4,7,8-HxCDF:	< 10 ng/kg pellets
1,2,3,7,8,9-HxCDF:	< 10 ng/kg pellets
1,2,3,6,7,8-HxCDF:	< 10 ng/kg pellets
2,3,4,6,7,8-HxCDF:	< 10 ng/kg pellets
1,2,3,4,6,7,8-HpCDF:	< 10 ng/kg pellets
1,2,3,4,7,8,9-HpCDF:	< 10 ng/kg pellets
OCDF:	< 10 ng/kg pellets

ATTACHMENTS

- Safety data sheet
- Confirmation of the absence of SVHC above 0.1wt% in the material
- Declaration on maximum heavy metal content, meeting the requirements of the Packaging and Packaging Waste Directive (in the future: Packaging and Packaging Waste Regulation)
- Quality assurance documentation, incl. testing plan
- Material characteristics as per EN 15344

CosPaTox