Incorporating recycled plastics into cosmetic packaging in Europe

Guidelines

elipso

FEBEA
FÉDÉRATION DES ENTREPRISES DE LA BEAUTÉ

Acknowledgements

This document was produced by a joint ELIPSO-FEBEA working group. We would like to thank the experts from both associations' member companies for their contribution:

ALBEA	CHANEL	NUXE
ALPLA	L'OREAL	SISLEY
APTAR	LVMH	TEXEN

We would also like to thank the experts from IPC and Intertek.

March 2024 - Version 2

Why this guidance document?

This document does not constitute a legal interpretation of the regulations applicable to packaging intended for cosmetic products. It does not exempt any operator from their responsibilities in complying with these regulations.

In accordance with Regulation (EC) n°1223/2009 on cosmetic products, a cosmetic product placed on the market must be safe for human health under normal and reasonably foreseeable conditions of use. In order to meet this obligation, the person responsible for placing the product on the market must conduct a safety assessment based on the product's intended use and the anticipated systemic exposure to the ingredients.

Annex I of the Cosmetics Regulation details the information which must be taken into account in the cosmetic product safety report, including, with regard to the packaging material, the purity of substances and mixtures, evidence that the possible presence of prohibited substances as trace is technically unavoidable, and the relevant characteristics of the packaging material, in particular its purity and stability. This information is described in the European Commission Implementing Decision n°2013/674/EU.

In the absence of detailed regulatory provisions, a number of industry associations representing the cosmetic packaging value chain have developed a common framework regarding appropriate and relevant information on packaging materials to be communicated to the cosmetics safety assessor. **The advisory document describing this approach was published by Cosmetics Europe in June 2019[1].**

This advisory document is applicable to all materials but does not address the particular case of packaging materials (resins) derived from the recycling of household and industrial waste.

In the context of the circular economy and the European Green Deal, the incorporation of recycled materials is increasing and could become mandatory for plastic packaging components in Europe, as part of the revision of the Packaging Directive n°94/62/EC. The integration of recycled plastics is part of the eco-design approach. That's why, in consideration of the specific risks associated with recycling, and to meet a growing demand in this area, **ELIPSO and FEBEA are working together to secure the incorporation of recycled plastics into cosmetic products packaging. This corresponds to Action 23 of the "Etats Généraux de la filière Parfumerie - Cosmétique" of October 2020[2].**

This guidance document was developed by a joint ELIPSO-FEBEA working group involving experts from both associations.

This document is intended for companies producing recycled plastic materials, packaging suppliers and marketers of cosmetic products.

Disclaimer: This document is accurate at the time of publication. Some regulatory references may have been modified subsequently.

There is a complementary on-going work done by the Consortium CosPaTox. Its objective is to accomplish the so far missing specific safety standards for high-quality Post-Consumer Plastic Recyclates (PCRs) for cosmetics and other household packaging.

This consortium's unpublished "Voluntary industry guideline for the safety assessment of recycled plastics in packaging materials for cosmetic products and home care products", a guidance for recycled PE and PP, is scheduled for publication in 2024."

1 Cosmetics Europe. (2019). *Information Exchange on Cosmetic Packaging Materials Along the Value Chain in the Context of the EU Cosmetics Regulation Ec 1223/2009.* cosmeticseurope.eu/files/5015/6327/0864/Packaging_Advisory_document_-_June_2019.pdf

2 FEBEA. (2020). États généraux de la filière parfumerie-cosmétique : 30 mesures pour une relance gagnante et durable. https://www.febea.fr/actualites/etats-generaux-la-filiere-parfumerie-cosmetique-30-mesures-relance-gagnante-durable

Table of contents

INTRODUCTION

General information on the regulatory framework and scope of application

INTRODUCTION

1 General information on the Regulatory Framework and Scope of Application

This guidance document aims at securing the incorporation of recycled plastic into cosmetic products packaging. It is based on the Cosmetics Europe advisory document (2019), to transpose the principles applicable to virgin resins to recycled resins.

There are regulations governing recycled plastic resins intended for food contact, in particular Regulation (EU) n°2022/1616. They are detailed below as they can serve as a reference.

For packaging in direct contact with cosmetic products, Regulation (EU) n°2022/1616 on recycled plastic materials and articles intended to come into contact with foods may be a useful reference. Materials other than plastic are not covered here.

A. Regulatory framework common to all packaging placed on the market in the European Union

The REACH Regulation sets out obligations for the communication of information throughout the supply chain on packaging (articles), and specific restrictions on the use of certain substances that may have an impact on them. Directive n°94/62/EC imposes essential requirements, one of which around the content of heavy metals in plastic packaging.

These obligations apply to packaging, regardless of the origin of the raw material, whether virgin or recycled:

Regulation (EC) n°1907/2006 "REACH"	Directive n°94/62/EC on "Packaging and packaging waste"
Article 33: declaration of SVHC ≥ 0.1% (w/w) of material or finished article REACH Annex XVII - specific restrictions on the use of certain substances	Content of lead, cadmium, mercury and hexavalent chromium < 100 ppm (mg/kg of material)

Packaging manufacturers commit to confirming to cosmetics manufacturers that their packaging products comply with these two regulations.

The case of recycled plastics

Focus on the application of Regulations n°1907/2006 REACH and n°1272/2008 CLP to recycled materials.

Recyclers in Europe are exempted from the obligation[3] to register the monomer(s) or other substance(s) contained in the recycled polymer. This exemption applies under the conditions set out in Article 2(7)(d) of the REACH Regulation.

It is sufficient that a registration has been made for the substance by an operator in the same supply chain or by a company in another supply chain.

Point of caution

To import recycled materials in excess of 1 tonne/year from outside the European Union, REACH registration is compulsory (exemption from registration does not apply to imports). This requires various analyses to be carried out and may take some time to obtain. In this case, the operator applying for registration is considered an importer, but it is possible to use an only representative.

For more information on registration requirements for recycled or recovered substances, please refer to the Guide on Waste and Recovered Substances (echa.europa.eu).

Other Obligations

These are common to all polymer manufacturers:

- classification and labelling in accordance with the CLP Regulation (same classification methods as for the mixture);
- safety data sheet (SDS) if the polymer substance meets the criteria for classification as a hazardous substance, or if it is included in the list of candidate substances for authorisation, e.g. PBT or vPvB (Article 31) etc.

For further details, please refer to the ECHA guidance for monomers and polymers (version 3.0 February 2023), in particular point 3.2.1.4 "Case of a recycled polymer".

Declaration on the presence of hazardous substances and endocrine disruptors

Focus on French regulation (Articles 13-I and 13-II of the AGEC Law) related to packaging composition See Regulation on environmental claims and consumer information on products (ecologie.gouv.fr)

AGEC Law n°2020-105 of February 10, 2020 introduced provisions on consumer information on the presence of hazardous substances (Article 13-I) in waste-generating products and on the presence of endocrine disruptors (Article 13-II) in products.

With regard to Article 13-I, decree n°2021-1285 specifies that hazardous substances are:

1. substances of very high concern on the candidate list for authorisation (published on the ECHA website and updated twice a year);
2. substances presenting a comparable level of concern, the list and update of which are set by decree, after receiving the opinion of ANSES.

With regard to Article 13-II, Decree n°2021/1110 of August 23, 2021 stipulates that ANSES:

- identifies the substances known, presumed or suspected to be "endocrine disruptors" which must be declared by product marketers in an electronic format;
- determines the categories of products for which it will be required to declare the presence of suspected endocrine-disrupting substances.

The list of known/presumed endocrine disruptors (available in open data) and the list of suspected endocrine disruptors for certain product categories has been established by decree following an opinion from ANSES : decree of 28 September 2023 setting the list of substances presenting endocrine disrupting properties mentioned in I and II of article L. 5232-5 of the public health code and the categories of products presenting a particular risk of exposure mentioned in II of article L. 5232-5 of the public health code.

3 Provisions of Article 6, paragraphs 1 and 3 of the REACH Regulation. eur-lex.europa.eu

B. European regulatory framework applicable to packaging incorporating recycled plastic and intended for contact with foods

Plastic packaging waste used to produce recycled materials may be contaminated by substances linked to its previous use, by inappropriate use or by substances originating from non-food plastics. Given that it is impossible to identify all possible types of contamination, and that different plastic resins have different contaminant retention and release capacities, it is not possible to define precise characteristics applicable to all types of recycled plastic material.

To control the safety of a recycled material, it has therefore to be prepared (sorted and decontaminated) to meet the requirements of the intended uses and/or applications[4].

Regulation (EC) n°282/2008, repealed by Regulation (EU) n°2022/1616

Regulation (EC) n°282/2008, setting out the requirements with a general and generic framework for the application and authorisation of recycling processes, has been repealed in 2022. The new Regulation (EU) n°2022/1616 of September 15, 2022 is based on the approval of new technologies and the declaration of recycling facilities.

At the time of writing, two technologies are considered approved:

- closed-loop recycling;
- mechanical recycling of rPET (rPET with less than 5% of non-food consumer applications in the input), already the subject of positive opinions from the European Food Safety Agency (EFSA) under the previous Regulation.

These two technologies are deemed suitable under Regulation (EU) n°2022/1616 and may continue to be used under the conditions already laid down in the EFSA opinions.

Technologies that have not been recognised as suitable are considered as new technologies and must be submitted for authorisation. The marketing of recycled materials will be possible under enhanced conditions of monitoring and with greater analytical reporting requirements.

They may be deemed suitable at the end of the evaluation procedure, which is expected to take at least 2 years.

If the recycling process allows the return to the substances listed in Annex 1 of Regulation (EU) n°10/2011 (monomers or other starting substances), it is not affected by this new text.

What about offcuts and scrap from the production of plastics intended to come into contact with foodstuffs?

They do not fall within the scope of Regulation (EU) n°2022/1616. They are considered suitable for food contact as they are, without the need for decontamination. Their management is based on the principle of good manufacturing practices, as laid down in Regulation (EU) n°10/2011 and described in Regulation (EC) n°2023/2006. This type of material is not considered as recycled according to ISO 14 021[5].

Mechanical recycling processes

Mechanical recycling consists in grinding and cleaning plastic resins in order to reduce contamination resulting from their previous use below a threshold that does not present a risk to the consumer considering the intended use.

For food contact, this is now governed by Regulation (EU) n°2022/1616, which lays down three main principles:

- the level of decontamination required during the recycling process, which depends on "pre-treatment" (waste source, sorting efficiency etc.) and decontamination technology;
- the verification of the effectiveness of recycling processes in order to guarantee the level of decontamination;
- the enhanced monitoring of decontamination efficiency by analysing contaminants at the start and end of the process.

Under Regulation (EC) n°282/2008, EFSA had published a scientific guide[6] on the criteria to be used to assess the safety of a mechanical recycling process designed to produce recycled PET suitable for food contact. At present, there is no such guidance for other resins: there are no mechanical recycling processes positively evaluated by EFSA that would enable other resins to be recycled for food contact, apart from a few processes using a closed-loop supply chain.

---

4 Article 2 of Regulation (EU) n°2022/1616. eur-lex.europa.eu

5 AFNOR. (2016). NF EN ISO 14021 : Marquage et déclarations environnementaux - Autodéclarations environnementales (Étiquetage de type II) - Environmental labels and declarations - Self-declared environmental claims (Type II environmental labelling). boutique.afnor.org/fr-fr/norme/nf-en-iso-14021/marquage-et-declarations-environnementaux-autodeclarations-environnementale/fa059946/57523

6 Food Safety. *Resources for plastic recyclers.* food.ec.europa.eu/safety/chemical-safety/food-contact-materials/plastic-recycling/resources-plastic-recyclers_en

Focus on the use of recycled material behind a functional barrier

Under Regulation (EC) n°282/2008, a functional barrier (defined under Article 13 of Regulation (EU) n°10/2011) could be a means of controlling potential risks associated with undesirable substances.

Under Regulation (EU) n°2022/1616, functional barriers are now considered as new technologies.

There are other approaches adopted by third countries, such as the United States.

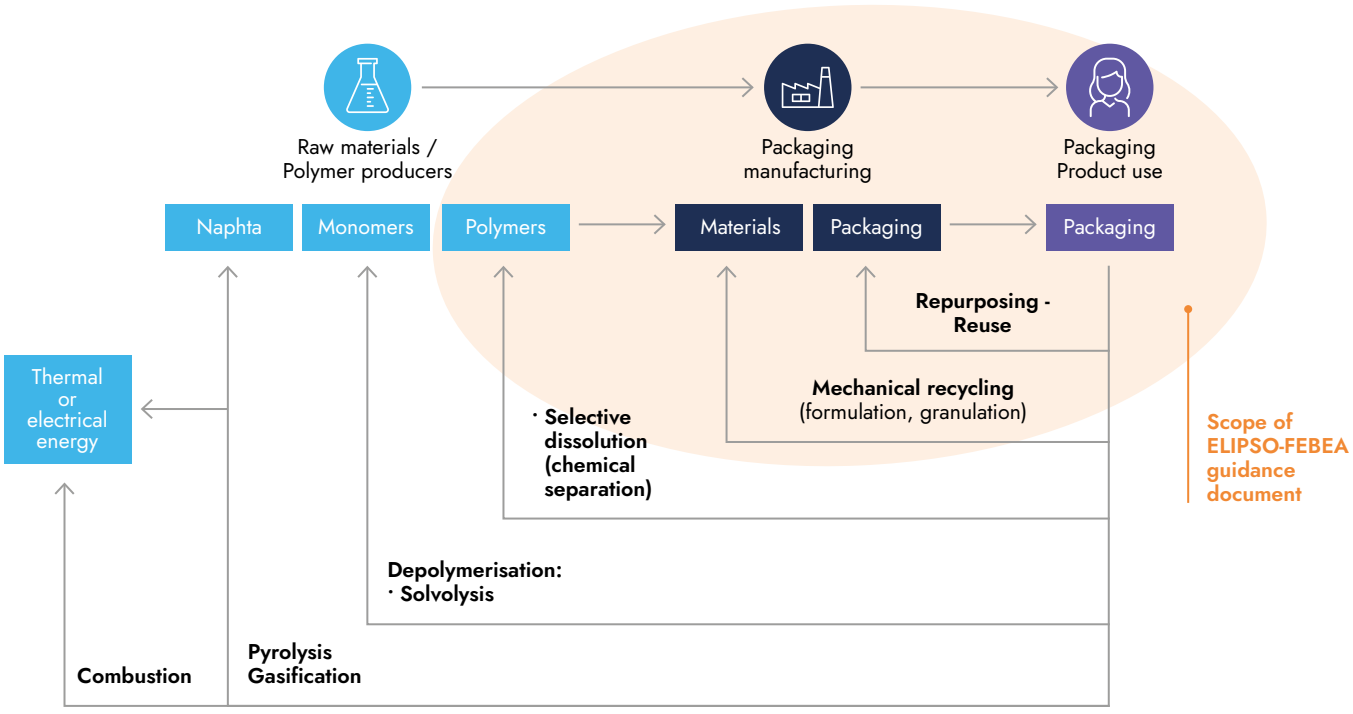
C. Scope of the ELIPSO-FEBEA guidance document

This guidance document applies to materials derived from mechanical recycling (including dissolution) and from certain chemical recycling processes which do not allow the return to substances listed in Annex 1 of Regulation (EU) N° 10/2011 (monomers or other starting substances).

It does not apply to recycled plastic materials and articles made from monomers and starting substances listed in Regulation (EU) n°10/2011 and obtained via the chemical depolymerization of plastic materials and articles. These processes are outside the scope of Regulation (EU) n°2022/1616. These materials are subject to Regulation (EU) n°10/2011 for food contact and the Cosmetics Europe advisory document applies here.

This guidance document applies to recycled resins with a positive opinion or letter of no objection, or not, from authorities such as EFSA or FDA.

Diagram taken from Elipso's Guidance on chemical recycling of plastic packaging November 2022



Recycling allows to go back to different stages of the plastic packaging manufacturing process, by degrading the molecular structure of plastics to a greater or lesser extent. Chemical recycling, on the other hand, is a process that modifies the chemical structure of used plastics by converting them into shorter molecules, ready to be used for new chemical reactions.

However, the technology used may have an impact on the potential presence of residual contaminants in the material. These elements must be taken into account when carrying out the risk assessment.

The ELIPSO-FEBEA guidance document does not apply to recycled plastic materials and articles which are:

· manufactured from monomers;

· from starting substances listed in Regulation (EU) n°10/2011;

· obtained via the chemical depolymerization of plastic materials and articles.

These processes indeed fall outside the scope of Regulation (EU) n°2022/1616, and these materials are subject to Regulation (EU) n°10/2011 for food contact. The Cosmetics Europe advisory document then applies.

D. Important considerations on the origin and nature of recycled materials

There are different types of resins to choose from, depending on the functionalities required. In the food industry, the main resins in use are PE, PP, PET and PS.

This document focuses on the three resins most commonly used in cosmetics: PE, PP and PET.

Note: in cosmetics, other resins are used, such as styrenic polymers (ABS, SAN), polycarbonatverifier sorptiones, POM...
These are collected and recycled through different channels from those for packaging and are governed by different regulations, which means that undesirable substances may be present for cosmetic use. Caution is therefore required when it comes to the possible use of these recycled resins in cosmetic packaging.

For example, flame retardants used in electronic products do not comply with either cosmetics or food regulations.

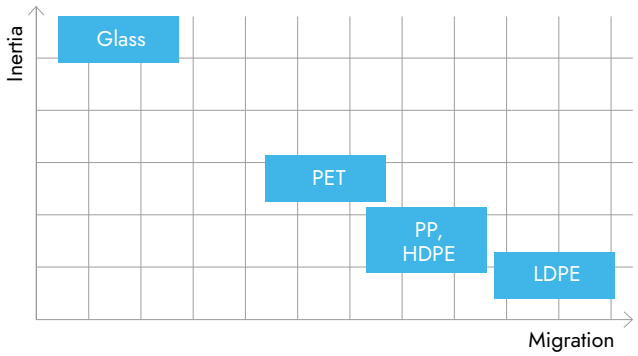
It is important for packaging manufacturers and marketers to consider the following points:

Sorption capacity or "Inertia" of the polymer

This is the basic parameter affecting the recyclability of packaging plastics. The inertia of packaging polymers decreases in the order illustrated in the diagram below[7]. PET, for example, is harder to contaminate than PP, HDPE and LDPE.

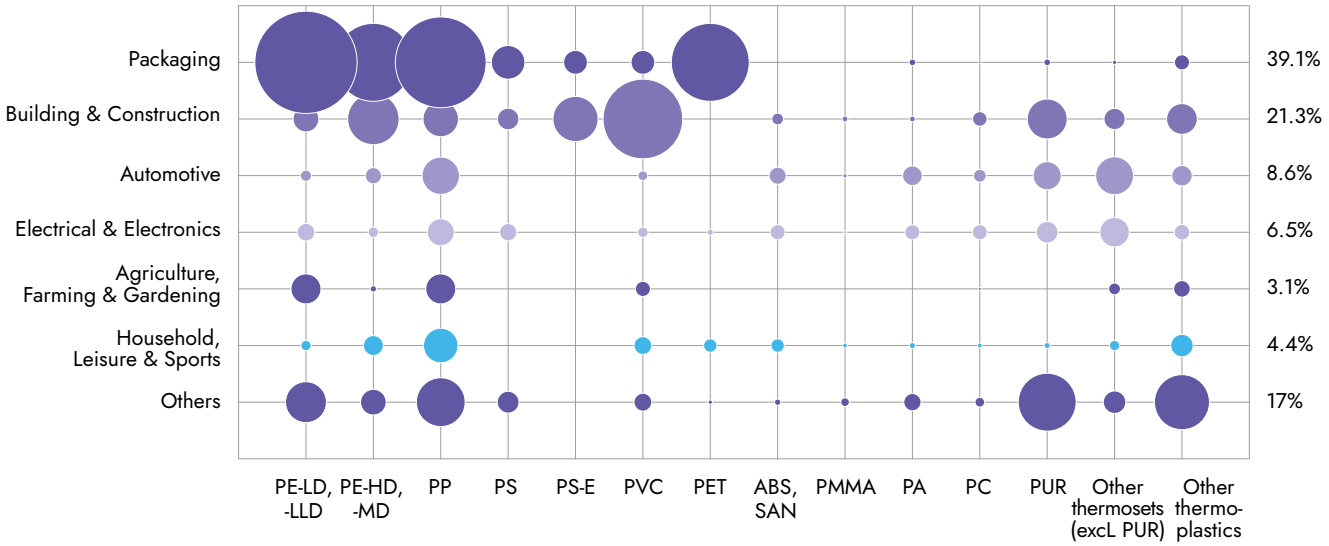
As a general rule, the higher the inertia of a material, the lower the potential for contamination in nature and quantity by compounds exogenous to the formulation, and the lower the risk of undesirable migration from the recycled packaging.

Migration potential of resins [7]



7 Welle, F. (2005). *Develop a food grade HDPE recycling process.* researchgate.net/publication/284158562_Develop_a_food_grade_HDPE_recycling_process

***European plastics converters demand by application and type* (Plastics Europe)**



Source: Conversio Market & Strategy GmbH based on the input of the Plastics Europe Market Research Group (PEMRG) The above data are rounded estimations. Demand data are built on estimations of quantities bought by European converters, including imports. Demand for recycled plastics and bio-based/bio-attributed plastics is not included. Polymers that are not used in the conversion of plastic parts and products (i.e., for textiles, adhesives, sealants, coatings, etc.) are not included. Numbers behind this graph are available upon request. Plastics - the Facts figures on PA only cover PA6 and PA66).

Physico-chemical properties of resins

These can vary considerably, and particularly their diffusion properties. They can impact the diversity of contaminants (nature/quantity) and the required decontamination efficiency for a given molecular weight range with regard to the target application.

The case of PET: its diffusion barrier properties limit the range of possible contaminants and/or substances that can be released from the recycled resin into the food or cosmetic formulation. Only molecular weight below 300 Daltons should be considered[6].

The case of polyolefins: substances with molecular weights of up to 1,000 Daltons can be absorbed and diffused within the polymer matrix during the life cycle of the packaging-product combination, taking into account possible inappropriate uses[8].

Packaging design

The origin of materials to be recycled must be taken into account when considering decorative elements or functional components. They may contain substances that can cause contamination and make the material unsuitable for food contact when recycled (varnishes, inks, glues, additives, other associated components etc.).

Intended use of the packaging

The initial content of the packaging may result in a contamination of the packaging material. For example, the contaminants in food packaging will be different from those in packaging for household cleaning products (detergents), chemical products (DIY, gardening) or cosmetics.

The choice of inputs (food versus non-food packaging) is crucial, and the choice of decontamination process is critical to the quality of the resin, depending on the subsequent application of the recycled material.

Inappropriate use of packaging

When a consumer uses packaging to contain a product of a different nature, this can lead to the contamination of the packaging with substances that are not expected, hence the importance of the decontamination process.

It is reasonable to assume that these inappropriate uses are similar whatever the resin under consideration, as this practice is generally linked to the form of container (bottle, jerrycan etc.).

8 Palkopoulou, S., Joly, C., Feigenbaum A. & al. (2016). *Critical review on challenge tests to demonstrate decontamination of polyolefins intended for food contact applications.* Trends in Food Science and Technology, 49, 110-120. doi.org/10.1016/j.tifs.2015.12.003

The purpose of this document is to help operators in the industry demonstrate that the recycling process used reduces potential contamination to a level that poses no risk to human health for cosmetic use.

E. General information on recycling processes for food contact

Although it is not mandatory to use "food contact" quality materials for cosmetic packaging, the European Commission's Guidelines on the application of Annex I of the Cosmetics Regulation (Decision n°2013/674/EU) specify that Regulation (EC) n°1935/2004 on materials and articles in contact with foodstuffs is a useful reference for cosmetic packaging.

Various mechanical recycling processes are available for food contact. The efficiency of some of these processes has been assessed by an official health agency: in Europe, the European Food Safety Agency (EFSA); in the USA, the Food and Drug Administration (FDA).

1. European regulations for "food contact" recycled plastics

The list of processes positively assessed by EFSA and their potential restrictions under Regulation (EC) n°282/2008 is available at efsa.europa.eu.

Under this Regulation, EFSA assesses the efficiency of each process individually. The processes positively evaluated by EFSA for polyolefins are presented in annex to this guidance document.

When does a positive EFSA opinion guarantee safety?

Only under the following conditions:

- the inputs (source of material to be recycled) are the same as those for which the recycling process has been evaluated;
- the material is recycled following every step described in the process that has been evaluated by EFSA;
- the material is used in accordance with the conditions laid down in the authorisation file (maximum authorised percentage, nature of foodstuffs, conditions of use).

Note: the above guarantees apply to the evaluation of the process. They do not prejudge the quality of the material with regard to other applicable regulations (e.g. global and specific migrations according to Regulation (EU) n°10/2011 for food contact, or skin sensitisers according to Regulation (EC) n°1272/2008 also known as CLP, or restrictions/prohibitions specific to the Cosmetics Regulation etc.).

Risk assessment according to EFSA[9]

The challenge tests (see definition) established for PET make it possible to check that the recycling processes guarantee decontamination levels that eliminate any health risk.

In terms of risk management, the daily exposure to chemicals considered acceptable by EFSA is 0.0025 µg/kg bw/day (based on the Kroes publication)[10]. This translates into 0.15 µg/kg of food, based on 1 kg of food consumed and an average body weight of 60 kg for adults.

When modelling migration from recycled PET resins, the previous limit was raised to 0.75 µg/kg of food, given the overestimation factor in the assessment of migration by modelling.

For young children and infants, these data must be adjusted and a specific assessment should be carried out.

9 EFSA (2011). *Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food.* EFSA Journal 2011; 9(7):2184. [25 pp.]. https://doi.org/10.2903/j.efsa.2011.2184

10 Kroes R., Renwick A.G., Cheeseman M., & al. European branch of the International Life Sciences Institute. *Structure-based thresholds of toxicological concern (TTC): guidance for application to substances present at low levels in the diet.* Food Chem Toxicol. 2004 Jan;42(1):65-83. https://doi.org/10.1016/j.fct.2003.08.006. PMID: 14630131

NB: in the absence of authorisations from the European Commission, certain resins were authorised in France under an AFSSA (now ANSES) guidance still valid for a threshold of 1.5 µg/per person[11].

In the European register (food.ec.europa.eu), on the "suitable" recycling techniques under Regulation (EU) n°2022/1616 for food contact, only materials recycled using a process for PET and closed and controlled loops that have received a positive opinion from EFSA are deemed safe for the intended application. They must be published in a European register: *Ressources for plastic recyclers* (food.ec.europa.eu).

Under Regulation (EU) n°2022/1616, the technology owner must assess the decontamination effectiveness of the technology and propose a monitoring plan. Each recycler must be listed in a public register: in particular, they must specify the process used and the installations concerned and implement the monitoring plan recommended by the technology owner.

2. US regulations for "food contact" recycled plastics

The FDA reviews recycling processes for food contact plastics on a case-by-case basis. It invites recyclers to submit information on their process for evaluation and comment (*Use of Recycled Plastics in Food Packaging (Chemistry Considerations): Guidance for Industry* - FDA[12]). In response, the FDA issues "No Objection" letters to operators, allowing them to use recycled materials from these processes in food packaging.

A list of existing No Objection letters is available on the FDA website: www.accessdata.fda.gov.

The FDA gives its opinion but leaves the responsibility for product safety to the operator. Once a No Objection Letter has been issued for a decontamination technology, the FDA does not issue any further No Objection Letter: users of this technology must provide proof that the process used at their facility complies with the dossier that was the subject of the No Objection Letter (this proof may be provided by an external expert).

It should be noted that a No Objection Letter (NOL) from the FDA only provides certain safety guarantees under the following conditions:

- the inputs (source of material to be recycled) are the same as those for which the recycling process has been assessed;
- the material is recycled following every step described in the process that has been evaluated by the FDA;
- the material is used in accordance with the conditions laid down in the authorisation dossier (maximum percentage authorised, nature of the foodstuffs, conditions of use).

Risk assessment according to the FDA

In terms of risk management, the daily exposure considered acceptable by the FDA is 0.025 µg/kg bw/day:

- the residual level of any contaminant must be determined so as not to exceed a **daily exposure of 1.5 µg/per person, i.e. 0.025 µg/kg bw/day**, the threshold for which the daily intake of these contaminants represents a negligible risk[13]. This maximum threshold depends on the density and thickness of the polymer, as well as the average consumption rate;
- the above applies to adults (average weight 60 kg). For children, a specific assessment must be carried out, in particular by modifying the average weight.

11 AFSSA. (2005). Seuil de préoccupation toxicologique pour l'analyse de risque sanitaire des substances chimiques dans les aliments. anses.fr/en/system/files/AAAT-Ra-PreoccupationToxico.pdf

12 FDA. (2021). *Use of Recycled Plastics in Food Packaging (Chemistry Considerations) : Guidance for Industry.* fda.gov/media/150792/download

13 EFSA. More, S. J., Bampidis, V., Benford, D., & al. (2019). *Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment.* EFSA Journal, 17(6). https://doi.org/10.2903/j.efsa.2019.5708

3. Comparison between EU and US systems

	EU	USA
Evaluation responsibility	EFSA	Evaluation by the operator, validation by the FDA.
Evaluation	Regulation (EC) n°282/2008: recycling process to be assessed for each material as a whole (inputs, equipment). Regulation (EU) n°2022/1616: technology pre-assessed* by the national competent authority before launch, then assessed by EFSA after a minimum of 2 years' monitoring. (*no details of an administrative or scientific assessment available at the time of writing)	Recycling process usable provided that similar inputs are used and that the technology/equipment has already been evaluated and a letter of no objection from the FDA has been obtained.
List of evaluated processes	Regulation (EC) n°282/2008 repealed by Regulation (EU) n°2022/1616: Register (in the process of publication) according to Regulation n°2022/1616; in the meantime, opinions published prior to its entry into force remain valid and are available here: efsa.europa.eu	accessdata.fda.gov
Obligation for users of the same process	Regulation n°282/2008: registration at European level and similar obligations to process owners. Regulation n° 2022/1616: registration of recyclers on a European Commission website and compliance with the conditions of implementation of the technology. A facility may be based outside Europe.	Under licence. Third-party verification recommended. Foreign companies can obtain letters of equivalence provided they comply with the initial No Objection Letter (NOL).

F. Selection of materials for recycling

For recycled materials intended for food contact, materials and articles complying with the provisions of Regulation (EU) n°10/2011 must be used in the recycling process (for the mechanical recycling of PET, Regulation (EU) n°2022/1616 sets out a maximum tolerance of 5% of materials and articles used in contact with non-food materials or substances).

The factors affecting the quality and composition of the raw materials to be recycled are:

· the nature of the resin in use;

· the type of products contained in the packaging (migration from the content to the container);

· the country of origin and its collection and sorting policy (presence of packaging intended for several uses);

· the method of collection of the material to be recycled (closed loop, deposit for recycling, selective collection of household packaging etc.);

· the origin of the recycled material (household packaging vs. other sectors);

· the presence of varnishes, inks, glues and additives.

Plastic objects can be over-sorted at the recycler's premises. Because of their physico-chemical properties, some materials such as polyolefins may require further sorting (over-sorting at the recycler) to ensure that the recycled plastics comply with the requirements of Article 3 of Regulation (EC) n°1935/2004. For other materials, PETs for example, the safety of recycled plastic can be ensured with a lower sorting efficiency given their previous use in contact with foodstuffs, such as what can reasonably be expected from household waste collection systems. The sorting efficiency required for each material must be determined on a case-by-case basis.

There are no similar regulatory constraints for recycled materials intended for the cosmetics industry. However, most manufacturers producing or recycling polymers for the packaging sector use food contact as a standard for their production. The additives used to transform the resins can then vary depending on the applications and the intended sector[14].

14 Cosmetics Europe. (2019). *Information Exchange on Cosmetic Packaging Materials Along the Value Chain in the Context of the EU Cosmetics Regulation Ec 1223/2009.* cosmeticseurope.eu/files/5015/6327/0864/Packaging_Advisory_document_-_June_2019.pdf

2 Evaluation of recycled plastic materials for cosmetic packaging

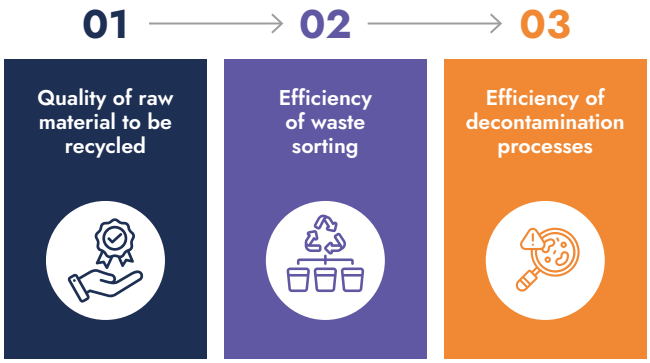
2 Evaluation of recycled plastic materials for cosmetic packaging

A. Objectives

To describe the tests required to approve a recycled material.

In accordance with Cosmetics Regulation (EC) n°1223/2009, safety assessment is a requirement for any packaging in direct contact with the cosmetic product. As a reminder, in any case, the recycled material must comply with other regulatory requirements outlined in the previous section (in particular those of the REACH Regulation and the Directive n°94/62/EC for heavy metals).

The safety of mechanically recycled plastic materials and articles, including those derived from dissolution, is ensured through a combination of the following three factors: quality of the inputs to be recycled, sorting efficiency and effectiveness of the recycling processes aimed at reducing contamination.



This section describes the tests required to approve the recycled material. The tests to be carried out to control stability are defined in part 3 of this document.

This safety assessment must be carried out with regard to the intended use.

B. General considerations on risk assessment for cosmetic use

When the packaging is intended to come into contact with a cosmetic product, the safety assessment of the material must take into account:

- the type of product: rinsed/non-rinsed;
- the characteristics of the formula (galenic, pH, dry/fatty/aqueous etc.);
- the area(s) of application (e.g. whole body, eyes, oral cavity etc.);
- the amount per application, duration and frequency of use;
- normal and reasonably foreseeable routes of exposure;
- the target population(s) (e.g. adults, families, children under 3);
- the type of substances to be assessed, such as skin sensitisers or allergens.

The publication of the draft Packaging and Packaging Waste Regulation (PPWR) on 30 November 2022[15] (definition in Article 3 paragraph 40) defines cosmetic packaging as "sensitive contact" and requires high quality recycled material.

In the specific case of products for children, babies and other sensitive populations, it is up to the assessor to take into account the intended users and the assessment conditions.

15 *Proposal for a revision of EU legislation on Packaging and Packaging Waste.* (2022). https://environment.ec.europa.eu/publications/proposal-packaging-and-packaging-waste_en

In the case of resins containing SVHC substances included on the candidate list for authorisation in concentrations of more than 0.1%, the recycler must provide this information in the SDS. It is recommended that this information be ascertained by analysis. Several laboratories offer this type of characterisation. In the same way, for heavy metals, the information must be communicated in accordance with current regulations on packaging and packaging waste.

For the use of a recycled material which has been authorised for food contact, please refer to section C below: *"Assessment of a recycled material suitable for food contact for cosmetic use".*

In other cases, please refer to the paragraph *"Assessment of a recycled material not assessed for food contact for the intended cosmetic use".*

Important notice - unrelated to product toxicity

It is important to monitor any organoleptic change, which may indicate a problem of compatibility between the packaging and its content:

- **Odour:** in certain cases of deposits from household products (e.g. washing powder, fabric softener, washing-up liquid etc.), some odours may persist. To limit/avoid such problems, it is necessary to ensure an effective combination of input quality and decontamination efficiency.

  Despite the efficiency of decontamination processes such as devolatilization, some small, highly volatile molecules may persist. This can be difficult to address, given the very low thresholds at which an odour is perceptible. A study[16] by IPC (French Industrial Technical Centre for Plastics and Composites) showed that the olfactory threshold (15 ppb) of a sensory panel for certain compounds is below the analytic detection threshold, despite extensive decontamination.

- **Colour:** a priori, changes in colour, apart from aesthetic considerations, will have no impact on the content of cosmetic products. However, it very rarely happens that the pigments responsible for the colour can migrate into the content. The absence of any change in the organoleptic properties of the formula, including colour, is one of the points to be verified (compatibility test) before the product is placed on the market.

The cosmetics safety assessor may be consulted to narrow down the range of products in which to incorporate recycled material. The risk assessment may also depend on the ability of the recycled material to release migrating substances into the cosmetic formula.

For all the resins not suitable for food contact or to complement the assessments that may be carried out by the EFSA and the FDA (simulants not equivalent, storage conditions not equivalent etc.), a risk analysis may be carried out.

C. Assessment of a recycled material suitable for food contact for cosmetic use

Where the process has received an EFSA opinion or a No Objection Letter from the FDA, a case-by-case risk assessment must be carried out depending on the foreseeable cosmetic use.

Three criteria are important:

- the maximum percentage of post-consumer recycled plastic (PCR) authorised for food contact by EFSA or the FDA;
- the type of product or food;
- the conditions of use.

In the United States, the FDA classifies food products into 9 different types (acidic, non-acidic, aqueous etc.). These tables can be used as a reference: they list the types of food (Food type I to IX) and conditions of use defined by the FDA[17] (CFR 21 section 176.170 tables 1 and 2). It is necessary to check that the conditions of use applied are consistent with the use of the cosmetic product.

For example, condition of use E (*Room temperature filled and stored - no thermal treatment in the container)* could be applicable to a cosmetic product, as it is mainly used at room temperature. On the other hand, condition G (*Frozen storage - no thermal treatment in the container)* is not suitable at all.

16 Joint action project - unpublished, available on request - Return to clean materials from detergent packaging and containing certain substances which, despite effective decontamination, are still detected by the sensory panel.

17 FDA (2012). *Packaging & Food Contact Substances (FCS).* fda.gov/food/food-ingredients-packaging/packaging-food-contact-substances-fcs

Where the recycled material has been authorised for food contact (i.e. for a given type of foodstuff and conditions of use), it is up to the assessor to determine whether these conditions are similar/compatible with those of the intended cosmetic use.

If the conditions of authorisation are only partially met, it is always possible to assess the blocking elements on a case-by-case basis, without having to start the risk assessment process from scratch.

For example, unless a further assessment is carried out:

- a recycled resin authorised for dry foodstuffs can only be used for cosmetic powders;
- a resin authorised for aqueous formulas cannot be used for fatty formulas;
- a resin authorised for short contact cannot be used for longer contact.

When looking for substances of interest, it is important to take into account elements such as sampling, simulants adapted to the foreseeable use (cosmetic formula) etc. These elements are explained in section E, and the packaging/formula combination must be validated. Additional analyses are required because food contact does not cover all the requirements for cosmetics (e.g. skin sensitisers).

Not all **skin sensitisers** are assessed under food contact regulations in Europe or the United States. To complement the agencies' assessment, the assessor should ensure that this concern about skin sensitisers is addressed, including requests for additional information or additional testing (see table in paragraph 2.E.4).

This information should be provided by the resin supplier to the packaging manufacturer. The SDS must list skin sensitisers present at a level of at least 0.1% for category 1B or 1, and 0.01% for category 1A (according to CLP Regulation n°1272/2008).

D. Assessment of a recycled material not assessed for food contact for the intended cosmetic use

This section applies to recycled materials which have not undergone any assessment.

This situation may arise with three types of inputs:

- food packaging for which a return to food contact is not planned;
- packaging for non-food products;
- plastic materials which are not covered by regulations on packaging itself.

In these cases, the quality of the materials is essential, and their previous use can have an impact on the level of contamination. There are regulations on packaging assessment with varying degrees of restrictions: medicines, cosmetics, household products, chemical products (DIY etc.).

The geographical origin, presence and type of decoration may also result in varying contaminants.

A specific strategy then needs to be established, the aim being to identify the substances of interest likely to be still present after mechanical recycling, including dissolution, and likely to migrate into cosmetic formulas.

This part only concerns the assessment of the risks associated with the migration of substances released from packaging containing recycled material into the cosmetic formula. The aim is not to fully characterise the recycled material, but to carry out tests to assess the substances likely to migrate from the material into the formula.

The safety assessment approach used to qualify the material is detailed in the following paragraph. It involves carrying out various types of standard tests, such as testing the migration of specific substances of interest. These tests can then be complemented by an analytical screening in order to identify unintentionally added substances (NIAS), such as contaminants and degradation products arising from the recycling process.

E. Proposed methodology for assessing substances of interest within the material

For processes not favourably evaluated for food contact or evaluated with restrictions of use or judged not transferable to the cosmetic formula, the following steps are recommended in order to validate the effectiveness of the decontamination with regard to the expected uses.

1. Methodology for the identification of substances of interest

A substance of interest refers to any substance which may be found in the packaging and which presents an immediate or future risk to human health by compromising the safety of the finished cosmetic product, and a risk to the environment.

Screening refers to any analytical technique which makes it possible to identify, by extraction or migration, the presence of substances, whether in a resin or in a recycled plastic-based packaging. In some cases, it is possible to identify the substance and even quantify it. Certain substances of interest can be detected on this scale.

It is advisable to start with a screening according to the below conditions to assess the level of contamination after the decontamination process. This allows to draw up an initial list of substances of concern, by identifying relevant peaks and their toxicological profile.

It is advisable to carry out specific analyses after the decontamination process, on the substances listed in section 2.E.4. This step will allow to obtain further information on the substances of interest and will complete the list of substances identified by the screening.

2. Sampling and test conditions for the purpose of analysis

In the case of recycled resins, priority should be given to researching the substances of interest present in the recycled material. Substances added during the manufacturing of the packaging should also be considered, in accordance with Cosmetics Europe's advisory document (additives, mixtures of materials, substances potentially generated during conversion etc.).

The assessment may cover:

- pellets to assess the decontamination of recycled resins exiting the recycling process, depending on the operator performing the risk assessment;
- materials after hot processing of the pellets (injected/moulded/thermoformed/extruded components, sheets of similar dimensions etc.).

Screening pellets provides useful information more quickly, but the surface/volume ratio is more conservative and difficult to measure; some volatile compounds may disappear and some substances may appear during processing.

Screening materials after processing provides the advantage of being closer to the reality of usage and of taking into account changes in volatile components and NIAS that may be formed during processing.

The quantity to be analysed depends on the analysis methods chosen, according to the needs of the laboratory.

Preparing samples for analysis

The surface/volume ratio can have a significant impact on the migration of substances.

It is recommended to use the standard ratio of 6 dm²/kg which is used in the food industry (see Annex 6 of the Cosmetics Europe Advisory Document). When assessing the risks associated with the quantities found, one should take into account the actual ratio for the application in question.

Choice of simulant(s)

The choice of simulant(s) depends on the nature of the cosmetic formula.

Food simulants can be used for cosmetic contact, in accordance with the Cosmetics Europe advisory document of June 2019: *"For most cosmetic formulations, the physical/chemical properties relevant for migration from the packaging correspond to the properties of typical food stuff. Therefore, a similar expert judgement approach can be taken to decide whether information based on a particular food/simulant is applicable to the cosmetic formulation."*

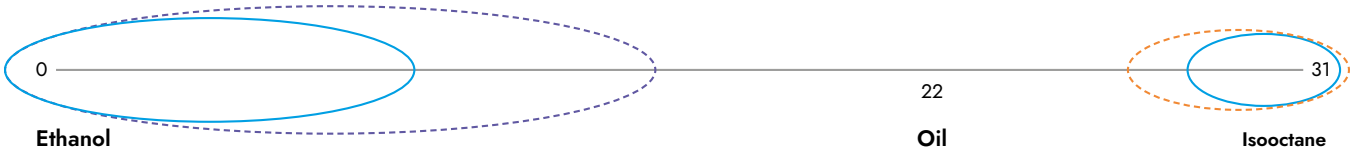
In this case, the user must verify that the simulant that has been used is suitable for the cosmetic product under consideration.

For food contact, simulants are defined in Annex III of Regulation (EU) n°10/2011 according to the physico-chemical characteristics of foodstuffs.

Simulant	Composition	Physico-chemical characteristics of foodstuffs
A	Ethanol 10 % (v/v)	Aqueous product
B	Acetic Acid 3% (w/v)	Aqueous product with pH below 4.5
C	Ethanol 20 % (v/v)	Aqueous product containing up to 20% alcohol and containing a significant quantity of organic ingredients which make it more lipophilic
D1	Ethanol 50 % (v/v)	Oily product containing more than 20% alcohol Oil/water emulsion
D2	Vegetable oil containing less than 1% unsaponifiable matter*	Oily product Water/oil emulsion
E	Poly(2,6-diphenyl-p-phenylene) oxide, particle size 60-80 mesh, pore size 200 nm	Dry product Powder

* It can be difficult to carry out a migration test with vegetable oil, from a technical analytical point of view. In this case, isooctane and 95% (v/v) ethanol can be used instead of vegetable oil. The test conditions must be validated by the laboratory. Recommendations on the selection of an alternative simulant are based on the rule of similarity: the closer the polarity of the "migrating" molecule and of the simulant, the better the solubility of the migrant in the simulant. The systematic approach is based on the potential use of the two alternative food simulants ethanol 95% (v/v) and isooctane, because they represent the two extremes in terms of polarity. As a measure of polarity, the octanol-water partition coefficient ($K_{o/w}$) is used because there is an abundance of scientific literature and numerous estimation procedures. Care must be taken when choosing an alternative simulant and ensuring polymer/solvent compatibility.

Polarity scale based on octanol/water partition coefficients



Ethanol 95% (v/v) is not suitable for properly extracting inorganic substances. Inorganic substances, particularly metallic trace elements, should be analysed by extraction in 3% acetic acid.

The choice of simulant to be used depends on the physico-chemical characteristics of the cosmetic formula and the substances tested for, according to the analytical test carried out, as shown in the table below[18].

Test	Simulant
Global migration	Simulants A, B, C, D1, D2 and E (annex III of Regulation N°10/2011)
Phtalates migration	Ethanol 95 %
PAH migration	Isooctane
Heavy metals migration	Acetic acid 3%
PAA migration	Acetic acid 3%
Screening NIAS	Ethanol 95% (worst-case approach for food applications)

18 Joint Research Centre, Institute for Health and Consumer Protection. Rijk, R., Franz, R., Bustos, J., et al., *Training workshop "Safety of food contact materials: technical guidelines for testing migration under Regulation (EU) n°10/2011", Hoekstra, E.(editor), Publications Office, 2015.* data.europa.eu/doi/10.2788/377927

Migration in these simulants corresponds to the worst cases, as they can go as far as extraction.

Food packaging simulants do not cover all the specificities of cosmetic products.

The test laboratory can advise on the simulant to use, taking into account the type of cosmetic formula and the material.

If the final application is known, the choice of simulants can be refined according to the physico-chemical characteristics of the cosmetic formula.

The choice of the solvent ethanol 95% (v/v) as an alternative simulant to represent lipophilic contents overcomes a certain number of analytical reservations, such as the possibility of a reaction between the simulant and the molecules of interest and the less stringent analytical detection limits in this medium. It covers the majority of applications[19].

For cosmetic products in powder form: according to the EMA (European Medicine Agency) Guideline on plastic primary packaging materials for active substances and medicinal products (CPMP/QWP/4359/03 and EMEA/ CVMP/205/04), the risk of container-content interactions is considered low for solid active substances and solid dosage forms[20]. Consequently, the migration of substances present in recycled packaging intended for powder formulations can be considered low.

Migration into powders can be tested using the simulant E recommended for the food industry.

Choice of testing conditions

The choice of testing conditions is governed by analytical technical considerations.

To cover long storage times at room temperature, it is usual to act on the temperature as a condition which accelerates and maximises the migration process.

For example, for specific migrations, a 10-day test at 60°C covers all storage times of more than 6 months at room temperature or below, including hot-fill conditions and/or heating to 70°C ≤ T ≤ 100°C for up to t = 120/2^$_{[(T-70)/\ 10]}$ minutes.

The specific conditions applicable to contact times greater than 30 days at room temperature and below are described in Regulation (EU) n°10/2011 as amended (Annex V. Chapter 2. Point 2.1.4.d) (see page 132 of the September 2020 version).

Important note

Some materials cannot withstand these temperatures; these conditions can be reviewed by the laboratory. It is possible to review the time/temperature combination which reflects reality and does not alter the article. The test conditions should be adjusted in conjunction with the laboratory and the marketer.

Important note

The thickness of the materials can have an impact on the level of migration and the time needed for this migration to occur. The test conditions should be adjusted in conjunction with the laboratory and the marketer.

19 Nesslany, F., & Marzin, D. (1999). *A micromethod for the in vitro micronucleus assay. Mutagenesis,* 14(4), 403-410. https://doi.org/10.1093/mutage/14.4.403

20 EMEA. (2005). *Guideline On Plastic Immediate Packaging Materials.* ema.europa.eu. ema.europa.eu/en/documents/scientific-guideline/guideline-plastic-immediate-packaging-materials_en.pdf

Choice of analysis techniques

The analytical equipment listed in the table below can be used to identify most of the substances which can still be present after recycling[21].

List of analytical equipment

Substances categories	Volatiles / semi-volatiles	Non-volatiles	Inorganic
Preparation of samples for analysis (type of injection)	· Headspace analysis. · Dynamic sampling (purge and trap GC). · Solid phase microextraction (SPME). · Liquid injection. · Thermo-desorption (TDU).	Not applicable	Not applicable
Analysis technique	· Gas chromatography (GC) - quantitative or semi-quantitative analysis.	· High-performance liquid chromatography (HPLC). · Ultra high-performance liquid chromatography (UHPLC).	· Detection by optical emission spectroscopy. · Inductively coupled plasma mass spectrometry (ICP-MS). · Other semi-quantitative techniques (XRF) - to be explored.
Detection methods	· Flame ionisation detector (FID). · Or mass spectrometry (EI-MS / CI-MS).	Detection technique: · UV · MS · HRMS	

The information in this table is for guidance only. For further details, please refer to expert reports and bibliographical sources.

In some cases, pre-concentration may be necessary.

It is advisable to set up a metrological validation of the method.

3. Expression of results

Migration test results may be reported in mg/kg of material or mg/kg of simulant, depending on the test. To allow for a proper toxicological assessment, values should be expressed in mg/kg of simulant[18].

The case described below corresponds to one of the worst-case scenarios, assuming total migration.

21 ISLI (2015). Koster S., Bani-Estivals M.H., Bonuomo M. , et al. *Guidance on Best Practices on the Risk Assessment of Non Intentionally Added Substances (NIAS) in Food Contact Materials and Articles* – ILSI Europe Series. Figure 4 - page 34. ilsi.eu/publication/guidance-on-best-practices-on-the-risk-assessment-of-non-intentionally-added-substances-nias-in-food-contact-materials-and-articles

Total transfer calculation:

- Calculation 1

$C._{Formula}$ (µg/g) = $M_{Material}$ (g) x $C._{Material}$ (µg/g) / $M_{Formula}$ (g)

- Calculation 2 (if thickness and contact surface are known)

It is also possible to calculate a concentration in the cosmetic formula by using the formulas explained in the Plastics Europe document RISK ASSESSMENT OF NON-LISTED SUBSTANCES (NLS) AND NOT-INTENTIONALLY ADDED SUBSTANCES (NIAS) UNDER ARTICLE 19[22], hereafter:

$$C\ Food\ (mg/kg) = \frac{C\ Polymer\ (mg/kg)\ .\ d\ Polymer\ (g/cm^3)\ .\ S\ Packaging\ (cm^2)\ .\ e\ Packaging\ (cm)}{M\ food\ (g)}$$

$$C\ Food\ (mg/kg) = \frac{C\ Polymer\ (mg/kg)\ .\ d\ Polymer\ (g/cm^3)\ .\ S\ Packaging\ (cm^2)\ .\ e\ Packaging\ (cm)}{d\ Food\ (g/cm^3)\ .\ V\ Food\ (cm^3)}$$

· C Food: concentration of the substance in the food

· C Polymer: concentration of the substance in the polymer

· d Polymer: density of the polymer

· S Packaging: contact area of the packaging material

· e Packaging: thickness of the packaging material

· M Food: weight of the food in contact with the material

· d Food: density of the food

· V Food: volume of the food in contact with the material[22]

When certain analyses are not feasible, computational modelling tools are available (2015 JRC guide[20]).

First of all, it is important to select a modelling tool that is robust, agile, relevant and adapted to the desired cosmetic application.

Most modelling tools overestimate the level of actual migration and therefore enable predictions/estimates to be generated with a certain degree of precaution, thus ensuring consumer safety. However, for some tools, safety factors also need to be taken into account in order to adjust the prediction.

Ultimately, if the modelling result is below a set limit, a decision can be taken. On the other hand, if the result is above this limit, then a theoretical risk has been identified. However, it will be necessary to refine the hypotheses and carry out an analytical test to establish whether the non-compliance is confirmed (to avoid false-negatives/positives).

A prediction/estimate can also be considered. This means testing compliance by resorting to predictive models, provided that the following are available:

· data on the physico-chemical properties of polymers;

· industrial technical data (polymer composition);

· data on the storage and distribution of packaged products.

The essential input data shall cover:

· the identity of the molecule;

· its initial concentration in the material;

· material geometry: layer thickness, surface in contact;

· contact duration;

· contact temperature.

22 Plastics Europe. (2014). *Risk Assessment of non-listed substances (NLS) and non-intentionally added substances (NIAS) under Article 19 of Commission Regulation (EU) n°10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.* plasticseurope.org/wp-content/uploads/2021/11/20141010ra_for_non_listed_substances_and_nias_under_article.pdf

The development of predictive approaches has been encouraged in recent years, both in Europe by DG-SANCO (Directorate General for Health and Consumer Protection) and in North America by the FDA. Tools have already been published and are available, as are the conclusions of the SMT-CT98-7513 European working group, which bring together the main information in the field.

For further information, the JRC (Joint Research Centre), the European laboratory in charge of these issues, offers a resource document[26].

National and European research programs have led to the development of migration modelling tools[23].

4. Identification of substances of interest for assessment purposes

The risk assessment must target, as a minimum, the substances of highest concern within the categories listed below:

- CMR substances according to CLP Regulation (EC) n°1272/2008;
- substances identified as SVHC on the candidate list, including endocrine disruptors[24] ;
- substances listed in Annex I of Regulation (EU) n°10/2011 for plastics intended for food contact and subject to Specific Migration Limits (SML);
- substances subject to restriction in Annex II (including certain metals) of Regulation (EU) n°10/2011 for plastics intended for food contact;
- substances listed in Annexes II and III of Cosmetics Regulation (EC) n°1223/2009;
- skin sensitisers in accordance with CLP Regulation (EC) n°1272/2008;
- substances subject to restriction/authorisation under REACH Regulation (EC) n°1907/2006.

In accordance with the Cosmetics Europe advisory document of June 2019[14], it is necessary to declare the identity and concentration of the following substances when present in the packaging or packaging material:

- substances subject to restriction (Annex II or III of Regulation (EC) n°1223/2009), including CMR Cat 1A, 1B or 2 substances: 10 ppm in the material or 100 ppb in migration;
- substances classified as skin sensitisers Cat 1A in the CLP Regulation (EC) n°1272/2008: 100 ppm in the material or 100 ppb in migration;
- substances classified as skin sensitisers Cat 1 or 1B in CLP Regulation (EC) n°1272/2008: 1000 ppm in the material or 1000 ppb in migration.

The 100 ppb threshold (in a relevant simulant) requires highly sophisticated analytical techniques targeting the molecule of interest. Even if it can be detected below 100 ppb, identification and quantification are not always possible. This threshold may be reduced as available techniques evolve. The limits of quantification are higher than the limits of detection, which makes quantification complicated or even impossible at low levels such as 100 ppb.

23 Food Packaging Forum (2018). *Migration modeling*. foodpackagingforum.org/food-packaging-health/migration-modeling

24 ECHA. Liste des substances extrêmement préoccupantes candidates en vue d'une autorisation. echa.europa.eu/fr/candidate-list-table

EFSA and WHO have proposed an exposition level of 0.15 µg/person/day or 0.0025 µg/kg bw/day as a sufficiently protective TTC value, including for DNA-reactive genotoxic chemicals (Kroes et al, 2004[25], EFSA 2016[26]).

EFSA scientists (EFSA, 2019[27]) proposed excluding from the TTC approach substances with specific properties such as aflatoxins, azoxy- or N-nitroso-type substances, benzidines, steroids and those with bioaccumulation potential (e.g. polyhalogenated-dibenzo-dioxins, -dibenzofurans and -biphenyls). European experts (EFSA, 2019[27]) have also recommended excluding inorganic substances, proteins, nanomaterials, radioactive substances, organosilicon substances and metals in elemental, ionic or organic form. However, in the case of organic salts, where the counterion is an essential metal (e.g. sodium), EFSA recommends that the TTC approach could be applied to the organic ion.

However, it should be noted that the TTC approach is not an alternative to the risk assessment specific to a chemical substance, but a screening tool used to decide whether a more in-depth toxicological assessment is needed (EFSA, 2016[26]). Furthermore, there is currently no effective approach to assess genotoxic and carcinogenic risks from exposure to multiple DNA-reactive genotoxic carcinogens. Current regulatory policy for chemicals relies on assessing genotoxic and carcinogenic risks on an individual basis[28].

Kroes et al (2007[29]) have indicated that it is scientifically justified to use the TTC approach and the database that supports the TTC values established for food chemicals, for the safety assessment of cosmetic ingredients.

The table below presents an indicative list by family of detectable substances of interest, representative of possible contamination, equipment and analysis conditions. Each operator may add substances and analyses which they consider relevant.

This list is not exhaustive.

It should be emphasised that no single method of analysis can identify all the substances listed below:

- **the database of NIAS substances may vary from one laboratory to another. A discussion with the laboratory that will carry out the analyses on the substances of interest is critical in order to define the substances to be analysed (standards) by the laboratory, which will also allow to define the quantification limits for each substance;**
- **specific migrations should also be carried out;**
- **representative substances of interest should be targeted within each family (for example, for phthalates, target those which are SVHC and carcinogenic).**

25 Kroes R., Renwick A.G., Cheeseman M., & al. *Structure-based thresholds of toxicological concern (TTC): guidance for application to substances present at low levels in the diet. Food Chem Toxicol.* 2004;42:65–83. https://doi.org/10.1016/j.fct.2003.08.006

26 EFSA (2016). *Review of the Threshold of Toxicological Concern (TTC) approach and development of new TTC decision tree. EFSA Support Publ.* 2016;13:1–50. efsa.europa.eu/en/supporting/pub/en-1006

27 EFSA (2019). More S.J., Bampidis V., Benford, D., & al. *Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment.* EFSA Journal 2019;17(6):5708, 17 pp. https://doi.org/10.2903/j.efsa.2019.5708

28 Munro I.C., Ford R.A. , Kennepohl E, & al. *Correlation of structural class with no-observed-effect levels: a proposal for establishing a threshold of concern. Food Chem Toxicol.* 1996;34:829–867. https://doi.org/10.1016/s0278-6915(96)00049-x

29 Kroes R., Renwick A.G., Feron V., & al. *Application of the threshold of toxicological concern (TTC) to the safety evaluation of cosmetic ingredients.* Food and Chemical Toxicology Volume 45, Issue 12, December 2007, Pages 2533-2562. https://doi.org/10.1016/j.fct.2007.06.021

Family of substances	Source	Possible equipment	Analysis conditions
PAH	-	LC-MS ou LC-fluo GC-MS	Isooctane Ethanol 95 % (see JRC conversion tables, from page 87[18])
Phtalates	-	GC-MS	Ethanol 95 %
Antioxidants	-	GC-MS LC-MS for some HPLC	Ethanol 95 %
PFAS	-	LC-MS/ MS	Directly in the material - See methodology used in the Danish study of July 2021[30] (paragraphs 4.3.4 and 4.3.5)
SVHC	-	ICP-OES or GC-MS or LC-MS	Extraction in an organic solvent
Skin sensitisers	Cosmetics & Detergents	GC-MS	Thermodesorption
Inorganic substances (including heavy metals and other metals)	-	ICP	Acetic acid 3 %
PAA (primary aromatic amines)	Inks	LC-MS	Acetic acid 3 %
Bisphenols		GC-MS or LC-MS	Ethanol 95 %
Nonylphenols	Degradation of antioxidants	GC-MS	Ethanol 95 %

Given the analytical and feasibility difficulties, one may consider working by family of chemical substances.

For organic compounds, the preferred methods are the chromatographic ones (gas or liquid). For inorganic compounds, the preferred method is ICP (Inductively Coupled Plasma).

The items in the table above are given for guidance only. Some bibliographical sources may be useful. For example, the ILSI report of April 2023[31] constitutes a source of reference.

30 Ministry of Environment of Denmark (2021). *Initial safety asssessment of recycled plastic for packaging of cosmetic products.* Environmental Protection Agency. Environmental project n°2174. July 2021. www2.mst.dk/Udgiv/publications/2021/07/978-87-7038-330-1.pdf

31 ILSI (2023). Oldring P., Faust B., Gude T., & al. *An Overview of Approaches for Analysing NIAS from different FCMs.* ilsi.eu/publication/an-overview-of-approaches-for-analysing-nias-from-different-fcms

5. Further consideration in risk assessment

It is not always possible to identify substances of interest through the analyses carried out with existing databases. In such cases, in order to identify any genotoxic potential, bioassays may be considered as a complement to the analytical approach.

There are various methods, for example:

- Bacterial reverse mutation test (OCDE 471[32] - Ames test), in vitro micronucleus test on mammalian cells (OCDE 487[33] - Micronucleus): these methods make it possible to demonstrate mutagenic potential or the appearance of chromosomal aberrations, respectively. They have been validated by the OECD and are widely used for regulatory purposes;

· miniaturised genotoxicity tests ("Mini Ames[34]", "Mini Micronucleus[19]", AMES MPF and NanoAMES used in the food and/or pharmaceutical industries, etc.): initially developed for screening tests, these methods show a good correlation of results with their OECD equivalent. They are less expensive and require a smaller quantity of test material;

· GreenScreen HC™, ToxTracker® ACE, DNA Damage Response Pathway: these methods have also been developed for screening purposes. They can be used to identify the mechanisms of action that could lead to genotoxic potential. They are inexpensive and require little test material.

These studies are carried out on the simulant after extraction. It is important to ensure that the simulant is compatible with the test being carried out; a change of solvent is generally necessary. Because of biological detection limits, a concentration stage is necessary. Isolating certain fractions of substances may be considered in order to guarantee the correct performance of the test or better predictability. Recommendations on the application of bioassays in materials safety assessment have been issued by Shilter et al. (2019)[35]. Caution must be exercised regarding the risk of false positives or false negatives.

Additional information: for substances that have been identified but not quantified, determining the maximum concentration in the packaging that does not represent a risk to the consumer may be useful for having a discussion with the packaging supplier. An example of retro-calculation is available in the FDA document (version 2021[12]) concerning suitability for food contact (to be transposed to contact with cosmetics).

32 OCDE (2020), Test n°471: *Bacterial Reverse Mutation Test,* OECD Guidelines for the Testing of Chemicals, Section 4, Éditions OCDE, Paris, https://doi.org/10.1787/9789264071247-en

33 OCDE (2016), Essai n°487 : Essai in vitro de micronoyaux sur cellules de mammifères, Lignes directrices de l'OCDE pour les essais de produits chimiques, Section 4, Éditions OCDE, Paris (In vitro mammalian cell micronucleus test, OECD Guidelines for Testing of Chemicals, Section 4, OECD Publishing, Paris). https://doi.org/10.1787/9789264264878-fr

34 Flamand N., Meunie J. R., Meunier P.A., & al. (2001). *Mini mutagenicity test: a miniaturized version of the Ames test used in a prescreening assay for point mutagenesis assessment. Toxicology in vitro,* 15(2), 105-114. https://doi.org/10.1016/s0887-2333(01)00003-0

35 Schilter B., Burnett K., Eskes C., & al. (2019) *Value and limitation of in vitro bioassays to support the application of the threshold of toxicological concern to prioritise unidentified chemicals in food contact materials. Food Addit Contam Part A Chem Anal Control Expo Risk Assess.* 2019 Dec;36(12):1903-1936. doi: 10.1080/19440049.2019.1664772. Epub 2019 Sep 24. PMID: 31550212. https://doi.org/10.1080/19440049.2019.1664772

3 Controlling the stability of the recycling process for cosmetic use

3 Controlling the stability of the recycling process for cosmetic use

A. Objective

The aim is to check the stability of the recycling process evaluated previously across batches. How can this be done? Through reproducible analyses based on recognised protocols, according to the principles of conventional metrology.

One should be able to carry out these analyses as part of regular quality monitoring at industrial level, and the results must be assessable by all users, with identified limits enabling them to determine whether the batch is acceptable or not.

B. Choice of approach

There are two possible methods for monitoring the stability of the recycling process: analytical control and/or chemical fingerprinting.

Analytical control method:

This involves identifying and quantifying, batch by batch, the presence of a set of so-called control contaminants.

· the choice of these contaminants is defined in paragraph 3.C;

· the choice of control procedure is defined in paragraph 3.D.

FingerPrint method:

The chemical fingerprinting methodology is internationally recognised as the reference approach for the quality control of medicinal plants. It has been approved by the FDA, the EMA, the WHO, French agencies and many others, and has been the subject of numerous publications[36] [37]. It is now applied in many fields other than medicinal plants, and can be adapted for batch-by-batch validation of recycled resins. Establishing the profile or chemical fingerprint of a recycled resin requires a series of chromatographic analyses (LC-MS or GCMS) to be carried out on different samples and/or different batches of this resin.

The common chromatographic peaks from the fingerprints of the different samples will be used to establish a standard fingerprint of chemical markers characteristic of a resin. The chemical fingerprint thus established will serve as a reference and basis for comparison with future batches in order to assess their quality and the stability of the recycling process. Statistical analysis methods such as Principal Component Analysis (PCA)[38] and Hierarchical Classification Analysis (HCA) can be used to process the data and assess batch quality.

---

36 Tistaert C., Dejaegher B., & Vander Heyden Y. (2011). *Chromatographic separation techniques and data handling methods for herbal fingerprints: a review.* Analytica Chimica Acta. 2011 Apr 1;690(2):148-61 https://doi.org/10.1016/j.aca.2011.02.023

37 Peñalver R., Marín C., Arroyo-Manzanares N., & al. *Authentication of recycled plastic content in water bottles using volatile fingerprint and chemometrics.* Chemosphere. 2022 Jun;297:134156. https://doi.org/10.1016/j.chemosphere.2022.134156

38 Welle F, & Horner G. (2008). *New strategies in on-line screening analysis and compliance test procedures for plastic materials.* Poster presentation at the 4th international Symposium on Food Packaging, 19-21 November 2008, Prague. http://www.ivv.fraunhofer.de/content/dam/ivv/en/documents/Forschungsfelder/Produktsicherheit-und-analytik/New_strategies_in_on-line_screening_analysis.pdf

A comparison between the two methods:

Approaches	Advantages	Disadvantages
Analytical control method	· Some contaminants recur quite frequently. · Easy-to-implement control and automatic conclusion. · Markers common to all degrees in a polymer family.	· Not all contaminants are searched for and analysed. · There may be some variation depending on the inputs.
FingerPrint method	· All the contaminants are looked for and the profile obtained is compared with the one obtained at the previous assessment stage.	· It is difficult to say whether a deviation is acceptable or not, and at what threshold a batch is significantly different. · Requires expertise in statistics for data analysis. · Each supplier must carry out its own analyses - needing around ten batches to develop its standard.

The recommendation is to use the approach that is easiest to implement in a so-called routine control, bearing in mind that the aim is to check the stability of the recycling process, the effectiveness of which has already been assessed. In this guidance document, the "analytical control" method seems to be the quickest and most economical to carry out and is the one described in the following pages.

C. Selection of control contaminants

The selection of control contaminants (hereafter referred to as markers) aims at covering the physico-chemical characteristics and properties of a wide range of potential contaminants. They should be chosen according to the following criteria:

· be representative of the type of contamination possible;

· cover the range of contaminants in terms of volatility/non-volatility and polarity/non-polarity;

· if not common, have the highest level of hazard;

· permit to be compliant with the safety requirements for cosmetic use;

· select only chemical substances to which a CAS number can be assigned.

Based on the available bibliographical data and the results of the tests carried out by the participants, a list of contaminants is presented below. The control contaminants do not represent a family of substances, nor a family of risks. This list is not exhaustive and is subject to change. Bibliographical sources are given in Annex E.

This list represents a minimum. Other substances must be analysed to meet regulatory requirements, such as those of the REACH Regulation (EC) n°1907/2006, the Cosmetics Regulation (EC) n°1223/2009 and the Packaging Directive n°94/62/EC.

This list of contaminants has been drawn up for the three resins covered by these guidelines: PE, PP and PET.

List of common markers for the three resins:

Name	CAS Number	Analytical tool	Possible origin
Limonene	5989-27-5	GC/MS	Packaged product (contamination of packaging by packaged product)
Bis(2-ethylhexyl) phthalate (DEHP)	117-81-7	GC/MS	Packaging (ink, varnish, etc.)
n-Hexyl salicylate	6259-76-3	GC/MS	Packaged product (contamination of packaging by packaged product)
Isopropyl myristate	110-27-0	GC/MS	Packaged product (contamination of packaging by packaged product)
Toluene	108-88-3	GC/MS	Packaging (inappropriate use, degradation of inks and varnishes etc.)
Benzene	71-43-2	GC/MS	Packaging (inappropriate use, degradation of inks and varnishes etc.)
Benzophenone	119-61-9	GC/MS LC/MS	Packaging (inks and varnishes etc.)
Aluminium and its salts (lactate, citrate, sulphate, potassium, glycinate, benzoate, chloride, hydrochloride...)	7429-90-5	ICP-MS	Packaged product and packaging
Bisphenol A (BPA)	80-05-7	GC/MS	Packaging (inks and varnishes etc.)

List of additional markers for PET:

Name	CAS Number	Analytical tool	Possible origin
Acetaldehyde	75-07-0	GC/MS	Packaging (PET degradation)

List of additional markers for PP and PE:

Name	CAS Number	Analytical tool	Possible origin
Tris(2,4-di-tert-butylphenyl) Phosphite: Irgafos 168 and their degradation products in recycled polyolefins or Irganox® 1010 and their degradation products in recycled polyolefins	31570-04-4 or 6683-19-8	GC/MS LC/MS	Packaging (additives)
Phosphate form of Irgafos: Tris(2,4-di-tert-butylphenyl) Phosphate	95906-11-9	GC/MS LC/MS	Packaging (additives)
Chimasorb® 944 and their degradation products in recycled polyolefins	71878-19-8	LC/MS	Packaging (additives)
2,4-dimethyl benzaldehyde	15764-16-6	GC/MS	Packaged product (sorbitol degradation)
Aniline and 4,4'-diaminodiphenylmethane	62-53-3, 101-77-9	GC/MS	Packaged product, adhesive, pigment or azo dye impurities, PAA
Tinuvin® 328 (2-(benzotriazol-2-yl)-4,6-bis(2-methylbutan-2-yl)phenol)	25973-55-1	GC/MS	Packaging (UV stabiliser)
2,6-Bis(1,1-dimethyl)-4-methylphenol (BHT)	128-37-0	GC/MS	Packaging and packaged product (antioxidant)
2,4-Di-tert-butylphenol	96-76-4	GC/MS	Packaging (antioxidant degradation)

Sampling

In accordance with paragraph 2.E.2, the assessment may be carried out on the pellets to gauge the decontamination of the recycled resins leaving the recycling line, or on the materials after the pellets have been processed under heat.

The quantity of material to be analysed depends on the analysis methods chosen, according to the needs of the laboratory.

D. Process stability control plan

The frequency of checks and the size of batches must be substantiated by the results obtained during the assessment of the recycling process, but also make these checks operational (feasibility and appropriate response time).

Interpretation of results and criteria for batch acceptability

The aim is to ensure sufficient and reproducible quality. The choice of markers has two objectives:

- **to assess the quality of the batches:** the markers selected are also substances of interest, representative of a type of contamination and are not intended to reproduce the test plan already carried out when the source of the recycled material was selected. For example, limonene is considered here to be representative of allergens because of its very low regulatory threshold, its low molecular weight and its recurrence in the material;
- **to assess qualitative and quantitative variation between batches:** the markers should allow to assess the variability from one batch to another, in relation to the effectiveness of decontamination, in order to establish confidence intervals. This assessment must take account of the measurement deviation specific to the method used (see paragraph 2). A control plan and measurement charts must be drawn up.

Once the markers have been identified, measurements are taken for each batch using the equipment defined above, according to a predefined sampling plan. This plan must be defined by batch and across batches. Pending the forthcoming guidelines in Regulation (EU) n°2022/1616, various specific regulations or standards can be used as a reference for establishing the sampling plan: Regulation (EU) n°691/2013[39] amended Regulation (EU) n°333/2007[40] and ISO standard 10725[41].

In the event of non-compliance, the cause should be investigated with the recycler. If there is a risk, the batch should be rejected.

The acceptability of the thresholds for inter-batch variability depends on the conditions of use, the final use of the product and the dimensions of the finished product. This is a collective responsibility all along the value chain.

Sampling should initially include all batches, but sampling frequency can be reduced once the average values obtained are stable. The frequency of sampling should in any case be maintained at an appropriate level to detect trends and/or other changes in the levels of contamination of batches, and to determine whether the presence of contaminants is recurring.

E. Controls and information to be reported

Regardless of the intended use, the recycled material should not be classified as dangerous in accordance with the definitions in Article 3 and Annex I of Regulation (EC) n°1272/2008 (CLP), and should meet the requirements relating to the marketing of SVHCs set out in Article 56 of Regulation (EC) n°1907/2006 REACH, as well as the marketing restriction on persistent organic pollutants (POPs) set out in Article 3 of Regulation (EU) n°2019/1021 ("end of waste" criteria proposed by the JRC[6]).

In addition, in order to enable the user of the recycled material to check that the packaging complies with Directive n°94/62/EC on packaging and packaging waste, the following heavy metals should be screened for and quantified: lead, cadmium, mercury and hexavalent chromium.

In order to demonstrate compliance with the above requirements, analysis results or documents, such as certificates, should be provided throughout the value chain, at a frequency to be agreed on a case-by-case basis.

39 Commission Regulation (EU) n°691/2013 of 19 July 2013 amending Regulation (EC) n°152/2009 laying down the methods of sampling and analysis.

40 Commission Regulation (EC) n°333/2007 of 28 March 2007 laying down the sampling methods and the analysis methods for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs.

41 ISO 10725:2000(fr). Acceptance sampling plans and procedures for the inspection of bulk materials iso.org/obp/ui/fr/#iso:std:iso:10725:ed-1:v1:fr

References
in order of appearance in the document

1. Cosmetics Europe. (2019). *Information Exchange on Cosmetic Packaging Materials Along the Value Chain in the Context of the EU Cosmetics Regulation Ec 1223/2009.* cosmeticseurope.eu/files/5015/6327/0864/Packaging_Advisory_document_-_June_2019.pdf

2. FEBEA. (2020). États généraux de la filière parfumerie-cosmétique : 30 mesures pour une relance gagnante et durable. febea.fr/fr/vos-produits-cosmetiques/actualites/etats-generaux-la-filiere-parfumerie-cosmetique-30-mesures

3. Provisions of Article 6 paragraphs 1 and 3 of the REACH Regulation. eur-lex.europa.eu

4. Article 2 of Regulation (EU) n°2022/1616. eur-lex.europa.eu

5. AFNOR. (2016). NF EN ISO 14021 : Environmental labels and declarations - Self-declared environmental claims (Type II labelling). boutique.afnor.org/fr-fr/norme/nf-en-iso-14021/marquage-et-declarations-environnementaux-autodeclarations-environnementale/fa059946/57523

6. Food Safety. *Resources for plastic recyclers.* food.ec.europa.eu/safety/chemical-safety/food-contact-materials/plastic-recycling/resources-plastic-recyclers_en

7. Welle, F. (2005). *Develop a food grade HDPE recycling process. ResearchGate.* researchgate.net/publication/284158562_Develop_a_food_grade_HDPE_recycling_process

8. Palkopoulou, S., Joly, C., Feigenbaum A. & al. (2016). *Critical review on challenge tests to demonstrate decontamination of polyolefins intended for food contact applications.* Trends in Food Science and Technology, 49, 110-120. doi.org/10.1016/j.tifs.2015.12.003

9. EFSA (2011). Panel on food contact materials, enzymes, flavourings and processing aids (CEF); *Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food.* EFSA Journal 2011; 9(7):2184. [25 pp.]. https://doi.org/10.2903/j.efsa.2011.2184

10 - Kroes R., Renwick A.G., Cheeseman M., & al. *European branch of the International Life Sciences Institute. Structure-based thresholds of toxicological concern (TTC): guidance for application to substances present at low levels in the diet.* Food Chem Toxicol. 2004 Jan;42(1):65-83. https://doi.org/10.1016/j.fct.2003.08.006. PMID: 14630131

11. AFSSA. (2005). Seuil de préoccupation toxicologique pour l'analyse de risque sanitaire des substances chimiques dans les aliments (Threshold of toxicological concern for health risk analysis of chemical substances in foodstuffs). anses.fr/en/system/files/AAAT-Ra-PreoccupationToxico.pdf

12. FDA. (2021). Use *of Recycled Plastics in Food Packaging (Chemistry Considerations) : Guidance for Industry.* fda.gov/media/150792/download

13 - EFSA. More, S. J., Bampidis, V., Benford, D., & al. (2019). *Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment.* EFSA Journal, 17(6). https://doi.org/10.2903/j.efsa.2019.5708

14. Cosmetics Europe. (2019). *Information Exchange on Cosmetic Packaging Materials Along the Value Chain in the Context of the EU Cosmetics Regulation Ec 1223/2009.* cosmeticseurope.eu/files/5015/6327/0864/Packaging_Advisory_document_-_June_2019.pdf

15. *Proposal for a revision of EU legislation on Packaging and Packaging Waste.* (2022). https://environment.ec.europa.eu/publications/proposal-packaging-and-packaging-waste_en

16. Collective action project - unpublished, available on request - Return to clean material from detergent packaging containing certain substances which, despite effective decontamination, are still detected by the sensory panel.

17. FDA (2012). *Packaging & Food Contact Substances (FCS).* fda.gov/food/food-ingredients-packaging/packaging-food-contact-substances-fcs

18. Joint Research Centre, Institute for Health and Consumer Protection, Rijk, R., Franz, R., Bustos, J., et al., *Training workshop "Safety of food contact materials: technical guidelines for testing migration under Regulation (EU) n°10/2011"*, Hoekstra, E.(editor), Publications Office, 2015. https://data.europa.eu/doi/10.2788/377927

19. Nesslany, F., & Marzin, D. (1999). *A micromethod for the in vitro micronucleus assay. Mutagenesis, 14(4)*, 403-410. https://doi.org/10.1093/mutage/14.4.403

20. EMEA. (2005). *Guideline On Plastic Immediate Packaging Materials.* www.ema.europa.eu. ema.europa.eu/en/documents/scientific-guideline/guideline-plastic-immediate-packaging-materials_en.pdf

21. ISLI (2015). Koster S., Bani-Estivals M.H., Bonuomo M., et al. *Guidance on Best Practices on the Risk Assessment of Non Intentionally Added Substances (NIAS) in Food Contact Materials and Articles* – ILSI Europe Series. Figure 4 - page 34. ilsi.eu/publication/guidance-on-best-practices-on-the-risk-assessment-of-non-intentionally-added-substances-nias-in-food-contact-materials-and-articles

22. Plastics Europe. (2014). *Risk Assessment of non-listed substances (NLS) and non-intentionally added substances (NIAS) under Article 19 of Commission Regulation (EU) n°10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.* plasticseurope.org/wp-content/uploads/2021/11/20141010ra_for_non_listed_substances_and_nias_under_article.pdf

23. Food Packaging Forum (2018). *Migration modeling.* foodpackagingforum.org/food-packaging-health/migration-modeling

24. ECHA. Candidate list of substances of very high concern for authorisation echa.europa.eu/fr/candidate-list-table

25. Kroes R., Renwick A.G., Cheeseman M., & al. *Structure-based thresholds of toxicological concern (TTC): guidance for application to substances present at low levels in the diet. Food Chem Toxicol.* 2004;42:65–83. https://doi.org/10.1016/j.fct.2003.08.006

26. EFSA (2016). *Review of the Threshold of Toxicological Concern (TTC) approach and development of new TTC decision tree. EFSA Support Publ.* 2016;13:1–50. efsa.europa.eu/en/supporting/pub/en-1006

27. EFSA (2019). More S.J., Bampidis V., Benford, D., & al. *Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment.* EFSA Journal 2019;17(6):5708, 17 pp. https://doi.org/10.2903/j.efsa.2019.5708

28. Munro I.C., Ford R.A., Kennepohl E, & al. *Correlation of structural class with no-observed-effect levels: a proposal for establishing a threshold of concern. Food Chem Toxicol.* 1996;34:829–867. https://doi.org/10.1016/s0278-6915(96)00049-x

29. Kroes R., Renwick A.G., Feron V., & al. *Application of the threshold of toxicological concern (TTC) to the safety evaluation of cosmetic ingredients.* Food and Chemical Toxicology Volume 45, Issue 12, December 2007, Pages 2533-2562. https://doi.org/10.1016/j.fct.2007.06.021

30. Ministry of Environment of Denmark (2021). *Initial safety asssessment of recycled plastic for packaging of cosmetic products*. Environmental Protection Agency. Environmental project n°2174. July 2021. www2.mst.dk/Udgiv/publications/2021/07/978-87-7038-330-1.pdf

31. ILSI (2023). Oldring P., Faust B., Gude T., & al. *An Overview of Approaches for Analysing NIAS from different FCMs.* ilsi.eu/publication/an-overview-of-approaches-for-analysing-nias-from-different-fcms

32. OCDE (2020), Test n°471: *Bacterial Reverse Mutation Test,* OECD Guidelines for the Testing of Chemicals, Section 4, Éditions OCDE, Paris. https://doi.org/10.1787/9789264071247-en

33. OCDE (2016), Test No. 487: In Vitro Mammalian Micronucleus Test, OECD Guidelines for Testing of Chemicals, Section 4, OECD Publishing, Paris. https://doi.org/10.1787/9789264264878-fr

34. Flamand N., Meunie J. R., Meunier P.A., & al. (2001). *Mini mutagenicity test: a miniaturized version of the Ames test used in a prescreening assay for point mutagenesis assessment. Toxicology in vitro,* 15(2), 105-114. https://doi.org/10.1016/s0887-2333(01)00003-0

35. Schilter B., Burnett K., Eskes C., & al. (2019) *Value and limitation of in vitro bioassays to support the application of the threshold of toxicological concern to prioritise unidentified chemicals in food contact materials. Food Addit Contam Part A Chem Anal Control Expo Risk Assess.* 2019 Dec;36(12):1903-1936. doi: 10.1080/19440049.2019.1664772. Epub 2019 Sep 24. PMID: 31550212. https://doi.org/10.1080/19440049.2019.1664772

36. Tistaert C., Dejaegher B., & Vander Heyden Y. (2011). *Chromatographic separation techniques and data handling methods for herbal fingerprints: a review.* Analytica Chimica Acta. 2011 Apr 1;690(2):148-61 https://doi.org/10.1016/j.aca.2011.02.023

37. Peñalver R., Marín C., Arroyo-Manzanares N., & al. *Authentication of recycled plastic content in water bottles using volatile fingerprint and chemometrics.* Chemosphere. 2022 Jun;297:134156. https://doi.org/10.1016/j.chemosphere.2022.134156

38. Welle F, & Horner G. (2008). *New strategies in on-line screening analysis and compliance test procedures for plastic materials.* Poster presentation at the 4th international Symposium on Food Packaging, 19-21 November 2008, Prague. ivv.fraunhofer.de/content/dam/ivv/en/documents/Forschungsfelder/Produktsicherheit-und-analytik/New_strategies_in_on-line_screening_analysis.pdf

39. Commission Regulation (EU) n°691/2013 of 19 July 2013 amending Regulation (EC) n°152/2009 laying down the methods of sampling and analysis.

40. Commission Regulation (EC) n°333/2007 of 28 March 2007 laying down the sampling methods and the analysis methods for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs.

41. ISO 10725:2000(fr). Plans et procédures d'échantillonnage pour acceptation pour le contrôle de matériaux en vrac (Acceptance sampling plans and procedures for the inspection of bulk materials) iso.org/obp/ui/fr/#iso:std:iso:10725:ed-1:v1:fr

42 – FDA (2021). *Guidance for Industry: Use of Recycled Plastics in Food Packaging* (Chemistry Considerations). fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-use-recycled-plastics-food-packaging-chemistry-considerations

Acronyms

ABS	Acrylonitrile Butadiene Styrene
AGEC	Anti Gaspillage et Economie Circulaire (Anti Waste and Circular Economy)
ANSES	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (French National Agency for Food, Environmental and Occupational Health and Safety)
CLP	Classification Labelling Packaging
CMR	Carcinogenic, Mutagenic, Toxic to Reproduction
ECHA	European Chemicals Agency
EFSA	European Food Safety Agency
EMA	European Medicine Agency
FDA	Food and Drug Administration
HDPE	High-density polyethylene
JRC	Joint Research Centre
LDPE	Low density polyethylen
NOL	No Objection Letter
PAH	Polycyclic aromatic hydrocarbons
PBT	Persistent, Bioaccumulative, Toxic
PCR	Post Consumer Recycled plastic
PE	Polyethylene
PET	Polyethylene terephthalate
PFAS	Per- and polyfluoroalkylated substances
POM	Polyoxymethylene
POP	Persistent Organic Pollutants
PP	Polypropylene
PPWR	Packaging and Packaging Waste Regulation
PS	Polystyrene
REACH	Registration, Evaluation and Authorisation of Chemicals
rPET	Recycled polyethylene terephthalate
SAN	Styrene-Acrylonitrile
SDS	Safety Data Sheet
SML	Specific Migration Limits
SVHC	Substance of Very High Concern
TTC	Toxicological Threshold of Concern
vPvB	very Persistant, very Bioaccumulative
WHO	World Health Organization

Glossary

Challenge test or "surrigate contaminant testing"
For more details, see the FDA's description of surrogate contaminant testing (section B, chapter 5[42]).

Contact
The Guidelines for the application of Annex I of the Cosmetics Regulation (Decision N° 2013/674/EU) specify that the relevant characteristics of the packaging material in direct contact with the product are important for the safety of the cosmetic product. It is also important to take into account the risk of migration due to continuity of the material.
For food contact, the regulatory requirements apply to materials or articles which are not in direct contact with food but which may reasonably be expected to transfer their constituents to food under normal and reasonably foreseeable conditions of use, which may be the case, for example, of secondary packaging used for the transport of pre-packaged food (Regulation (EU) n°1934/2005).

Converter
Within the meaning of Regulation (EU) n°2022/1616: any natural or legal person who carries out one or more post processing unit operations.

CosPaTox
The industry Consortium CosPaTox stands for Cosmetics, Packaging and Toxicology. The aim is to accomplish the so far missing specific safety standards for high-quality Post-Consumer Plastic Recyclates (PCRs) for cosmetics and other household packaging as well as the implementation of on-site measurement methods for recyclers.

Functional barrier
One or more layers of any type of material which limits the transfer of substances present in the outer layers of the packaging. For more details, please refer to Article 13 of Regulation (EU) n°10/2011 and its amendments.

"Pre-consumer" material
Material diverted from the waste stream during a manufacturing process. This excludes the reuse of materials such as those from reprocessing, regrind or residues generated during a given process and which can be recovered [for re-use] within the same process that generated them.

"Post-consumer" material
Material generated by households or by commercial, industrial or institutional facilities in their role as end-users of the product which can no longer be used for the purpose for which it was designed. This includes returns of material from the distribution chain.

Product loops in a closed and controlled chain
Product loops in which the products circulate within a controlled system of reuse and distribution and in which the recycled materials come only from these elements within the chain, so that the accidental introduction of external material corresponds to the minimum technically possible.

Recycled material[5]
Material regenerated from a material recovered [for re-use] by means of a manufacturing process, and transformed into a final product or a component intended to be incorporated into a product.

Recycler
As defined in Regulation (EU) n°2022/1616: any natural or legal person who applies a decontamination process.

Recycling
Any recovery operation by which waste materials are reprocessed into products, materials or substances whether for the original or other purposes. It includes the reprocessing of organic material but does not include energy recovery and reprocessing into materials that are to be used as fuels or for backfilling operations (definition in Directive 2008/98/EC on waste).

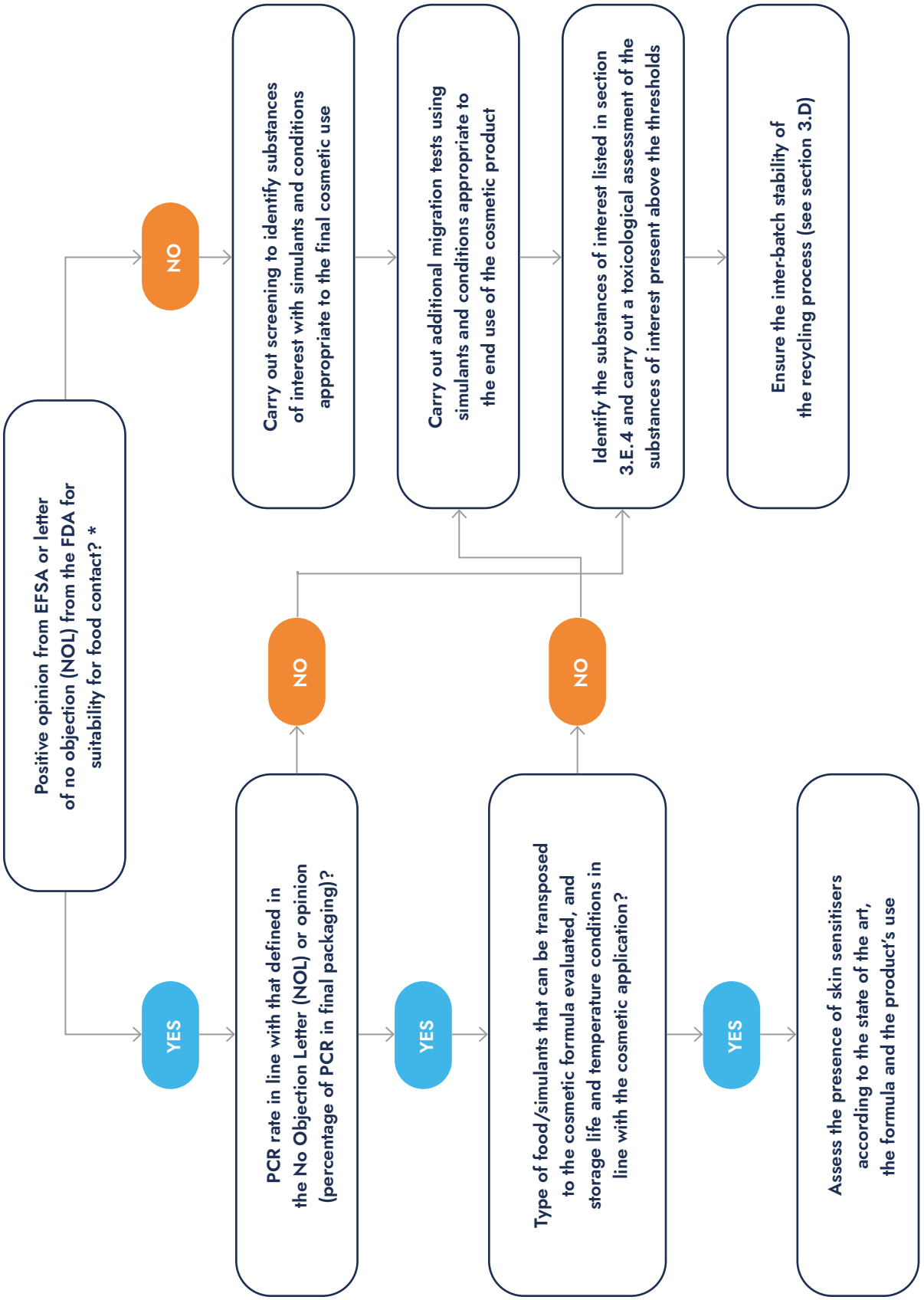
Recycling process
Sequence of individual operations that is intended to manufacture recycled plastic materials and articles through pre-processing, a decontamination process and post-processing, and which is based on a specific recycling technology (definition in Regulation (EU) n°2022/1616).

42 FDA (2021). *Guidance for Industry: Use of Recycled Plastics in Food Packaging (Chemistry Considerations)*. fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-use-recycled-plastics-food-packaging-chemistry-considerations

Annexes

ANNEX A

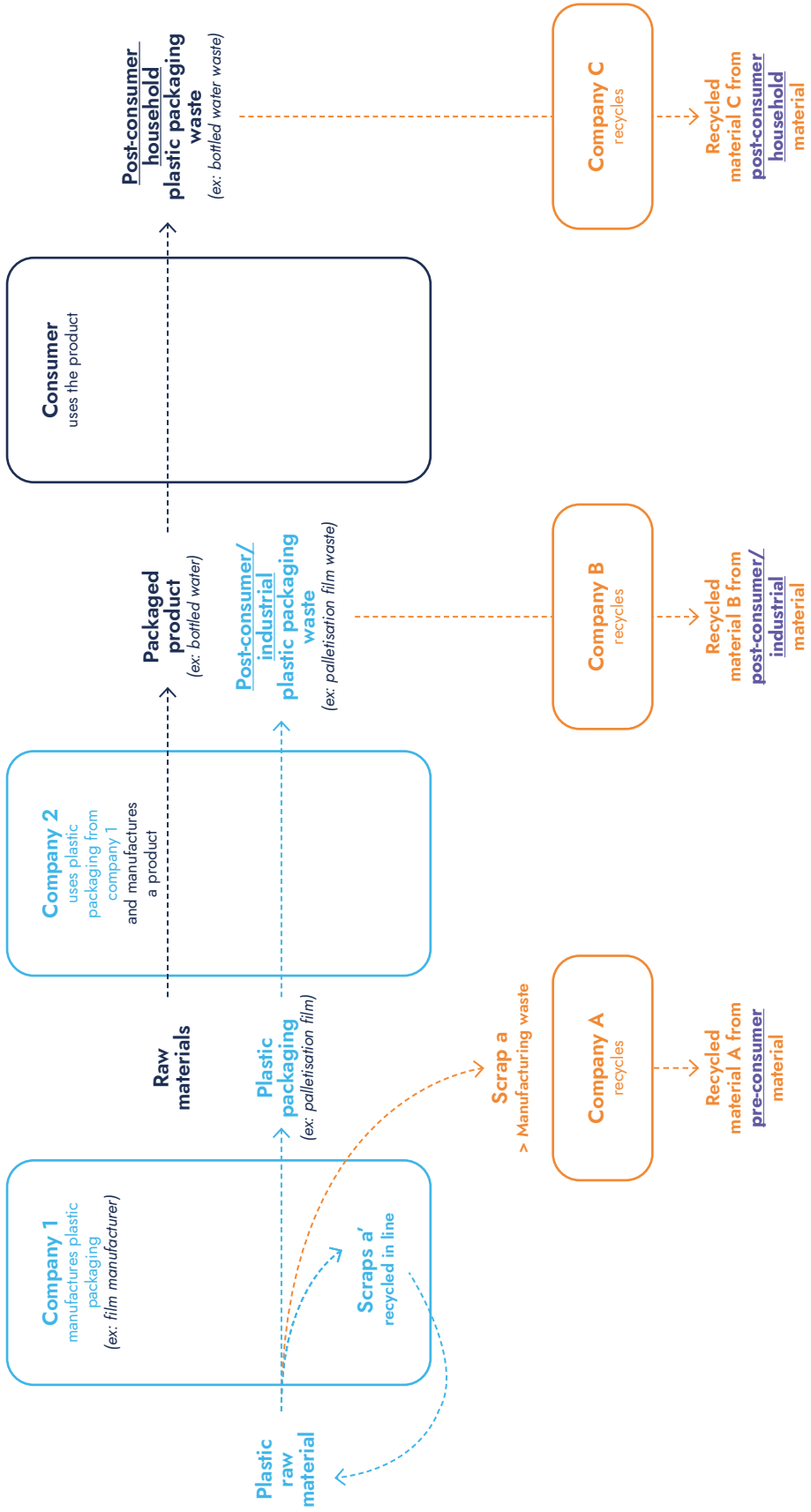
Diagram showing the different ways in which recycled material can be incorporated into cosmetic packaging



*according to the toxicologist's assessment depending on the application considered (see Section 1.E on EFSA/FDA differences).

ANNEX B

ELIPSO diagram "Types of recycled materials according to their origin"



ANNEX C

Processes with a positive opinion from the EFSA (other than PET)

Extraction from the EFSA database on polyolefins as at 14 June 2021

Source: www.efsa.europa.eu, keyword used: RECYCL – extraction des avis scientifiques uniquement

Process Name	EC Number	Type of resin/ product	Closed Loop	Restriction(s) on Use	Link to the EFSA document
Petra Polimeri	RECYC089	PP trays and inserts	YES	used at up to 30% with virgin PP to make new recycled trays in contact with whole fresh fruit and vegetables at room temperature or below	efsa.europa.eu/en/efsajournal/pub/3780
Morssinkhof Plastics	RECYC0142	HDPE or PP crates, boxes, trays, pallets and containers	YES	used in contact with dry foods, fruit and vegetables, pre-packaged and unpackaged meat	efsa.europa.eu/en/efsajournal/pub/5117
INTERSEROH Step 1	RECYC069	PP trays	YES	used in contact with whole fruit and vegetables	efsa.europa.eu/en/efsajournal/pub/2912
INTERSEROH Step 2	RECYC070	PP trays	YES	used in contact with whole fresh fruit and vegetables at room temperature or below	efsa.europa.eu/en/efsajournal/pub/3308
PP crates CHEP	RECYC003	PP trays	YES	used in contact with whole fruit, vegetables and pre-packaged meat	efsa.europa.eu/en/efsajournal/pub/1929
Pokas Arcadian Recycle Ltd	RECYC130	PP and HDPE food packaging	YES	various food packaging	efsa.europa.eu/en/efsajournal/pub/4583
Schoeller Arca Systems	RECYC075	PP and HDPE trays	YES	used in contact with meat, whole fruit and vegetables at room temperature or below	efsa.europa.eu/en/efsajournal/pub/3187
CO.N.I.P.	RECYC040	PP and HDPE trays	YES	used in contact with whole, unpeeled fruit and vegetables at room temperature or below	efsa.europa.eu/en/efsajournal/pub/3157
CLRrHDPE et Biffa Polymers		HDPE bottles and PP trays	YES	trays used in contact with raw, unpeeled fruit, vegetables and mushrooms for storing, at room temperature or below	efsa.europa.eu/en/efsajournal/pub/4016

ANNEX D

Extract from Annex 6 of the Cosmetics Europe advisory document (June 2019)

Comparison of consumer exposure scenarios between food packaging and cosmetic packaging

It is reasonable to assume that consumer exposure to the same substance from a cosmetic, typically by absorption through the skin, is not intrinsically more hazardous than exposure from food, typically by ingestion (except potentially for skin sensitisation, see below).

Thus, any difference in risk from food packaging vs. cosmetic packaging will arise from differences in exposure between these uses. The calculation of exposure to substances in food contact materials is based on the assumption of a consumer eating each day 1 kg of a food packed in 6 dm^2 of a particular material. Cosmetic packs tend to be much smaller than food packs and hence may have a higher surface area to weight ratio than 6 dm^2/kg. However, the usage of cosmetics is much lower, the generally accepted figure being 17,4 g of cosmetics rather than 1 kg of food per consumer per day (SCCS Notes of Guidance for testing of cosmetic substances and their safety evaluation, 8th Revision 2012, SCCS/1501/12).

As a common worst case of a high surface area to weight ratio, a 40 mm x 70 mm sachet could contain 2 g of product, giving a surface to volume ratio of 280 dm^2/kg. The consumer using 17.4 g of this product would, in theory, be exposed to migration from 280 x 0.0174 = 4,9 dm^2 of packaging. This is still less than their exposure from 6 dm^2 of food packaging.

On this basis, it is reasonable and conservative to consider that the surface area's to be used in consumer exposure scenarios are comparable for food packaging and for cosmetics. Furthermore, systemic availability of substances in food via the oral route is typically higher than availability of dermally applied substances.

ANNEX E

Bibliographical sources relating to the list of markers (control contaminants)

Name	CAS Number	Bibliographical Source
Limonene	5989-27-5	Published: Bayer, 2002; Franz et al., 2004; Nerin et al., 2003; Triantafyllou et al., 2002. Internal research: confidential industrial document. Camacho and Karlsson, 2000 Bayer, 2002 Smither Rapra, 2014.
Bis(2-ethylhexyl) phthalate (DEHP)	117-81-7	Keresztes et al., 2013; WRAP, 2012, internal research: confidential industrial document, 2019.
Tris(2,4-di-tert-butylphenyl) Phosphite : Irgafos 168 and their degradation products in recycled polyolefins or Irganox® 1010 and their degradation products in recycled polyolefins	31570-04-4 or 6683-19-8	Coulier et al., 2007), WRAP, 2012. Internal research: confidential industrial document, 2019, 2011a, 2021b.
2,4-dimethyl benzaldehyde	15764-16-6	Internal research: industrial document confidential, 2019 (2019), WRAP (2012).
n-Hexyl salicylate, isopropyl myristate	6259-76-3 110-27-0	Internal research: industrial document confidential, 2019 (2019, 2021a, 2021b), WRAP (2010).
Toluene	108-88-3	Franz et al (2004a, 2004b).
Aniline and 4,4'-diaminodiphenylmethane	62-53-3, 101-77-9	Fávaro Perez (2019) Padula.
Benzophenone	119-61-9	Geueke et al. (2018), WRAP (2010).
Tinuvin® 328 (2-(benzotriazol-2-yl)- 4,6-bis (2-methylbutan-2-yl)phenol)	25973-55-1	Dutra et al. (2014), Smithers Rapra (2014).

Other Sources

Confidential work by a group member, NIAS Testing report, 2019.

Confidential work by a group member, NIAS Testing report, 2020.

Bayer F, 2002. *Polyethylene terephthalate recycling for food-contact applications: testing, safety and technologies: a global perspective. Food Additives and Contaminants, Vol. 19, Supplement, 111-134.*

Camacho, W., Karlsson, S., 2000. *Quality-determination of recycled plastic packaging waste by identification of contaminants by GCeMS after microwave assisted extraction (MAE). Polym. Degrad. Stabil. 71 (1), 123-134.*

Coulier, L., Orbons, H.G.M., Rijk, R., 2007. *Analytical protocol to study the food safety of (multiple-) recycled high-density polyethylene (HDPE) and polypropylene (PP) crates: influence of recycling on the migration and formation of degradation products. Polym. Degrad. Stabil. 92 (11), 2016-2025.*

Dutra, C., Pezo, D., Freire, M.T.D., Nerin, C., Reyes, F.G.R., 2011. *Determination of volatile organic compounds in recycled polyethylene terephthalate and high density polyethylene by headspace solid phase microextraction gas chromatography mass spectrometry to evaluate.*

Dutra et al (2014). *Migration of Residual Nonvolatile and Inorganic Compounds from Recycled Post- Consumer PET and HDPE. J. Braz. Chem. Soc., Vol. 25, n°4, 686-696, 2014.*

Ericksen et al (2018). *Contaminants in plastic recycling: influence of metals on the quality of reprocessed plastics. Waste Management Volume 79, Sept 2018, pp:595-606.*

Franz R., Bayer F. and Welle F., 2004a: *Guidance and Criteria for Safe Recycling of Post-Consumer Polyethylene Terephthalate into New Food Packaging Applications. Report EUR 21155 - Luxembourg: Office for Official Publications of the European Communities ISBN 92-894-6776-2; cpf.jrc.it.*

Franz R, Mauer A and Welle F, 2004b. *European Survey on Post-consumer Poly(ethylene terephthalate) Materials to Determine Contamination Levels and Maximum Consumer Exposure from Food Packages Made from Recycled PET. Food Additives and Contaminants 21 (3), 265 – 286 (2004).*

Geueke et al. (2018) *Food packaging in the circular economy: Overview of chemical safety aspects for commonly used materials. Journal of Cleaner Production 193 (2018) 491e505.*

Incarnato, L., Di Maio, L., Acierno, D., Denaro, M., Arrivabene, L., 1998. *Relationships between processing-structure-migration properties for recycled polypropylene in food packaging. Food Addit. Contam. 15 (2), 195-202.*

Kroes et al. (2007). *Application of the threshold of toxicological concern (TTC) to the safety evaluation of cosmetic ingredients. Food Chem Toxicol 2007 Dec;45(12):2533-62.*

Nerin, C., Albinana, J., Philo, M.R., Castle, L., Raffael, B., Simoneau, C., 2003. *Evaluation of some screening methods for the analysis of contaminants in recycled polyethylene terephthalate flakes. Food Addit. Contam. 20 (7), 668e677.*

OSHA comments from the January 19, 1989 Final Rule on Air Contaminants Project extracted from 54FR2332 et Seq. (www.cdc.gov : Niosh > OSHA).

Perez, M. Â. F. et al. *Primary Aromatic Amines in Kitchenware: Determination by Liquid Chromatography-Tandem Mass Spectrometry, Journal of Chromatography A 2019, 1602, 217–227.*

Pivnenko et al. 2016a. *Recycling of plastic waste: Presence of phthalates in plastics from households and industry. Waste Manag. 2016 Aug;54:44-52.*

Pivnenko K., 2016. *Waste material recycling: Assessment of contaminants limiting recycling. Department of Environmental Engineering, Technical University of Denmark (DTU).*

Puype, F., Samsonek, J., Knoop, J., Egelkraut-Holtus, M., Ortlieb, M., 2015. *Evidence of waste electrical and electronic equipment (WEEE) relevant substances in polymeric food-contact articles sold on the European market. Food Addit. Contam. A. 32 (3), 410e426.*

Samsonek, J., Puype, F., 2013. *Occurrence of brominated flame retardants in black thermo cups and selected kitchen utensils purchased on the European market. Food Addit. Contam. A. 30 (11), 1976e1986.*

Simoneau C, van den Eede L, Valzacchi S (2012) *Identification and quantification of migration of chemicals from plastics baby bottles used as substitutes for polycarbonate. Food Additives and Contaminants, 2012, pp.1. ff10.1080/19440049.2011.644588ff. ffhal-00777735.*

Smithers Rapra and Smithers Pira, 2014. FS241007. *Final report; Develop a post-market test for recycled food contact materials.*

WRAP (2010) Final report. Scoping study into food grade polypropylene recycling Project code: MDP027.

WRAP (2012) Final report. Food grade decontamination trials of household PP waste. Project code IMT003-101.

Welle, F., 2005. *Post-consumer contamination in high-density polyethylene (HDPE) milk bottles and the design of a bottle-to-bottle recycling process. Food Addit. Contam. 22 (10), 999e1011.*

Wid, H., Leufv, A., Nielsen, T., 2005. *Identification of chemicals, possibly originating from misuse of refillable PET bottles, responsible for consumer complaints about off-odours in water and soft drinks. Food Addit. Contam. 22 (7), 681e692.*

Whitt, M., Brown, W., Danes, J.E., Vorst, K.L., 2016. *Migration of heavy metals from recycled polyethylene terephthalate during storage and microwave heating. J. Plast. Film Sheet 32 (2), 189e207.*

Whitt, M., Vorst, K., Brown, W., Baker, S., Gorman, L., 2013. *Survey of heavy metal contamination in recycled polyethylene terephthalate used for food packaging. J. Plast. Film Sheet 29 (2), 163e173.*

WRAP (2011) Final report. Development of a Food-Grade Recycling Process for Post-Consumer Polypropylene Project code: MDP039.

Photo credits: Freepik - **Production:** Apocope - March 2024 — Version 2 - **English translation:** Heloïse Prieur

elipso

FEBEA
FÉDÉRATION DES
ENTREPRISES DE LA BEAUTÉ