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GUIDANCE

Scientific Guidance on the criteria for the evaluation and on the preparation of applications for the safety assessment of post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food

EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) | Claude Lambré | José Manuel Barat Baviera | Claudia Bolognesi | Andrew Chesson | Pier Sandro Cocconcelli | Riccardo Crebelli | David Michael Gott | Konrad Grob | Marcel Mengelers | Alicja Mortensen | Gilles Rivière | Inger-Lise Steffensen | Christina Tlustos | Henk Van Loveren | Laurence Vernis | Holger Zorn | Vincent Dudler | Maria Rosaria Milana | Constantine Papaspyrides | Maria de Fátima Tavares Poças | Gianluca Colombo | Daniele Comandella | Alexandros Lioupis | Remigio Marano | Irene Pilar Munoz Guajardo | Elisa Savini | Vasiliki Sfika | Emmanouil Tsochatzis | Katharina Volk | Evgenia Lampi

Correspondence: fip@efsa.europa.eu

Abstract

In the context of entry into force of Regulation (EU) 2022/1616, EFSA updated the scientific guidance to assist applicants in the preparation of applications for the authorisation or for the modification of an existing authorisation of a 'post-consumer mechanical PET' recycling process (as defined in Annex I of Regulation (EU) 2022/1616) intended to be used for manufacturing materials and articles intended to come into contact with food. This Guidance describes the evaluation criteria and the scientific evaluation approach that EFSA will apply to assess the decontamination capability of recycling processes, as well as the information required to be included in an application dossier. The principle of the scientific evaluation approach is to apply the decontamination efficiency of a recycling process, obtained from a challenge test with surrogate contaminants, to a reference contamination level for post-consumer PET, set at 3 mg/kg PET for a contaminant resulting from possible misuse. The resulting residual concentration of each surrogate in recycled PET is then compared to a modelled concentration in PET that is calculated using generally recognised conservative migration models, such that the related migration does not give rise to a dietary exposure exceeding 0.0025 µg/kg body weight (bw) per day. This is the lowest threshold for toxicological concern (TTC) value, i.e. for potential genotoxicity, below which the risk to human health would be negligible. The information to be provided in the applications relates to: the recycling process (i.e. collection and pre-processing of the input, decontamination process, post-processing and intended use); the determination of the decontamination efficiency by the challenge test; the self-evaluation of the recycling process. On the basis of the submitted data, EFSA will assess the safety of the mechanical PET recycling process.

KEYWORDS
applications, evaluation principles, guidance, mechanical PET recycling, post-consumer, safety assessment

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1 | INTRODUCTION

1.1 | Background and Terms of Reference

Background

Recycled plastic must comply with Article 3 of Regulation (EC) 1935/2004[1]. To this end, Regulation (EC) No 282/2008[2] required that recycled plastics used to manufacture materials and articles intended for food contact are obtained only from processes authorised by the Commission, following a safety assessment performed by EFSA. EFSA consequently published guidelines on recycling of plastics (EFSA, 2008) and criteria for the safety evaluation of poly(ethylene terephthalate) (PET) recycling processes (EFSA CEF Panel, 2011), setting out requirements for the technical information to be supplied within an application for the authorisation of a recycling process and principles for evaluating mechanical PET recycling processes, respectively.

On 10 October 2022, Regulation (EU) 2022/1616[3] entered into force, providing a new legal basis for recycled plastic materials and articles intended to come into contact with foods and repealing Regulation (EC) No 282/2008, and introducing new definitions (Article 2 of Regulation (EU) 2022/1616).

Article 18 of Regulation (EU) 2022/1616 defines a procedure for EFSA to provide an opinion as to whether a recycling process is capable of applying a suitable recycling technology so that plastic materials and articles manufactured with it meet Article 3 of Regulation (EC) No 1935/2004 and are microbiologically safe. In addition, Article 17 sets out the procedure on the preparation of applications for the authorisation of recycling processes, including requirements for the content of the technical dossier to be submitted by an applicant.

In the context of Regulation (EU) 2022/1616 and on the basis of the EFSA evaluations of applications for authorisations submitted in accordance with Regulation (EC) No 282/2008, post-consumer mechanical PET recycling is considered as a suitable recycling technology for which recycling processes are subject to individual authorisations (Annex I, Table 1 of Regulation (EU) 2022/1616).

According to Article 20 of Regulation (EU) 2022/1616:

'1. The Authority shall publish detailed guidance, following the agreement with the Commission, concerning the preparation and the submission of the application, taking into account standard data formats, where they exist in accordance with Article 39f of Regulation (EC) No 178/2002, which shall apply mutatis mutandis.

2. For each suitable recycling technology for which the authorisation of individual recycling processes is required, the Authority shall publish scientific guidance describing the evaluation criteria and the scientific evaluation approach it will use to evaluate the decontamination capability of those recycling processes. The guidance shall specify the information required to be included in an application dossier for the authorisation of a recycling process applying that specific technology.'

It is, therefore, appropriate to elaborate a scientific guidance specifically for post-consumer mechanical PET recycling processes.

Terms of Reference

The CEP Panel is requested by EFSA to prepare a scientific guidance on post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food.

To this end, the previously published scientific opinions providing the context for the evaluation of recycling processes (i.e. guidelines on recycling plastics (EFSA, 2008) and criteria for safety evaluation of PET recycling processes (EFSA CEF Panel, 2011)) should be

- updated, taking into account the new legislative context of Regulation (EU) 2022/1616 as well as new scientific evidence, if available, and
- integrated into one scientific guidance specifically for post-consumer mechanical PET recycling processes, presenting and discussing the evaluation criteria and the scientific evaluation approach that will be used to evaluate the decontamination capability of such recycling processes as well as requirements for the content of the technical dossier.

The task should be completed by 30 June 2024.

[1]Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17.

[2]Commission Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006. OJ L 86, 28.3.2008, p. 9–18.

[3]Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008. C/2022/6146. OJ L 243, 20.9.2022, p. 3–46.

2 | SCOPE OF THE GUIDANCE

According to Article 2(3)1 of Regulation (EU) 2022/1616, a 'recycling technology' is defined as 'a specific combination of physical or chemical concepts, principles and practices to recycle a waste stream of a certain type and collected in a certain way into recycled plastic materials and articles of a specific type and with a specific intended use, and includes a decontamination technology'.

A recycling process is defined as 'a sequence of unit 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' (Article 2(3)3 of Regulation (EU) 2022/1616; see Figure 1).

According to Article 7(3a) of Regulation (EU) 2022/1616, the decontamination installation (i.e. specific equipment operating a decontamination process) shall be 'located at a single recycling facility, which is organised so as to ensure that no new contamination of recycled plastic or recycled plastic materials and articles can occur'.

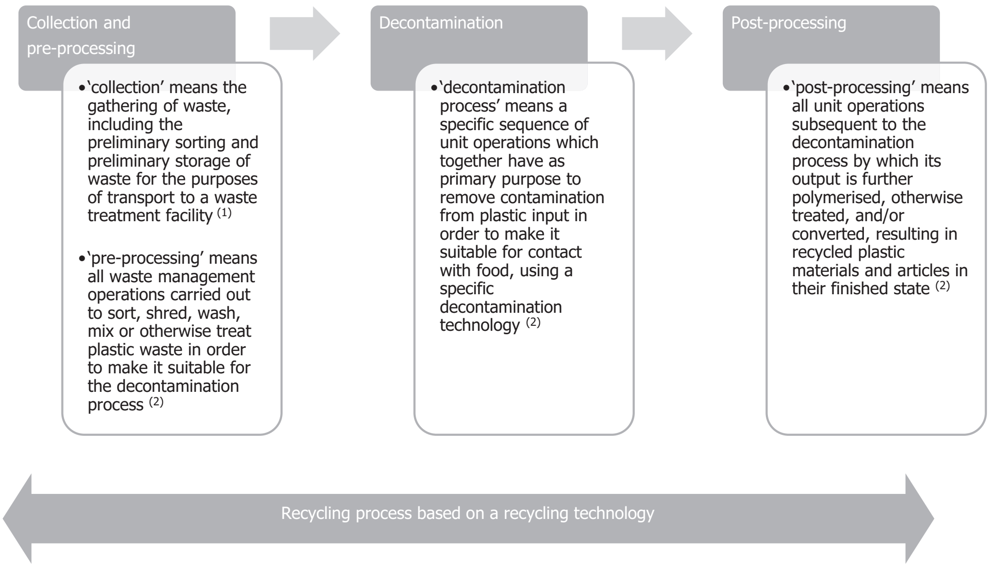

FIGURE 1 Overview of the three stages of a recycling process, including the definition of the stages as laid down in (1) Directive 2008/98/EC[4] on waste and (2) Commission Regulation (EU) 2022/1616.

This specific guidance document focuses on individual processes related to the suitable technology 'post-consumer mechanical PET recycling' as defined in Annex I, Table 1 of Regulation (EU) 2022/1616 (recycling technology number 1). Some of the specifications of this suitable technology are shown in Table 1.

TABLE 1 Definition of the suitable technology 'post-consumer mechanical PET recycling', adapted from Annex I, Table 1 of Regulation (EU) 2022/1616.

Polymer type	Short description of the recycling technology	Specification of plastic input	Specification of output	Subject to the authorisation of individual processes	Recycling scheme applies
PET	Mechanical recycling	Only PET PCW containing maximum 5% of materials and articles that were used in contact with non-food materials or substances	Decontaminated PET, final materials and articles not to be used in microwave and conventional ovens; additional specifications may apply to output from individual processes	Yes	No

Abbreviations: PCW, post-consumer waste; PET, polyethylene terephthalate.

According to Article 17(1), in order to obtain an authorisation for an individual recycling process based on the technology 'post-consumer mechanical PET recycling', an application shall be submitted by a natural person or legal entity ('applicant') that developed the decontamination process of the recycling process, either exclusively for its own purposes as a recycler or for the sale or licensing of recycling or decontamination installations to recyclers.

[4]Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives. OJ L 312, 22.11.2008, p. 3–30.

Moreover, if a recycling process is already authorised, the authorisation holder may apply for a modification of the authorisation of a recycling process (Article 22). In that case, the application shall be accompanied, among others, by a technical dossier containing the information required in Article 17(5).

The aim of this guidance document is to set out

- the evaluation criteria and the scientific evaluation approach for post-consumer mechanical PET recycling processes (Section 4),[5] and
- the requirements for the content of the technical dossier for post-consumer mechanical PET recycling processes that applicants should submit as part of their initial application for authorisation or in an application for modification of an authorisation of a recycling process (Section 5).[6]

For information regarding the administrative aspects of preparing an application for the authorisation or modification of authorisation of post-consumer mechanical PET recycling processes, EFSA's 'Recycling processes – Administrative guidance' should be consulted (EFSA, 2024).

The draft scientific guidance underwent a targeted and a public consultation from 13 December 2023 to 11 January 2024 and 07 February to 20 March 2024, respectively. The comments received and how they were taken into account when finalising the scientific guidance are published as Annex B of this output.

3 | LITERATURE REVIEW

This guidance document has been developed taking into account the latest scientific evidence produced since 2011, date in which the criteria for the safety evaluation of PET were first published (EFSA CEF Panel, 2011).

In order to investigate whether new data/information of relevance for the safety evaluation of mechanical PET recycling have become available since the publication of the criteria (EFSA CEF Panel, 2011), a literature review has been conducted. Details on the search strategy and the review process are outlined in Annex A. Relevant studies retrieved during the review have been reported throughout Sections 4 and 5 and/or related Appendices.

4 | CRITERIA FOR THE EVALUATION OF POST-CONSUMER MECHANICAL PET RECYCLING PROCESSES

4.1 | General principles for the safety assessment of recycled plastics for manufacturing materials and articles intended for contact with food

PET is characterised by the use of a limited range of additives and a low diffusion of potential migrants into and from the polymer matrix. It is, by far, the worldwide most frequently recycled polymer for food contact uses. Consequently, most knowledge on mechanical recycling exists for PET, which facilitated developing specific criteria to evaluate its recycling.

The health risks associated with the use of recycled plastic materials and articles in contact with food arise from the possible migration into the packaged food of contaminants present in the recycled plastics. In the case of recycled PET, the following sources of contamination have to be considered:

a. Contaminants from possible misuse.[7]
b. Non-authorised monomers and additives. Regulation (EU) 2022/1616 requires that plastic materials used as input in recycling processes are manufactured in accordance with the Community legislation on plastic food contact materials (FCM) and articles, i.e. their composition should comply with Regulation (EU) No 10/2011.
c. Contaminants from commercial non-food PET consumer applications, such as cosmetics, personal hygiene products or household cleaner.
d. Materials and articles other than PET, such as poly(vinyl chloride) (PVC), polycarbonate, styrenics, polyolefins and glues from caps, sleeves or labels, or polyamides from multilayered materials. Their presence results from incomplete sorting and separation and may introduce contaminants as such (either from the materials and articles or from substances contained in them).
e. Degradation products. During the various steps of the recycling process, especially at high temperature treatments, the polymeric chain may break down to smaller molecules. Additives as well as contaminants from other sources (e.g. non-PET plastics) may react and form new compounds.
f. Other materials and chemicals present in the waste collection.
g. Components from the food previously packaged in the PET containers.
h. Chemicals introduced in the recycling process, such as detergents and alkali used for washing.

[5] Updated version of the criteria for safety evaluation of PET recycling processes (EFSA CEF Panel, 2011).

[6] Updated version of the guidelines on recycling plastics (EFSA, 2008).

[7] Food-contact PET containers are 'misused' when filled with, e.g. household chemicals, fuels or similar, leading to potential contamination of PET to be recycled.

Chemicals in the recycled plastic are of concern, if they migrate into the food in amounts which could endanger human health. Taking into account the above-mentioned potential sources of contamination, it must be demonstrated that the recycling process is capable of applying the suitable technology for PET so that plastic materials and articles manufactured with it meet Article 3 of Regulation (EC) No 1935/2004, i.e. they do not transfer their constituents to food in quantities which could (a) endanger human health, (b) bring about an unacceptable change in the composition of the food and (c) bring about a deterioration in the organoleptic characteristics thereof, and are also microbiologically safe.

The quality of the input, the efficiency of the recycling process to remove contaminants and the intended uses of the recycled plastic are crucial aspects for the safety assessment. Therefore, the control of the pre-established specifications of the input, in the frame of a process management under adequate good manufacturing practices, is mandatory to set and to maintain the compliance of the recycled product.

The efficiency of the recycling process is determined experimentally by a so-called challenge test. The objective of this test is to challenge a recycling process or its parts relevant for the decontamination, with respect to its ability to reduce possible contamination, irrespective of the source of the contamination. To this end, plastic is contaminated with model chemicals selected as surrogate contaminants and then introduced into the recycling process. The residual concentration of the surrogate contaminants after the process is determined and used for estimating the decontamination efficiency of the recycling process for these surrogates.

For the safety assessment, the decontamination efficiency of the process needs to be assessed against a reference input contamination level and the potential migration of residual contaminants from recycled articles into the intended foods. The aim of this section is to present the evaluation procedure for this particular safety assessment concept.

4.2 | Principles of the evaluation scheme

The underlying principle of the evaluation is to apply the measured decontamination efficiency, obtained from a challenge test, to a conservative reference contamination level for misuse contaminants in order to calculate the residual concentration of potential contaminants in recycled PET (Cres). Cres for each surrogate is then compared to a modelled concentration in PET (Cmod), calculated using generally recognised conservative migration models. Cmod corresponds to a migration that is not expected to give rise to a dietary exposure exceeding the threshold below which the risk to human health would be negligible.

Therefore, when Cres is lower or equal than Cmod, the process is considered able to produce an output which is not of safety concern for the defined conditions of use.

4.3 | Reference contamination level of the input

4.3.1 | Contamination levels of post-consumer PET bottles from food contact use

To establish a reference contamination level of the recycling input, several studies investigating to which extent and at which frequency collected PET may be contaminated were identified and examined. In this section, focus will be laid on the study that is used as the basis for the reference contamination level (see Section 4.3.2); details on other studies falling into the context of contamination of post-consumer PET from food contact use are reported in Appendix A.1.

At European level, the EU project FAIR-CT98-4318 'Recyclability' provided sufficient statistical data to estimate average contamination levels in collected PET and the incidence of severe contamination cases. In this study, washed and dried post-consumer PET flakes obtained from thousands of soft drink bottles collected in 12 European countries were analysed (European Commission, 2004; Franz et al., 2004). As the most typical post-consumer contaminant, limonene (the main odour constituent of citrus fruits, also present in many household cleaning products) was found at an average concentration of 2.9 mg/kg and at a maximum of about 20 mg/kg. Miscellaneous contaminants related to plastics, such as adipates, phthalates and erucamide, occurred sporadically and at concentrations lower than 0.2 mg/kg, except for one case – dioctyl adipate – at 0.5 mg/kg.

4.3.2 | Derivation of a reference contamination level from misuse of food contact PET articles

Since there were no recent relevant studies on the contamination levels of post-consumer PET bottles for the European market, the Panel still considered appropriate to base the reference contamination level on data from the EU survey, project FAIR-CT98-4318 (European Commission, 2004; Franz et al., 2004). According to the EU survey of the project FAIR-CT98-4318, the highest misuse contamination levels in three cases of washed and dried PET flakes were found for two chemicals: toluene and xylene. By attributing them to three different recycled PET bottles, the authors estimated that these contamination levels were in the range of 2000–3000 mg/kg (xylene), 2000–3000 mg/kg (toluene) and 4500–6750 mg/kg (toluene) for the three bottles, respectively. As the total number of bottles was around 7000–10,000, the percentage of bottles contaminated by misuse was estimated to be 0.03%–0.04%.

Taking into account the dilution effect deriving from the high amount of non-misused bottles, the authors estimated that the highest concentrations of toluene in the recycling feedstock would have been ranging from 1.4 to 2.7 mg/kg PET.

This calculation was done by attributing the incidence of the misused bottles (0.03%–0.04%) to the highest estimated levels of contamination (toluene in the range of 4500 to −6750 mg/kg PET). Therefore, on the basis of the available data, these figures were used to derive the potential concentration of a single substance in post-consumer PET due to misuse by consumers for the purpose of these evaluation criteria.

Thus, the Panel concluded that the evaluation criterion to be used as the reference contamination level for misuse for individual substances in the input of a mechanical PET recycling process is set at 3 mg/kg PET, corresponding to the rounded worst-case figure obtained from the experimental data.

Having reviewed the available data (see Appendix A.1), the Panel concluded that it cannot be assumed that the contamination of non-EU input is equivalent to EU input. However, in the absence of reliable data and taking into account the conservatism in the assumptions used (Section 4.4.3), the Panel decided to continue using the reference contamination level of 3 mg/kg as basis for evaluating mechanical PET recycling processes independent of the origin.

4.3.3 | Considerations for the presence of PET containers from non-food contact applications in the collected PET

In collection systems of post-consumer PET, a percentage of containers used for non-food applications, such as mouthwash, detergents, shampoos, household cleaning products, medicines, garden chemicals or DIY 'Do It Yourself'/ home improvement products (e.g. paint removers, furniture polish) can be present. The following aspects should be considered regarding the incorporation of non-food PET containers into the PET recycling streams:

(i) the PET used as input to recycling processes, independently of its geographical origin, must comply with the requirements set out in Article 6 and in Table 1 of Annex I of Regulation (EU) 2022/1616.
It was clarified by Plastics Europe that all grades of PET packaging resins sold by European manufacturers and placed on the EU market are food contact grades (Plastics Europe, 2010). In addition, Regulation (EU) 2022/1616 sets out that the plastic input for post-consumer mechanical PET recycling (recycling technology nr. 1 in Annex I of Regulation (EU) 2022/1616) may contain a maximum of 5% (w/w) of materials and articles that were used in contact with non-food materials or substances.

(ii) chemicals contained in non-food products may be absorbed by the PET container and introduce non-food substances into the recycling process. This case is different from misuse by the consumer and so some specific considerations are due. Studies reporting on the contamination of non-food contact articles are referenced in Appendix A.2.

The Panel considers that if the recycling process is shown (by the challenge test) to be able to remove surrogate contaminants, this applies to all possible contaminants represented by the surrogates, irrespectively of their origin. However, in any case, containers coming from non-food uses should not intentionally be included as input for the recycling stream. The Panel noted that, by establishing that the proportion of PET from non-food consumer applications should be no more than 5% in inputs from post-consumer collection systems, further conservatism is included in the evaluation criteria. By respecting this proportion, the highest average concentrations of 15 mg methyl salicylate/kg non-food PET containers (Bayer, 2002; referenced in Appendix A.2) and 20 mg 2-butanone/kg non-food PET containers (Franz and Welle, 2020; referenced in Appendix A.2) would have been reduced to levels below the reference contamination level for misuse (3 mg/kg).

High individual concentrations non-food PET containers were found for ethanol (440, 940 and 1110 mg/kg; Franz and Welle (2020) referenced in Appendix A.2). Taking into account a detection frequency of 8.3% (three out of 36 samples) and applying the threshold of maximum 5% non-food containers in the input stream, the contamination level would be at 4.5 mg/kg. The Panel considered that this is in the range of the reference contamination level of 3 mg/kg and further noted that ethanol exposure from recycling is expected to contribute negligibly to dietary ethanol intake (Reimann et al., 2023).

4.4 | Criterion of migration of potential contaminants

For the safety assessment, it has to be demonstrated that the recycling process is capable of applying the suitable recycling technology it uses so that plastic materials and articles manufactured with it are microbiologically safe and meet Article 3 of Regulation (EC) No 1935/2004, i.e. they do not transfer their constituents to food in quantities which could (a) endanger human health, (b) bring about an unacceptable change in the composition of the food and (c) bring about a deterioration in the organoleptic characteristics thereof. To this end, it has to be demonstrated that the dietary exposure via migration into food of a potential unknown contaminant does not exceed a level of dietary exposure below which the risk to human health would be negligible.

It is impossible to predict the identity of contaminants potentially present in post-consumer PET used as input of a recycling process and to ensure that they are not genotoxic. Therefore, a level of dietary exposure that can be considered of negligible risk to human health must take this possibility into account.

4.4.1 | Dietary exposure related to a negligible risk to human health

A human exposure threshold value has been developed to define an exposure level for chemicals with structural alerts that raise concern for potential genotoxicity, below which the probability for adverse effect for human health is negligible.[8] This threshold is 0.15 µg/person per day for a person of 60 kg body weight (bw), corresponding to 0.0025 µg/kg bw per day (EFSA Scientific Committee, 2019; Kroes et al., 2004). This threshold value is generally considered low enough to address concern over all toxicological effects.

As a pragmatic approach, the Panel considered that an unknown contaminant possibly present in PET feedstock has been sufficiently removed, if its residual concentration in the recycled PET cannot give rise to a migration in food that could result in a dietary exposure higher than 0.0025 µg/kg bw per day or 0.15 µg/per person per day for a person of 60 kg body weight. In this way, it is ensured that any unknown contaminant possibly present is treated in a conservative way.

The following considerations underline the conservatism of an intake up to 0.0025 µg/kg bw per day of any potential contaminant that may migrate from recycled PET:

- Genotoxic compounds are generally not allowed to be placed on the market in consumer products (European Commission, 2006) and, therefore, the probability of a contamination of the post-consumer PET by misuse with substances classified as genotoxic, if any, is low.
- Functional groups associated with genotoxicity of molecules are often highly reactive. If they were present, they would be expected to react in PET during the recycling process at high temperatures. This would decrease their potential residual concentration and, hence, their migration (AFSSA, 2006).

Some structural classes of substances were identified to be of such high potency that even dietary exposure below this threshold level would be associated with a high probability of a significant carcinogenic risk (Cheeseman et al., 1999; Kroes et al., 2004). These high potency genotoxic carcinogens comprise aflatoxin-like-, N-nitroso- and azoxy-compounds. However, none of them are likely to be available to consumers and therefore to become source of contamination (e.g. storing chemicals in post-consumer PET containers).

In case the applicant places no restriction in the use of the recycled PET, the Panel will apply the default scenario of infants (scenario A), since infants constitute the population group with the highest potential exposure. According to the EFSA Scientific Committee (2017), it is expected that infants are exclusively fed on breast milk and/or infant formula during the period from birth to 16 weeks. The Panel noted that in the latter case, reconstitution of the formula could take place with water that was packaged in a bottle or another container made of rPET, and therefore considered it appropriate to take this scenario into account as a source of infants' exposure to potential migrants. A consumption of 260 mL/kg bw per day (P95) is proposed for infants below 16 weeks of age (EFSA Scientific Committee, 2017). From this figure, it can be derived that the highest concentration of a substance in the water used for reconstitution that would ensure that the dietary exposure of 0.0025 µg/kg bw per day is not exceeded is 0.00962 µg/kg food (= ~ (0.0025 µg/kg bw per day)/(0.260 kg food/kg bw per day)).[9] For other population groups and/or food categories, the respective concentrations in food would be higher due to the lower food consumption per body weight (Appendix C).

4.4.2 | Calculation of migration criteria

In order to determine whether the recycling process results in material that meets the above dietary exposure criteria, the migration of potential residual contaminants is estimated by use of mathematical migration models (Begley et al., 2005; Hinrichs & Piringer, 2001; Hoekstra et al., 2015). These are based on the following principal assumptions: (1) the migration follows a diffusive process (Fick's law) and is not controlled by other kinetic steps; (2) the migrants are homogeneously distributed in the material; (3) their diffusion coefficients are estimated with a model that overestimates their migration (e.g. Piringer model); (4) the equilibrium solubility of the migrant in the material and the food is governed by the partition coefficient K, corresponding to high solubility in the food.

In PET, the migration calculated by generally recognised diffusion models (Hoekstra et al., 2015) overestimates the real migration. The degree of overestimation depends on the characteristics of the plastic, the migrant structure and the temperature during migration. Also, it increases with increasing molecular mass of the migrant.

[8]To cover the endpoint of cancer, a human exposure threshold value of 1.5 µg/person/day was derived by the US Food and Drug Administration (FDA) (Rulis, 1986, 1989, 1992) to be applied to substances that do not contain a structural alert for genotoxicity/carcinogenicity. The threshold value was derived by mathematical modelling of risks from animal bioassay data on over 500 known carcinogens, based on their carcinogenic potency. Assuming that only 10% of untested chemicals were carcinogenic, at this exposure level, 96% of the chemicals would pose less than 1 in a million lifetime risk for cancer (Munro, 1990; Barlow et al., 2001). In 1995, the FDA incorporated this threshold value in its TOR policy for substances present in FCM (FDA, 1995). Kroes et al. (2004) refined the threshold for the endpoint of cancer by deriving a value of 0.15 µg/person/day for substances with a structural alert for genotoxicity.

[9]In the previous version of the Scientific Opinion on the criteria for safety evaluation of PET mechanical recycling processes (EFSA CEF Panel, 2011), the exposure scenario for infants had been based on a consumption of 150 g/kg bw per day (derived from a daily consumption of 0.75 L water by an infant weighing 5 kg (WHO, 2003)). Since updated consumption figures for infants below the age of 16 weeks have been established by the EFSA Scientific Committee (2017), the CEP Panel decided to amend the food consumption for the infant scenario from 150 g/kg bw per day to 260 mL/kg bw per day.

On the basis of the available experimental data (Franz & Welle, 2008; Welle & Franz, 2008), the Panel calculated an overestimation factor of 5 for substances with a molecular mass around 150 Da and noted that higher overestimation factors should be applied for higher molecular mass substances migrating from PET. As the overestimation factor could not be estimated for each molecular mass due to the lack of robust experimental data, the Panel decided to apply a tiered approach, considering a factor of 5 for substances with a molecular mass less than or equal to 150 Da, and a factor of 10 for those over 150 Da.

This approach corrects the inherent flaw in the current migration model, while taking into account potentially highly migrating contaminants (i.e. substances with MW ≤ 150 Da). Regarding substances with molecular mass > 150 Da, the factor 10 reflects the increase of the overestimation factor due to higher molecular masses. The value of 10 is considered conservative enough to ensure that Cmod levels are not too high to underestimate contaminants likely to migrate.

The migration criterion for substances in food (or food simulant) satisfying the dietary exposure criterion for infants is calculated to be 0.0481 μg/kg (= 5 × 0.00962 μg/kg) or 0.0962 μg/kg (= 10 × 0.00962 μg/kg), according to the molecular mass of the migrant. The migration criterion figures will be used in the calculation of Cmod (see Appendix D). It should be noted that these figures (0.0481 or 0.0962 μg/kg food) are used for these calculations only and are not to be understood as migration limits.

To satisfy the evaluation criterion, the recycling process has to be demonstrated to be able to decontaminate the PET input material to a Cres not higher than the Cmod. Parameters and examples of calculation of the Cres and Cmod as well as a table with the Cmod values for the most commonly used surrogates in challenge tests are given in Appendix D.

The migration criteria obtained by assuming the related overestimation factors of 5 and 10 for the modelled migration and the exposure scenarios are reported in Table 2. Detailed calculations are available in Appendix C.

TABLE 2 Exposure scenarios with the related migration criteria.

Scenario	Food categories[a]	Food consumption (g/kg bw per day)	Migration criteria for substances ≤ 150 Da (μg/kg food)	Migration criteria for substances > 150 Da (μg/kg food)
A	1	260	0.0481	0.0962
B	2 and 3	80	0.156	0.312
C	4	20	0.625	1.250

[a]As defined in Table 1 of the scientific opinion on recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materEFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2016): (1) Water and baby bottle contents such as reconstituted milk formula; (2) Milk, other liquid milk-based products and other non-alcoholic drinks (e.g. fruit and vegetable juices); (3) Solid foods specifically intended for infant and toddlers; (4) Foodstuffs not covered by categories 1, 2 and 3.

4.4.3 | Considerations on the assumptions used, uncertainties and their likely impact

1. There are no recent surveys on the frequency and severity of the contamination of post-consumer PET waste streams other than the EU project FAIR-CT98-4318 (European Commission, 2004; Franz et al., 2004).
2. The migration model used is known to overestimate migration from PET because of the inbuilt conservative parameters (Hoekstra et al., 2015). The overestimation for small surrogate molecules, like toluene, is close to 5, and increases with the molecular mass of the substances. In the applied procedure, a factor of 5 is applied for surrogates with a molecular mass lower than or equal to 150 Da. For surrogates with a molecular mass greater than 150 Da, a factor of 10 is applied.
   In the scientific literature, other approaches[10] have been proposed to reduce the overestimation of the currently generally recognised model. These approaches are supported by different validation data, but so far none of the approaches has been included in the list of the generally recognised models (Hoekstra et al., 2015).
3. The migration calculations are based on the assumption that all food and drink consumed each day is in contact with PET consisting of 100% recyclate (unless stated otherwise) and has been in contact for 12 months at 25°C before consumption. These conditions of contact are, in most cases, conservative, since food/drinks will be consumed earlier.
   With regard to applications of rPET for microwave/oven uses, it is noted that the migration model results in high uncertainties at the high temperatures applied during such uses; therefore, they are excluded from the scope of the technology, as also indicated in Table 1 of Annex I of Regulation (EU) 2022/1616.
4. Taking into account the collection systems, the presence of possibly genotoxic contaminants in recycled PET, if any, is likely to be sporadic. A survey on the proportion of mutagens among a representative sample of chemicals indicated a prevalence of substances that are mutagenic in the Ames test of 22% (Zeiger & Margolin, 2000). This percentage will be an overestimate, considering the restricted access to genotoxic compounds (see Section 4.4.1). Therefore, the applied toxicological threshold based on chronic exposure to genotoxic substances is considered conservative.

Considering the points above, the Panel considered that, if the recycling process is able to reduce the reference contamination to a Cres less than or equal to a Cmod, the potential migration of contaminants does not give rise to a dietary

[10]Diffusion coefficients were calculated from the relationship between molecular volume and activation energy of diffusion (Welle, 2013; Ewender and Welle, 2014, 2022), from molecular dynamic simulation (Wang et al., 2010), from a probabilistic approach (Brandsch, 2017), and from optimal experimental design (Martinez-Lopez and Mauricio-Iglesias, 2022).

exposure exceeding the threshold of toxicological concern proposed by Kroes et al. (2004) for substances with a structural alert for genotoxicity.

4.5 | Application of the key parameters for the evaluation scheme

As reported in Section 4.2, the underlying principle of the evaluation is to apply the decontamination efficiency of a recycling process, measured by a challenge test with high contamination levels, to a conservative reference contamination level of 3 mg/kg PET in order to calculate Cres.

For the most conservative scenario, i.e. that for drinking water/infants (scenario A), for each surrogate in the recycled PET, Cres is compared to the corresponding Cmod leading to a migration criterion of 0.0481 or 0.0962 μg/kg food for MW ≤ 150 Da or > 150 Da, respectively, calculated under defined conditions of uses. Modelling parameters used to correlate Cmod with the migration criteria are reported in Appendix D.

When Cres is equal or below Cmod for each surrogate contaminant, it can be concluded that the migration of unknown contaminants in food will be below the conservatively modelled migration of 0.0481 or 0.0962 μg/kg food.

If Cres exceeds Cmod, due to the conservatism incorporated in many evaluation factors, the applicant can provide further information to prove the safety of the process or restrict the intended uses (e.g. by reducing the percentage of recycled PET in the final articles or choosing a different exposure scenario/food category, i.e. from scenario A to scenario B or C).

The relationship between the key parameters for the evaluation scheme, based on the example of exposure scenario A, is shown in Figure 2. The migration criteria for the other exposure scenarios (i.e. scenarios B and C) are described in Table 2 and in Appendix C. Cmod values for the surrogates commonly used in challenge tests and for all exposure scenarios are provided in Appendix D.

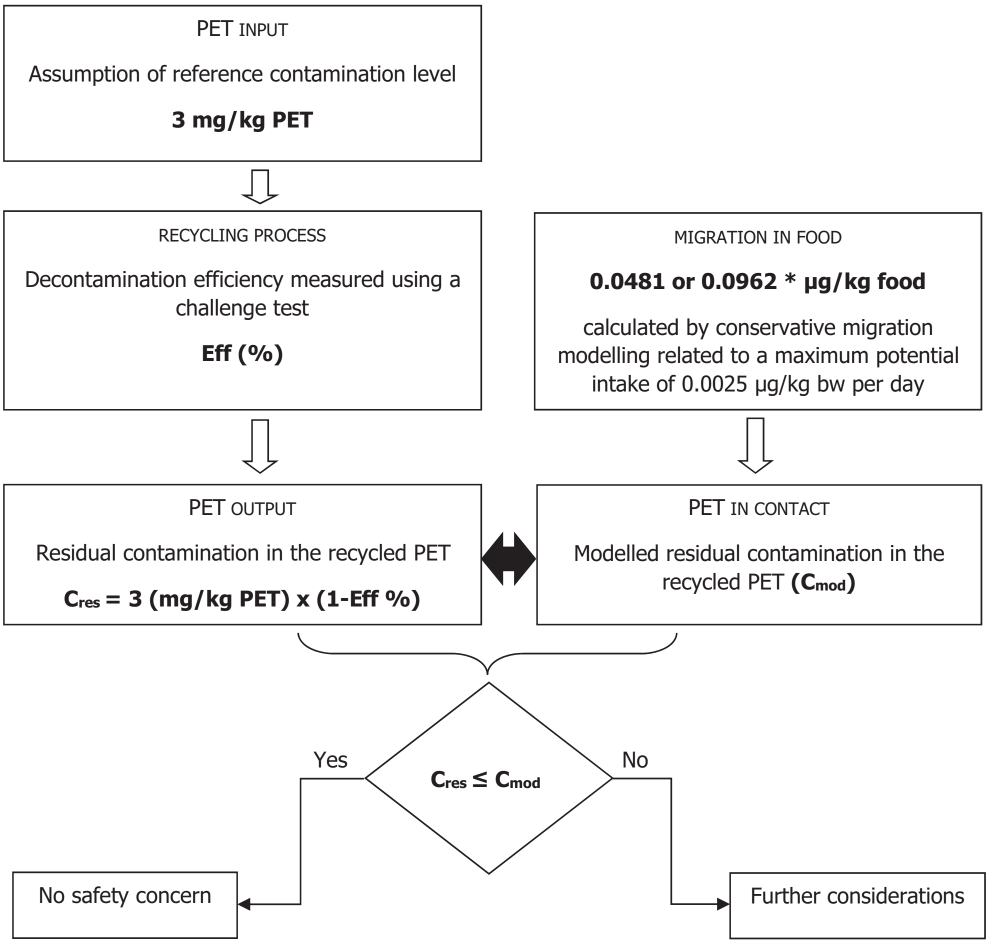

FIGURE 2 Example of the relationship between the key parameters for the evaluation scheme, based on the most conservative scenario A. The figures are derived from the application of the human exposure threshold value of 0.0025 μg/kg bw per day applying the factors of 5 and 10 related to the overestimation of modelling. *Depending on the molecular mass of the surrogate substance.

5 | CONTENT OF THE TECHNICAL DOSSIER FOR POST-CONSUMER MECHANICAL PET RECYCLING PROCESSES

As outlined in recital 25 of Regulation (EU) 2022/1616, ‘preparing an application for authorisation requires from the applicant an intricate knowledge of the recycling process concerned, and in order to avoid that several applications for the same recycling process are submitted, … only the business operator who developed the recycling process, and not any recycler using it, may apply for authorisation'.

The requirements for the content of the technical dossier described in the following sections are defined in line with Articles 6, 7, 8, 17(5) and 18(4) of Regulation (EU) 2022/1616.

The following sections lay out what information is expected to be contained in the technical dossier. If some of the data stipulated in the guidance are not considered by the applicant as relevant to a particular case, they may be omitted provided that the omission is fully scientifically justified.

5.1 | Recycling process

5.1.1 | Collection and pre-processing

The characteristics of the initial plastic input influence the final quality of the recycled material. Therefore, the upstream operations of collection and pre-processing of the waste material are essential to generate a plastic input suitable for the decontamination process.

In the following sections, the data requirements for the collection, pre-processing and specification of the pre-processed plastic input are laid out.

5.1.1.1 | *Collection*

The technical dossier should confirm that the collection of plastic waste will have to be conducted in line with Article 6 of Regulation (EU) 2022/1616.

The specific points for which a quality control procedure is required during collection have to be provided by the applicant.

In case additional details on the collection mode are available to the applicant (e.g. specific origin of waste, collection system), these should also be provided in the technical dossier.

5.1.1.2 | *Pre-processing*

A description of the pre-processing, i.e. 'waste management operations carried out to sort, shred, wash, mix or otherwise treat plastic waste in order to make it suitable for the decontamination process' has to be provided.

Where the decontamination process requires a special pre-treatment (apart from shredding, washing and drying) of the input and this is performed at facilities different from the decontamination facility (see also Section 2 for requirements related to the decontamination installation), more specific information on this pre-treatment should be provided.

Furthermore, the technical dossier should confirm that the pre-processing will have to meet the requirements laid down in line with Article 6 of Regulation (EU) 2022/1616.

Finally, the specific points for which a quality control is required during pre-processing have to be provided by the applicant.

In case any additional details on the pre-processing are available to the applicant, these should also be provided in the technical dossier.

5.1.1.3 | *Specification of the pre-processed plastic input*

In addition to the PET originating from post-consumer PET, the input may also contain materials and articles that were used in contact with non-food materials or substances and that were not removed completely during the steps of pre-processing. According to row 1 of Table 1 of Annex I of Regulation (EU) 2022/1616, the maximum amount of non-food contact PET is set to 5%. The technical dossier should confirm that the input will have to meet this requirement.

Specification of the pre-processed input with regard to at least the following parameters should be provided:

- Flake dimensions, such as range and average of thickness, size distribution. (These characteristics have to be covered by the input material used in the challenge test).
- Bulk density (range and average).
- Plastics other than PET, e.g. PVC, styrenics, polyamide, polyolefins, polycarbonate (taking into account potential degradation during recycling and further processing[11]).
- Glue.
- Other specification parameters, e.g. dust, moisture, metal, cellulose, if considered relevant for the proper functioning of the process.

[11]The input material of the decontamination process may contain materials and articles made of polymers other than PET that are not completely removed during preprocessing. At the high temperatures applied during recycling and further processing, these polymers may partially degrade to low and intermediate molecular mass products (e.g. benzene (see also Appendix A.3), styrene from styrenics and bisphenol A from polycarbonates). The decontamination process largely removes low molecular mass degradation products, but during further processing, they are likely to be formed again and, hence, to remain in the PET.

5.1.2 | Decontamination process

As a general prerequisite for the decontamination, the requirements in Article 7 of Regulation (EU) 2022/1616 apply.

5.1.2.1 | *Decontamination installation*

a. Equipment

The technical dossier shall contain a description of the equipment used in the unit operations (steps) of the decontamination process, with a clear identification and distinction of the steps from input to output. The design and assembly of the main and auxiliary equipment pieces (e.g. reactors, stirring systems, vessels, extruders, crystallisers, preheaters, pelletisers) should be described in detail and supported by technical drawings and photos.[12] Design details that may affect the parameters relevant for the decontamination efficiency should be specified.

In particular, the following aspects should be clearly addressed, and supported by data, where relevant:

- Brand name if any, version and date of introduction of the decontamination installation
- Principal function of the decontamination equipment part(s) (e.g. SSP reactor, extruder, preheater), type of reactor (e.g. stirring tank, fluidised bed, plug-flow), type of special extruders (e.g. extruders with planetary sections, satellite screws), type of special melt-polymerisation installations;
- Design and position of stirring tools; set-up of stirring system, including number and type of rotating tools, if any;
- Heating/cooling systems, vacuum or flowing gas, position and design of gas and vacuum ports, purification of circulated gases;
- Size of the equipment: dimensions and capacity for a given recyclate density for the various sizes brought to the market
    - A non-exhaustive list of examples of dimensions is shown below:
        - For a conventional reactor or vessel: e.g. cross section surface and height, stirrer length (if any).
        - For an extruder type reactor: e.g. screw(s) length and diameter, position of vacuum ports along the length of the extruder, as well as shape and dimensions of the die(s).
    - For a melt-polymerisation installation: e.g. diameter and number of any melt orifices (dies) as well shape and dimensions of any melt tanks used and of any moving blades into the melt.
    - In case other types of reactors/systems are used, the corresponding parameters should be provided.

b. Operation

The technical dossier shall contain information on the operation of all equipment parts belonging to the same process. It should also be provided for different installation sizes, if applicable. In particular, the following aspects should be clearly addressed in the technical dossier, and supported by data, where relevant:

- Operating parameters (e.g. residence time, temperature, pressure, gas flow rate);
- Operation mode (e.g. batch, continuous);
- Capacity, load and filling level;
- Throughput/discharge rate;
- Rotation parameters (e.g. rotation speed of stirrer, screw of special extruders, blades or drums in special installations);
- Geometrical dimensions (i.e. length and thickness) of the pellets formed and/or treated within the decontamination process;
- Temperature gradient along the axes of the reactor;
- Melt surface area exposed to the decontamination conditions;
- Considerations on the degree of mixing in the equipment.

The operating parameters of the steps of the decontamination process should be provided following the instructions laid down in the administrative guidance document (EFSA, 2024).

An identification of the critical steps of the decontamination process should be provided, together with an analysis of the possible consequences of an incidental failure of compliance of some critical parameters with pre-established values.

[12]Schemes, drawings, photos, etc., have to be provided with appropriate resolution and readability.

5.1.2.2 | *Quality control procedures*

According to Article 17(5)f of Regulation (EU) 2022/1616, the technical dossier shall contain a description of the quality control procedures applied at each unit operation of the decontamination process. In the context of the suitable technology 'post-consumer mechanical PET recycling', this requirement is interpreted as follows:

Applicants are not required to submit complete quality control procedures, as it is up to the recyclers to design, document and operate such procedures as appropriate for the use of their recycling installation(s) located at a specific recycling facility.

However, the dossier should highlight the specific points for which a quality control procedure is required to keep those parameters under control that are relevant to achieve sufficient and consistent decontamination.

In particular, laboratory procedures, procedures aiming at achieving compliance with critical parameters and actions carried out after deviations from critical operating parameters have occurred, which the applicant deems relevant, should be indicated.

5.1.2.3 | *Diagrams*

The following diagrams, in appropriate resolution and readability, have to be provided in the technical dossier:

- a simple block diagram of all unit operations used in the decontamination process that provides a reference to the input, output and quality control procedures applied by each operation (in line with Article 17(5)d of Regulation (EU) 2022/1616); and
- a piping and instrumentation diagram of the decontamination process in accordance with section 4.4 of ISO 10628-1:2014, showing only the instrumentation relevant for decontamination (in line with Article 17(5)e of Regulation (EU) 2022/1616).

As per Article 18(4) of Regulation (EU) 2022/1616, the process flow diagram shall be included in the opinion of EFSA. Therefore, the applicant should provide a process flow diagram of the decontamination process that discerns the order of the distinct unit operations […] and that schematically presents the set-up of the unit operations (in line with Article 18(4) d of Regulation (EU) 2022/1616). In case the diagram contains sensitive data/information, the applicant is requested to provide both a confidential and a non-confidential version.

5.1.2.4 | *Characterisation of the output*

It has to be indicated which types of output are obtained from the decontamination process, e.g. flakes, pellets, sheets.

Furthermore, specifications of the output on the intrinsic viscosity should be provided.

Other parameters should also be provided if considered relevant for the process.

5.1.3 | Post-processing and intended uses

After recycling, PET flakes or pellets are processed (post-processing) by converters into articles for final use. The recycled material may inherently have a restriction or limitation of use (e.g. max. % of recycled material in the article, type of food contact).

In the following sections, the data requirements for the post-processing, intended uses as well as instructions and labelling are laid out.

As a general prerequisite for post-processing, the requirements in Article 8 of Regulation (EU) 2022/1616 and in Annex I, Table 1, column 6 have to be met.

5.1.3.1 | *Post-processing*

A description of any required post-processing, i.e. 'all unit operations subsequent to the decontamination process by which its output is […] treated, and/or converted, resulting in recycled plastic materials and articles in their finished state' (Art 2.3(11) of Regulation (EU) 2022/1616), has to be provided. Examples of post-processing steps include pre-form injection and bottle blowing, sheet lamination and thermoforming into trays or cups, injection of articles.

5.1.3.2 | *Intended uses*

With regard to the intended uses of the recycled PET, information on the following aspects should be provided in the technical dossier:

- Type of final materials/articles, e.g. tray, bottles, films;
- Maximum percentage of recycled PET used for the final material/article;
- Type of intended food (including a statement on whether the recycled PET is intended for contact with drinking water or infant food): The applicant should choose among the scenarios indicated in Appendix C;
- Time and temperature conditions of the final use.

In case there are uses for which the recycled PET is not suitable, these also have to be indicated. Importantly, it should be noted that according to row 1 of Table 1 of Annex I of Regulation (EU) 2022/1616, the final materials and articles are not to be used in microwave and ovens.

5.1.3.3 | *Instructions and labelling to be provided to convertors and to end-users of the recycled plastic materials and articles*

Instructions and labelling that are relevant for the use of the recycled PET materials and articles by converters and end-users have to be listed, e.g. degree of needed mixing with virgin PET and restrictions in the conditions of use, e.g. not for microwave/oven use.

5.2 | Determination of the decontamination efficiency of the recycling process

To determine the decontamination efficiency of the recycling process, a specially designed experiment, called 'challenge test', shall be performed. For that purpose, the input PET is experimentally contaminated with selected substances (surrogates mimicking potentially occurring contaminants), before being submitted to the step(s) of the recycling process that is/are relevant for decontamination and that should be representative of the industrial process.

The surrogate concentrations are experimentally determined before and after decontamination and are used as a basis for deriving the decontamination efficiency (i.e. percentage of removal of the surrogates). The large majority of current industrial processes involves washed and dried flakes coming from PET bottles as input material. The use of other types of PET articles as input material is possible, but the representativeness for the industrial decontamination process must be considered. For instance, a challenge test can only cover recycling processes with input that has the same or lower thickness than the input used in the challenge test, provided that the decontamination step is performed on flakes. Relevant considerations supported by data are needed to demonstrate representativeness in other specific cases.

5.2.1 | Contamination procedure

The surrogates for the contamination of the post-consumer PET must mimic the physical and chemical properties of the potential contaminants, mainly their polarity and their molecular mass. These two parameters influence the affinity to the polymer, to the washing media and to the food, the migration rate and the volatility.

The surrogates used in the challenge test are substances with different molecular mass and polarity representative of all possible contaminants of concern (FDA, 2021; Pennarun et al., 2005). The set of surrogates generally used comprises toluene, chlorobenzene, chloroform, methyl salicylate, phenylcyclohexane, benzophenone and methyl stearate (Begley et al., 2002; FDA, 2021; Franz et al., 2004; Pennarun et al., 2005). It should be noted, however, that surrogates that are not stable during the decontamination process should not be used.

Since the surrogates should mimic contaminants in the input PET, they should penetrate the PET at least as deeply as contaminants would in a worst case of a misuse, such as a liquid stored in the bottle over a long period of time.

The artificially generated contamination levels fed into a recycling process for a challenge test should typically be at least 250 mg/kg PET to allow an appropriate determination of the cleaning efficiency of the technology (for background information on the sorption of chemicals into PET, refer to Appendix B).

The contamination of the PET material can be conducted as follows:

- The surrogates are added to the PET material, generally flakes, either as neat mixture of the surrogates or a solution of the surrogates in a solvent. Then the PET material should be kept at time and temperature conditions that simulate diffusion into PET during 1 year at 25°C.[13] Mixing of the PET material is required at any stage to achieve homogeneous distribution of the surrogates. Afterwards, the contaminated material should be washed with organic solvent or suitable detergent in order to remove the surplus of surrogates on the surface of the material; the applicant should provide data or evidence supporting that this washing after the contamination guarantees that the surface contamination is removed to a sufficient extent that it does not lead to an overestimation of the decontamination efficiency; or
- the surrogates could be mixed with the material directly in an extruder. This would result in a homogeneous contamination of the extruded material, which would not need any rinsing or washing.

In both cases, the entire quantity of PET required to perform the challenge test could be contaminated directly or, alternatively, a masterbatch approach could be used.

[13]These conditions may be selected based in Annex V (Section 2.1.4) of Regulation (EU) No 10/2011 laying down specific conditions for migration. Although this annex is related to compliance testing (migration outwards of the material into food or simulants), it may also be applied to diffusion into the PET during the contamination step of the material to be used in the challenge test. However, applicants could also consider aspects that accelerate diffusion, e.g. use of solvents or swelling effects, in order to assure a penetration of surrogates into the PET.

The technical dossier shall contain a description of the contamination procedure, including the following information:

- Characterisation of the material to be contaminated: origin, type (e.g. flakes) and dimensions, such as range and average of thickness, size distribution (these characteristics have to be representative of the input material used in the recycling process) as well as range and average of bulk density;
- List of surrogates used (i.e. chemical names and structure, molecular mass) and amounts added;
- Amount of contaminated material;
- Mode of addition of the surrogates to the material;
- Time and temperature conditions for soaking and storage;
- Handling conditions to promote homogenisation;
- Conditions of rinsing or washing (i.e. solvent/detergent, volume of liquid, time/temperature).

5.2.2 | Challenging of steps of relevance for the decontamination

a. Equipment

The challenge test could be performed at industrial scale, in a pilot plant or at laboratory scale.

Similar to what is requested in Section 5.1.2.1, a description of the equipment used in the challenge test, with a clear identification and distinction of the steps from input to output, should be provided. The design and assembly of main and auxiliary equipment pieces (e.g. reactors, stirring systems, vessels, extruders, crystallisers, preheaters, pelletisers) used in the steps of the challenge test should be described in detail and supported by technical drawings or photos.[14] Design details that may affect the parameters relevant for the decontamination efficiency should be specified.

If the challenge test is performed in industrial installation, a reference to the description of the equipment as provided in line with Section 5.1.2 is sufficient. However, if the challenge test is conducted in a pilot plant or at laboratory scale, the following aspects should be clearly addressed in the technical dossier, and supported by data, where relevant:

- Scale (laboratory scale, pilot plant scale)
- Principal function of the decontamination equipment part(s) (e.g. SSP reactor, extruder, pre-heater), type of reactor (e.g. stirring tank, fluidised bed, plug-flow), type of special extruders (e.g. extruders with planetary sections, satellite screws), type of special melt-polymerisation installations;
- Design and position of stirring tools; set-up of stirring system including number and type of rotating tools, if any;
- Heating/cooling systems, vacuum or flowing gas, position and design of gas and vacuum ports, purification of circulated gases.
- Size of the equipment: dimensions and capacity for the specific recyclate density used in the challenge test (for a non-exhaustive list of examples of dimensions of equipment, refer to Section 5.1.2.1).

b. Operation

The technical dossier should contain information on the operation of the equipment used in the challenge test. In particular, the following aspects should be clearly addressed and supported by data, where relevant:

- Operating parameters (e.g. residence time, temperature, pressure, gas flow rate): As the challenge test is conducted under defined conditions, the operating parameters should be provided as precise values (i.e. without using symbols such as ≤, ≥, < or >, or their equivalent words);
- Operation mode (e.g. batch, continuous);
- Capacity, load and filling level;
- Throughput/discharge rate;
- Rotation parameters (e.g. rotation speed of stirrer, screw of special extruders, blades or drums in special installations;
- Geometrical dimensions (i.e. length and thickness) of the pellets formed and/or treated within the decontamination process;
- Temperature gradient along the axes of the reactor;
- Melt surface area exposed to the decontamination conditions;
- Considerations on the degree of mixing in the equipment (in comparison with the production process);
- Material and corresponding amount used in the challenge test (e.g. only contaminated material or mixture of contaminated and non-contaminated material; in the latter case, the ratio of contaminated vs non-contaminated material should be provided);

[14]Schemes, drawings, photos, etc., have to be provided with appropriate resolution and readability.

- Considerations on cross-contamination[15] with non-contaminated flakes or pellets, if applicable.

In case the challenge test was performed in a small-scale industrial installation, pilot plant or at laboratory scale, a scaling-up evaluation should be provided. It should be explained why and how the conditions used and the results obtained from the small-scale industrial installation, the pilot plant facilities or the laboratory are representative of the operating conditions and performance of the full-scale industrial line or lines of different sizes.

The operating parameters of the steps of the challenge test should be provided following the instructions laid down in the administrative guidance document (EFSA, 2024). If the industrial process does not run under conditions at least as severe (i.e. better decontamination efficiency) as those used in the challenge test, explanations on the effect of differences on the decontamination efficiency of the industrial process should be provided.

5.2.3 | Determination of surrogate levels

The surrogate concentrations in the material used as input for the challenge test (i.e. washed or rinsed material before decontamination) as well as in the final, decontaminated output, should be determined via exhaustive extraction. Possible losses of surrogates during storage or transportation between steps should be taken into account, when relevant.

In case of continuous decontamination step with mixing, the effect of the residence time on the decontamination efficiency should be evaluated by providing surrogate concentrations at different sampling times.

In other cases, surrogate levels in the material sampled at intermediate steps of the challenge test should also be provided, if relevant.

Information and data demonstrating the representativeness and homogeneity of samples taken should be provided, e.g. through the number of samples, amount of sampled material, sampling methods, sampling times.

- For the washed and dried material before decontamination:
    - at least 10 samples after contamination, with a proof of adequate homogeneity including statistical evaluation;
    - additionally, in case the contaminated material is transferred to another place or stored for a time period, at least three samples before entering the decontamination process (considering a 'Single sampling plan', ISO 3951-2, 2013).
- For the material sampled during (when relevant) or after decontamination: at least 3 samples per sampling time (considering a 'Single sampling plan', ISO 3951-2, 2013)

Each sample should contain at least 1 g of material.

In case a mixture of non-contaminated and contaminated material is used as input, the concept of cross-contamination[10] (i.e. transfer of surrogates from the contaminated to non-contaminated material) should be considered. The surrogate levels after decontamination should be determined in both, the initially contaminated and the initially non-contaminated material or by analysing the mixture of the two (containing the same ratio of initially contaminated and the initially non-contaminated flakes as in the input material).

Performance characteristics of the analytical method according to the 'Note for Guidance for Food Contact Materials' (EFSA AFC Panel, 2008; Section 5 – data on residual content of substance in the food contact material) and considerations on the suitability of the method used for the analysis of the surrogates should be provided, supported by raw data and chromatograms.

5.2.4 | Derivation of the decontamination efficiency

The decontamination efficiency should be calculated based on the surrogate levels in the material before and after decontamination. If different challenge tests are performed for individual steps of the decontamination process, the decontamination efficiencies should be combined in order to calculate the overall efficiency of the process. The technical dossier should detail the calculations done by the applicant in a spreadsheet.

In case a mixture of non-contaminated and contaminated material is used, the issue of cross-contamination should be taken into account when performing the calculations of the decontamination efficiency.

[15]The possibility of cross contamination arises in case only a small batch of contaminated flakes is produced and this is then bulked up using a large quantity of non-contaminated flakes to provide sufficient material to run the pilot plant or the industrial plant at a realistic capacity/throughput. In such a case, the contaminated flakes are traced for example by using colour – so green flakes may be contaminated and mixed with uncoloured non-contaminated flakes. This allows the contaminated ('green') flakes to be picked out after the decontamination process and analysed for residual levels of the surrogates. Cross-contamination refers to the phenomenon whereby the surrogates may transfer between the flakes and so, if only the green flakes are analysed, a reduced concentration determined in the 'green' flakes does not demonstrate that the decontamination process has removed the surrogates from the batch since a fraction of the surrogates may have simply redistributed/equilibrated (cross-contaminated) from green to uncoloured flakes.

5.3 | Self-evaluation of the recycling process

In order to assess the safety of the recycling process towards the established evaluation criteria (see Section 4), the applicant should provide a comprehensive reflection of Cres vs. Cmod values, with a view on whether the requested uses fit with the results. For that purpose, the Cmod values indicated in Appendix D for the most commonly used surrogates and the different exposure scenarios should be used.

If the rPET needs to be mixed with virgin PET in order to meet the evaluation criteria, the percentage of dilution with virgin PET should be calculated, where applicable.

ABBREVIATIONS

bw	body weight
CEF Panel	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel	Panel on Food Contact Materials, Enzymes and Processing Aids
CLH	Harmonised classification and labelling
Cmod	modelled concentration in PET
Cres	residual concentrations in PET
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)
rPET	recycled poly(ethylene terephthalate)

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CONFLICT OF INTEREST
If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR
Internal mandate

QUESTION NUMBER
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PANEL MEMBERS
José Manuel Barat Baviera, Claudia Bolognesi, Andrew Chesson, Pier Sandro Cocconcelli, Riccardo Crebelli, David Michael Gott, Konrad Grob, Claude Lambré, Evgenia Lampi, Marcel Mengelers, Alicja Mortensen, Gilles Rivière, Vittorio Silano (until 21 December 2020†), Inger-Lise Steffensen, Christina Tlustos, Henk Van Loveren, Laurence Vernis, and Holger Zorn.

WAIVER
In accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management a waiver was granted to an expert of the Working Group. Pursuant to Article 21(6) of the aforementioned Decision, the concerned expert was allowed to take part in the preparation and discussion scientific output but was not allowed to take up the role of rapporteur within that time frame. Any competing interests are recorded in the respective minutes of the meetings of the CEP Panel Working Group on Recycling Plastics.

NOTE
This output supersedes the previous outputs: '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' (https://doi.org/10.2903/j.efsa.2011.2184) and 'Guidelines on submission of a dossier for safety evaluation by the EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food - Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC)' (https://doi.org/10.2903/j.efsa.2008.717).

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†Deceased.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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APPENDIX A

Overview of studies related to contamination of post-consumer PET from (non-)food applications and contamination of final articles produced from rPET

A.1 | STUDIES ON CONTAMINATION LEVELS OF POST-CONSUMER PET FROM FOOD CONTACT USES (INCLUDING CONTAMINATION BY MISUSE)

A review of the literature data was conducted by Franz and Welle (2003). The contaminants reported were mainly from food-related flavouring substances, e.g. limonene from beverages and other substances like methyl salicylate from cosmetics and personal hygiene products. Typical concentrations in collected PET were in the mg/kg range. Miscellaneous substances from other sources were reported to be in the range of 1 mg/kg PET or lower. The Panel noted that almost all studies had been done on a limited number of samples from which no fully reliable statistics on the contamination incidence can be derived.

Bayer (2002) studied contamination levels in five different types of collected PET in the USA. Four types were food containers from deposits and curbsides, and one consisted of non-food containers sorted from curbside stream (see further details on the non-food stream in Appendix A.2). In total, 121 substances were identified from these five feedstock PET materials after washing and drying. The sum of all detectable substances in the food PET containers was estimated to be 28.5 mg/kg PET, with limonene being the predominant contaminant with a maximum concentration of 18 mg/kg. Hexanal and benzaldehyde were identified in the food contact feedstocks at concentrations of 1 and 3.4 mg/kg, respectively. All compounds were directly traceable to the original contents of the containers.

In the context of the EU project FAIR-CT98-4318 'Recyclability' (European Commission, 2004; Franz et al., 2004), approximately 250 samples of virgin PET and of super-cleaned post-consumer recycled PET (rPET) were analytically screened (European Commission, 2004; Franz et al., 2004). rPET could not be distinguished from virgin PET: It contained the same substances that are related to PET, such as acetaldehyde and monomers, and did not show any non-PET-related substance in the gas chromatograms. In three samples of washed post-consumer PET flakes from Brazil, compounds such as aldehydes, alcohols, o-cresol, m-cresol, toluene, xylenes, styrene, cumene, 1,2,3-trimethylbenzene, durene, naphthalene, benzaldehyde, limonene and myrcene were found. The highest concentration of 15.941 mg/kg was measured for toluene, followed by 4.059 mg/kg for p-xylene (Fabris et al., 2010). Both values exceed the reference contamination level of 3 mg/kg. However, the Panel considered the number of samples investigated in the study (three samples) too small to deduct statistically sound conclusions.

In four samples of Brazilian conventionally cleaned (defined by the authors as sorting, grinding, washing, drying and extrusion) PET flakes, compounds such as styrene, o-xylene, benzaldehyde, 4-ethyl-1,2-dimethylbenzene, limonene, nonanal, 10-methylnonadecane, 2,6-dimethyl-octadecane, heneicosane, dodecane, tritetracontane, tetratetracontane, isobutyl octadecyl ester phthalic acid, bis(2-ethylhexyl) ester hexanedioic acid were reported. Selected compounds were quantified in the ranges of 0.802–0.931 mg/kg for benzaldehyde, 1.491 mg/kg for 2,4-di-tert-butylphenol and 0.441 mg/kg for 2,6-di-tert-butyl-4-methylphenol. (Dutra et al., 2011). The Panel noted that all concentrations found were covered by the reference contamination level of 3 mg/kg.

In 57 batches of washed and dried PET flakes obtained[16] from post-consumer PET bottles collected from three different recycling plants in China, 212 volatile compounds were tentatively identified. For unambiguously identified substances (e.g. toluene, 1,2-benzenedicarboxylic acid bis(2-methylpropyl) ester, dibutyl phthalate, 4-(1, 1-dimethylpropyl)-phenol, isophorone, phenol, 1,4-dichloro-benzene, safrole, naphthalene, styrene, tetradecyl-oxirane, 1-(4-methyl-2-thienyl) ethanone and naphthalene derivatives) quantification was carried out. The highest concentration was found for naphthalene derivatives, with levels of up to 13.43 mg/kg (at a detection frequency of 100%), which the Panel noted to be above the reference contamination level of 3 mg/kg (Dong et al., 2023).

No relevant new data on contamination by misuse has been identified in the literature review.

A.2 | STUDIES ON CONTAMINATION LEVEL OF POST-CONSUMER PET FROM NON-FOOD CONTACT USES

In a comprehensive study (Bayer, 2002), the concentrations of contaminants were measured in non-food contact applications (sorted from post-consumer waste), composed of containers used for mouthwash, soaps/shampoos and household cleaners. The sum of all detected substances was estimated to be 39 mg/kg, with 15 mg/kg being the highest concentration for an individual substance (methyl salicylate, widely used in mouthwash products and household cleaners). Other substances were quantified at concentrations of 5.2 mg/kg (carvacrol), 3.5 mg/kg (limonene), 2 mg/kg (benzaldehyde) and 1 mg/kg (hexanal). They were directly traceable to the original contents of the containers.

In a study by Begley et al. (2002), carried out on three PET bottles used for non-food applications obtained from collection bins in the US, the following substances were found: 130–204 mg methyl salicylate/kg in the wall of an antiseptic mouthwash bottle, 1 mg triclosan/kg in a hand soap bottle and 1.6 mg limonene/kg in a paint remover bottle. The authors noted that the mouthwash contained 21% ethanol, which tends to swell PET and increase the solubility in PET.

[16]Flakes were obtained from bottles by milling, washing, sink-float separation, drying, elutriation and flakes sorting.

In a study by Franz and Welle (2020), 36 PET containers used from six different non-food product categories were examined for contaminants. The empty containers (previously used for dishwashing detergent, antifreeze and dish-rinsing agents, mouthwash products, kitchen and bathroom sanitary cleaning product, shampoos or shower gels and liquid soap products) were washed with 10% ethanol in order to remove surface contamination. While for the majority of cases, the mean concentrations were below 10 mg/kg found, 2-butanone was at a mean of 20 mg/kg; even higher concentrations were found for ethanol (440 mg/kg in sanitary products, 940 mg/kg in antifreeze/dishwashing products and 1110 mg/kg in shampoo products).

A.3 | STUDIES ON CONTAMINATION OF THE FINAL ARTICLES PRODUCED FROM RPET

Pinter et al. (2021) found benzene at up 0.25 mg/kg in recycling input, which was eliminated below the detection limit of 0.03 mg/kg rPET after decontamination (extrusion-SSP-extrusion), with no differences among 11 cycles of recycling.

In a comparative study (van Velzen et al., 2020) between bottles made from virgin and recycled PET, benzene was not detectable (limit of detection: 0.1 mg/kg) in virgin PET pellets or bottles from virgin PET. However, in bottles made from 100% recycled PET benzene, levels up to 1.8 mg/kg were found, resulting in a measured migration of up to 0.44 μg/L. The authors linked the presence of benzene to the contamination of the input material with PVC that is thermally degraded. They noted that the bottles were produced in a small-scale production facility and that the processing parameters of the bottle blowing process were different (i.e. longer residence times) than at commercial level. Hence, the benzene levels in the examined bottles and the related migration were probably higher than when bottles were industrially produced. No data on the PVC content in the input material was provided, but there was a clear correlation between presence of chlorine in the PET and the migration of benzene from PET bottles to water after 10 days at 40°C.

Overall, the Panel noted that the origin of benzene from PET recycling processes has not been clearly established yet. The concentration of benzene in rPET depends on the quality of the input and the processing conditions.

APPENDIX B

Sorption of chemicals into PET

The sorption of chemicals into PET is addressed due to its relevance to the deliberate contamination of flakes for the challenge test (see Section 5.2.1). It is influenced by factors such as the physical and chemical properties of the contaminants (mainly their polarity and molecular size), the contact time and temperature, the use of aggressive solvents (acetone, ethanol, etc.) causing swelling of PET, PET morphology (crystallinity), the substance in contact with PET being pure or in a mixture, and, finally, whether the PET is in the form of flakes or strips cut from PET bottles or whole bottles. This explains the variability of the experimental results.

Sorption of chemicals of different molecular mass and polarity into PET flakes and strips were reported from 28 to 1100 mg per kg PET (Begley et al., 2002; Demertzis et al., 1997), with most values below 500 mg/kg PET.

Sorption into flakes was reported to be up to one order of magnitude higher than into PET bottles (Komolprasert and Lawson, 1995). Under realistic conditions, sorption of chemicals with different molecular mass and polarity into PET bottles ranged from 0.3 to 600 mg/kg, for most of the tested chemicals below 500 mg/kg PET.

No relevant new related data have been identified in the literature review.

APPENDIX C

Exposure scenarios to derive migration criteria from the human exposure threshold value and food consumption

From the human exposure threshold value for substances with a structural alert for genotoxicity of 0.0025 μg/kg bw per day (Kroes et al., 2004) and on the basis of food consumption and body weights, it is possible to derive different exposure scenarios depending on population group and/or food categories. These scenarios, explained below, are based on

- the consumption values outlined in the 'Guidance on the risk assessment of substances present in food intended for infants below 16 weeks of age' (EFSA Scientific Committee et al., 2017), and
- the food categories (1–4) and respective consumption values as defined in the 'Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials' (EFSA CEF Panel, 2016).

Scenario A

According to the EFSA Scientific Committee (2017), the food consumption to be considered for infants below 16 weeks of age is 260 mL/kg bw per day (P95). During the period from birth to 16 weeks, it is expected that infants are exclusively fed on breast milk and/or infant formula. For the latter case, it is assumed that reconstitution of the formula takes place with water that was packaged in a bottle or another container made of rPET. On the basis of the human exposure threshold value of 0.0025 μg/kg bw per day, the corresponding maximum migration of a substance is 0.00962 μg/kg food. Conservatively assuming a general overestimation of the modelled migration by a factor of 5 for substances ≤ 150 Da and 10 for substances > 150 Da, the migration criterion is 0.0481 μg/kg food and 0.0962 μg/kg food, respectively.[17]

Scenario B

According to the Table 1 of the EFSA CEF Panel (2016), the food consumption of category 2 foods is driven by toddlers (i.e. young children aged from 12 months up to and including 36 months) and it is 80 g/kg bw per day. This value is based mainly on the consumption of milk, other liquid milk-based products or non-alcoholic beverages (other than water which is covered by scenario A). A conservative scenario of exposure would be to consider that all these types of food are packaged in recycled PET. On the basis of the human exposure threshold value of 0.0025 μg/kg bw per day, the corresponding maximum migration of a substance is 0.0312 μg/kg food. Conservatively assuming a general overestimation of the modelled migration by a factor of 5 for substances ≤ 150 Da and a factor 10 for substances > 150 Da), the migration criterion is 0.156 μg/kg food and 0.312 μg/kg food, respectively.[18]

The CEP Panel agreed that this scenario will be used also for category 3 foods, i.e. solid foods specifically intended for infant and toddlers. As noted by the CEF Panel (2016), for the consumption of category 3 foods (50 g/kg bw per day), the ready-to-eat meals was the driving food category. For these foods in particular, glass jars with metal lids and plastic sealing gaskets are commonly used, and considering the current technological status of packaging for this type of foods, recycled PET seems to be of little relevance. Therefore, in the context of this guidance, the food consumption for this category of foods is covered by the more conservative category 2 foods, which is close to the consumption of the rest of the foods in category 3.

Scenario C

In the previous version of the 'Scientific Opinion on the criteria for safety evaluation of PET mechanical recycling processes' (EFSA CEF Panel, 2011), an exposure scenario for adults had been included. The exposure to migrants from food packaging was based on the consumption of 1 kg of food (including beverages) packaged with a material containing the substance of interest, for a 60 kg body weight adult, which corresponds to a packaged food consumption of 16.7 g/kg bw/day (European Commission, 2001). This consumption value is very close to the one of food category 4 (20 g/kg bw per day) which is established for food contact applications other than water, infant formula, milk, liquid milk-based products and non-alcoholic beverages, and solid foods specifically intended for infant and toddlers (i.e. those foods that are not covered by categories 1–3) (EFSA CEF Panel, 2016). Additionally, it was considered that alcoholic beverages should be included in this category. Overall, it was considered that the level of consumption of 20 g/kg bw per day is appropriate to cover the consumption by

[17] $0.0025\,\frac{\mu g\ \text{contaminant}}{\text{kg bw per day}} / 260\,\frac{\text{g food}}{\text{kg bw per day}} \approx 0.00962$ μg/kg food (rounded).

By applying the factor 5 for modelling overestimation, the obtained migration criterion is 0.0481 μg/kg food: $0.00962\,\frac{\mu g}{\text{kg food}} * 5 = 0.0481\,\frac{\mu g}{\text{kg food}}$.

By applying the overestimation factor 10, the migration criterion is 0.0962 μg/kg food.

[18] $0.0025\,\frac{\mu g\ \text{contaminant}}{\text{kg bw per day}} / 80\,\frac{\text{g food}}{\text{kg bw per day}} \approx 0.0312$ μg/kg food (rounded).

By applying the factor 5 for modelling overestimation, the obtained migration criterion is 0.156 μg/kg food: $0.031\,\frac{\mu g}{\text{kg food}} * 5 \approx 0.156\,\frac{\mu g}{\text{kg}}$ food (rounded).

By applying the overestimation factor 10, the migration criterion is 0.312 μg/kg food (rounded).

all population groups (EFSA CEF Panel, 2016). Therefore, the CEP Panel decided to replace the former 'adult scenario' with the scenario linked to food category 4.

A conservative scenario of exposure is to assume that all the types of food of category 4 are packaged in recycled PET. On the basis of the human exposure threshold value of 0.0025 μg/kg bw per day, the corresponding maximum migration of a substance is 0.125 μg/kg food. Conservatively assuming a general overestimation of the modelled migration by a factor of 5 for substances ≤ 150 Da and 10 for substances > 150 Da, the migration criterion is 0.625 μg/kg food and 1.25 μg/kg food, respectively.[19]

[19] $0.0025 \frac{\mu g \text{ contaminant}}{\text{kg bw per day}} / 20 \frac{\text{g food}}{\text{kg bw per day}} = 0.125\ \mu g/\text{kg food}$.

By applying the factor 5 for modelling overestimation, the obtained migration criterion is 0.625 μg/kg food: $0.125 \frac{\mu g}{\text{kg food}} * 5 = 0.625 \frac{\mu g}{\text{kg food}}$.

By applying the overestimation factor 10, the migration criterion is 1.25 μg/kg food.

APPENDIX D

Modelling parameters and examples of calculations

The Cmod values have been calculated using the AKTS SML software (v 6.7) and the Migratest software (Migratest EXP, updated 2022).

- Modelling parameters used to calculate concentration in PET (Cmod) corresponding to the migration criteria for the Scenarios A, B, C:
- Long term ambient storage, a shelf life of 1 year at 25°C.
- Good solubility of the migrant in the food simulant ($K_{P/F} = 1$).
- A food contact material or article made entirely with 100% recycled PET.
- A surface area to volume ratio of 6 dm^2 PET to 1 kg food/drink.
- A material thickness of 300 µm.
- A PET density of 1.375 g/cm^3
- Modelling parameters Ap′ = 3.1 and $\tau = 1577$ used to estimate the diffusion coefficient in PET (Hoekstra et al., 2015).

The combination of these parameters has been generally recognised to ensure an overestimation of migration from PET under the above conditions (Hoekstra et al., 2015). Therefore, the Panel agreed to use these values for all scenarios to calculate the Cmod presented in Table D.1 for the most common surrogate contaminants.

TABLE D.1 Molecular mass (Mr) and Cmod for the most common surrogate contaminants corresponding to migration levels for scenarios A, B and C and calculated by diffusion modelling (Hoekstra et al., 2015) using the parameters described above.

Surrogate	Mr (Da)	Cmod (mg/kg PET) scenario A	Cmod (mg/kg PET) scenario B	Cmod (mg/kg PET) scenario C
Toluene	92.1	0.04	0.13	0.51
Chlorobenzene	112.6	0.05	0.15	0.60
Chloroform	119.4	0.05	0.16	0.63
Methyl salicylate	152.2	0.12	0.40	1.60*
Phenylcyclohexane	160.3	0.13	0.42	1.69*
Benzophenone	182.2	0.15	0.49	1.96
Lindane	290.8	0.28	0.92	3.67*
Methyl stearate	298.5	0.29*	0.95*	3.82*

*Deviation of one unit of the last digit may occur when using different software.

– Example of calculation of Cres and comparison with Cmod for phenylcyclohexane

- Exposure scenario A (Appendix C).
- Surrogate: Phenylcyclohexane (molecular mass 160.3 Da) as representative of chemicals that are at the same time non-polar and non-volatile.
- Modelling parameters as above.
- Decontamination efficiency for a given recycling process in the technical dossier, obtained from the challenge test is 98.5%
- Calculation of Cres:

The reference contamination level in the PET feedstock to be recycled is 3 mg/kg PET. By applying the decontamination efficiency percentage to the reference contamination level, the Cres after the recycling process is: Cres = 3mg/kg × (1–0.985) = 0.05 mg/kg PET.

- Comparison between Cres and Cmod:

In this case, the concentration of phenylcyclohexane in PET after the decontamination (Cres = 0.05 mg/kg PET) is not higher than the modelled concentration in PET, the Cmod of 0.13 mg/kg PET (related to a migration of 0.0962 µg/kg food for surrogates with Mr > 150 Da). Therefore, according to the decontamination efficiency demonstrated in the challenge test, the process would be able to reduce the level of migration in food of unknown contaminants represented by the surrogate contaminant phenylcyclohexane below the conservatively modelled migration of 0.0962 µg/kg food.

ANNEX A

Literature review

A.1 | SEARCH FOR STUDIES

In order to investigate whether new data/information of relevance for the safety evaluation of mechanical PET recycling have become available since the publication of the PET criteria (EFSA CEF Panel, 2011), a literature review has been conducted.

The following topics of interest were defined:

- Search 1: incidental contamination of post-consumer PET materials and articles; contamination by misuse; surrogates for challenge test
- Search 2: sorption of chemical into PET
- Search 3: migration modelling
- Search 4: aging

The bibliographic searches were performed in the sources of information indicated below that were identified in line with the topics of interest.

Name of the database	Platform
PubMed	PubMed (NLM)
Scopus	Elsevier (Scopus.com)
Web of Science. Core Collection • Science Citation Index Expanded • Book Citation Index - Science • Conference Abstracts Proceedings - Science • Emerging Citation Index • Current Chemical Resources • Index Chemicus	Web of Science (Clarivate)

The following criteria for selecting studies related to report characteristics were applied during the searches.

Time	**In**	For topics 1–3 (previously addressed in the PET criteria (EFSA CEF Panel, 2011)): Published as of 2010 (to cover the publication period) For topic 4 (new area of interest not previously covered in PET criteria (EFSA CEF Panel, 2011)): no restriction in date
	Out	For topics 1–3: Published before 2010 For topic 4: no restriction in date
Language	**In**	English
	Out	Other languages
Publication type	**In**	– Primary studies (i.e. studies generating new data) – Reports from national/international risk assessment bodies and published reviews will be used to identify relevant references – Conference abstracts or posters
	Out	– Letters to the editor – Expert opinions – Editorials – Theses

The search strings for searches 1–4 are reported in A.2.

The outcome in terms of number of records retrieved in the searches is reported below.

	PubMed	Scopus	Web of science CC	Total	Total after de-duplication
Search 1	358	1246	864	2468	1437
Search 2	260	1613	1112	1985	1930
Search 3	241	612	536	1389	798
Search 4	368	1478	1703	3549	2116

The retrieved records were screened against pre-established eligibility criteria. The study selection process was carried out in two steps:

1. Step 1: title and abstract screening, to exclude obviously irrelevant records. All other apparently relevant records or those of unclear relevance were moved to the following step.
2. Step 2: full-text screening, to select records for inclusion or exclusion.

These steps were performed by two independent reviewers in parallel to minimise the risk of error using DistillerSR (Evidence Partners, Ottawa, Canada).

The bibliographies of pertinent reviews identified through the selection process were scrutinised to identify additional studies.

The records resulting as included (i.e. potentially relevant) after full-text screening were further examined by the experts of the Working Group and a final decision on the relevance was taken following a discussion among the experts. Considerations on the relevant records for searches 1 and 3 have been included throughout Section 4. The Working Group concluded that the articles retrieved for searches 2 and 4 did not include consistent evidence that would be of relevance for the context of this guidance document.

In addition, the websites of the FDA (Food and Drug Administration), as well as trade associations such as ILSI and Fraunhofer were searched to retrieve reports and other documents relevant to the questions of interest (see A.3). Decernis (gComply), a global regulatory reference database, was searched to identify relevant regulations.

A.2 | LITERATURE SEARCHES (BIBLIOGRAPHIC SOURCES)

➔ Search 1 (Incidental contamination of post-consumer PET materials and articles, Contamination by misuse, Surrogates for challenge test)

PubMed
Date of the search: 03/05/2023

Set	Query	Results	Comments
#12	#11 AND ("English"[Language]) AND ("2010/01/01"[Date - Publication]: "3000"[Date - Publication])	358	Language: English Time limit: published from 2010 forward
#11	#8 OR #10	407	((((PET) AND (Recycling/Post-consumer/misuse)) OR (rPET)) AND (Packaging) AND (Contamination/ Surrogate)) OR (((PET) OR (rPET)) AND (Packaging) AND (Decontamination))
#10	(#1 OR #4) AND #6 AND #9	168	((PET) OR (rPET)) AND (Packaging) AND (Decontamination)
#9	"Decontamination"[Mesh] OR "de contamina*"[tiab] OR decontamina*[tiab] OR "cleaning efficiency"[Title/Abstract:~3] OR "cleaning efficient"[Title/Abstract:~3] OR "cleaning efficiently"[Title/Abstract:~3]	18,649	Search for concept: Decontamination
#8	#5 AND #6 AND #7	393	(((PET) AND (Recycling/Post-consumer/misuse)) OR (rPET)) AND (Packaging) AND (Contamination/Surrogate)
#7	"Equipment Contamination"[Mesh] OR "Food Contamination"[Mesh] OR spik*[tiab] OR fortif*[tiab] OR "challenge test*"[tiab] OR contamina*[tiab] OR (concentration*[tiab] AND (compound*[tiab] OR substance*[tiab])) OR NIA[tiab] OR NIAs[tiab] OR "Non-intentionally added substance*"[tiab] OR nonvolatile*[tiab] OR "non volatile*"[tiab] OR pollutant*[tiab] OR semivolatile*[tiab] OR "semi volatile*"[tiab] OR surrogat*[tiab] OR volatile*[tiab] OR impurit*[tiab] OR "black spot*"[tiab] OR colorant*[tiab] OR colourant*[tiab] OR "optical brightener*"[tiab] OR pigment*[tiab] OR stabilizer*[tiab] OR stabiliser*[tiab] OR residu*[tiab] OR label*[tiab] OR adhesiv*[tiab] OR ink[tiab] OR inks[tiab] OR ((chemical*[tiab] OR substance*[tiab]) AND (analys*[tiab] OR screen*[tiab] OR test*[tiab]))	2,634,203	Search for concept: Contamination/Surrogate

(Continues)

(Continued)

Set	Query	Results	Comments
#6	"Food Packaging"[Mesh] OR "Product Packaging"[Mesh:NoExp] OR bottle*[tiab] OR container*[tiab] OR flake*[tiab] OR FCM[tiab] OR FCMs[tiab] OR "food contact*"[tiab] OR Packag*[tiab] OR packing[tiab] OR "consumer product*"[tiab] OR pellet*[tiab] OR preform*[tiab] OR sheet*[tiab]	373,508	Search for concept: Packaging
#5	#3 OR #4	2529	((PET) AND (Recycling/Post-consumer/misuse)) OR (rPET)
#4	rPET[tiab]	97	Search for concept: rPET
#3	#1 AND #2	2486	(PET) AND (Recycling/Post-consumer/misuse)
#2	"Equipment Reuse"[Mesh] OR "Recycling"[Mesh] OR "After consumed"[Title/Abstract:~3] OR "After consumer"[Title/Abstract:~3] OR "After consumers"[Title/Abstract:~3] OR "After consumption"[Title/Abstract:~3] OR "Correct use"[Title/Abstract:~3] OR "Correct used"[Title/Abstract:~3] OR "Correct uses" OR "Correctly used"[Title/Abstract:~3] OR "Incorrect use"[Title/Abstract:~3] OR "Incorrect used"[Title/Abstract:~3] OR "Incorrect uses"[Title/Abstract:~3] OR "incorrectly used" OR misuse*[tiab] OR misusi*[tiab] OR "Post consum*"[tiab] OR Postconsum*[tiab] OR Reclam*[tiab] OR "recovery stream*" OR Recycl*[tiab] OR "re use*"[tiab] OR "re usi*"[tiab] OR Reuse*[tiab] OR Reusi*[tiab] OR Upcycl*[tiab]	149,9248	Search for concept: Recycling/Post-consumer/misuse
#1	"Polyethylene Terephthalates"[Mesh] OR "Polyethylene Terephthalate*"[tiab] OR "Poly Ethylene Terephthalate*"[tiab] OR "Polyethylene Terephtalate*"[tiab] OR "Poly Ethylene Terephtalate*"[tiab] OR PET[tiab] OR PETE[tiab] OR rPET[tiab] OR "Plastics"[Majr:NoExp] OR plastic[ti] OR plastics[ti] OR "Thermoplastic polyester*"[tiab] OR 25038–59-9[tiab]	168,971	Search for concept: PET

Scopus
Date of the search: 03/05/2023

Set	Query	Results	Comments
#12	#11 AND LANGUAGE(English) AND PUBYEAR >2009	1246	Language: English Time limit: published from 2010 forward
#11	#8 OR #10	1605	((((PET) AND (Recycling/Post-consumer/misuse)) OR (rPET)) AND (Packaging) AND (Contamination/Surrogate)) OR (((PET) OR (rPET)) AND (Packaging) AND (Decontamination))
#10	(#1 OR #4) AND #6 AND #9	289	((PET) OR (rPET)) AND (Packaging) AND (Decontamination)
#9	TITLE-ABS-KEY("de contamina*" OR decontamina* OR (cleaning W/3 efficien*))	49,660	Search for concept: Decontamination
#8	#5 AND #6 AND #7	1528	(((PET) AND (Recycling/Post-consumer/misuse)) OR (rPET)) AND (Packaging) AND (Contamination/Surrogate)

(Continued)

Set	Query	Results	Comments
#7	TITLE-ABS-KEY(spik* OR fortif* OR “challenge test*” OR contamina* OR (concentration* AND (compound* OR substance*)) OR NIA OR NIAs OR “Non-intentionally added substance*” OR nonvolatile* OR “non volatile*” OR pollutant* OR semivolatile* OR “semi volatile*” OR surrogat* OR volatile* OR impurit* OR “black spot*” OR colorant* OR colourant* OR “optical brightener*” OR pigment* OR stabilizer* OR stabiliser* OR residu* OR label* OR adhesiv* OR ink* OR ((chemical* OR substance*) W/3 (analys* OR screen* OR test*)))	6,243,684	Search for concept: Contamination/Surrogate
#6	TITLE-ABS-KEY (bottle* OR container* OR flake* OR fcm OR fcms OR “food contact*” OR packag* OR packing OR “consumer product*” OR pellet* OR preform* OR sheet*)	1,705,279	Search for concept: Packaging
#5	#3 OR #4	21,687	((PET) AND (Recycling/Post-consumer/misuse)) OR (rPET)
#4	TITLE-ABS-KEY (rPET)	422	Search for concept: rPET
#3	#1 AND #2	21,481	(PET) AND (Recycling/Post-consumer/misuse)
#2	TITLE-ABS-KEY((after W/3 consumed) OR (after W/3 consumer) OR (after W/3 consumers) OR (after W/3 consumption) OR (correct W/3 use) OR (correct W/3 used) OR “Correct uses” OR (correctly W/3 used) OR (incorrect W/3 use) OR (incorrect W/3 used) OR (incorrect W/3 uses) OR “incorrectly used” OR misuse* OR misusi* OR “Post consum*” OR Postconsum* OR Reclam* OR “recovery stream*” OR Recycl* OR “re use*” OR “re usi*” OR Reuse* OR Reusi* OR Upcycl*)	1,588,796	Search for concept: Recycling/Post-consumer/misuse
#1	TITLE-ABS-KEY(“Polyethylene Terephthalate*” OR “Poly Ethylene Terephthalate*” OR “Polyethylene Terephtalate*” OR “Poly Ethylene Terephtalate*” OR PET OR PETE OR “Thermoplastic polyester*”) OR TITLE(plastic OR plastics) OR AUTHKEY(plastic OR plastics) OR CASREGNUMBER(25038-59-9)	415,683	Search for concept: PET

WoS
Date of the search: 24/04/2023

Set	Query	Results	Comments
#12	#11 AND LA = (English) AND PY = (2010–2500)	864	Language: English Time limit: published from 2010 forward
#11	#8 OR #10	1053	((((PET) AND (Recycling/Post-consumer/misuse)) OR (rPET)) AND (Packaging) AND (Contamination/Surrogate)) OR (((PET) OR (rPET)) AND (Packaging) AND (Decontamination))
#10	(#1 OR #4) AND #6 AND #9	290	((PET) OR (rPET)) AND (Packaging) AND (Decontamination)
#9	TS = (“de contamina*” OR decontamina* OR (cleaning NEAR/3 efficien*))	41,185	Search for concept: Decontamination
#8	#5 AND #6 AND #7	993	(((PET) AND (Recycling/Post-consumer/misuse)) OR (rPET)) AND (Packaging) AND (Contamination/Surrogate)

(Continues)

(Continued)

Set	Query	Results	Comments
#7	TS = (spik* OR fortif* OR "challenge test*" OR contamina* OR (concentration* AND (compound* OR substance*)) OR NIA OR NIAs OR "Non-intentionally added substance*" OR nonvolatile* OR "non volatile*" OR pollutant* OR semivolatile* OR "semi volatile*" OR surrogat* OR volatile* OR impurit* OR "black spot*" OR colorant* OR colourant* OR "optical brightener*" OR pigment* OR stabilizer* OR stabiliser* OR residu* OR label* OR adhesiv* OR ink* OR ((chemical* OR substance*) NEAR/3 (analys* OR screen* OR test*)))	4,048,158	Search for concept: Contamination/Surrogate
#6	TS = (bottle* OR container* OR flake* OR FCM OR FCMs OR "food contact*" OR packag* OR packing OR "consumer product*" OR pellet* OR preform* OR sheet*)	1,355,269	Search for concept: Packaging
#5	#3 OR #4	11,881	((PET) AND (Recycling/Post-consumer/misuse)) OR (rPET)
#4	TS = (rPET)	311	Search for concept: rPET
#3	#1 AND #2	11,804	(PET) AND (Recycling/Post-consumer/misuse)
#2	TS = ((after NEAR/3 consumed) OR (after NEAR/3 consumer) OR (after NEAR/3 consumers) OR (after NEAR/3 consumption) OR (correct NEAR/3 use) OR (correct NEAR/3 used) OR "Correct uses" OR (correctly NEAR/3 used) OR (incorrect NEAR/3 use) OR (incorrect NEAR/3 used) OR (incorrect NEAR/3 uses) OR "incorrectly used" OR misuse* OR misusi* OR "Post consum*" OR "recovery stream*" OR Postconsum* OR Reclam* OR Recycl* OR "re use*" OR "re usi*" OR Reuse* OR Reusi* OR Upcycl*)	480,825	Search for concept: Recycling/Post-consumer/misuse
#1	TS = ("Polyethylene Terephthalate*" OR "Poly Ethylene Terephthalate*" OR "Polyethylene Terephtalate*" OR "Poly Ethylene Terephtalate*" OR PET OR PETE OR 25038–59-9 OR "Thermoplastic polyester*") OR TI = (plastic OR plastics) OR AK = (plastic OR plastics)	388,723	Search for concept: PET

➔ Search 2 (sorption of chemicals into PET)

PubMed
Date of the search:25/04/2023

Set	Query	Results	Comments
#5	#4 AND ("english"[Language]) AND ("2010/01/01"[Date - Publication]: "3000"[Date - Publication])	260	Language: English Time limit: published from 2010 forward
#4	#1 AND #2 AND #3	409	PET AND Sorption AND Packaging
#3	"Food Packaging"[Mesh] OR "Product Packaging"[Mesh:NoExp] OR bottle*[tiab] OR container*[tiab] OR flake*[tiab] OR FCM[tiab] OR FCMs[tiab] OR "food contact*"[tiab] OR Packag*[tiab] OR Packing[tiab] OR "consumer product*"[tiab] OR pellet*[tiab] OR preform*[tiab] OR sheet*[tiab]	372,886	Search for concept: Packaging
#2	"Absorption"[Mesh] OR "Diffusion"[Mesh] OR absorb*[tiab] OR diffus*[tiab] OR "partition coefficient*"[tiab] OR Solubility[tiab] OR Solubl*[tiab] OR sorbed[tiab] OR sorption*[tiab]	1,041,724	Search for concept: Sorption

(Continued)

Set	Query	Results	Comments
#1	"Polyethylene Terephthalates"[Mesh] OR "Polyethylene Terephthalate*"[tiab] OR "Poly Ethylene Terephthalate*"[tiab] OR "Polyethylene Terephtalate*"[tiab] OR "Poly Ethylene Terephtalate*"[tiab] OR PET[tiab] OR PETE[tiab] OR rPET[tiab] OR "Plastics"[Majr:NoExp] OR plastic[ti] OR plastics[ti] OR "Thermoplastic polyester*"[tiab] OR 25038-59-9[tiab]	168,725	Search for concept: PET

Scopus
Date of the search 25/04/2023

Set	Query	Results	Comments
#5	#4 AND LANGUAGE(English) AND PUBYEAR >2009	1613	Language: English Time limit: published from 2010 forward
#4	#1 AND #2 AND #3	2585	PET AND Sorption AND Packaging
#3	TITLE-ABS-KEY (Bottle* OR Container* OR "consumer product*" OR Flake* OR "food contact*" OR FCM OR FCMs OR Packag* OR packing OR Pellet* OR Preform* OR Sheet*)	1703,034	Search for concept: Packaging
#2	TITLE-ABS-KEY (absorb* OR diffus* OR "partition coefficient*" OR solubility OR solubl* OR sorbed OR sorption*)	3,157,745	Search for concept: Sorption
#1	TITLE-ABS-KEY("Polyethylene Terephthalate*" OR "Poly Ethylene Terephthalate*" OR "Polyethylene Terephtalate*" OR "Poly Ethylene Terephtalate*" OR PET OR PETE OR rPET OR "Thermoplastic polyester*") OR TITLE(plastic OR plastics) OR AUTHKEY(plastic OR plastics) OR CASREGNUMBER(25038–59-9)	415,089	Search for concept: PET

Web of Science Core Collection
Date of the search 25/04/2023

Set	Query	Results	Comments
#5	#4 AND LA = (English) AND PY = (2010-2500)	1112	Language: English Time limit: published from 2010 forward
#4	#1 AND #2 AND #3	1746	PET AND Sorption AND Packaging
#3	TS = (Bottle* OR Container* OR "consumer product*" OR Flake* OR "food contact*" OR FCM OR FCMs OR Packag* OR packing OR Pellet* OR Preform* OR Sheet*)	1,345,998	Search for concept: Packaging
#2	TS = (absorb* OR diffus* OR "partition coefficient*" OR solubility OR solubl* OR sorbed OR sorption*)	2,400,218	Search for concept: Sorption
#1	TS = ("Polyethylene Terephthalate*" OR "Poly Ethylene Terephthalate*" OR "Polyethylene Terephtalate*" OR "Poly Ethylene Terephtalate*" OR PET OR PETE OR rPET OR 25038–59-9 OR "Thermoplastic polyester*") OR TI = (plastic OR plastics) OR AK = (plastic OR plastics)	387,112	Search for concept: PET

➔ Search 3 (migration modelling)

PubMed
Date of the search:25/04/2023

Set	Query	Results	Comments
#6	#5 AND ("english"[Language]) AND ("2010/01/01"[Date - Publication]: "3000"[Date - Publication])	241	Language: English Time limit: published from 2010 forward
#5	#1 AND #2 AND #3 AND #4	282	PET AND Migration AND Models AND Packaging/Food
#4	"Food Packaging"[Mesh] OR "Product Packaging"[Mesh:NoExp] OR "Food and Beverages"[Mesh] OR Beverage*[tiab] OR Bottle*[tiab] OR Container*[tiab] OR drink[tiab] OR drinks[tiab] OR Flake*[tiab] OR Food*[tiab] OR FCM[tiab] OR FCMs[tiab] OR Packag*[tiab] OR packing[tiab] OR Pellet*[tiab] OR Preform*[tiab] OR Sheet*[tiab]	1,575,283	Search for concept: Packaging/Food
#3	"Models, Theoretical"[Mesh] OR Model*[tiab] OR Prediction*[tiab] OR Simulation*[tiab] OR Software*[tiab]	5,231,248	Search for concept: Models
#2	"Diffusion"[Mesh] OR diffus*[tiab] OR "distribution coefficient*"[tiab] OR "glass transition temperature*"[tiab] OR migrat*[tiab] OR "partition coefficient*"[tiab] OR Solubility[tiab] OR Solubl*[tiab]	1,196,315	Search for concept: Migration
#1	"Polyethylene Terephthalates"[Mesh] OR "Polyethylene Terephthalate*"[tiab] OR "Poly Ethylene Terephthalate*"[tiab] OR "Polyethylene Terephtalate*"[tiab] OR "Poly Ethylene Terephtalate*"[tiab] OR PET[tiab] OR PETE[tiab] OR rPET[tiab] OR "Plastics"[Majr:NoExp] OR plastic[ti] OR plastics[ti] OR "Thermoplastic polyester*"[tiab] OR 25038–59-9[tiab]	168,725	Search for concept: PET

Scopus
Date of the search: 25/04/2023

Set	Query	Results	Comments
#6	#5 AND LANGUAGE (english) AND PUBYEAR >2009	612	Language: English Time limit: published from 2010 forward
#5	#1 AND #2 AND #3 AND #4	912	PET AND Migration AND Models AND Packaging/Food
#4	TITLE-ABS-KEY (Beverage* OR Bottle* OR Container* OR drink OR drinks OR Flake* OR food* OR FCM OR FCMs OR Packag* OR Packing OR Pellet* OR Preform* OR Sheet*)	3,414,393	Search for concept: Packaging/Food
#3	TITLE-ABS-KEY (Model* OR Prediction* OR Simulation* OR Software*)	19,809,214	Search for concept: Models
#2	TITLE-ABS-KEY (diffus* OR "distribution coefficient*" OR "glass transition temperature*" OR migrat* OR "partition coefficient*" OR Solubility OR Solubl*)	3,485,770	Search for concept: Migration
#1	TITLE-ABS-KEY ("polyethylene terephthalate*" OR "poly ethylene terephthalate*" OR "polyethylene terephtalate*" OR "poly ethylene terephtalate*" OR pet OR pete OR rpet OR "thermoplastic polyester*") OR TITLE (plastic OR plastics) OR AUTHKEY (plastic OR plastics) OR CASREGNUMBER (25,038–59-9)	415,089	Search for concept: PET

Web of Science
Date of the search: 25/04/2023

Set	Query	Results	Comments
#6	#5 AND LA = (English) AND PY = (2010-2500)	536	Language: English Time limit: published from 2010 forward
#5	#1 AND #2 AND #3 AND #4	774	PET AND Migration AND Models AND Packaging/Food

(Continued)

Set	Query	Results	Comments
#4	TS = (Beverage* OR Bottle* OR Container* OR drink OR drinks OR Flake* OR food* OR FCM OR FCMs OR Packag* OR Pellet* OR Preform* OR Sheet* OR packing)	2,578,526	Search for concept: Packaging/Food
#3	TS = (Model* OR Prediction* OR Simulation* OR Software*)	13,399,199	Search for concept: Models
#2	TS = (diffus* OR "distribution coefficient*" OR "glass transition temperature*" OR migrat* OR "partition coefficient*" OR Solubility OR Solub*)	2,681,765	Search for concept: Migration
#1	TS = ("Polyethylene Terephthalate*" OR "Poly Ethylene Terephthalate*" OR "Polyethylene Terephtalate*" OR "Poly Ethylene Terephtalate*" OR PET OR PETE OR 25038-59-9 OR "Thermoplastic polyester*") OR TI = (plastic OR plastics) OR AK = (plastic OR plastics)	387,112	Search for concept: PET

➔ Search 4 (aging)

PubMed
Date of the search: 09/08/2023

Set	Query	Results	Comments
#12	#11 Filters: English	368	English
#11	#10 OR #7	381	Search 1 OR Search 2
#10	#13 AND #2 AND #6 Filters: Review	12	Search 2: Plastics AND Recycling AND Aging AND Reviews
#9	#8 AND #2 AND #6	369	Plastics AND Recycling AND Aging
#8	"Plastics"[Majr:NoExp] OR plastic[ti] OR plastics[ti]	36,901	Search for concept: Plastics
#7	#5 AND #6	293	Search 1: (((PET) AND (Recycling)) OR (rPET)) AND (Aging)
#6	Age[tiab] OR Aged[tiab] OR Ageing[tiab] OR Ages[tiab] OR Aging[tiab] OR "breakdown product*"[tiab] OR degrad*[tiab] OR durab*[tiab] OR stabiliser*[tiab] OR stabilizer*[tiab]	4,024,199	Search for concept: Aging
#5	#3 OR #4	1262	((PET) AND (Recycling)) OR (rPET8
#4	rPET[tiab]	104	Search for concept: rPET
#3	#1 AND #2	1217	(PET) AND (Recycling)
#2	"Equipment Reuse"[Mesh] OR "Recycling"[Mesh] OR "Decontamination"[Mesh] OR "de contamina*"[tiab] OR decontamina*[tiab] OR Reclam*[tiab] OR Recycl*[tiab] OR "recovery stream*"[tiab] OR "re use*"[tiab] OR "re usi*"[tiab] OR Reuse*[tiab] OR Reusi*[tiab] OR Upcycl*[tiab]	116,209	Search for concept: Recycling
#1	"Polyethylene Terephthalates"[Mesh] OR "Polyethylene Terephthalate*"[tiab] OR "Poly Ethylene Terephthalate*"[tiab] OR "Polyethylene Terephtalate*"[tiab] OR "Poly Ethylene Terephtalate*"[tiab] OR PET[tiab] OR PETE[tiab] OR "Thermoplastic polyester*"[tiab] OR 25038–59-9[tiab]	136,326	Search for concept: PET

Scopus
Date of the search: 09/08/2023

Set	Query	Results	Comments
#12	#11 AND (LIMIT-TO (LANGUAGE, "English"))	1478	English
#11	#10 OR #7	1547	Search 1 OR Search 2
#10	#10 AND DOCTYPE(re)	263	Search 2: Plastics AND Recycling AND Aging AND Reviews
#9	#8 AND #6 AND #2	1981	Plastics AND Recycling AND Aging
#8	TITLE (plastic OR plastics) OR AUTHKEY (plastic OR plastics)	183,080	Search for concept: Plastics

(Continues)

(Continued)

Set	Query	Results	Comments
#7	#5 AND #6	1354	Search 1: (((PET) AND (Recycling)) OR (rPET)) AND (Aging)
#6	TITLE-ABS-KEY(Age OR ages OR aged OR ageing OR Aging OR "breakdown product*" OR degrad* OR durab* OR stabiliser* OR stabilizer*)	11,864,159	Search for concept: Aging
#5	#3 OR #4	6728	((PET) AND (Recycling)) OR (rPET)
#4	TITLE-ABS-KEY (rPET)	438	Search for concept: rPET
#3	#1 AND #2	6621	(PET) AND (Recycling)
#2	TITLE-ABS-KEY("de contamina*" OR decontamina* OR Reclam* OR Recycl* OR "recovery stream*" OR "re use*" OR "re usi*" OR Reuse* OR Reusi* OR Upcycl*)	601,683	Search for concept: Recycling
#1	TITLE-ABS-KEY("Polyethylene Terephthalate*" OR "Poly Ethylene Terephthalate*" OR "Polyethylene Terephtalate*" OR "Poly Ethylene Terephtalate*" OR PET OR PETE OR 25038–59-9 OR "Thermoplastic polyester*") OR CASREGNUMBER(25038–59-9)	244,622	Search for concept: PET

WoS
Date of the search: 09/08/2023

Set	Query	Results	Comments
#12	#11 AND LA = English	1703	Language
#11	#10 OR #7	1742	Search 1 OR Search 2
#10	#9 and Review Article (Document Types)	307	Search 2: Plastics AND Recycling AND Aging AND Reviews
#9	#8 AND #2 AND #6	1730	Plastics AND Recycling AND Aging
#8	TI = (plastic OR plastics) OR AK = (plastic OR plastics)	1504	Search for concept: Plastics
#7	#5 AND #6	1540	Search 1: (((PET) AND (Recycling)) OR (rPET)) AND (Aging)
#6	TS = (Age OR ages OR aged OR ageing OR Aging OR "breakdown product*" OR degrad* OR durab* OR stabiliser* OR stabilizer*)	5,118,775	Search for concept: Aging
#5	#3 OR #4	5553	((PET) AND (Recycling)) OR (rPET)
#4	TS = (rPET)	325	Search for concept: rPET
#3	#1 AND #2	5471	(PET) AND (Recycling)
#2	TS = ("de contamina*" OR decontamina* OR Reclam* OR Recycl* OR "recovery stream*" OR "re use*" OR "re usi*" OR Reuse* OR Reusi* OR Upcycl*)	419,590	Search for concept: Recycling
#1	TS = ("Polyethylene Terephthalate*" OR "Poly Ethylene Terephthalate*" OR "Polyethylene Terephtalate*" OR "Poly Ethylene Terephtalate*" OR PET OR PETE OR 25038–59-9 OR "Thermoplastic polyester*")	271,290	Search for concept: PET

A.3 | LITERATURE SEARCHES (INSTITUTIONS)

ILIS Global Website (https://ilsi.org/search/)

Date of the search: 08/09/2023
Method: search engine of the website (https://ilsi.org/search/)

Search	Results
Recycle - Filter by publication	3
Recycling – Filter by publication	3

(Continued)

Search	Results
Recycled – Filter by publication	0
Polyethylene terephthalate – Filter by publication	3

Method: search in Google (https://www.google.es)

Search	Results
recycling Polyethylene terephthalate site:https://ilsi.org/	4
recycle Polyethylene terephthalate site:https://ilsi.org/	4
recycled Polyethylene terephthalate site:https://ilsi.org/	3
recycle PET site:https://ilsi.org/	4
recycling PET site:https://ilsi.org/	6
recycled PET site:https://ilsi.org/	4

Fraunhofer (https://publica.fraunhofer.de/)

Date of the search: 11/09/2023
Method: search engine of the website

Search	Results
Recycl*pet – Start date 2010	36
recycl* Polyethylene terephthalate – Start date 2010	19

Method: search in Google (https://www.google.es)

Search	Results
recycling Polyethylene terephthalate site:https://publica.fraunhofer.de/ Time limit 1 ene 2010 – 31 dic 2023	18
recycle Polyethylene terephthalate site:https://publica.fraunhofer.de/ Time limit 1 ene 2010 – 31 dic 2023	9
recycled Polyethylene terephthalate site:https://publica.fraunhofer.de/ Time limit 1 ene 2010 – 31 dic 2023	9
recycle PET site:https://publica.fraunhofer.de/ Time limit 1 ene 2010 – 31 dic 2023	19
recycling PET site:https://publica.fraunhofer.de/ Time limit 1 ene 2010 – 31 dic 2023	29
recycled PET site:https://publica.fraunhofer.de/ Time limit 1 ene 2010 – 31 dic 2023	19

FDA (https://www.fda.gov/)

Date of the search: 05/09/2023
Method: search engine of the website

Search	Results
recycling "Polyethylene terephthalate" Content from 01/01/2010 to 05/09/2023	3
recycle "Polyethylene terephthalate" Content from 01/01/2010 to 05/09/2023	2
recycled "Polyethylene terephthalate" Content from 01/01/2010 to 05/09/2023	2
recycling PET Content from 01/01/2010 to 05/09/2023	15
Recycle PET Content from 01/01/2010 to 05/09/2023	19
recycled PET Content from 01/01/2010 to 05/09/2023	16

Method: search in Google (https://www.google.es)

Search	Results
recycling Polyethylene terephthalate site:https://www.fda.gov/ Time limit 1 ene 2010 – 31 dic 2023	16
recycle Polyethylene terephthalate site:https://www.fda.gov/ Time limit 1 ene 2010 – 31 dic 2023	19
recycled Polyethylene terephthalate site:https://www.fda.gov/ Time limit 1 ene 2010 – 31 dic 2023	23
recycle PET plastic site:https://www.fda.gov/ filetype:pdf Time limit 1 ene 2010 – 31 dic 2023	19
recycling PET plastic site:https://www.fda.gov/ filetype:pdf Time limit 1 ene 2010 – 31 dic 2023	19
recycled PET plastic site:https://www.fda.gov/ filetype:pdf Time limit 1 ene 2010 – 31 dic 2023	19

ANNEX B

Targeted and public consultations on the draft Scientific Guidance on the criteria for the evaluation and on the preparation of applications for the safety assessment of post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food

The Outcome of the targeted and public consultations can be found in the online version of this output ('Supporting information' Section).