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SCIENTIFIC OPINION

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[1]

EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

This scientific opinion of EFSA deals with the criteria to be used for safety evaluation of a recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food.
The principle of the evaluation is to apply the cleaning efficiency of a recycling technology or process, obtained from a challenge test with surrogate contaminants, to a reference contamination level for post consumer PET, conservatively set a 3 mg/kg PET for a contaminant resulting from possible misuse. The resulting residual concentration of each contaminant in recycled PET (Cres) is then compared to a modelled concentration in PET (Cmod). This Cmod is calculated using generally recognized conservative migration models such that the related migration does not give rise to a dietary exposure exceeding 0.0025 µg/kg bw/day, the human exposure threshold value for chemicals with structural alerts raising concern for potential genotoxicity, below which the risk to human health would be negligible.
The default scenario, when the recycled PET is intended for general use, is that of an infant weighing 5 kg and consuming every day 0.75 l of water coming from a water bottle manufactured from 100% recycled PET. According to this scenario, it can be derived that the highest concentration of a substance in water that would ensure that the dietary exposure of 0.0025 µg/kg bw/day is not exceeded, is 0.017 µg/kg food. Taking into account that generally agreed diffusion modelling overestimates migration by at least 5 times, a calculated migration less than 0.1 µg/kg in food would satisfy the above criterion for the default exposure scenario. In the case of the other exposure scenarios for adults and toddlers, the relevant migration criterion will accordingly be 0.75 and 0.15 µg/kg food.

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1 On request of the CEF Panel, Question No EFSA-Q-2010-01501, adopted on 6 July 2011.

2 Panel members: Arturo Anadón, Mona-Lise Binderup, Wilfried Bursch, Laurence Castle, Riccardo Crebelli, Karl-Heinz Engel, Roland Franz, Nathalie Gontard, Thomas Haertlé, Trine Husøy, Klaus-Dieter Jany, Catherine Leclercq, Jean-Claude Lhuguenot, Wim Mennes, Maria Rosaria Milana, Karla Pfaff, Kettil Svensson, Fidel Toldrá, Rosemary Waring, Detlef Wölfle. One member of the Panel, Roland Franz declared an interest as his Institute has submitted applications for the evaluation of recycling processes. This was considered as a conflict of interest and he was requested to leave the room during discussion and adoption of the opinion. Correspondence: cef-unit@efsa.europa.eu

3 Acknowledgement: The Panel wishes to thank the members of the Working Group on Recycling process for the preparation of this opinion: Laurence Castle, Vincent Dudler, R. Franz, Nathalie Gontard, Eugenia Lampi, Maria Rosaria Milana, Cristina Nérin, Constantine Papaspyrides, Karla Pfaff, and EFSA's staff members Eric Barthelemy and Dimitrios Spyropoulos for the support provided to this EFSA scientific output. R. Franz participated as hearing expert to answer to questions and to provide comments on the draft opinion.

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Therefore if a recycling process is able to reduce an input reference contamination of 3 mg/kg PET to a Cres not higher than a Cmod corresponding to the relevant migration criterion, the potential dietary exposure cannot be higher than 0.0025 µg/kg bw/day and recycled PET manufactured with such recycling process is not considered of safety concern.

The Panel considered appropriate that the proportion of PET from non-food consumer applications should be no more than 5% in the input to be recycled.

KEY WORDS

Food contact materials, Plastics, Poly(ethylene terephthalate), PET, Recycling process, Evaluation, Safety.

SUMMARY

Following the publication of the Regulation (EC) No 282/2008 of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods and the relevant EFSA Guidelines on submission of a dossier for safety evaluation by the EFSA, many dossiers have been submitted to EFSA for evaluation dealing with recycling processes for polyethylene terephthalate (PET) food contact materials.

These processes use as an input post consumer PET to produce recycled PET intended for food contact applications.

The CEF Panel is currently evaluating these PET recycling processes and has developed criteria specific to this type of plastic which are used during the evaluation process. For the sake of transparency and in order to inform all stakeholders on the considerations followed for the risk assessment of PET recycling processes, the CEF Panel considers that these criteria should be published. Thus, the scientific opinion describes the risk assessment approach used by the Panel and provides arithmetic values for the criteria specific to the evaluation of recycling processes for PET intended to be used in food contact materials.

The underlying principle of the evaluation is to apply the cleaning efficiency of a recycling technology or process to a reference contamination level for post consumer PET. The resulting residual concentration in recycled PET (Cres) is then compared to a modelled concentration in PET (Cmod). This Cmod is calculated using generally recognized conservative migration models such that the related migration cannot give rise to a dietary exposure exceeding the threshold below which the risk to human health would be negligible.

The decontamination efficiency of the recycling process is determined by means of especially designed challenge tests using sets of surrogate contaminants. These surrogates are substances with different molecular weights and polarities representative of possible chemical classes of contaminants of concern. The surrogates are added at exaggeratedly high levels in the plastic PET input to be recycled. Their initial concentration and their final concentration, after the recycling process, is determined analytically. The decontamination efficiency is expressed as percentage of reduction of a surrogate present in the decontaminated PET compared to its initial level before it entered the process.

The establishment of a reference contamination level for an unknown contaminant potentially present in the input of a PET recycling process is based on experimental data of an EU survey. In this survey performed in the framework of a European project thousands of collected PET bottles were examined. Post-use residual substances were identified as food related substances (limonene, up to 20 mg/kg - average 2.9 mg/kg PET) and plastic related substances (adipates, phthalates, erucamide dioctyl adipate up to 0.5 mg/kg). Rare cases of bottles misused by the consumers (i.e. refilled with organic solvents) were identified and the highest level in the misused PET bottles was for toluene (6750 mg/kg PET). An incidence of 0.03-0.04 % of misused bottles was estimated. Based on these figures, it was estimated that as a worst case the contamination of the recycling PET feedstock with toluene would have been ranging from 1.4 to 2.7 mg/kg PET. Thus, the evaluation criterion to be used as the reference contamination level for misuse for individual substances in the input of a PET recycling process is set at 3 mg/kg PET, corresponding to the highest figure obtained from the experimental data. Results from another survey in the USA and from theoretical considerations on the nature and sorption of the possible misuse contaminants support the conservatism of this value.

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 a

dietary exposure which can be considered of negligible risk to human health must take into account this possibility, too.

As a pragmatic approach, the Panel considers that this dietary exposure should be below 0.0025 µg/kg bw/day for an unknown contaminant possibly present. This is the human exposure threshold value for chemicals with structural alerts raising concern for potential genotoxicity. Generally, this threshold value is low enough to address concern over all toxicological effects. Thus, it is ensured that any unknown contaminant possibly present is treated in a conservative way.

As regards the exposure scenario, the Panel considers that the most conservative scenario is that of an infant weighing 5 kg and consuming every day 0.75 l of water (WHO, 2003) coming from a water bottle manufactured from 100% recycled PET. From this figure, it can be derived that the highest concentration of a substance in water that would ensure that the dietary exposure of 0.0025 µg/kg bw/day is not exceeded is 0.017 µg/kg food. This scenario is applied as default when the recycled PET is intended for general use.

The Panel noted that for other categories of the population, toddlers and adults, due to the lower food consumption per kg bw, the respective concentrations in food would be higher and that other exposure scenarios can be formulated.

Taking into account the overestimation of migration by the generally agreed diffusion modelling, a calculated migration less than 0.1 µg/kg in food would satisfy the above criterion for the default exposure scenario. In the case of the other exposure scenarios for adults and toddlers, the relevant migration criterion will accordingly be 0.75 and 0.15 µg/kg food respectively.

The Panel considers that if a recycling process is able to reduce an input reference contamination of 3 mg/kg PET to a Cres not higher than a Cmod corresponding to the relevant migration criterion, the potential dietary exposure cannot be higher than 0.0025 µg/kg bw/day. Recycled PET manufactured with such recycling process is therefore not considered of safety concern.

In collection systems of post consumer PET, a percentage of containers used for non-food applications such as containers for mouthwash, detergents, shampoos, household cleaning products, medicines, garden chemicals and DIY "Do It Yourself "/home improvement products (e.g. paint removers, furniture polish) can be present. The contamination can originate from the presence of PET non compliant with the current EC Regulation on plastics in contact with foodstuffs or from the sorption of the chemicals from the non-food product. As a pre-requisite, the Panel considers that input based on containers coming from non-food uses should not be intentionally used. The Panel considered appropriate that the proportion of PET from non-food consumer applications should be no more than 5% in the input to be recycled.

In the case the above conditions are not fulfilled, the petitioner must provide further information to prove the safety of the process.

The Panel considers that the control of the pre-established and appropriate specifications of the input in the frame of a process management under good manufacturing practices (GMP) is mandatory to ensure the compliance of the recycled product with the requirements set out in the safety evaluation.

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BACKGROUND

According to the Regulation (EC) No 282/2008 of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods (EC, 2008), recycled plastics used to manufacture materials and articles intended for food contact shall be obtained only from processes authorised by the Commission following a safety assessment performed by the European Food Safety Authority (EFSA). This procedure has been established in Articles 5 of the Regulation No (EC) 282/2008 and articles 8 and 9 of the 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[4].

On 1 July 2008 the EFSA published "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" (EFSA, 2008). They give guidance on the administrative and technical data required for the evaluation by the EFSA of the risks originating from the potential migration of substances from food contact recycled plastic materials and articles into food. These guidelines cover recycling processes for all types of plastic.

Following the publication of the guidelines the CEF Panel received a high number of applications for processes producing recycled plastic for food contact uses which mainly deal with PET recycling.

The CEF Panel is currently evaluating PET recycling processes and has developed criteria specific to this type of plastic which are used during the evaluation process.

For transparency and in order to inform all stakeholders on the considerations followed for the risk assessment of PET recycling processes, the CEF Panel considers that these criteria should be published.

TERMS OF REFERENCE

On the basis of the recycling applications dossiers examined by the CEF Panel and the relevant scientific literature, the CEF Panel is asked to prepare a scientific opinion on the evaluation criteria used for evaluating recycling processes producing recycled PET intended to be used for manufacture of materials and articles in contact with food. The scientific opinion should describe the risk assessment approach used by the Panel and provide arithmetic values for the evaluation criteria specific to the evaluation of PET recycling processes for food contact uses.

[4] This Regulation replaces Directive 89/109/EEC of 21 December 1988, OJ L 40, 11.2.1989, P.38

1. Introduction

According to Regulation (EC) No 282/2008 on recycled plastic materials and articles intended for contact with food, recycled plastics shall be obtained only from processes authorized by the Commission following a safety assessment performed by EFSA (European Food Safety Authority). EFSA has published a guideline document on data requirements for evaluation of a recycling process prior to its authorisation (EFSA, 2008).

PET is characterized by a limited range of additives used and a low diffusion of potential migrants in the polymer matrix. It is by far the most frequently worldwide recycled polymer for food contact uses. Consequently, most knowledge on recycling exists for PET and allows developing specific criteria to evaluate PET recycling. These criteria are only applicable to recycling of PET. A general outline of the process to produce recycled PET starting from collected post consumer PET is shown in Appendix I.

The risks associated to 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 contaminants are considered:

a) Contaminants from possible misuse. PET containers used for food may be misused by consumers after food consumption to store chemicals.

b) Contaminants from non-food contact PET applications:

  - Non-authorised monomers and additives. The Regulation EC 282/2008 requires that plastic materials used as input in recycling processes are manufactured in accordance with Community legislation on plastic food contact materials and articles. However, in case of PET originating from third countries there is no adequate information and the use of not authorised substances cannot be excluded.
  - Chemicals from non-food consumer products. PET containers can be used in contact with non-food products (cosmetics, personal hygiene products, household cleaner) and sorb non-food substances.

c) Chemicals from materials other than PET, such as PVC, polyolefins and glues from caps, sleeves or labels, or polyamides from multilayered materials. Their presence can result from incomplete sorting and separation.

d) Chemicals used in the recycling process. Chemicals such as detergents and alkali used for the washing represent another possible source of contamination.

e) Degradation products of the plastic. During the various steps of the recycling process, e.g. high temperature treatments, the polymeric chain may break down to smaller molecules and any additives or sorbed compounds may react and be converted into new compounds.

f) Components of the food packaged in the PET containers might be sorbed, giving rise to a possible contamination of the plastic to be recycled.

Chemicals are of concern if they are present in the recycled plastic and if they migrate into the food in amounts which could endanger human health. Therefore, the control of the pre-established and appropriate specifications of the input in the frame of a process management under adequate good manufacturing practices are mandatory to set and to maintain the compliance of the recycled product. The quality of the input, the efficiency of the recycling process to remove contaminants, and the intended use of the recycled plastic, are all crucial points for the risk assessment. Taking into account all the above mentioned potential sources of contamination of the input, it has to be demonstrated that the process is able to reduce contamination to levels not posing a risk to human health for the intended use of the final product.

The EFSA guidelines (EFSA, 2008) require an experimental determination of the cleaning efficiency of the recycling process. This is generally achieved by a so-called ‘challenge test’. The objective of this test is to challenge a recycling technology or a whole process with respect to its ability to reduce possible contamination, irrespective of the source of the contamination. For this purpose, plastic is highly contaminated with model chemicals as surrogate contaminants. The choice of surrogate substances should cover the physico-chemical characteristics and properties (e.g. polarity and volatility) of a wide range of possible contaminants. This contaminated plastic is then introduced into the recycling process and the residual concentration of the surrogate contaminants is determined after the process, hence yielding the decontamination/cleaning efficiency of the recycling process.

For the overall risk assessment, the cleaning efficiency of the technology needs to be assessed on the basis of a reference input contamination level and the potential migration of residual contaminants from recycled articles into foods. The aim of this document is to present the evaluation procedure for this particular risk assessment concept.

2. The principles of the evaluation scheme

The underlying principle of the evaluation is to apply the measured cleaning efficiency of a recycling technology or process, obtained from a challenge test with surrogate contaminants at highly exaggerated levels, to a conservative reference contamination level for misuse contaminants in PET in order to calculate the residual concentration of contaminants in recycled PET (Cres). The resulting residual concentration for each contaminant is then compared to a modelled concentration in PET (Cmod). This Cmod is calculated using generally recognized conservative migration models and it corresponds to a migration which cannot give rise to a dietary exposure exceeding the threshold below which the risk to human health would be negligible.

Therefore, when Cres is not higher than Cmod, it is considered that the process is able to produce an output which is not likely to be of safety concern for the defined conditions of use.

3. Derivation of the key parameters

3.1. Reference contamination level of the input

3.1.1. Overview of contamination, data on post consumer PET bottles

Several studies have been carried out to investigate to which extent and at which incidence collected plastics may be contaminated. PET is the most frequently studied material.

A review of the literature data can be found in Franz (2003). Typical contaminants reported are mainly from food-related flavouring substances such as limonene from beverages and other substances such as methyl salicylate from cosmetics and personal hygiene products. Typical concentrations of these substances in collected PET have been found to be in the ppm (mg/kg) range. Miscellaneous substances from other sources are reported to be in the range of 1 mg/kg PET or lower. Almost all studies have been done on a limited number of samples from which no fully reliable statistics on the contamination incidence can be derived

However, at the European level, one study, the EU project FAIR-CT98-4318, provides 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 (Franz *et al.,* 2004a, b). As the most typical post consumer contaminant limonene (the main odour constituent of citrus fruits but also used in many household

cleaning products) was found at average levels of 2.9 mg/kg and at a maximum concentration of about 20 mg/kg. Miscellaneous contaminants related to plastics such as adipates, phthalates, erucamide and other occurred sporadically and at levels lower than 0.2 mg/kg except for in one case – dioctyl adipate – at 0.5 mg/kg. Also rare cases of misused bottles were identified. It was found that in three cases, the particular bottles had obviously been misused by filling them with household chemicals, fuels or similar. The chemicals found in these three cases were (i) toluene at 4500-6750 mg/kg PET, (ii) toluene at 2000-3000 mg/kg, and (iii) xylene at 2000-3000 mg/kg.
In the EU project FAIR CT98-4318 approximately 250 samples of virgin PET and of supercleaned post consumer recycled PET (R-PET) were analytically screened. R-PET could not be distinguished from virgin PET: it did contain the same substances related to PET such as acetaldehyde and monomers and did not show in the gas chromatograms any foreign substance peaks.

Another relevant study on the contamination levels in five different types of collected PET in the USA has also been published (Bayer, 2002). Four types were food containers (deposit and curbsides) and one was non-food containers sorted from curbside stream. The non-food PET was composed of mouthwash, soaps/shampoos and household cleaner containers. In total 121 substances were identified from these five feedstock materials after washing and drying. The total contamination from all substances found in deposit material of food PET containers, which means the sum of all detectable substances, was estimated to be 28.5 mg/kg in washed and dried flakes. Limonene was the predominant contaminant with a maximum concentration of 18 mg/kg. The total contamination in non-food containers was estimated to be 39 mg/kg in washed and dried PET flakes with methyl salicylate being the predominant compound at a concentration of 15.3 mg/kg. Hexanal and benzaldehyde were identified in both food deposit and non-food feedstocks at a concentration up to 3.4 mg/kg. Limonene and carvacrol were identified in non-food feedstocks at 3.5 and 5.2 mg/kg respectively. All compounds are traceable directly to the original contents of the containers.

In another study, carried out only on three individual non-food PET bottles obtained directly from collection bins for recycling plastic bottles in the US, Begley *et al.*, found from 130 to 204 mg methyl salicylate/kg in the wall of a antiseptic mouth wash bottle, 1 mg triclosan/kg in a hand soap bottle and 1.6 mg limonene/kg in a paint remover bottle (Begley *et al.*, 2002). He noted that the mouth rinse contained 21 % ethanol which is a solvent that can swell PET and increase the solubility parameters in PET.

3.1.2. Incidence data on contamination cases by misuse

How often does a severe contamination case by misuse occur? From the EU project FAIR CT98-4318, three bottles out of 7000 to 10 000 bottles were grossly misused, resulting in an estimated incidence level of approximately 0.03 % to 0.04 %.

Two other studies have reported incidence data. In the first study it is reported that quality control hydrocarbon sniffers to check refillable bottles caused rejects in the range of 0.3 to 1 % (Allen and Blakistone, 1994). However, the majority of the rejects were due to flavour components from foods previously contained and not from contaminants. In the second study (Bayer *et al.*, 1994) an incidence of contamination of 1 bottle out of 10 000 bottles (0.01 %) is reported but without providing further details on the substances. Therefore, figures provided by these two studies are not considered representative for the risk assessment.

3.1.3. Data on sorption of chemicals into PET

Most of available data on sorption into PET are related to experimental studies on flakes and strips while only one study reports the sorption of chemicals into whole, intact PET bottles.

The sorption of chemicals into PET is influenced by factors such as the physical and chemical properties of the contaminants (mainly their polarity and their molecular size), the contact time and temperature, the use of aggressive solvents causing swelling of PET (acetone, ethanol, etc.), PET morphology (crystallinity) and whether the PET is flakes, strips cut from PET bottle walls or whole bottles. This explains the variability of the experimental results.

As regards sorption into PET flakes and strips, the obtained sorption of chemicals with different molecular weight and polarity ranges from 28 to 818 mg solvent/kg PET. In one extreme case of contact with pure benzene, a level of 7383 mg/kg PET (Komolprasert and Lawson, 1995; Demertzis *et al.*, 1997; Franz, 1999; Begley *et al.*, 2002) was found. At this stage, it should be noted that severe sorption of chemicals into PET will lead to visible changes (deformation, swelling, discolouring). Therefore, in realistic conditions that would not cause a physical change of the bottles, sorption ranges from 28 to 818 mg/kg in PET with most of the values below 500 mg/kg PET.

Sorption into flakes can be up to one order of magnitude higher than in PET bottles (Komolprasert and Lawson, 1995). This being said, the estimated sorption of chemicals with different molecular weight and polarity in realistic conditions ranges from 0.3 to 600 mg/kg in PET bottles with most of the tested chemicals below 500 mg/kg for PET bottles.

3.1.4. Derivation of a reference contamination level from misuse of food contact PET applications

Taking into account surveys on contamination of post consumer PET used for recycling and experimental data on sorption properties of chemicals in PET, the Panel considered appropriate to base the reference contamination level on data from the EU survey, project FAIR-CT98-4318, on contamination of post consumer PET bottles (Franz *et al.*, 2004a, b).

In this EU survey, the highest misuse contamination levels in washed and dried PET flakes were found for two solvents: toluene and xylene. By attributing these levels 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 each bottle. Taking into account that the total number of bottles was 7000-10000, the total percentage of the bottles contaminated by misuse was 0.03-0.04 %.

Taking into account the dilution effect deriving from high amounts of non misused bottles, the authors estimated that the maximum concentrations of toluene (the obtained worst case in the FAIR Project) in the recycling feedstock would have been ranging from 1.4 to 2.7 mg/kg PET. This calculation was done by attributing the whole 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 can be used to assess potential concentration of a single substance in post consumer PET due to misuse for the purpose of these evaluation criteria.

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

3.1.5. 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 and DIY

"Do It Yourself "/home improvement products (e.g. paint removers, furniture polish) can be present. For these non-food PET containers, two potential contamination sources must be taken into account.

1. Is all PET for non-food consumer products food grade PET? According to the Regulation (EC) 282/2008, as a regulatory pre-requisite, the plastic input for recycling must originate from plastic materials and articles that have been manufactured in accordance with Community legislation on plastic food contact materials and articles. 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. All of these resins comply with Directive 2002/72/EC and its subsequent amendments (PlasticsEurope, 2010). The FDA has also received the information from the plastics industry that verifies that all PET resin used to manufacture containers in the USA is authorized for food-contact use (FDA, 2006). If the input does not come from Europe or the USA, it shall be demonstrated that it originates from plastic materials and articles that have been manufactured in accordance with Community legislation on plastic food contact materials and articles (Regulation (EC) 282/2008).

2. Chemicals contained as part of the non-food product may be sorbed by the PET container and so the input of "non-food" PET containers leads to the potential direct introduction of non-food substances into the recycling process. This case can be differentiated from misuse by the consumer and so some specific considerations are due.
   In a comprehensive study (Bayer, 2002), the highest average concentration of contaminants measured in a stream of exclusively non-food contact plastics (sorted from post consumer waste) and composed of mouthwash, soaps/shampoos and households cleaners containers was 15 mg/kg for methyl salicylate which is a chemical commonly used in mouthwashes and household cleaners. The next highest chemicals were 3.5 mg/kg for limonene and 2 mg/kg for benzaldehyde.

As a pre-requisite, the Panel considers that input based on containers coming from non-food uses should not intentionally be used.

If, as the result of the challenge test, recycling process is shown to be able to remove surrogate contaminants, this of course applies to all possible contaminants represented by the surrogates, irrespectively of their origin

Information from the applications submitted to EFSA indicate that collection/sorting systems allow to get input for recycling process containing no more than 5% of PET containers from non-food applications.
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. In fact, by respecting this proportion, also the highest average concentration level of 15 mg methyl salicylate/kg non-food PET containers would have been reduced at levels in the same range or below the reference contamination level for misuse.

Therefore, in the input to be recycled, no more than 5% of PET containers from non-food contact uses should be present and adequate information should be given to EFSA in order to assess how this content is kept under control. As regards higher percentages of presence of non-food PET containers, adequate information on the composition of the input is necessary to derive *ad hoc* figures for a case by case evaluation approach.

3.2. Decontamination/cleaning efficiency of the recycling process: Challenge test

To determine the decontamination efficiency of the recycling process, specially designed challenge tests are performed, based on use of surrogate contaminants. These surrogates are substances with different molecular weights and polarities representative of possible chemical classes of contaminants of concern that were demonstrated to be suitable to monitor the behaviour of plastic during recycling (Pennarun *et al.*, 2005; FDA, 2006).

In addition to the general recommendations expressed in the chapter 3.2.3. of the EFSA guidelines (EFSA, 2008), the following ones should be considered for mechanical recycling of PET.

3.2.1. Representativeness of the processing parameters

The challenge test could be performed at the industrial scale or at a pilot plant or even at laboratory scale. In any case, the minimum values of the critical processing parameters (e.g. temperature, pressure, average residence time , gas flow) used for the challenge test should be provided. It should be explained why and how the conditions used and the results obtained from the pilot plant facilities or in the laboratory are representative of the processing conditions and performance of the full scale industrial line. If the plant does not run under conditions at least as severe (i.e. better cleaning efficiency) as those used in the challenge test, explanations should be provided on the effect of eventual differences on the decontamination efficiency of the plant.

3.2.2. Artificial contamination of the input

It should be demonstrated that the contamination with surrogates is not mainly on the surface of the plastic that could over-estimate the decontamination efficiency.

Contamination levels must be high enough to allow proper analysis of the remaining concentrations in the cleaned PET. On the other hand, too high levels may over–challenge technical cleaning performance by affecting it negatively. Therefore, the artificially generated contamination levels fed into a recycling process for a challenge test should typically be in a range between 250 and 1000 mg/kg PET of a surrogate in PET to allow an appropriate determination of the cleaning efficiency of the technology.

3.2.3. Cross-contamination

In some cases, challenge tests are performed with a mixture of non-contaminated flakes and contaminated flakes. During the process/challenge test, cross-contamination (i.e. transfer of surrogates from the contaminated to non-contaminated flakes) may occur. The decontamination efficiency should then be determined on the basis of the total amount of residual surrogates, measured in both contaminated and initially non-contaminated flakes/pellets.

3.3. Criterion of migration of potential contaminants

For the purpose of safety assessment, it has to be demonstrated that the recycling process is capable of removing efficiently any contamination from the input that could endanger human health. 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 which can be considered of negligible risk to human health must take into account this possibility, too.

3.3.1. *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[5]. This threshold is 0.15µg/person/day, for a person of 60 kg body weight, corresponding to 0.0025 µg/kg bw/day (Kroes *et al.*, 2004) [6]. Generally, this threshold value is low enough to address concern over all toxicological effects.

As a pragmatic approach, the Panel considers that an unknown contaminant possibly present in PET feedstock has sufficiently been removed if its residual concentration in recycled PET cannot give rise to migration in food which could result in a dietary exposure higher than 0.0025 µg/kg bw/day or 0.15µg/per person/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 support the conservativism of an intake up to 0.0025 µg /kg bw/day of any potential contaminant which may migrate from recycled PET:

- genotoxic compounds are generally not allowed to be placed on the market in consumer products (EC, 2006) and therefore contamination of the post consumer PET with genotoxic compounds, if any, is expected to be sporadic.
- many functional groups associated to a possible genotoxicity of the 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 strongly decrease their potential residual concentration available for migration (AFSSA, 2006).

Some structural groups were identified to be of such high potency that dietary exposure even 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 these high potency genotoxic carcinogens are likely to be available to consumers and be stored in PET containers after their use in contact with food.

In the case that the applicant places no restriction in the use of the recycled PET and since infants constitute the population with the highest potential exposure, the default scenario considered is that of an infant weighing 5 kg and consuming every day 0.75 l of water (WHO, 2003), corresponding to a food consumption of 150 g/kg bw/day. From this figure, it can be derived that the highest concentration of a substance in water that would ensure that the dietary exposure of 0.0025 µg/kg bw/day is not exceeded is 0.017 µg/kg food. It should be noted that for other categories of the population, toddlers and adults, due to the lower food consumption per kg bw, the respective concentrations in food would be higher (Appendix II).

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[5] 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 food contact materials (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 containing a structural alert for genotoxicity.

[6] An opinion of the Scientific Committee of EFSA on the concept of threshold of toxicological concern is under preparation and expected later this year or start of the next year.

Other exposure scenarios can be formulated, depending on the intended food contact applications of the PET articles containing recyclate.

3.3.2. Calculation of migration levels

In order to get suitable parameters to evaluate the data from the recycling process in the light of the above criterion, the migration of potential residual contaminants is estimated by use of migration models (Begley *et al.*, 2005; EC, 2010).

The migration calculated by generally recognized diffusion models overestimates the real migration around 5 to 100 times (Welle *et al.*, 2008; EC, 2010). The degree of overestimation depends on the diffusion properties of migrants in PET. Therefore, the overestimation is taken into account by inclusion of the lower figure of 5 in the derivation of a migration criterion and subsequently the corresponding Cmod, rather than the upper figure of 100. In fact, using the higher figure would result in Cmod levels too high to take sufficiently into account potentially highly migrating contaminants. The migration criterion for food satisfying the above criterion for infants is calculated to be 0.1 µg/kg (= ~ 5 × 0.017 µg/kg) in food or food simulant. In fact, the real migration corresponding to the modelled migration of 0.1 µg/kg food would be around 0.001-0.02 µg/kg food. The figure of 0.1 µg/kg food will be used further in the backwards calculation of Cmod (see Appendix III). It should be stressed that the figure of 0.1 µg/kg food is used for calculations only, and does not represent an accepted level of migration.

To satisfy the evaluation criterion, the PET recycling process has to be demonstrated able to decontaminate the input up to a residual concentration (Cres) not higher than the Cmod. Parameters and examples of calculation of the Cres and Cmod as well as a table with the Cmod for the most commonly used surrogates in challenge tests are given in Appendix III. In the calculation supporting the values for Cmod given in the Appendix III, it is assumed that final articles are manufactured with 100 % recycled PET.

For the other exposure scenarios described in Appendix II for adults and toddlers, the relevant migration criterion, obtained by assuming an overestimation factor of 5 for the modelled migration, will be 0.75 and 0.15 µg/kg food respectively.

3.3.3. Considerations on the assumptions used, any uncertainties, and their likely impact

1. There are no recent surveys of the frequency and severity of the contamination of post-consumer PET waste streams, other than the EU project FAIR-CT98-4318 (Franz *et al.*, 2002, 2004a, b). It is not known whether the present situation would correspond to different contamination figures.

2. The migration modelling is known to overestimate migration from PET because of the inbuilt conservative parameters (EC, 2010). The overestimation increases with the molecular weight of the surrogates being for small surrogates molecules, like toluene, close to 5, and for larger molecules from 10 up to at least 100 times (Welle *et al.*, 2008).

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) in contact for 12 months at 25°C before consumption. These conditions of contact are, in most cases conservative since food/drink will be consumed earlier.

4. Taking into account the collection systems, the presence of unknown and possibly genotoxic contaminants in recycled PET, if any, is likely to be sporadic. Therefore the application of a

toxicological threshold based on chronic exposure to possibly genotoxic substances increases the conservativism of the present approach.

Considering all the uncertainties, safety factors and assumptions, the real potential migration of any contaminants from a recycled PET obtained by a process that is able to reduce an input reference contamination of 3 mg/kg PET to a residual concentration (Cres) corresponding to a modelled migration which may not give rise to a dietary exposure exceeding the threshold of toxicological concern proposed by Kroes *et al.* (2004) for substances with a structural alert for genotoxicity and considered not of safety concern. Given the nature and origin of these uncertainties, safety factors and assumptions, the criteria described herein are applicable only to the recycling of PET. Different approaches and criteria may be applicable to the recycling of other materials.

4. Application of the key parameters for the evaluation scheme

As said in chapter 2, the underlying principle of the evaluation is to apply the measured cleaning efficiency of recycling technologies and processes, obtained from a challenge test with highly exaggerated contamination levels, to a conservative reference contamination level of 3 mg/kg PET in order to calculate residual concentrations of contaminants in recycled PET (Cres). It is assumed that final articles are manufactured with 100 % recycled PET.

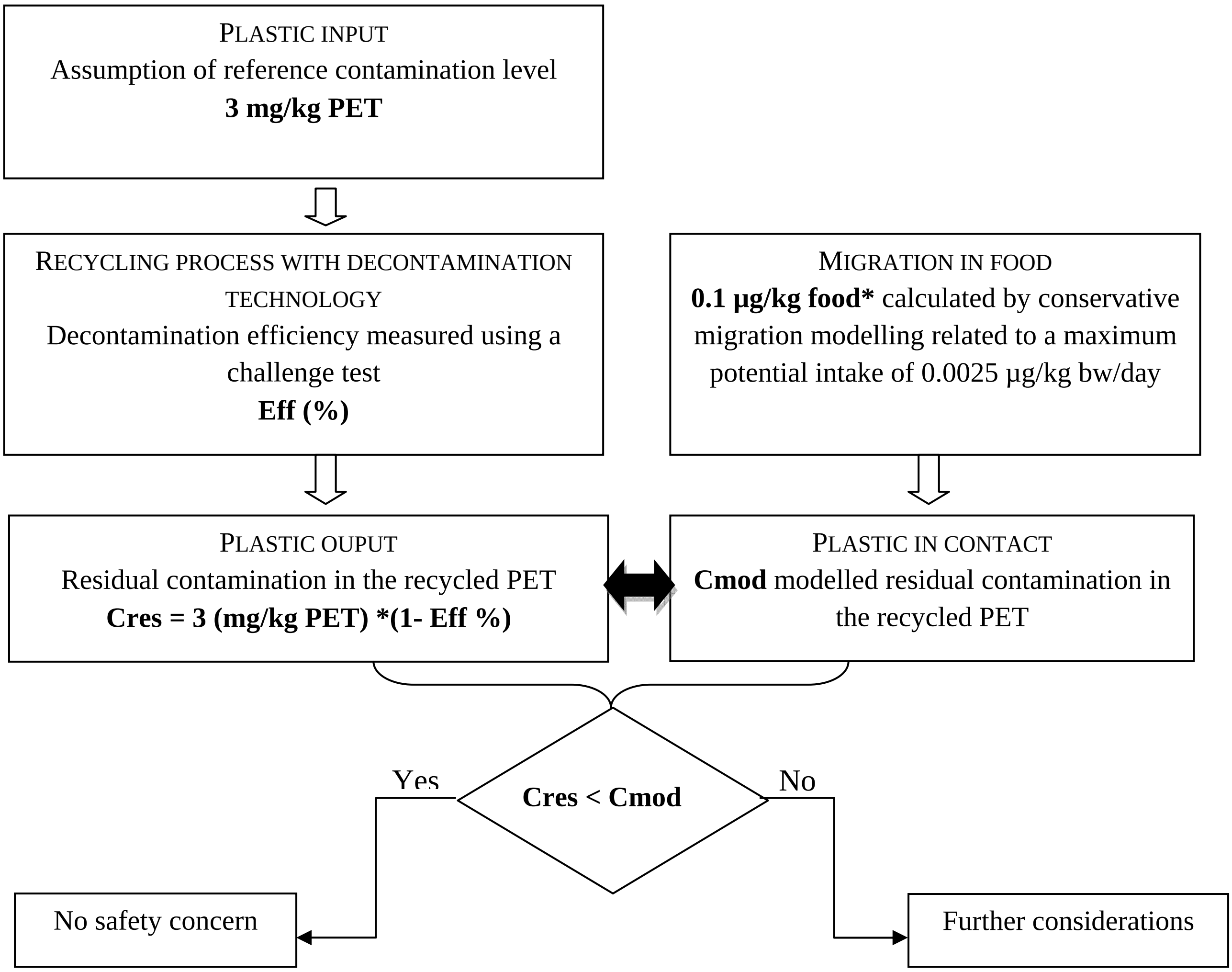
For the default scenario, these resulting residual concentrations for each surrogate in recycled PET are then compared to conservative concentrations in PET (Cmod) leading to a migration criterion of 0.1 µg/kg food calculated using generally recognized conservative migration modelling (Piringer and Hinrichs, 2001; EC, 2010) under defined conditions of uses. Modelling parameters used to correlate concentration in PET (Cmod) with migration of 0.1µg/kg food are reported in Appendix III.

When Cres < Cmod for each surrogate contaminant, it can be derived that the migration of unknown contaminants in food will be below the conservatively modelled migration of 0.1 µg/kg food.

If Cres > Cmod, due to the conservatism incorporated in many evaluation factors, it is possible that the petitioner provides further information to prove the safety of the process. Alternatively, the applicant could restrict the intended uses (e.g. by reducing the percentage of recycled PET in the final articles).

In the case of the other exposure scenarios for adults and toddlers described in Appendix II, the relevant migration criterion will accor1dingly be 0.75 and 0.15 µg/kg food or food simulant. Cmod should be recalculated according to Appendix III.

Figure 1: Relationship between the key parameters for the evaluation scheme



**: Default scenario (Infant). For adults and toddlers, the migration criterion will be 0.75 and 0.15 µg/kg food respectively.*

CONCLUSIONS

The underlying principle of the evaluation is to apply the cleaning efficiency of a recycling technology or process, obtained from a challenge test with surrogate contaminants, to a reference contamination level for post consumer PET, conservatively set a 3 mg/kg PET for a contaminant resulting from possible misuse. This reference level was derived from the results of an EU survey performed in the framework of a European project. The resulting residual concentration of each contaminant in recycled PET (Cres) is then compared to a modelled concentration in PET (Cmod). This Cmod is calculated using generally recognized conservative migration models such that the related migration may not give rise to a dietary exposure exceeding the threshold below which the risk to human health would be negligible.

As a pragmatic approach, the Panel considers that this dietary exposure should be below 0.0025 µg/kg bw/day. This is the human exposure threshold value for chemicals with structural alerts raising concern for potential genotoxicity. This threshold value is low enough to address concern over any other toxicological effects. Thus, it is ensured that any unknown contaminant possibly present is treated in a conservative way.

As regards the exposure scenario, the Panel considers that the most conservative scenario is that of an infant weighing 5 kg and consuming every day 0.75 l of water (WHO, 2003) coming from a water bottle manufactured from 100 % recycled PET. From this figure, it can be derived that the highest concentration of a substance in water that would ensure that the dietary exposure of 0.0025 µg/kg bw/day is not exceeded is 0.017 µg/kg food. This scenario is applied as default when the recycled PET is intended for general use.

The Panel noted that for other categories of the population, toddlers and adults, due to the lower food consumption per kg bw, the respective concentrations in food would be higher and that other exposure scenarios can be formulated.

Taking into account the overestimation of migration by the generally agreed diffusion modelling (EC, 2010), a calculated migration less than 0.1 µg/kg in food would satisfy the above criterion for the default exposure scenario. In the case of the other exposure scenarios for adults and toddlers, the relevant migration criterion will accordingly be 0.75 and 0.15 µg/kg food respectively.

The Panel considers that if a recycling process is able to reduce an input reference contamination of 3 mg/kg PET to a Cres not higher than a Cmod corresponding to the relevant migration criterion, the potential dietary exposure cannot be higher than 0.0025 µg/kg bw/day. Recycled PET manufactured with such recycling process is therefore not considered of safety concern.

The Panel considered appropriate that the proportion of PET from non-food consumer applications should be no more than 5 % in the input to be recycled.

In the case the above conditions are not fulfilled, the petitioner must provide further information to prove the safety of the process.

The Panel considers that the control of the pre-established and appropriate specifications of the input in the frame of a process management under good manufacturing practices (GMP) is mandatory to ensure the compliance of the recycled product with the requirements set out in the safety evaluation.

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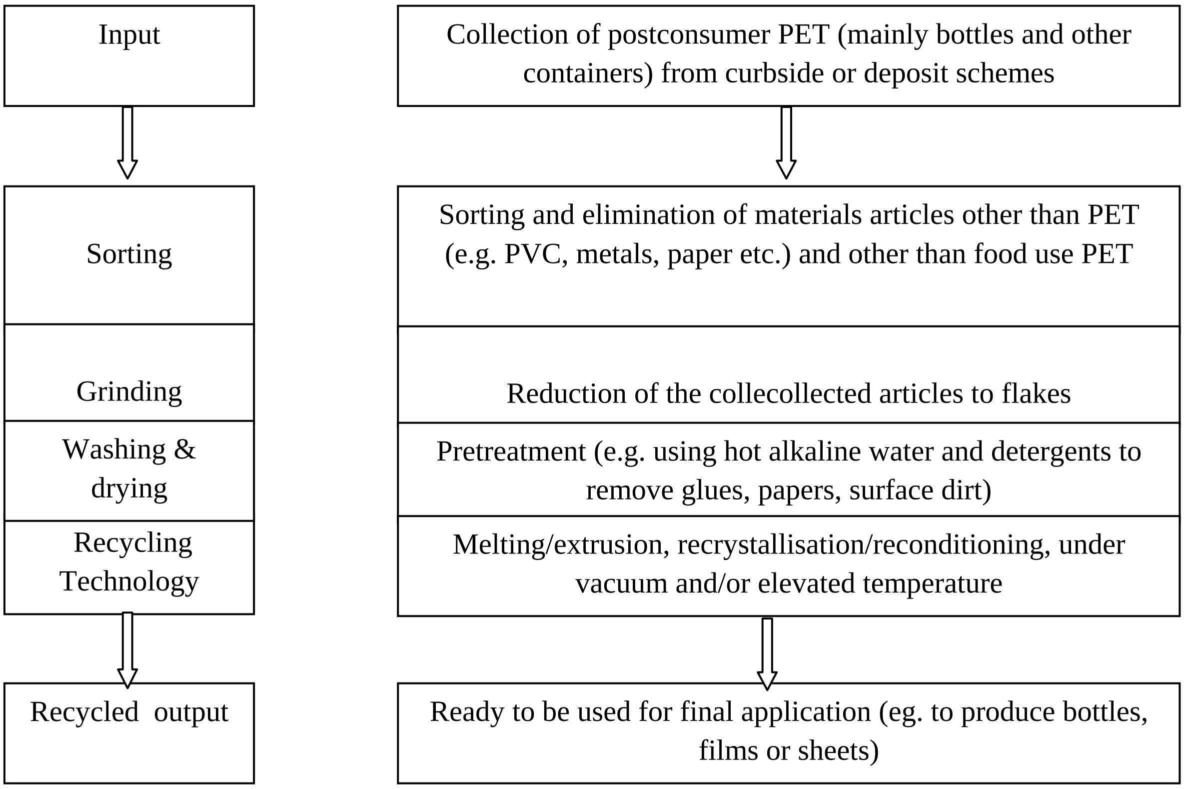
APPENDICES

APPENDIX I

GENERAL SCHEME FOR THE PRODUCTION OF RECYCLED PET AND CORRESPONDING ACTIONS



APPENDIX II

EXPOSURE SCENARIOS TO DERIVE MIGRATION FIGURES 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/day (Kroes *et al.,* 2004) and on the basis of food consumption and body weights and it is possible to derive different scenario for adults, children and infants. Scenarios for specific uses can be also formulated, depending on the intended food contact applications of the recycled PET.

Adults:

The model currently used to assess potential exposure to residues from food packaging is that 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) (EC, 2001). It is assumed in this scenario that 1 kg of food ingested daily is packaged in recycled PET.

On the basis of the human exposure threshold value of 0.0025 µg/kg bw/day, the corresponding maximum migration of a substance is 0.15 µg/kg food. Assuming, conservatively a general overestimation of the modelled migration by at least 5 times, the migration criterion is calculated to be 0.75 µg /kg food.

Toddlers:

According to data available, in the EFSA Comprehensive European Food Consumption Database (EFSA 2011), for toddlers aged from 1 to 4 years, the 95th percentile consumption of all beverages including bottled water and milk and excluding tap water, is up to around 90 g/kg bw/day (mainly due to high milk consumption per kg bw). A conservative scenario of exposure would be to consider that all these beverages are packaged in recycled PET.

On the basis of the human exposure threshold value of 0.0025 µg/kg bw/day, the corresponding maximum migration of a substance is 0.028 µg/kg food. Assuming, conservatively a general overestimation of the modelled migration by at least 5 times, the migration criterion is calculated to be 0.15µg/kg food.

Infants:

The reference scenario is that of infants (5 kg body weight) fed daily with infant formula powder reconstituted with 0.75 L water (WHO, 2003). It is assumed in this scenario that all the water used is packaged in recycled PET bottles. It corresponds to a water consumption of 150g/kg bw /day. On the basis of the human exposure threshold value of 0.0025 µg/kg bw/day, the corresponding maximum migration of a substance is 0.017 µg/kg food. Assuming, conservatively a general overestimation of the modelled migration by at least 5 times, the migration criterion is calculated to be 0.1µg/kg food.

APPENDIX III

MODELLING PARAMETERS AND EXAMPLES OF CALCULATIONS

A. MODELLING PARAMETERS USED TO CALCULATE CONCENTRATION IN PET (C_{MOD}) CORRESPONDING TO MIGRATION OF 0. 1 µg/kg FOOD

For long term ambient storage, a shelf life of 1 year at 25°C.

Good solubility of the migrant in food simulant is assumed, ($K_{p,F}$=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 is assumed.

For the calculation of the diffusion coefficient in PET for contact temperatures below or equal to 70°C as a modelling parameter Ap' = 3.1 is used and τ = 1577 (EC, 2010).

NOTES:

a) The same parameters can be used to calculate C_{Mod} corresponding to migration of 0.15 µg/kg food or 0.75 µg/kg food.

b) The combination of these parameters has been generally recognized to ensure overestimation of migration from PET under the above conditions (EC, 2010). Under different application conditions (for example for ovenable PET trays or films), the modelling parameters should be selected according to the above reference and an adequate argumentation should be given. Time and temperature conditions (e.g. hotfill) should be selected according to the Regulation (EC) 10/2011 (EC, 2011).

B. EXAMPLE OF CALCULATION OF CRES AND CMOD FOR PHENYLCYCLOHEXANE

Exposure scenario is for infant (Appendix II).
Surrogate: Phenylcyclohexane (Molecular weight 160 Da) as representative of chemicals that are at the same time non-polar and non-volatile.
Modelling parameters as above (A.).

Decontamination efficiency for a given recycling process in the technical dossier, obtained from the challenge test is 98.5 %

Calculation of Cres

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 x (1- 0.985)= 0.05 mg/kg PET.

Calculation of Cmod

The modelled concentration of phenylcyclohexane in the recycled PET (*Cmod*) corresponding to a migration of 0.1 µg/kg food (criterion for infant scenario) is 0.14 mg phenylcyclohexane/kg.

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 (*Cmod= 0.14 mg/kg PET)*. 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 0.1 µg/kg food.

C. CMOD FOR THE MOST COMMON SURROGATE CONTAMINANTS CORRESPONDING TO A MIGRATION LEVEL OF 0.1 µG/KG FOOD AND CALCULATED BY DIFFUSION MODELLING (EC, 2010) USING THE ABOVE PARAMETERS

Surrogate	M W (Da)	Cmod (mg/kg PET)
Toluene	92	0.09
Chlorobenzene	113	0.09
Methyl salicylate	152	0.13
Phenylcyclohexane	160	0.14
Benzophenone	182	0.16
Lindane	291	0.31
Methyl stearate	298	0.32

Notes

a) This Table is for the default scenario (Infants). Cmod corresponding to other scenarios (adults, toddlers) can be calculated by using the parameters in point A.

b) Other figures could be considered if appropriate scientific argumentations, when necessary supported by experimental data, is provided to EFSA.

DEFINITIONS AND ABBREVIATIONS

Experimental Contamination Level: Artificially generated concentration of a surrogate in PET (normally flakes) for being introduced into a recycling process for the purpose of a challenge test.

Cleaning Efficiency: Cleaning efficiency as established in the challenge test, from Experimental Contamination Level and concentration remaining in the PET material after challenge test).

Misuse: The use of PET food containers by consumers after food consumption to store chemicals.

Reference Contamination Level: the concentration level of an unknown misuse contaminant in PET washed and dried flakes used as inpu for recycling, by default 3 mg/kg PET.
Residual concentration (Cres) of a surrogate in the PET product: It is obtained by multiplying (1- cleaning efficiency %) from the challenge test by the Reference Contamination Level.

Modelled Concentration (Cmod): Modelled concentration in PET correlating with the migration criteria (0.1 µg/kg in food for infant exposure scenario). Conservative estimation (based on generally recognized migration modelling) of the concentration of a substance (surrogate or other contaminant) in PET which would cause a migration of 0.1 µg/kg in food after 12 months contact at 25°C. Other Cmod can be calculated by the corresponding migration criteria for the other exposure scenarios (adults, toddlers)