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Safety assessment of the process Starlinger recoSTAR HDPE FC 1 – PET2PET used to recycle post-consumer HDPE closures into food contact closures

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Abstract

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) assessed the safety of the recycling process Starlinger recoSTAR HDPE FC 1 – PET2PET. The process is intended to recycle food grade high-density polyethylene (HDPE) closures from post-consumer PET beverage bottle streams to produce recycled HDPE pellets using the technology Starlinger recoSTAR HDPE (FC 1). The recycled pellets are intended to be used at up to 100% for the manufacture of new closures for direct contact with mineral water and other beverages for long-term storage at room temperature. The recycling process comprises the sorting of the HDPE closures from the bottles, their conventional recycling, their pre-drying, their extrusion into pellets and their decontamination in a continuous reactor. The dossier contained insufficient data. Notably, the data provided did not include an adequate description of the process to allow a clear understanding of the main steps and operating parameters of the technology; the data did not allow to demonstrate that the challenge test is representative of the industrial process, hence, that it is suitable for determining the decontamination efficiency of the process; the data did not allow to estimate the residual concentration (C_{res}) for HDPE closures from PET beverage bottles. The Panel noted the limited efficiency of the technology to remove contaminants with a molecular weight above 400 Da and which would migrate into water and other beverages. Based on the submitted information, the Panel concluded that the applicant has not demonstrated in an adequately performed challenge test or by other appropriate evidence that the recycling process is able to reduce contamination of the HDPE flakes originating from PET beverage bottles to a concentration that does not pose a risk to human health.

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[†] Deceased.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Recycled plastic materials and articles shall only be placed on the market if they contain recycled plastic obtained from an authorised recycling process. Before a recycling process is authorised, EFSA's opinion on its safety is required. This procedure has been established in Article 5 of Regulation (EC) No 282/2008¹ of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004² of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the Member States Competent Authorities which transmit the applications to the European Food Safety Authority (EFSA) for evaluation.

In this case, EFSA received, from the Federal Ministry of Labour, Social Affairs, Health and Consumer Protection, Republic of Austria, an application for evaluation of "Recycled HDPE Closures for Direct Food Contact Application", European Union (EU) register No RECYC180. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2019-0296. The dossier was submitted on behalf of PET to PET Recycling Österreich GmbH.

According to Article 5 of Regulation (EC) No 282/2008 of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods, EFSA is required to carry out risk assessments on the risks originating from the migration of substances from recycled food contact plastic materials and articles into food and deliver a scientific opinion on the recycling process examined.

According to Article 4 of Regulation (EC) No 282/2008, EFSA will evaluate whether it has been demonstrated in a challenge test, or by other appropriate scientific evidence, that the recycling process is able to reduce the contamination of the plastic input to a concentration that does not pose a risk to human health. The poly(ethylene terephthalate) (PET) materials and articles used as input of the process as well as the conditions of use of the recycled PET make part of this evaluation.

2. Data and methodologies

2.1. Data

The applicant has submitted a dossier following the 'EFSA guidelines for the submission of an application for the safety evaluation of a recycling process to produce recycled plastics intended to be used for the manufacture of materials and articles in contact with food, prior to its authorisation' (EFSA, 2008). Applications are submitted in accordance with Article 5 of the Regulation (EC) No 282/2008.

Additional information was provided by the applicant during the assessment process in response to the request from EFSA sent on 15 April 2020 (see Documentation provided to EFSA).

The following information on the recycling process was provided by the applicant and used for the evaluation:

- General information:
 - general description,
 - existing authorisations.
- Specific information:
 - recycling process steps and technology,
 - characterisation of the input,
 - determination of the decontamination efficiency,
 - characterisation of the recycled plastic,
 - intended application in contact with food,
 - compliance with the relevant provisions on food contact materials and articles,
 - process analysis and evaluation,
 - operating parameters.

¹ Regulation (EC) No 282/2008 of the European parliament and of the council 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.

² 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.

2.2. Methodologies

The principles followed up for the evaluation are described here. The risks associated with the use of recycled plastic materials and articles in contact with food come from the possible migration of chemicals into the food in amounts that would endanger human health. The quality of the input, the efficiency of the recycling process to remove contaminants as well as the intended use of the recycled plastic are crucial points for the risk assessment (see guidelines on recycling plastics; EFSA, 2008).

The CEP Panel considered the criteria for the safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for the manufacture of materials and articles in contact with food described in the scientific opinion developed by the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (EFSA CEF Panel, 2011). The principle of the evaluation is to apply the decontamination 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 at 3 mg/kg PET for contaminants resulting from possible misuse. The residual concentration of each surrogate contaminant in recycled PET (C_{res}) is compared with a modelled concentration of the surrogate contaminants in PET (C_{mod}). This C_{mod} is calculated using generally recognised conservative migration models so that the related migration does not give rise to a dietary exposure exceeding 0.0025 µg/kg body weight (bw) per day (i.e. the human exposure threshold value for chemicals with structural alerts for genotoxicity), below which the risk to human health would be negligible. If the C_{res} is not higher than the C_{mod} , the recycled PET manufactured by such recycling process is not considered of safety concern for the defined conditions of use (EFSA CEF Panel, 2011).

In addition, the CEP Panel considered the previous assessment of HDPE recycling processes (EFSA CEF Panel, 2015). The opinion outlines the applicability of the criteria for the safety evaluation of a mechanical recycling process to produce recycled PET (EFSA CEF Panel, 2011) to HDPE, and discusses the criteria specific to the safety evaluation of the recycled HDPE.

The assessment was conducted in line with the principles described in the EFSA Guidance on transparency in the scientific aspects of risk assessment (EFSA, 2009) and considering the relevant guidance from the EFSA Scientific Committee.

3. Assessment

3.1. General information³

According to the applicant, the recycling process 'Starlinger recoSTAR HDPE FC 1 – PET2PET' is intended to recycle food grade high-density polyethylene (HDPE) closures, from post-consumer PET beverage bottles, to pellets using the Starlinger recoSTAR HDPE (FC 1) technology. The recycled pellets are intended to be used in a mass fraction up to 100% for the manufacture of new closures. These closures are intended to be used in direct contact with mineral water and other beverages for long-term storage at room temperature. Hot fill, oven heating and microwave are excluded.

3.2. Description of the process

3.2.1. General description⁴

The recycling process produces recycled HDPE pellets from closures used on PET beverage bottles coming from post-consumer collection systems, such as curbside and deposit systems. The recycling process comprises the steps mentioned below.

Input

- Step 1: Post-consumer HDPE closure flakes coming from the recycling of PET beverage bottles are processed by the applicant into hot caustic and surfactant-washed flakes that are then wrung out.

Decontamination and production of recycled HDPE material

- Step 2: The flakes are pre-dried, then extruded into pellets with vacuum degassing
- Step 3: The pellets are treated in a continuous reactor under temperature and [REDACTED]

³ Technical dossier/Add data May 21/3_update2_PET2PET_Technical_Dossier_confidential, section 3.1.

⁴ Technical dossier/Add data May 21/3_update2_PET2PET_Technical_Dossier_confidential, section 3.1.1.

The operating conditions of the processes have been provided to EFSA. However, not all relevant parameters were adequately reported.

According to the applicant, the recycled pellets, the final product of the process, are controlled against volatile organic contaminants. The recycled pellets are intended to be converted by other companies into new closures for bottles used for long-term storage at room temperature, such as bottles for mineral water and other beverages (e.g. soft drinks, energy drinks and juices).

3.2.2. Characterisation of the input⁵

According to the applicant, the input material for the recycling process consists of hot caustic and surfactant-washed flakes from closures used on PET beverage bottles from post-consumer collection systems (curbside and deposit systems).

A small fraction of the PET bottles holding the HDPE closures may originate from non-food applications, such as bottles used for soap, mouth wash or kitchen hygiene agents. According to the applicant, the PET bottles are sorted before recycling such that the proportion of these non-food container fraction does not exceed 1%. Therefore, the proportion of non-food contact HDPE closures is expected to be the same, not exceeding 1%. No information was provided to support that this non-food contact fraction originates from HDPE that has been manufactured in accordance with Community legislation on plastic food contact materials, as required by the Regulation (EC) 282/2008 Art. 4.b on plastic recycling. The applicant stated that it cannot be guaranteed that non-food contact closures will be made from compliant raw materials.

During the conventional recycling⁶ of the post-consumer PET beverage bottles, PET and HDPE flakes are separated by swim/sink separation (based on density). Subsequently, the HDPE flakes are hot caustic and surfactant-washed and mechanically dried to reduce the moisture to less than 1.5% (step 1). Technical data on the hot caustic and surfactant washed and dried flakes were provided, such as on physical properties and the residual content of cellulose, metals, dust (see Appendix A). No information was provided on the presence and separation of other polyolefins, such as polypropylene (PP) of which non-food contact closures may be made. PP has a density close to HDPE but a melting temperature higher than HDPE. Thus, it is expected not to be removed by the swim/sink separation and to be present in the washed and dried flakes (after step 1) while less decontaminated than HDPE.

3.3. Starlinger recoSTAR HDPE (FC 1) technology

3.3.1. Description of the main steps⁷

The general scheme of the technology is reported in Figure 1. This technology recycles HDPE flakes into pellets in a continuous process as described below.

Pre-drying and extrusion (step 2): The flakes are dried in a reactor under high temperature, then continuously extruded and melt-filtered to remove solid contaminants. The filtered melt is then extruded under vacuum degassing [REDACTED] Finally, the melt is pelletised.⁸ [REDACTED]

Decontamination (step 3): The pellets are treated [REDACTED] in a continuous reactor [REDACTED]. [REDACTED] From the information provided, it is not clear whether the reactor is operated under atmospheric pressure or vacuum, and if under vacuum, how [REDACTED] is applied.

⁵ Technical dossier/Add data May 21/3_update2_PET2PET_Technical_Dossier_confidential, section 3.2.2.

⁶ Conventional recycling includes commonly sorting, grinding, washing and drying steps and produces washed and dried flakes.

⁷ Technical dossier/Add data May 21/3_update2_PET2PET_Technical_Dossier_confidential, section 3.2.1., and Appendix D.

⁸ These steps are not considered by the applicant to be part of step 2 but are reported for clarity.

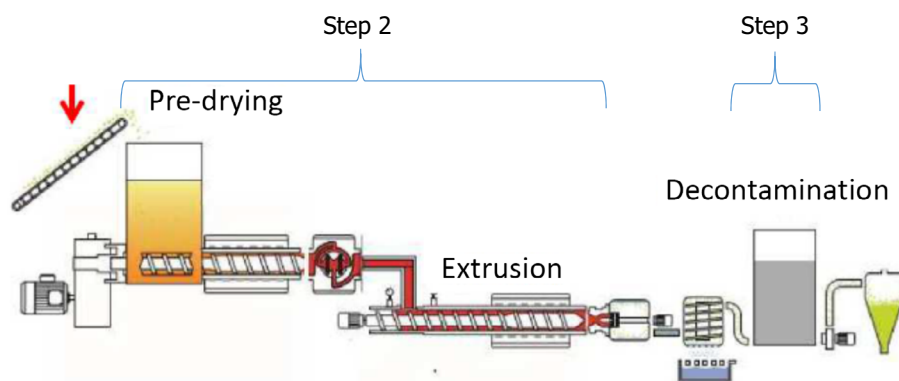


Figure 1: General flow chart of the Starlinger HDPE recoSTAR HDPE (FC 1) technology provided by the applicant

The process is run under defined operating parameters of temperature, pressure, [REDACTED] and residence time. However, not all relevant parameters were adequately reported. The dossier initially mentioned vacuum in the step 3. In response to the request by EFSA for additional data, the applicant declared that the step 3 is not operated under vacuum, while vacuum was reported in the given critical parameters, making unclear what the parameters are. The application of [REDACTED] to the reactor, which is important for assessing the representativity of the challenge test, was not properly addressed. Since the information provided to EFSA was incomplete, especially for step 3, the Panel was unable to derive an adequate, clear and complete description of the main steps and operating parameters of the technology.

3.3.2. Decontamination efficiency of the recycling process⁹

To demonstrate the decontamination efficiency of the recycling process, a challenge test was submitted to EFSA.

HDPE flakes were contaminated with toluene, chlorobenzene, limonene, phenylcyclohexane, benzophenone, butylsalicylate, methylpalmitate, diethylhexylphthalate and tris(2-ethylhexyl)trimellitate (TEHTM), used as surrogate contaminants. The surrogates include different polarities and molecular weights (up to 547 Da for TEHTM) to cover different chemical classes of contaminants of concern.

For the preparation of the contaminated HDPE flakes, a mixture of the liquid and solid surrogates was added to the conventionally recycled post-consumer HDPE flakes and stored for 7 days at 50°C with periodical agitation. After contamination, the HDPE flakes were washed in small-scale commercial washing line. The residual concentration of the surrogates in flakes was determined before and after the washing.

The steps 2 and 3 were challenged with only contaminated flakes and pellets; hence, cross-contamination phenomena can be excluded.¹⁰ The step 2 (pre-drying and extrusion) was challenged at Starlinger facilities at industrial scale of [REDACTED]. The step 3 was challenged at laboratory scale. [REDACTED]

[REDACTED] It is not clear how the pellets were [REDACTED]. Moreover, all characteristics of the reactor, such as the main installation, the auxiliary equipment and the functioning of the operating parameters, were requested, but not sufficiently documented to assess the representativity of the challenge test for step 3.

The flakes analysed after the washing and the pellets analysed at the end of steps 2 and 3 were considered. Decontamination efficiency was calculated based on the concentration of surrogates in the contaminated flakes before the pre-drying and extrusion (step 2) and in the treated pellets after the decontamination reactor (step 3). The results are summarised below in Table 1.

⁹ Technical dossier/Add data May 21/3_update2_PET2PET_Technical_Dossier_confidential/section 3.2.3.

¹⁰ 'Cross-contamination', as meant in the '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' is the transfer of surrogate contaminants from the initially contaminated to the initially not contaminated material (EFSA CEF Panel, 2011).

Table 1: Efficiency of the decontamination of the Starlinger recoSTAR HDPE (FC 1) technology in the challenge test

Surrogates	Concentration of surrogates before step 2 (mg/kg HDPE)	Concentration of surrogates after step 2 (mg/kg HDPE)	Concentration of surrogates after step 3 (mg/kg HDPE)	Decontamination efficiency of steps 2 and 3 (%)
Toluene	133.8	2.1	< 0.3	> 99.8
Chlorobenzene	257.1	1.8	< 0.3	> 99.9
Limonene	550.9	16.9	< 0.3	> 99.9
Phenylcyclohexane	684.0	61.5	< 0.3	> 99.9
Benzophenone	756.8	186.3	< 0.5	> 99.9
Butylsalicylate	732.9	101.5	< 2.0	> 99.7
Methylpalmitate	797.9	549.8	< 3.8	> 99.5
Diethylhexylphthalate	569.1	476.6	96.5	83.0
tris(2-Ethylhexyl) trimellitate	941.8	648.1	751.7	20.2

As shown in Table 1, the overall decontamination efficiency ranges from more than 99.9% for chlorobenzene, limonene, phenylcyclohexane and benzophenone to 20.2% for TEHTM. Unexpectedly, the concentration of residual TEHTM is slightly higher after step 3 than step 2. This was not explained by the applicant. However, this does not affect the observation that the decontamination efficiency is limited for non-polar, non-volatile surrogates with a molecular mass above 400 g/mol.

3.4. Discussion

3.4.1. The recycling process

Considering the high temperatures (220°C) used in the extrusion of the flakes, the possibility of contamination by microorganisms can be discounted. Therefore, this evaluation focuses on the chemical safety of the final product.

Technical data, such as physical properties and information on residual content of cellulose, metals and dust, were provided for the hot caustic and surfactant washed and dried HDPE flakes (step 1). However, no information was provided on the presence, separation and residue levels of other polyolefins, such as PP, of which non-food contact closures may be made. PP has a density close to HDPE but a melting temperature higher than HDPE. Thus, it is expected not to be sorted by swim/sink separation and to be present in the washed and dried flakes (after step 1), while less decontaminated than HDPE.

The input material is closures used together with PET beverage bottles collected from post-consumer collection systems (curbside and deposit systems). A small fraction of the PET bottles holding the closures may originate from non-food applications, such as bottles used for soap, mouth wash or kitchen hygiene agents. According to the applicant, the PET bottles are sorted before recycling such that this proportion of non-food container fraction is no more than 1%. Therefore, the proportion of non-food contact HDPE closures is expected to be the same, not exceeding 1%.

According to Regulation (EC) No 282/2008, as a prerequisite, 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 (i.e. to avoid the input of non-authorised substances). This could be interpreted as the input of the process should be made with at least e.g. 99.9% food grade HDPE, which means that either the quality of the sorting should reach 99.9% food use materials (per se food contact grade) or it should be demonstrated that the 'non-food' use HDPE closures available from the EU domestic market are largely, if not completely, compliant with Regulation (EU) No 10/2011. In line with the approach for PET bottles (EFSA CEF Panel, 2011) and the opinion on HDPE bottles and other articles (EFSA CEF Panel, 2015), EFSA suggested to the applicant that plastic organisations and/or producers of closures should provide information on whether non-food contact HDPE closures available from the EU market are compliant with Regulation (EU) No 10/2011. If not compliant, differences from food grade HDPE were requested to be provided. The applicant answered that it is not possible to guarantee that the non-food contact closures will be made exclusively from raw material which is compliant with the Regulation (EU) No 10/2011. In view of the

limited information provided, the Panel considered that, in addition to the contamination of the non-food contact closures by their non-food content, the components such as additives used to manufacture non-food contact HDPE closures cannot be considered as food grade/authorised. The amount of an additive in HDPE closures may reach ca. 0.1%, which would correspond to 10 mg/kg HDPE when 1% non-food contact material is in the input of this recycling process.

According to the applicant, the following steps are those of the 'Starlinger recoSTAR HDPE (FC 1)' technology used to recycle the HDPE flakes into HDPE pellets: pre-drying and extrusion of flakes into pellets (step 2) and decontamination in the reactor (step 3). The operating parameters of temperature, residence time, pressure [REDACTED] have been provided to EFSA. However, [REDACTED] applied in the reactor was not clarified. The information provided did not allow to understand whether the decontamination reactor is operated under atmospheric pressure or vacuum, and if under vacuum, how [REDACTED] is applied. The characteristics of the reactor were not sufficiently detailed. Therefore, the Panel did not receive adequate, clear and complete descriptions of the main steps and operating parameters of the technology. This is important for the comparison with the challenge test and for assessing its representativity.

The decontamination reactor (step 3) is expected to be the most critical step for the decontamination, but, as shown in Table 1, pre-drying and extrusion under vacuum (step 2) are relevant too. Therefore, the two steps 2 and 3 are considered critical for the decontamination efficiency of the process. A challenge test to measure the decontamination efficiency was conducted on the steps 2 and 3 using only contaminated materials. The drying and extrusion (step 2) were challenged at industrial scale. The reactor (step 3) was challenged at laboratory scale. The Panel considered that the step 2 was correctly challenged according to the recommendations in the EFSA guidelines (EFSA, 2008). However, the description and operation of the reactor (step 3) did not allow to assess the representativity of the challenge test and the efficiency of the technology to decontaminate.

[REDACTED] Ageing due to repeated use and/or recycling could be responsible for the formation and possible accumulation of reaction and/or degradation products, e.g. additives, oligomers, polymer production aids and colorants. However, the quality of data provided was not sufficient to exclude building up of the reaction and/or degradation products.

3.4.2. Criteria for the safety evaluation of a mechanical recycling process to produce recycled plastics

In a previous assessment of HDPE recycling processes, the CEF Panel provided an overview of the criteria for the safety evaluation of a mechanical recycling process to produce recycled PET and their applicability to HDPE (EFSA CEF Panel, 2015, see section 2.5.2). In particular, the principle presented in the so-called 'PET criteria' opinion (EFSA CEF Panel, 2011) is applicable to any plastic, while some of the criteria used in the evaluation procedure are specific to PET and, therefore, cannot be applied to HDPE. The main criteria are outlined below for clarity and to support applications on plastics other than PET.

Applicable to any plastics:

- The evaluation principles for PET (EFSA CEF Panel, 2011), i.e. a mechanical recycling process is not of safety concern if the residual concentrations of potential unknown contaminants in the recycled materials (C_{res}) are not higher than a modelled safe concentration in plastic (C_{mod});
- The dietary exposure of 0.0025 $\mu\text{g}/\text{kg}$ bw per day to unknown contaminants possibly present in the plastic feedstock that should not be exceeded, and from which the migration criterion (e.g. 0.1 $\mu\text{g}/\text{kg}$ in food for infant exposure scenario) and C_{mod} are calculated;
- The exposure threshold and exposure scenarios used to determine the migration criterion.

Specific to plastic types:

- The reference contamination level of the washed and dried flakes from post-consumer articles;
- The sorption of chemicals contained as part of the non-food products and so the potential direct introduction of non-food substances into the recycling process;

- f) The modelling migration parameters used to estimate the migration criterion and to calculate the concentration C_{mod} ; new C_{mod} values specific to each plastic type need to be calculated, taking into account the conditions of use of the articles containing the recycled plastic;
- g) Considerations on the molecular weight and polarities of the surrogates to be used in the challenge test.

Deviation or another approach especially for the setting of the reference contamination could be considered, provided valid scientific reasons supported by robust data are submitted.

3.4.3. Application of the criteria for the safety evaluation of the recycling of post-consumer HDPE closures from PET beverage bottles

Here, taking into account the intended uses for bottles for mineral water and other beverages, the infant scenario, considering a 5 kg bw and a consumption of 150 g/kg bw per day, is deemed appropriate. On the basis of the human exposure threshold value of 0.0025 $\mu\text{g}/\text{kg}$ bw per day, the corresponding maximum migration of a substance is 0.017 $\mu\text{g}/\text{kg}$ food (above points b and c).

Migration modelling from polyolefins (f), including HDPE, is available (Piringer and Hinrichs, 2001) and recognised by the European legislation (EC, 2010). In line with the opinion of the CEF Panel (EFSA CEF Panel, 2015), the CEP Panel considered that C_{mod} values for the surrogates used in the challenge test can be calculated using the available migration modelling (EC, 2010) and applying to the migration criterion a factor of 2, said – by the applicant – to be more realistic than conservative. Therefore, the migration criterion is calculated to be 0.034 $\mu\text{g}/\text{kg}$ food. The parameters of the model used to calculate C_{mod} can be found in Appendix C (see footnote 11).

In the opinion from 2015, the CEF Panel recommended to acquire more knowledge on the possible contaminants sorbed into post-consumer HDPE articles used as input and covering potential polar and non-polar contaminants with molecular weights up to 1,000 Da (g). In this application, the highest molecular mass used in the challenge test was 546.8 Da (TEHTM) and its cleaning efficiency was 20%. A few additional surrogates covering polar and non-polar contaminants were requested to be used to cover a molecular mass range up to at least ca. 800 Da, showing also where the decontamination is no longer effective. In return, the applicant stated that substances with higher molecular weight than the TEHTM will have a 0% cleaning efficiency. A decrease in the decontamination efficiency towards 0% is plausible. However, without any experimental evidence, it was not possible to precisely evaluate the capacity of the process to decontaminate such low-volatile substances that could migrate when coming into contact with food.

With regard to the reference contamination level (d), the applicant used the 0.5 mg/kg HDPE from the EFSA CEF Panel opinion (2015) and provided a screening analysis on 24 post-consumer samples from typical input streams (washed flakes) and five virgin closures. However, in its opinion, the CEF Panel underlined that the 0.5 mg/kg HDPE 'does not apply to the evaluation of recycling process operating in the rest of Europe and more data should be provided for setting of a European reference contamination for HDPE as for PET'. As to the data provided, they are limited, and the samples are not sufficiently well described to ensure their representativeness. Considering that the closures originate from PET bottles, the incidence of misused HDPE closures is expected to be the same as for PET bottles. Furthermore, as the diffusivity in HDPE is much higher than in PET, the highest misuse contamination levels in washed and dried HDPE are expected to be not less than in PET washed and dried flakes (2,000–6,750 mg/kg, EFSA CEF Panel, 2011). Therefore, the CEP Panel expects the reference contamination for HDPE closures from beverage bottles to be not less than the reference contamination for PET bottles of 3 mg/kg. Consequently, the applicant was requested to provide additional data, such as a broad and statistically sound monitoring of post-consumer HDPE closures before recycling, focusing on misused bottles, the nature of the misuses and identity of the substances involved, the concentrations of these substances and the occurrence frequency in order to refine the contamination scenario and possibly modify the set of surrogates used for the challenge test. Instead of such information, the applicant provided a calculation based on a contamination of 1,000 mg/kg HDPE that is not acceptable without robust supporting and representative data when comparing with the highest misuse contamination levels in washed and dried PET flakes (2,000–6,750 mg/kg). Another approach could be considered, but should be well supported by robust data. Therefore, the Panel could not calculate the proper C_{res} to be compared with C_{mod} . In addition, the potential safety concern from the sorption of chemicals contained as part of the non-food product and so the potential direct introduction of non-food substances into the recycling process (f) and from non-authorised additives were not addressed. These could influence the reference contamination level.

The CEP Panel thought it was illustrative to report what the situation would be for a reference contamination of 3 mg/kg, if the representativity of the challenge test and if the efficiency of the technology to decontaminate had been adequately addressed (see Annex C).

Overall, despite a request for clarification,

- the data provided did not include an adequate and clear description of the process to allow a clear understanding of the main steps and operating parameters of the technology;
- the fraction of polyolefins other than HDPE was not characterised and their potential safety concern was not addressed;
- non-food contact HDPE closures that may be present up to 1% were not demonstrated to be manufactured in accordance with Community legislation on plastic food contact materials and articles;
- the potential safety concern from the sorption of chemicals contained as part of the non-food product and so the potential direct introduction of non-food substances into the recycling process was not addressed;
- no data were provided to evaluate the capacity of the process to decontaminate polar and non-polar contaminants with MW from 600 to 800 Da;
- the data provided did not allow to demonstrate that the challenge test, especially of the reactor (step 3), is representative to the industrial process, hence, to be suitable for determining the decontamination efficiency of the process;
- the data provided did not allow to estimate the reference contamination level and the residual concentration (C_{res}) for HDPE closures from PET beverage bottles.

The Panel also noted the limited efficiency of the technology to decontaminate contaminants with MW above 400 Da which would migrate into water and other beverages.

No alternative supported scientific approaches were brought forward to demonstrate the safety of the recycled closures.

4. Conclusions

The Panel concluded that the process 'Starlinger recoSTAR HDPE FC 1 – PET2PET' is not adequately characterised. Based on the information submitted to EFSA, the applicant has not demonstrated in an adequately performed challenge test or by other appropriate evidence that the recycling process is able to reduce the contamination of the HDPE flakes originating from closures of PET beverage bottles to a concentration that does not pose a risk to human health.

5. Documentation provided to EFSA

- 1) Initial dossier. December 2019. Submitted on behalf of PET to PET Recycling Österreich GmbH.
- 2) Additional data. May 2021. Submitted on behalf of PET to PET Recycling Österreich GmbH.

References

- EFSA (European Food Safety Authority), 2008. Guidelines for the submission of an application 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, prior to its authorisation. EFSA Journal 2008,6(7):717, 12 pp. <https://doi.org/10.2903/j.efsa.2008.717>
- EFSA (European Food Safety Authority), 2009. Guidance of the Scientific Committee on transparency in the scientific aspects of risk assessments carried out by EFSA. Part2: general principles. EFSA Journal 2009;7(5):1051, 22 pp. <https://doi.org/10.2903/j.efsa.2009.1051>
- EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), 2011. Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food. EFSA Journal 2011;9(7):2184, 25 pp. <https://doi.org/10.2903/j.efsa.2011.2184>
- EFSA CEF Panel (EFSA Panel on Food Contact Materials, Flavourings and Processing Aids), 2015. Scientific Opinion on the safety assessment of the processes 'Biffa Polymers' and 'CLRrHDPE' used to recycle high-density polyethylene bottles for use as food contact material. EFSA Journal 2015;13(2):4016, 25 pp. <https://doi.org/10.2903/j.efsa.2015.4016>

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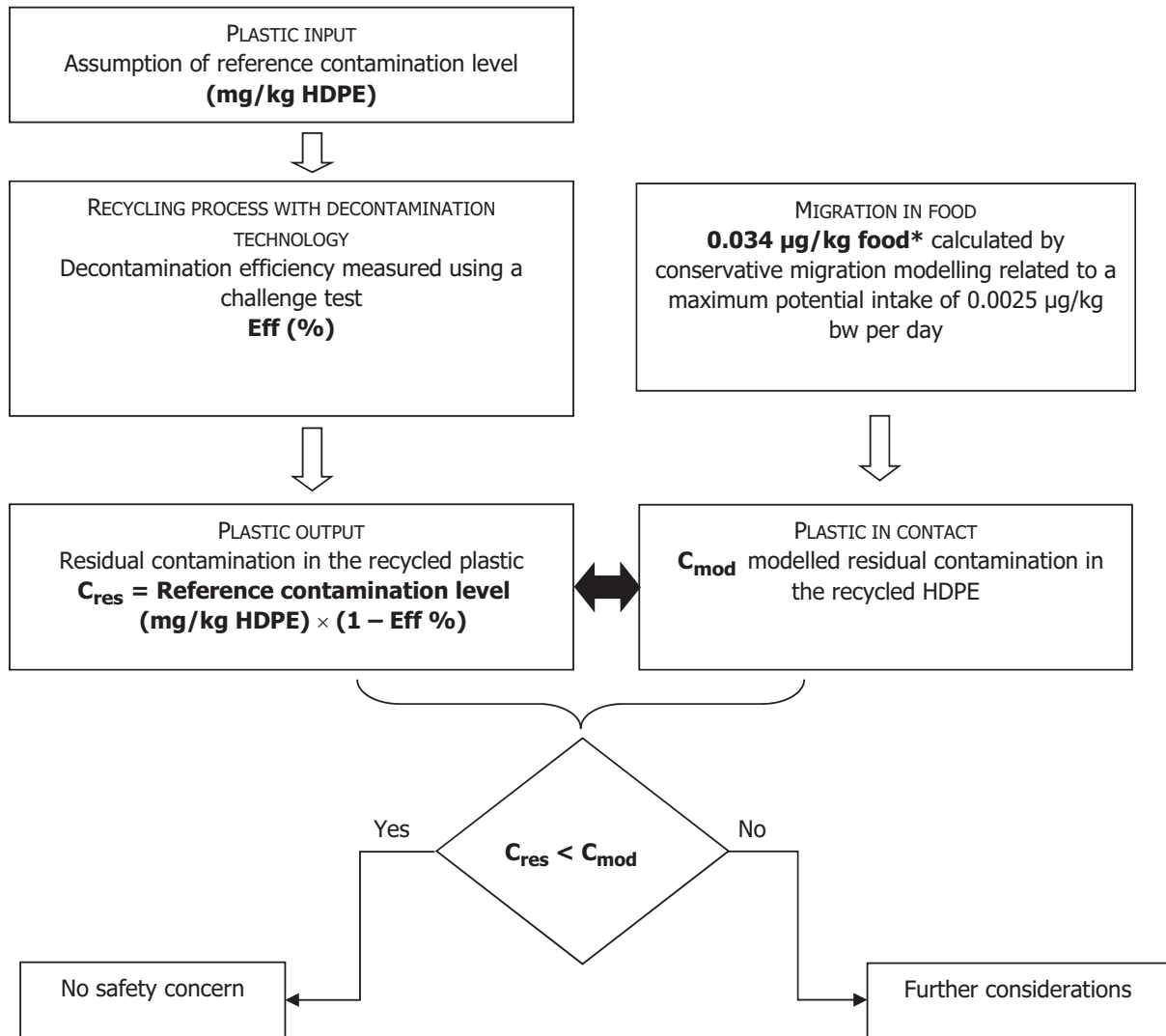
Abbreviations

bw	body weight
CEF	Food Contact Materials, Enzymes, Flavourings and Processing Aids Panel
CEP	Food Contact Materials, Enzymes and Processing Aids Panel
C_{mod}	modelled concentration in PET
C_{res}	residual concentrations in PET
HDPE	high density poly(ethylene)
PET	poly(ethylene terephthalate)
PP	poly(propylene)
TEHTM	tris(2-ethylhexyl)trimellitate

Appendix A – Technical data of the washed and dried flakes as provided by the applicant

Parameter	Value
Moisture max.	< 1.5%
Bulk density	250–500 kg/m ³
Cellulose (paper, wood)	100 ppm
Metal max.	50 ppm
Dust max.	0.5%

Appendix B – Relationship between the key parameters for the evaluation scheme



*: Default scenario (infant).

Appendix C – Illustrative decontamination efficiency derived from the challenge test

The CEP Panel thought illustrative to report what the situation would be for a reference contamination of 3 mg/kg, if the representativity of the challenge test and if the efficiency of the technology to decontaminate had been adequately addressed.

C_{mod}^{11} was estimated using a modelled migration of 0.034 $\mu\text{g}/\text{kg}$ food based on the standard scenario (0.0025 $\mu\text{g}/\text{kg}$ bw per day), the targeted population (infant, consumption of 150 g/kg bw, 5 kg bw) and a factor 2 (see Section 3.4.3) (Table C.1).

Table C.1: Decontamination efficiency derived from the challenge test: residual concentration of surrogate contaminants in recycled HDPE (C_{res}) calculated for 100% recycled HDPE and a reference contamination level of 3 mg/kg HDPE; calculated concentration of surrogate contaminants in HDPE (C_{mod}) corresponding to a modelled migration of 0.034 $\mu\text{g}/\text{kg}$ food after 365 days at 25°C

Substance	M_w [Da]	D.E. [%]	C_{res} [mg/kg PE]	C_{mod} [mg/kg PE]
Toluene	92.1	99.8	0.006	0.09
Chlorobenzene	112.6	99.9	0.003	0.09
Limonene	136.2	99.9	0.003	0.09
Phenylcyclohexane	160.3	99.9	0.003	0.09
Benzophenone	182.2	99.9	0.003	0.09
Butyl salicylate	194.2	99.7	0.009	0.09
Methyl palmitate	270.5	99.5	0.015	0.098
Diethylhexyl phthalate DEHP	390.6	83.0	0.510	0.15
Tris(ethylhexyl) trimellitate TEHTM	546.8	20.2	2.394	0.29

The residual concentrations (C_{res}) of the most volatile surrogates (up to methyl palmitate 270.5 Da) in HDPE would be lower than C_{mod} , whereas it is higher for the less volatile surrogates (from DEHP, 390.6 Da). Based on the above assumptions, the efficiency levels would allow to use at the maximum 12% recycled HDPE mixed with virgin material to produce new closures (calculation based on the cleaning efficiency of TEHTM).

¹¹ Estimations were performed with the programme SML 4.54; Piringer parameters for HDPE ($A'p = 14.5$ and $\tau = 1,577K$); Contact surface of 3.2 cm^2 (correspond to a closure diameter of ca. 2 cm); Volume: 1,000 mL; Material thickness: 1,250 μm ; Density of HDPE: 0.95; Diffusion time: 1 year; Temperature: 25°C; Partition coefficient food/material: 1.