Safety assessment of the process ‘POLY RECYCLING PET DIRECT IV+’, used to recycle post-consumer PET into food contact materials

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Abstract
The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP Panel) assessed the recycling process POLY RECYCLING PET direct IV+ (EU register number RECYC161). The input is hot caustic washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer food contact PET containing no more than 5% of PET from non-food consumer applications. The flakes are extruded to pellets, which are then further crystallised. Crystallised pellets are then preheated and fed into the solid-state polycondensation (SSP) reactor. Having examined the challenge test provided, the Panel concluded that the three steps, extrusion, crystallisation and SSP, are critical in determining the decontamination efficiency of the process. The operating parameters that control their performance are well defined: temperature, gas flow, pressure and residence time. It was demonstrated that this recycling process is able to ensure that the level of migration of potential unknown contaminants into food is below the conservatively modelled migration of 0.1 µg/kg food. Therefore, the Panel concluded that the recycled PET obtained from this process, intended to be used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs for long-term storage at room temperature, with or without hotfill, is not considered of safety concern. Trays made of this recycled PET are not intended to be used in microwave and conventional ovens, and such use is not covered by this evaluation.

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Keywords: PET direct IV+, Poly Recycling, food contact materials, plastic, poly (ethylene terephthalate) (PET), recycling process, safety assessment

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Note: The full opinion will be published in accordance with Article 10(6) of Regulation (EC) No 1935/2004 once the decision on confidentiality, in line with Article 20(3) of the Regulation, will be received from the European Commission. The text and table on the operational parameters (Appendix C) have been provided under confidentiality and they are redacted awaiting the decision of the Commission.

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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 for food contact 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 282/2008 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 1935/2004 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 an application from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, for evaluation of the recycling process POLY RECYCLING PET direct IV+, European Union (EU) register No RECYC161. The request has been registered in EFSA’s register of received questions under the number EFSA-Q-2018-00811. The dossier was submitted on behalf of POLY RECYCLING AG, Switzerland.

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 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 processes 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 POLY RECYCLING PET direct IV+ 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 shall be submitted in accordance with Article 5 of the Regulation (EC) No 282/2008.

Additional information was sought from the applicant during the assessment process in response to a request from EFSA sent on 15 May 2019 and was subsequently provided (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
  - characterisation of the input
  - determination of the decontamination efficiency of the recycling process
  - characterisation of the recycled plastic
  - intended application in contact with food
  - compliance with the relevant provisions on food contact materials and articles

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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 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 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 are 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 resulting 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 \( \mu \)g/kg bodyweight (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).

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 information

According to the applicant, the recycling process POLY RECYCLING PET direct IV+ is intended to recycle food grade PET materials to produce recycled PET pellets using the PET direct IV+ technology. The recycled PET pellets are intended to be used at up to 100% for the manufacture of recycled materials and articles. These final materials and articles are intended to be used in direct contact with all kinds of foodstuffs for long-term storage at room temperature, with or without hotfill.

3.2. Description of the process

3.2.1. General description

The recycling process POLY RECYCLING PET direct IV+ produces recycled PET pellets from PET materials coming from post-consumer collection systems, such as deposit, kerbside and mixed waste collection. The recycling process comprises the steps below.

Input

- In step 1, post-consumer PET is sorted and processed into hot caustic washed and dried flakes, which are used as the input of the process.

Decontamination and production of recycled PET material

- In step 2, the flakes are extruded into pellets at high temperature.
- In step 3, the PET is crystallised by heating with an inert gas flow, then further heated before introduction into step 4.
- In step 4, the pellets are processed in the solid-state polycondensation (SSP) reactor at high temperature and under vacuum.

The operating conditions of the process have been provided to EFSA.

The recycled PET pellets, the final product of the process, are checked against technical requirements, such as intrinsic viscosity, colour and black spots. They are intended to be converted by
other companies to recycled articles used for hotfill and/or long-term storage at room temperature. The recycled pellets may also be used for sheets that are thermoformed to make food trays. These articles are not intended to be used in microwave and conventional ovens.

3.2.2. Characterisation of the input

According to the applicant, the input material for the recycling process POLY RECYCLING PET direct IV+ consists of hot caustic washed and dried flakes obtained from PET materials (bottles, preforms, trays, sheets) previously used for food packaging, from post-consumer collection systems (kerbside and deposit systems) and mixed waste collection. A small fraction may originate from non-food applications, such as bottles for soap, mouth wash or kitchen hygiene agents. According to information from the applicant, the amount of this non-food container fraction will be kept below 5%.

Technical data for the washed and dried flakes are provided, such as information on physical properties and residual contents of poly(vinyl chloride) (PVC), polyolefins (PO), metals and dust (see Appendix A).

3.3. PET direct IV+ technology

3.3.1. Description of the main steps

The general scheme of the PET Direct IV+ technology, as provided by the applicant, is reported in Figure 1.

The washing step (Step 1, not reported in the scheme) may be performed by the applicant or by third parties.

- **Extrusion (step 2):** The flakes from the previous step are fed into an extruder at high temperature and atmospheric pressure.
- **Crystallisation (step 3):** The extruded pellets are crystallised at high temperature in a continuous reactor under inert gas at atmospheric pressure for a predefined residence time, then further heated before introduction into step 4.
- **SSP (step 4):** The crystallised pellets are introduced into the SSP reactor semi-continuously running under vacuum, at a predefined high temperature and for a predefined residence time.

![Figure 1: General scheme of the PET direct IV+ technology (provided by the applicant)](image)

The process is operated under defined operating parameters\(^3\) of temperature, pressure, gas flow and residence time.

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\(^3\) In accordance with Art. 9 and 20 of Regulation (EC) No 1935/2004, the parameters were provided to EFSA and made available to the applicant, the Member States and European Commission (see Appendix C).
3.3.2. Decontamination efficiency of the recycling process

To demonstrate the decontamination efficiency of the recycling process, a challenge test on the PET direct IV+ technology was submitted to EFSA.

PET flakes were contaminated with toluene, chlorobenzene, chloroform, methyl salicylate, phenylcyclohexane, benzophenone and methyl stearate, selected as surrogate contaminants. The surrogates were chosen in agreement with EFSA guidelines and in accordance with the recommendations of the US Food and Drug Administration. The surrogates include different molecular weights and polarities to cover possible chemical classes of contaminants of concern and were demonstrated to be suitable to monitor the behaviour of PET during recycling (EFSA, 2008).

Solid surrogates (benzophenone and methyl stearate) were mixed with liquid surrogates (toluene, chlorobenzene, chloroform, methyl salicylate and phenyl cyclohexane). Batches of contaminated PET were stored in a closed steel container for 7 days at 50°C with periodical agitation. The surrogates were decanted and the PET flakes rinsed with water and then air-dried. The concentration of the surrogates in this material was determined.

The PET direct IV+ technology was challenged in a pilot plant of the Starlinger facilities, using only contaminated flakes. The contaminated flakes were extruded into pellets (step 2), crystallised (step 3) and then submitted to a SSP reactor (step 4). The samples (flakes, then pellets) were analysed for the residual concentrations of the applied surrogates. Instead of being processed continuously, the SSP reaction was run in batch mode. Continuous working processes will result in a comparable cleaning efficiency as batch processes, provided the same temperature, pressure conditions and residence time are applied.

The decontamination efficiency of the process was calculated taking into account the amount of the surrogates detected in washed and dried contaminated flakes before extrusion (before step 2) and in pellets after SSP (step 4). When not detected, the limit of detection was considered for the calculation of the decontamination efficiency. The results are summarised in Table 1.

As shown in Table 1, the decontamination efficiency ranged from 98.8% for benzophenone to above 99.9% for toluene and chloroform.

Since the challenge test was performed with contaminated flakes only, cross-contamination phenomena can be excluded.

3.4. Discussion

Considering the high temperatures used during the process, 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 information on physical properties and residual contents of PVC, polyolefins, metals and dust, were provided for the input materials (washed and dried flakes, step 1). These are produced from PET containers previously used for packaging from post-consumer collection.

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Table 1: Efficiency of the decontamination by the PET direct IV+ technology in the challenge test

| Surrogates       | Concentration of surrogates before step 2 (mg/kg PET) | Concentration of surrogates after step 4 (mg/kg PET) | Decontamination efficiency (%) |
|------------------|--------------------------------------------------------|------------------------------------------------------|--------------------------------|
| Toluene          | 267.8                                                  | < 0.2\(^{(a)}\)                                       | > 99.9                        |
| Chloroform       | 376.5                                                  | < 0.1\(^{(a)}\)                                       | > 99.9                        |
| Chlorobenzene    | 467.8                                                  | 0.7                                                  | 99.9                           |
| Phenylcyclohexane| 572.4                                                  | 5.7                                                  | 99.0                           |
| Methyl salicylate| 410.9                                                  | 0.4                                                  | 99.9                           |
| Benzophenone     | 719.4                                                  | 8.8                                                  | 98.8                           |
| Methyl stearate  | 505.2                                                  | 3.2                                                  | 99.4                           |

PET: poly (ethylene terephthalate).
(a): Not detected at the limits of detection given.

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4 ‘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).
systems and mixed waste collection. However, a small fraction may originate from non-food applications, such as bottles for soap, mouthwash or kitchen hygiene agents. According to the applicant, the fraction of these non-food containers is kept below 5%, as recommended by the EFSA CEF Panel in its '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 CEF Panel, 2011).

The process is adequately described. The washing and drying of flakes from collected containers (step 1) is done either by the applicant or by third parties; according to the applicant, this step is under control. The following steps are those of the PET direct IV+ technology used to recycle the PET flakes into decontaminated PET pellets: extrusion into pellets (step 2), crystallisation (step 3) and SSP (step 4). The operating parameters of temperature, pressure, residence time and gas flow have been provided to EFSA.

A challenge test was conducted at pilot plant scale on process steps 2-4 (extrusion, crystallisation and SSP reactor) to measure the decontamination efficiency. In the POLY RECYCLING PET direct IV+ process, the operating parameters of these steps are at least as severe as those applied in the challenge test. The Panel considered that the challenge test was performed correctly according to EFSA guidelines (EFSA, 2008). Although the fourth step is expected to be most critical for the decontamination, steps 2 and 3 may be also relevant. Therefore, the Panel considered that all three steps are critical for the decontamination efficiency of the process. Consequently, the temperature for extrusion (step 2), the temperature, the gas flow and the residence time for crystallisation (step 3) and the temperature, the pressure and the residence time for SSP (step 4) should be controlled to ensure adequate performance of the decontamination. These parameters have been provided to EFSA.

The decontamination efficiencies obtained for each surrogate contaminant from the challenge test, ranging from 98.8% to above 99.9%, have been used to calculate the residual concentrations of potential unknown contaminants in pellets (Cres) in accordance with the evaluation procedure described in the 'Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET' (EFSA CEF Panel, 2011; Appendix B). By applying the decontamination percentages to the reference contamination level of 3 mg/kg PET, the Cres for the different surrogates is obtained (Table 2).

### Table 2: Decontamination efficiencies from the challenge test, residual concentrations of surrogate substances in recycled PET (Cres) and calculated concentrations of surrogate substances in PET (Cmod) corresponding to a modelled migration of 0.1 μg/kg food after 1 year at 25°C

| Surrogates          | Decontamination efficiency (%) | Cres (mg/kg PET) | Cmod (mg/kg PET) |
|---------------------|-------------------------------|------------------|------------------|
| Toluene             | > 99.9                        | < 0.003          | 0.09             |
| Chloroform          | > 99.9                        | < 0.024          | 0.10             |
| Chlorobenzene       | 99.9                          | 0.003            | 0.10             |
| Phenylcyclohexane   | 99.0                          | 0.030            | 0.14             |
| Methyl salicylate   | 99.9                          | 0.003            | 0.13             |
| Benzophenone        | 98.8                          | 0.006            | 0.16             |
| Methyl stearate     | 99.4                          | 0.018            | 0.32             |

PET: poly (ethylene terephthalate).

According to the evaluation principles (EFSA CEF Panel, 2011), the dietary exposure must not exceed 0.0025 μg/kg bw per day, below which the risk to human health is considered negligible. The Cres value should not exceed the modelled concentration in PET (Cmod) that could result in a migration giving rise to a dietary exposure exceeding the 0.0025 μg/kg bw per day, after 1 year at 25°C. Because the recycled PET is intended for general use for the manufacturing of articles containing up to 100% recycled PET, the most conservative default scenario for infants has been applied. Therefore, the migration of 0.1 μg/kg into food has been used to calculate Cmod (EFSA CEF Panel, 2011). The results of these calculations are shown in Table 2. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

As the residual concentrations (Cres) of all surrogates in the decontaminated PET are below the corresponding modelled concentrations in PET (Cmod), the Panel concluded that the recycling process POLY RECYCLING PET direct IV+ is able to ensure that the migration of unknown contaminants from
the recycled PET into food is below the conservatively modelled 0.1 μg/kg food at which the risk to human health is considered negligible.

4. Conclusions

The CEF Panel considered that the process POLY RECYCLING PET direct IV+ is adequately characterised and the main steps used to recycle PET flakes into decontaminated PET pellets have been identified. Having examined the challenge test provided, the Panel concluded that the three steps (extrusion, crystallisation and SSP) are critical for the decontamination efficiency of the process. The operating parameters to control their performance are the temperature for extrusion (step 2), the temperature, the gas flow and the residence time for crystallisation (step 3) and the temperature, the pressure and the residence time for SSP (step 4).

The Panel concluded that the recycling process POLY RECYCLING PET direct IV+ is able to reduce foreseeable accidental contamination of post-consumer food contact PET to a concentration that does not give rise to concern to human health if:

i) it is operated under conditions that are at least as severe as those applied in the challenge test used to measure the decontamination efficiency of the process; and

ii) the input of the process is washed and dried post-consumer PET flakes originating from materials and articles that have been manufactured in accordance with the EU legislation on food contact materials containing no more than 5% of PET from non-food consumer applications.

Therefore, the recycled PET obtained from the process POLY RECYCLING PET direct IV+ intended to be used up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs for long-term storage at room temperature, with or without hotfill, is not considered of safety concern. Trays made of this recycled PET are not intended to be used in microwave and conventional ovens and such use is not covered by this evaluation.

5. Recommendations

The Panel recommended periodic verification that the input to be recycled originates from materials and articles that have been manufactured in accordance with the EU legislation on food contact materials and that the proportion of PET from non-food consumer applications is no more than 5%. This adheres to good manufacturing practice and the Regulation (EC) No 282/2008, Art. 4b. Critical steps in recycling should be monitored and kept under control. In addition, supporting documentation should be available on how it is ensured that the critical steps are operated under conditions at least as severe as those in the challenge test used to measure the decontamination efficiency of the process.

Documentation provided to EFSA

1) Dossier "POLY RECYCLING PET direct IV+", October 2018. Submitted on behalf of POLY RECYCLING AG, Switzerland.

2) Additional data on the dossier "POLY RECYCLING PET direct IV+", July 2019. Submitted on behalf of POLY RECYCLING AG, Switzerland.

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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. Part 2: 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), 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
Abbreviations

bw  body weight
CEF  Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP  Food Contact Materials, Enzymes and Processing Aids
C$_{\text{mod}}$  Modelled modelled concentration in PET
C$_{\text{res}}$  Residual residual concentrations in PET
IV  intrinsic viscosity
PET  poly(ethylene terephthalate)
PVC  poly(vinyl chloride)
SSP  solid-state polycondensation
## Appendix A – Technical data of the washed flakes as provided by the applicant

| Parameter                        | Value          |
|----------------------------------|----------------|
| Moisture max.                    | < 2.5%         |
| Bulk density                     | 200–600 kg/m³ |
| PVC                              | < 200 ppm      |
| Polyolefins                      | < 100 ppm      |
| Other Plastics                   | < 200 ppm      |
| Metals                           | < 200 ppm      |
| Dust                             | < 1.5%         |
| Amount of non-food application PET | ≤ 5%          |

PVC: poly(vinyl chloride); PET: poly(ethylene terephthalate).
Appendix B – Relationship between the key parameters for the evaluation scheme (EFSA CEF Panel, 2011)

**PLASTIC INPUT**
Assumption of reference contamination level

3 mg/kg PET

**RECYCLING PROCESS WITH DECONTAMINATION TECHNOLOGY**
Decontamination efficiency measured using a challenge test

Eff (%)

**MIGRATION IN FOOD**

0.1 μg/kg food* calculated by conservative migration modelling related to a maximum potential intake of 0.0025 μg/kg bw per day

**PLASTIC OUTPUT**
Residual contamination in the recycled PET

\[ C_{res} = 3 \text{ (mg/kg PET)} \times (1 - \text{Eff} \%) \]

**PLASTIC IN CONTACT**

\[ c_{mod} \] modelled residual contamination in the recycled PET

\[ C_{res} < C_{mod} \]

Yes

No

Further considerations

No safety concern

*Default scenario (infant). For adults and toddlers, the migration criterion will be 0.75 and 0.15 μg/kg food respectively. The figures are derived from the application of the human exposure threshold value of 0.0025 μg/kg bw per day applying a factor of 5 due to the overestimation of modelling.
Appendix C – Table of Operational Parameters

| Parameter  | Value 1 | Value 2 | Value 3 | Value 4 |
|------------|---------|---------|---------|---------|
| Parameter A | Value A1 | Value A2 | Value A3 | Value A4 |
| Parameter B | Value B1 | Value B2 | Value B3 | Value B4 |
| Parameter C | Value C1 | Value C2 | Value C3 | Value C4 |

Note: Values A1 to C4 represent specific data related to the parameters.