SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 23 March 2021

doi: 10.2903/j.efsa.2021.6560

# Safety assessment of the process Plastrec, based on Polymetrix pellet technology, 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) assessed the safety of the recycling process Plastrec (EU register number RECYC181), which uses the Polymetrix pellet technology. The input is hot washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, mainly bottles, with no more than 5% PET from non-food consumer applications. The flakes are extruded into pellets, crystallised and subsequently decontaminated in a [redacted] solid-state polycondensation (SSP) reactor under high temperature and inert gas flow. The recycled pellets are 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. The Panel concluded that the dossier does not satisfy the requirements of the EFSA guidelines, because the data and clarifications provided by the applicant do not allow an adequate evaluation of the decontamination efficiency of the process. Consequently, the CEP Panel concluded that the applicant has not demonstrated that the recycling process is able to reduce contamination of the PET flake input to a concentration that does not pose a risk to human health.



**Keywords:** Polymetrix pellet, Plastrec Inc., food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

**Requestor:** Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany

**Question number:** EFSA-Q-2019-00294

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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 technical details of recycling steps 3 and 4 in sections 3.2.1 and 3.3.1 have been provided under confidentiality and they are redacted awaiting the decision of the Commission.

**Declarations of interest:** The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

**Suggested citation:** EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids), Lambré C, Barat Baviera JM, Bolognesi C, Chesson A, Cocconcelli PS, Crebelli R, Gott DM, Grob K, Mengelers M, Mortensen A, Rivière G, Steffensen I-L, Tlustos C, Van Loveren H, Vernis L, Zorn H, Dudler V, Milana MR, Papaspyrides C, Tavares Poças MF, Lioupis A and Lampi E, 2021. Scientific Opinion on the safety assessment of the process Plastrec, based on Polymetrix pellet technology, used to recycle post-consumer PET into food contact materials. EFSA Journal 2021;19(4):6560, 10 pp. https://doi.org/10.2903/j.efsa.2021.6560

**ISSN:** 1831-4732



The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

# Table of contents

# 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 282/2008[1] 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[2] 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 Plastrec, European Union (EU) register No RECYC181. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2019-00294. The dossier was submitted on behalf of Plastrec Inc., Canada.

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 Plastrec 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 2020 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,

[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.

— process analysis and evaluation,
— operating parameters.

## 2.2. Methodologies

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 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).

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[3]

According to the applicant, the recycling process Plastrec is intended to recycle food grade PET containers to PET pellets using the Polymetrix pellet technology. The recycled pellets are intended to be used at up to 100% for the manufacture of materials and articles that are intended to be used in direct contact with all kinds of foodstuffs for long-term storage at room temperature, with or without hotfill. The final articles are not intended to be used in microwave and conventional ovens.

## 3.2. Description of the process

### 3.2.1. General description[4]

The recycling process Plastrec produces recycled PET pellets from PET containers, mainly bottles, coming from post-consumer collection systems (kerbside and deposit systems).

The recycling process is composed of the four steps below, all performed by the applicant.

Input

- In step 1, the post-consumer PET containers are processed into washed and dried flakes.

Decontamination and production of recycled PET material

- In step 2, the flakes are extruded into pellets.
- In step 3, the pellets are crystallised and heated to the decontamination temperature.
- In step 4, the crystallised pellets are decontaminated during solid-state polycondensation (SSP) in a [redacted] reactor under high temperature and [redacted] gas flow.

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

[3] Technical dossier: Section 3.1.
[4] Technical dossier: Section 3.1.1.

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 into recycled articles used for hotfill and/or long-term storage at room temperature, such as bottles for mineral water, soft drinks and beer. The recycled pellets may also be used for sheets, which are thermoformed to make food trays. They 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 Plastrec consists of hot washed and dried flakes obtained from PET containers, mainly bottles, previously used for food packaging, from post-consumer collection systems (kerbside and deposit systems). A small fraction may originate from non-food applications. According to the applicant, the proportion of this non-food container fraction will be below 5%.

Technical data for the hot washed and dried flakes are provided, such as information on physical properties and on residual contents of moisture, poly(vinyl chloride) (PVC), polyolefins, polyamide, glue, cellulose (wood, paper) and metals (see Appendix A).

## 3.3. Polymetrix pellet technology

### 3.3.1. Description of the main steps[5]

The general scheme of the Polymetrix pellet technology, as provided by the applicant, is reported in Figure 1 and involves the following steps.

- Extrusion (step 2): The washed and dried flakes are fed into the extruder. The melt is filtered to remove solid particles.
- Crystallisation and heating (step 3): The extruded pellets are fed to a [redacted] reactor in which they are crystallised and heated up to the temperature of the [redacted] SSP reactor.
- Solid-state polycondensation (step 4): The crystallised pellets are [redacted] fed to a SSP reactor running under high temperature and [redacted] gas flow for a predefined residence time. [redacted]

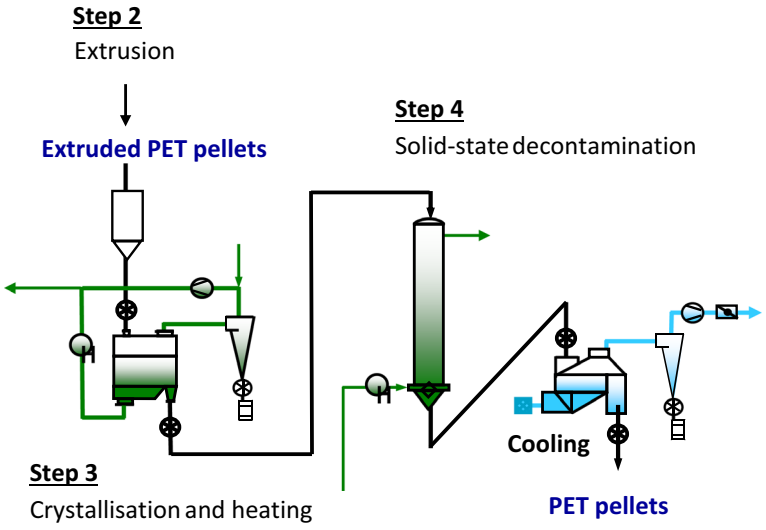


**Figure 1:** General scheme of the Polymetrix pellet technology (provided by the applicant)

The process is operated under defined operating parameters of temperature, pressure, gas flow and residence time.

[5] Technical dossier: Section 3.2.1 and Appendix D.

### 3.3.2. Decontamination efficiency of the recycling process[6]

To demonstrate the decontamination efficiency of the recycling process Plastrec, a challenge test was submitted to EFSA that was performed at pilot plant scale.

Contaminated PET pellets were produced during extrusion by adding toluene, chlorobenzene, phenylcyclohexane, benzophenone and methyl stearate, selected as surrogate contaminants in agreement with the EFSA guidelines and in accordance with the recommendations of the US Food and Drug Administration. The surrogates include different molecular masses 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).

PET was spiked with a solution containing the surrogates in a pilot plant twin screw extruder without degassing, resulting in a homogenous contamination of the pellets. To prevent possible agglomeration during the challenge test, the amorphous pellets were crystallised according to step 3. The concentrations of the surrogates were determined in these crystallised pellets used as starting material for the challenge test.

Three challenge tests were performed on the SSP reactor (step 4) performed in a pilot plant. Three decontamination temperatures, T1, T2 and T3 (T1 < T2 < T3) were tested for various defined residence times. For the main option, the applicant derived the required process temperature and residence time for the critical step 4 from the three challenge tests performed at three temperatures and various durations. The Panel noted that the process temperature was not directly tested, but derived by consecutive extrapolations from the data obtained in the challenge tests run at different temperatures. Not enough data were provided to evaluate this option.

The gas flow was many times higher than in the process to compensate for heat loss, but the Panel accepted the argument that above the gas velocity used in production, the diffusion within the pellets is limiting the removal of the contaminants, i.e. that the gas velocity no longer influences the decontamination (Huang and Walsh, 1998).

The contaminated clear PET pellets were mixed with a many times larger amount of blue, non-contaminated pellets in order to provide the quantity of material needed for the pilot plant. From the samples drawn after the SSP reactor, only the clear pellets were analysed for their residual concentrations of the applied surrogates. Since the challenge tests were performed with both contaminated and non-contaminated pellets, cross-contamination[7] may have occurred.

## 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, glue, plastics other than PET, wood, paper and metals, were provided for the input materials, i.e. washed and dried flakes (step 1). These flakes are produced from PET containers, mainly bottles, previously used for food packaging collected through post-consumer collection systems. However, a small fraction may originate from non-food applications, such as bottles for soap, mouth wash or kitchen hygiene agents. According to the applicant, the collection system and the process are managed in such a way that in the input stream this fraction will be 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).

According to information provided, the washing and drying of the flakes from the collected PET containers (step 1) is conducted by the applicant. The subsequent steps are those of the Polymetrix pellet technology used to recycle the PET flakes into decontaminated pellets: extrusion (step 2), crystallisation and heating (step 3) and decontamination in the SSP reactor (step 4). The operating parameters of temperature, pressure and residence time for step 3 and temperature, gas flow and residence time for step 4 have been provided to EFSA.

The dossier does not satisfy the requirements of the EFSA guidelines (EFSA, 2008) and the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to

[6] Technical dossier: Section 3.2.3 and Appendix E.

[7] 'Cross-contamination' (partitioning between clear and blue flakes), 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).

be used for manufacture of materials and articles in contact with food (EFSA CEF Panel, 2011). In particular, despite a request for clarification, a fundamental issue was not satisfactorily addressed. In fact, in the provided challenge tests, the contaminated clear PET pellets were mixed with a many times larger amount of blue non-contaminated pellets in order to obtain the quantity of material needed for the decontamination in the SSP pilot plant reactor (step 4). The decontamination efficiency was calculated by comparing the surrogate concentrations in the clear PET pellets before and after step 4. Transfer from the contaminated clear pellets to the non-contaminated blue pellets was not considered in the calculations, while the decontamination efficiency should have been determined on the basis of the total amount of residual surrogates, i.e. measured in both the contaminated and the initially non-contaminated pellets. The Panel noted that decontamination efficiencies, calculated only on the basis of residual surrogates in the contaminated clear pellets could be overestimated. After a request for additional data or scientific argumentation, the applicant provided a published study (Welle, 2016) reporting that cross-contamination was found at low mixing (dilution) ratios (e.g. 1:1), but that it becomes negligible at high mixing ratios (e.g. 1:50). However, the Panel had noted before (e.g. EFSA CEF Panel, 2017) that due to the high detection limits of the analytical method used the data provided by the applicant did not allow to exclude cross-contamination. Even a low concentration of surrogates in a large amount of initially non-contaminated flakes would have a strong effect on the residual amount of surrogates in the output.

The Panel noted that the dossier does not satisfy the requirements of the EFSA guidelines, because the data and clarifications provided by the applicant do not allow an adequate evaluation of the decontamination efficiency of the process.

## 4. Conclusions

The Panel concluded that, based on the information submitted to EFSA on the process Plastrec, 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 PET flake input to a concentration that does not pose a risk to human health.

## Documentation provided to EFSA

1) Dossier 'Plastrec'. August 2019. Submitted on behalf of Plastrec Inc., Canada.
2) Additional information, November 2020. Submitted on behalf of Plastrec Inc., Canada.

## 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. Part 2: general principles. EFSA Journal 2009;7 (5):1051, 22 pp. https://doi.org/10.2903/j.efsa.2009.1051

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Huang B and Walsh JJ, 1998. Solid-phase polymerisation mechanism of poly(ethylene terephthalate) affected by gas flow velocity and particle size. Polymer, 39, 6991–6999.

Welle F, 2016. Investigation into cross-contamination during cleaning efficiency testing in PET recycling. Resources, Conservation and Recycling, 112, 65–72.

## Abbreviations

bw body weight
CEF Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel on Food Contact Materials, Enzymes and Processing Aids

| | |
|---|---|
| $C_{mod}$ | modelled concentration in PET |
| $C_{res}$ | residual concentrations in PET |
| 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[8]

| Parameter | Value |
|---|---|
| Moisture max. | 1.5% |
| Moisture variation | ± 0.3% |
| Bulk density | 200–500 kg/m$^3$ |
| Material temperature | 10–60°C |
| PVC max. | 50 mg/kg |
| Glue | 50 mg/kg |
| Polyolefins max. | 50 mg/kg |
| Cellulose (paper, wood) | 50 mg/kg |
| Metals max. | 50 mg/kg |
| Polyamide max. | 2,000 mg/kg |

PVC: poly(vinyl chloride).

[8] Technical dossier: Section 3.2.2.