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Safety assessment of the process Martogg Group, based on EREMA Advanced 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 Panel) assessed the safety of the recycling process Martogg Group (EU register number RECYC207), which uses the EREMA Advanced technology. The input is hot washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, containing no more than 5% PET from non-food consumer applications. The flakes are heated in continuous reactors under vacuum before being extruded. 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 applicant has not provided a proper description of the process, has not demonstrated in an adequately performed challenge test, or provided 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. Therefore, the Panel could not conclude on the safety of the recycling process Martogg Group.

Keywords: EREMA Advanced, Martogg Group, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

Requestor: German Competent Authority (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit)

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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 on the recycling process step 4 in Section 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.

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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 the recycled plastic is from an authorised recycling process. Before a recycling process is authorised, the European Food Safety Authority (EFSA)'s opinion on its safety is required. This procedure has been established in Article 5 of Regulation (EC) No 282/2008[1] on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004[2] on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the competent authorities of Member States, which transmit the applications to EFSA for evaluation.

In this case, EFSA received, from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, an application for evaluation of the recycling process Martogg Group (EREMA Advanced technology), European Union (EU) register No RECYC207. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2020-00432. The dossier was submitted on behalf of Martogg Group, Australia.

According to Article 5 of Regulation (EC) No 282/2008 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 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).

Additional information was provided by the applicant during the assessment process in response to a request from EFSA sent on 22 October 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,
  - 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,
  - process analysis and evaluation,
  - operating parameters.

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

[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 risks associated to 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 (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 Martogg Group is intended to recycle food grade PET containers using the EREMA Advanced technology. The recycled PET is intended to be used at up to 100% for the manufacture of materials and articles to be used in direct contact with all kinds of foodstuffs, such as bottles for mineral water, soft drink and beer as well as sheets for thermoforming applications, for long-term storage at room temperature, with or without hotfill.

3.2. Description of the process

3.2.1. General description[4]

The recycling process Martogg Group produces recycled PET pellets from PET containers from post-consumer collection systems (kerbside and deposit systems).

The recycling process comprises the four steps below.

Input

- In step 1, post-consumer PET containers are processed into hot caustic washed and dried flakes. This step is performed by third parties.

Decontamination and production of recycled PET material

- In step 2, in a first continuous reactor, the flakes are heated to a high temperature under vacuum.
- In step 3, the flakes are further decontaminated in a second continuous reactor, again at a high temperature and under vacuum.
- In step 4, the decontaminated flakes are extruded to produce pellets.

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

Recycled PET pellets, the final products of the process, are checked against technical requirements, such as intrinsic viscosity, colour and black spots.

[3] Technical dossier, Section 3.1.1.
[4] Technical dossier, Sections 3.1.1, 3.2.1, 3.2.4.

3.2.2. Characterisation of the input[5]

According to the applicant, the input material for the recycling process Martogg Group consists of hot caustic washed and dried flakes obtained from PET containers, 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, this proportion will be no more than 5%.

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

3.3. EREMA Advanced technology

3.3.1. Description of the main steps[6]

The general scheme of the EREMA Advanced technology, as provided by the applicant, is reported in Figure 1. The steps are:

- Decontamination in the first continuous reactor (step 2):

The flakes are introduced into a first continuous reactor, with a bottom-mounted rotating device, in which they are heated to a high temperature under vacuum for a predefined residence time.

- Decontamination in the second continuous reactor (step 3):

The heated flakes from step 2 are fed into a second continuous reactor equipped with a bottom-mounted rotating device, running under high temperature and vacuum for a pre-defined residence time.

- Extrusion of the decontaminated flakes (step 4):

The flakes continuously introduced from the previous reactor are molten in the extruder [redacted] before the melt is converted into pellets.

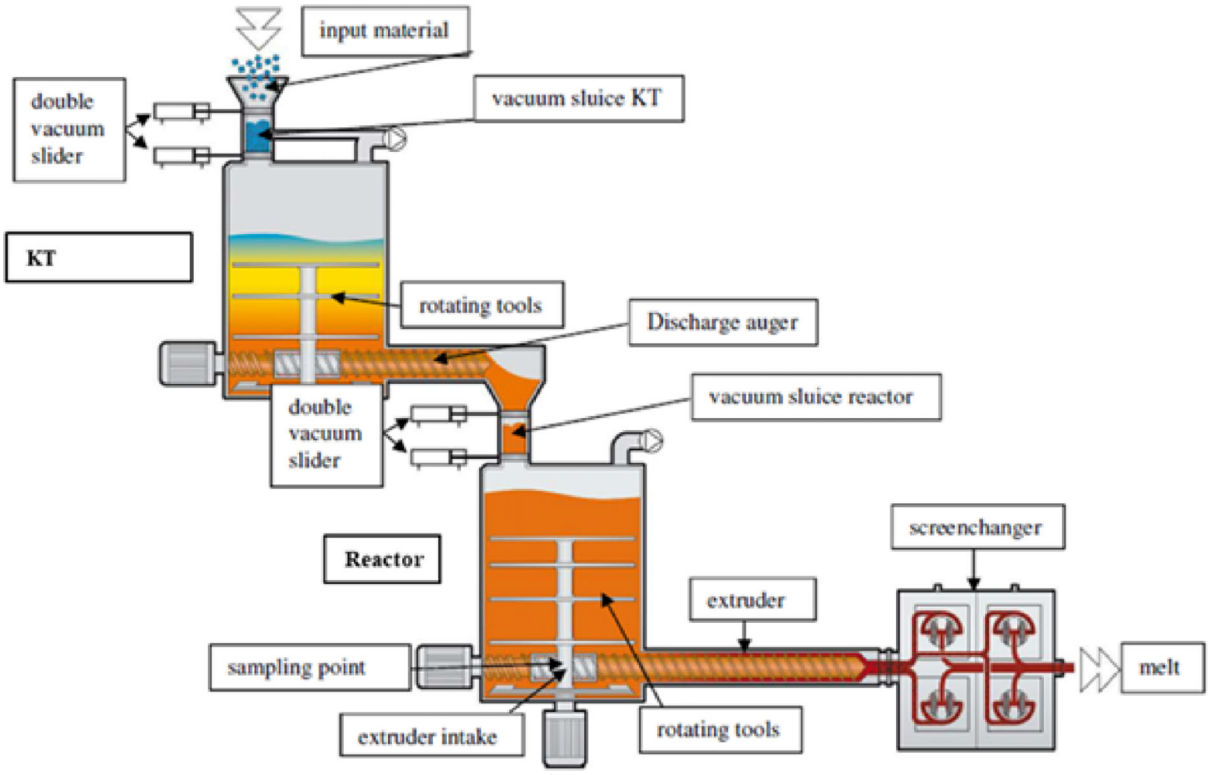

Figure 1: General scheme of the technology (provided by the applicant)

[5] Technical dossier, Section 3.2.2.
[6] Technical dossier, Section 3.2.1.

The process is run under defined operating parameters of temperature, pressure and residence time.

3.3.2. Decontamination efficiency of the recycling process[7]

To demonstrate the decontamination efficiency of the recycling process Martogg Group, a challenge test on steps 2 and 3 was submitted to EFSA.

PET flakes were contaminated with toluene, chlorobenzene, chloroform, methyl salicylate, phenylcyclohexane, benzophenone and methyl stearate, selected as surrogate contaminants in agreement with the EFSA guidelines (EFSA CEF Panel, 2011) and in accordance with the recommendations of the US Food and Drug Administration (FDA, 2006). 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).

For this purpose, 25 mL toluene, 25 mL chlorobenzene, 25 mL chloroform, 25 mL methyl salicylate, 25 mL phenyl cyclohexane, 25 g benzophenone and 25 g methyl stearate were added to 25 kg of conventionally recycled[8] post-consumer PET flakes. Sixteen such batches were produced and stored for 7 days at 50°C with periodical agitation. Afterwards, the contaminated flakes were rinsed with 10% ethanol and the concentrations of the surrogates in this material determined. The batches were mixed and then split into two lots of 200 kg, one of which was used for the challenge test relevant here.

The EREMA Advanced technology was challenged at an industrial-scale plant. The flakes (200 kg) were fed into the first reactor (step 2). Two samples were taken after step 2 and after step 3, and analysed for their residual concentrations of the applied surrogates.

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 specifications, such as information on physical properties and residual contents of PVC, glue, polyolefins, cellulose and metals were provided for the input materials (i.e. hot caustic washed and dried flakes, step 1). These are produced from PET containers, e.g. 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. According to the applicant, the collection system and the process is managed in such a way that in the input stream this fraction will be no more than 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 the information provided, the washing and drying of the flakes from the collected PET containers (step 1) is conducted by third parties. The subsequent steps are those of the EREMA Advanced technology used to recycle the PET flakes into decontaminated pellets: first continuous reactor (step 2), second continuous reactor (step 3) and extrusion (step 4). The operating parameters of temperature, pressure and residence time for steps 2–4 have been provided to EFSA.

The Panel noted that 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 be used for manufacture of materials and articles in contact with food (EFSA CEF Panel, 2011). Despite a request for clarification, no sufficiently detailed and consistent descriptions of the process and the challenge test were received to enable a confirmation that the challenge test appropriately represented the process.

This is illustrated by some examples:

1) There is diverging information in the dossier as regards the mode of operation of the challenge test: it is not consistently described whether the challenge test was run in continuous or batch mode and this could impact the derived residence time. It was therefore not possible to evaluate the challenge test with regard to its representativeness for the industrial process, which is consistently described as running in continuous mode.

[7] Technical dossier, Section 3.2.3 and Appendix E.
[8] Conventional recycling includes commonly sorting, grinding, washing and drying steps and produces washed and dried flakes.

2) The Panel considered that the description of the process steps 2 and 3 (including the rotating tools) was not sufficiently detailed and therefore it was not possible to fully evaluate these steps of the process with respect to movement and potential mixing of the flakes, as well as the impact on the residence time. Consequently, no comparison with the provided challenge test, presumably operated in a different mode (see point 1), was feasible.
3) Inconsistent information on filling percentages of the reactors used for the challenge test are provided in different parts of the dossier.
4) There is inconsistent information regarding the capacity/filling of the process reactors. Furthermore, the calculations of residence times for the process lines provided by the applicant do not match with the descriptions of the reactor sizes provided in other parts of the dossier. Based on the data on the reactor sizes, the filling percentages of the reactors and the throughput, the residence times that were calculated by the Panel are far from those indicated by the applicant.

Overall, no sufficiently detailed and consistent descriptions of the process and the challenge test were received. The data and clarifications provided by the applicant did not allow an adequate evaluation of the decontamination efficiency of the process.

4. Conclusions

The applicant has not provided a proper description of the process, has not demonstrated in an adequately performed challenge test, or provided 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. Therefore, the Panel could not conclude on the safety of the recycling process Martogg Group.

5. Documentation provided to EFSA

1) Dossier 'Martogg Group Recycling Process'. June 2020. Submitted on behalf of Martogg Group.
2) Additional data 'Martogg Group Recycling Process'. February 2021. Submitted on behalf of Martogg Group.

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

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Abbreviations

bw	body weight
CEF	EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP	EFSA Panel on Food Contact Materials, Enzymes and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentration in PET
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)

Appendix A – Technical specifications of the washed flakes as provided by the applicant

Parameter	Value
Moisture max.	1.5%
Moisture variation	± 0.5%/h
Bulk density	250–400 kg/m^3
Material temperature	10–60°C
PVC max.	50 mg/kg
Glue max.	1,000 mg/kg
Polyolefins max.	100 mg/kg
Cellulose (paper, wood)	100 mg/kg
Metals max.	100 mg/kg
PET dust max.	0.5%

PET: poly(ethylene terephthalate).