

Safety assessment of the process NGR LSP used to recycle post-consumer PET into food contact materials

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The declarations of interest of all scientific experts active in EFSA's work are available at <https://open.efsa.europa.eu/experts>

Abstract

The EFSA Panel on Food Contact Materials (FCM) assessed the safety of the recycling process NGR LSP (EU register number RECYC328). The input is hot washed and dried poly(ethylene terephthalate) (PET) flakes mainly originating from collected post-consumer PET containers, with no more than 5% PET from non-food consumer applications. The flakes are dried (step 2), melted in an extruder (step 3) and decontaminated during a melt-state polycondensation step under high temperature and vacuum (step 4). In step 5, the material is granulated. Having examined the challenge test provided, the Panel concluded that the melt-state polycondensation (step 4) is critical in determining the decontamination efficiency of the process. The operating parameters to control the performance of step 4 are the pressure, the temperature, the residence time and the characteristics of the reactor. It was demonstrated that this recycling process ensures that the level of migration of potential unknown contaminants into food is below the conservatively modelled migration of 0.0481 or 0.0962 µg/kg food, depending on the molar mass of a contaminant substance. Therefore, the Panel concluded that the recycled PET obtained from this process is not of safety concern, when used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs, including drinking water, for long-term storage at room temperature or below, with or without hot-fill. Articles made of this recycled PET are not intended to be used in microwave and conventional ovens and such uses are not covered by this evaluation.

KEYWORDS

food contact materials, next generation Recyclingmaschinen GmbH, NGR LSP, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

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1 | INTRODUCTION

1.1 | Background

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 Articles 17 and 18 of Commission Regulation (EU) 2022/1616¹ on recycled plastic materials intended to come into contact with foods. More specifically, according to Article 18 of Commission Regulation (EU) 2022/1616 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, to evaluate the microbiological safety of these materials and articles and to deliver a scientific opinion on the recycling process examined.

According to this procedure, the process developers submit applications to the competent authorities of Member States, which transmit the applications to EFSA for evaluation. In this case, EFSA received an application from the Austrian Competent Authority (Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz) for evaluating the recycling process NGR LSP, European Union (EU) register No RECYC328. The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2023-00498. The dossier was submitted by Next Generation Recyclingmaschinen GmbH, 4101 Feldkirchen an der Donau, Austria (see 'Documentation provided to EFSA').

1.2 | Terms of Reference

The Austrian Competent Authority (Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz) requested the safety evaluation of the recycling process NGR LSP, in compliance with Article 17 of Commission Regulation (EU) 2022/1616. The recycling process uses the recycling technology number 1 of the list of suitable recycling technologies of Table 1 of Annex 1 of Commission Regulation (EU) 2022/1616¹.

2 | DATA AND METHODOLOGIES

2.1 | Data

The applicant submitted a confidential and a non-confidential version of a dossier, following EFSA's 'Scientific Guidance on the criteria for the evaluation and on the preparation of applications for the safety assessment of post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food' (EFSA CEP Panel, 2024) and EFSA's 'Administrative guidance for the preparation of applications for the authorisation of individual recycling processes to produce recycled plastics materials and articles intended to come into contact with food' (EFSA, 2024).

Additional information was received from the applicant during the assessment process, in response to a request from EFSA sent on 25 March 2024 (see 'Documentation provided to EFSA').

In accordance with Art. 38 of the Regulation (EC) No 178/2002² and taking into account the protection of confidential information and the personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of the EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,³ the non-confidential version of the dossier has been published on Open.EFSA.⁴

According to Art. 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations⁴, EFSA carried out a public consultation on the non-confidential version of the application from 16 October to 06 November 2024 for which no comments were received.

The following information on the recycling process was provided by the applicant and used for the evaluation (EFSA CEP Panel, 2024; EFSA, 2024):

- Recycling process,
- Determination of the decontamination efficiency of the recycling process,
- Table of operating parameters,
- Self-evaluation of the recycling process.

¹Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Commission Regulation (EC) No 282/2008. OJ L 243, 20.9.2022, p. 3–46.

²Commission Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

³Decision available at: <https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements>.

⁴The non-confidential version of the dossier has been published on Open.EFSA and is available at the following link: <https://open.efsa.europa.eu/dossier/FCM-2023-13416>.

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 (EFSA CEP Panel, 2024).

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 guidance developed by the EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (EFSA CEP Panel, 2024). The principle of the evaluation is to apply the decontamination efficiency of a recycling 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, considering different dietary exposure scenarios (EFSA CEP Panel, 2024). 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 CEP Panel, 2024).

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

3 | ASSESSMENT

3.1 | General information⁵

According to the applicant, the recycling process NGR LSP is intended to recycle food grade PET containers. The recycled PET is intended to be used at up to 100% for the manufacture of materials and articles for direct contact with all kinds of foodstuffs, such as bottles for mineral water, soft drinks, juices and beer, for long-term storage at room temperature or below, with or without hot-fill. The final articles are not intended to be used in microwave or conventional ovens.

3.2 | Description of the process

3.2.1 | General description⁶

The recycling process NGR LSP produces recycled PET pellets from PET materials originating from post-consumer collection systems (kerbside and deposit collection systems).

Input

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

The decontamination process comprises the four steps below.

Decontamination and production of recycled PET material

- In step 2, the flakes are dried under gas flow at ████ temperature.
- In step 3, the flakes are extruded.
- In step 4, the material is decontaminated in a melt-state polycondensation process.
- In step 5, the melt is cooled down and granulated.

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

Pellets, the final product of the process, are checked against technical requirements, such as intrinsic viscosity, melting peak temperature and acetaldehyde concentration.

⁵Technical dossier, section 'Intended application in contact with food'.

⁶Technical dossier, sections 'Recycling process', 'Characterisation of the input' and 'Characterisation of the recycled plastic'.

3.2.2 | Characterisation of the pre-processed plastic input⁷

According to the applicant, the input material consists of hot washed and dried flakes obtained from PET materials, e.g. 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 will be no more than 5%, as specified in Article 7 and Table 1 of Annex I of Commission Regulation (EU) 2022/1616¹.

Technical specifications on the hot washed and dried flakes are provided, such as on physical properties and residual contents of moisture, poly(vinyl chloride) (PVC), polyolefins, polycarbonate (PC), polyamide (PA) and glue, polystyrene (PS) and acrylonitrile butadiene styrene (ABS) (see Appendix A).

3.3 | NGR LSP process

3.3.1 | Description of the main steps⁸

The process flow diagram of the NGR LSP process, as provided by the applicant, is reported in Figure 1. The steps are:

- **Drying (step 2):** The flakes are dried under gas flow at [REDACTED] temperature.
- **Extrusion (step 3):** The flakes from the previous step are melted in an extruder, filtered and pumped as a melt to the top of the reactor of step 4.
- **Melt-state polycondensation (step 4):** The melt is decontaminated under high temperature and vacuum. In this reactor, the molten polymer is exposed with a high surface to the vacuum applied. The reactor consists of two parts: within the vertical part, the melt passes through [REDACTED] the horizontal part that consists of a [REDACTED] chamber. [REDACTED] The material is slowly moved towards the end of the horizontal chamber by a pump. This step was considered to be most critical and, hence, the decontamination efficiency has been estimated for it by the challenge test.
- **Granulation (step 5):** The melt material is cooled down and pelletised.

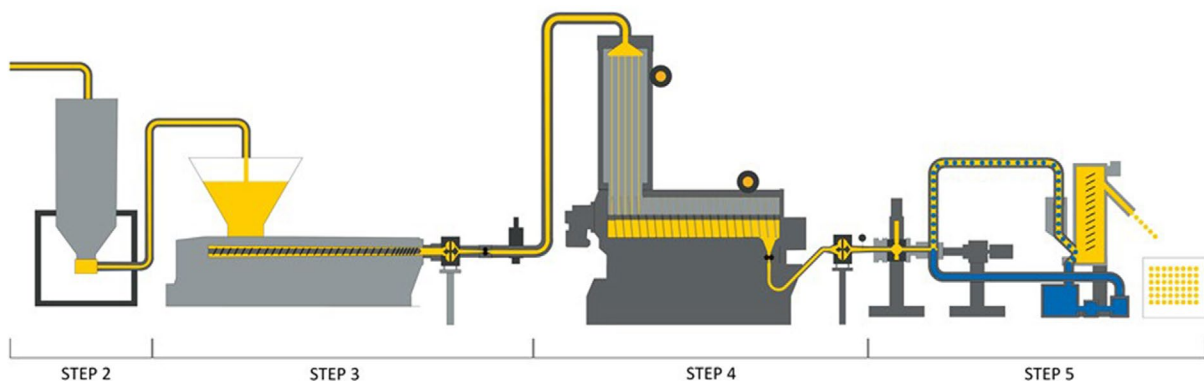


FIGURE 1 Process flow diagram of the NGR LSP process (provided by the applicant).

The process is run under defined operating parameters⁹ of temperature, pressure, gas flow and residence time. All critical parameters are monitored by sensors, shown in the piping and instrumentation diagram of the application. The parameter values are automatically reported via the relevant software and alerts are produced in case of deviations from the acceptable parameter values or ranges.¹⁰

3.3.2 | Decontamination efficiency of the recycling process¹¹

To demonstrate the decontamination efficiency of the recycling process NGR LSP, a challenge test performed at pilot plant scale on steps 4 and 5 was submitted to the EFSA.

⁷Technical dossier, section 'Characterisation of the input'.

⁸Technical dossier, sections 'Recycling process' and 'Determination of the decontamination efficiency of the recycling process'.

⁹In accordance with Art. 9 and 20 of Regulation (EC) No 1935/2004 the parameters were provided to EFSA by the applicant and made available to the Member States and the European Commission (see Appendix C).

¹⁰Technical dossier, Section 'Quality Assurance System'.

¹¹Technical dossier, Section 'Determination of the decontamination efficiency of the recycling process'.

TABLE 2 Decontamination efficiency from the challenge test, residual concentrations of the surrogates (C_{res}) related to the reference contamination level and calculated concentrations of the surrogates in PET (C_{mod}) corresponding to a modelled migration of 0.0481 $\mu\text{g}/\text{kg}$ ($= 5 \times 0.00962 \mu\text{g}/\text{kg}$) or 0.0962 $\mu\text{g}/\text{kg}$ ($= 10 \times 0.00962 \mu\text{g}/\text{kg}$) after 1 year at 25°C (C_{mod}).

Surrogates	Decontamination efficiency (%)	C_{res} for 100% rPET (mg/kg PET)	C_{mod} (mg/kg PET) Scenario A
Toluene	> 99.8	< 0.01	0.04
Chlorobenzene	> 99.9	< 0.002	0.05
Phenylcyclohexane	99.8	0.01	0.13
Benzophenone	96.0	0.12	0.15
Methyl stearate	99.7	0.01	0.29

Abbreviations: PET, poly(ethylene terephthalate); rPET, recycled poly(ethylene terephthalate).

On the basis of the provided data from the challenge test and the applied conservative assumptions, the Panel considered that under the given operating conditions the recycling process NGR LSP is able to ensure that the level of migration of unknown contaminants from the recycled PET into food is below the conservatively modelled migration of 0.0481 $\mu\text{g}/\text{kg}$ ($= 5 \times 0.00962 \mu\text{g}/\text{kg}$) or 0.0962 $\mu\text{g}/\text{kg}$ ($= 10 \times 0.00962 \mu\text{g}/\text{kg}$), depending on the molar mass of a contaminant substance into infant's food. At this level, the risk to human health is considered negligible when the recycled PET is used at up to 100% to produce materials and articles intended for contact with all types of foodstuffs, including drinking water (exposure scenario A), for long-term storage at room temperature or below, with or without hot-fill.

4 | CONCLUSIONS

The Panel considered that the process NGR LSP is adequately characterised and that the main steps used to recycle the PET flakes into decontaminated PET pellets have been identified. Having examined the challenge test provided, the Panel concluded that the melt-state polycondensation (step 4) is critical for the decontamination efficiency. The parameters to control the process performance are the pressure, the temperature, the residence time as well as the geometrical and operational characteristics of the reactor specified in Appendix C.

The Panel concluded that the recycling process NGR LSP is capable of reducing contamination of post-consumer food contact PET to a concentration that does not give rise to concern for a risk 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;
- (ii) the input material 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 and contain no more than 5% of PET from non-food consumer applications;
- (iii) the recycled PET obtained from the process NGR LSP is used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs, including drinking water, for long-term storage at room temperature or below, with or without hot-fill.

The final articles made of this recycled PET are not intended to be used in microwave and conventional ovens and such uses are not covered by this evaluation.

5 | RECOMMENDATION

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 Commission Regulation (EU) 2022/1616. 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.

6 | DOCUMENTATION PROVIDED TO EFSA

Dossier 'NGR LSP'. December 2023. Submitted by Next Generation Recyclingmaschinen GmbH, Austria.

Additional information, October 2024. Submitted by Next Generation Recyclingmaschinen GmbH, Austria.

ABBREVIATIONS

bw	body weight
CEF	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentration in PET
PET	poly(ethylene terephthalate)
SSP	solid-state polycondensation

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REQUESTOR

Austrian Competent Authority (Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz)

QUESTION NUMBER

EFSA-Q-2023-00498

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WAIVER

In accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management a waiver was granted to an expert of the Working Group. Pursuant to Article 21(6) of the aforementioned Decision, the concerned expert was allowed to take part in the preparation and discussion of the scientific output but was not allowed to take up the role of rapporteur within that time frame. Any competing interests are recorded in the respective minutes of the meetings of the FCM Panel Working Group on Recycling Plastics.

LEGAL NOTICE

Relevant information or parts of this scientific output have been blackened in accordance with the confidentiality requests formulated by the applicant pending a decision thereon by EFSA. The full output has been shared with the European Commission, EU Member States (if applicable) and the applicant. The blackening may be subject to review once the decision on the confidentiality requests is adopted by EFSA and in case it rejects some of the confidentiality requests.

REFERENCES

- 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*, 7(5), 1051. <https://doi.org/10.2903/j.efsa.2009.1051>
- EFSA (European Food Safety Authority). (2024). Administrative guidance for the preparation of applications on recycling processes to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food. *EFSA Journal*, EN-8968. <https://doi.org/10.2903/sp.efsa.2024.EN-8968>
- EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids). (2024). Scientific guidance on the criteria for the evaluation and on the preparation of applications for the safety assessment of post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food. *EFSA Journal*, 22(7), 8879. <https://doi.org/10.2903/j.efsa.2024.8879>
- FDA (Food and Drug Administration). (2021). Guidance for industry: Use of recycled plastics in food packaging: Chemistry considerations. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-use-recycled-plastics-food-packaging-chemistry-considerations>

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APPENDIX A

Specifications of the pre-processed input material as provided by the applicant¹²

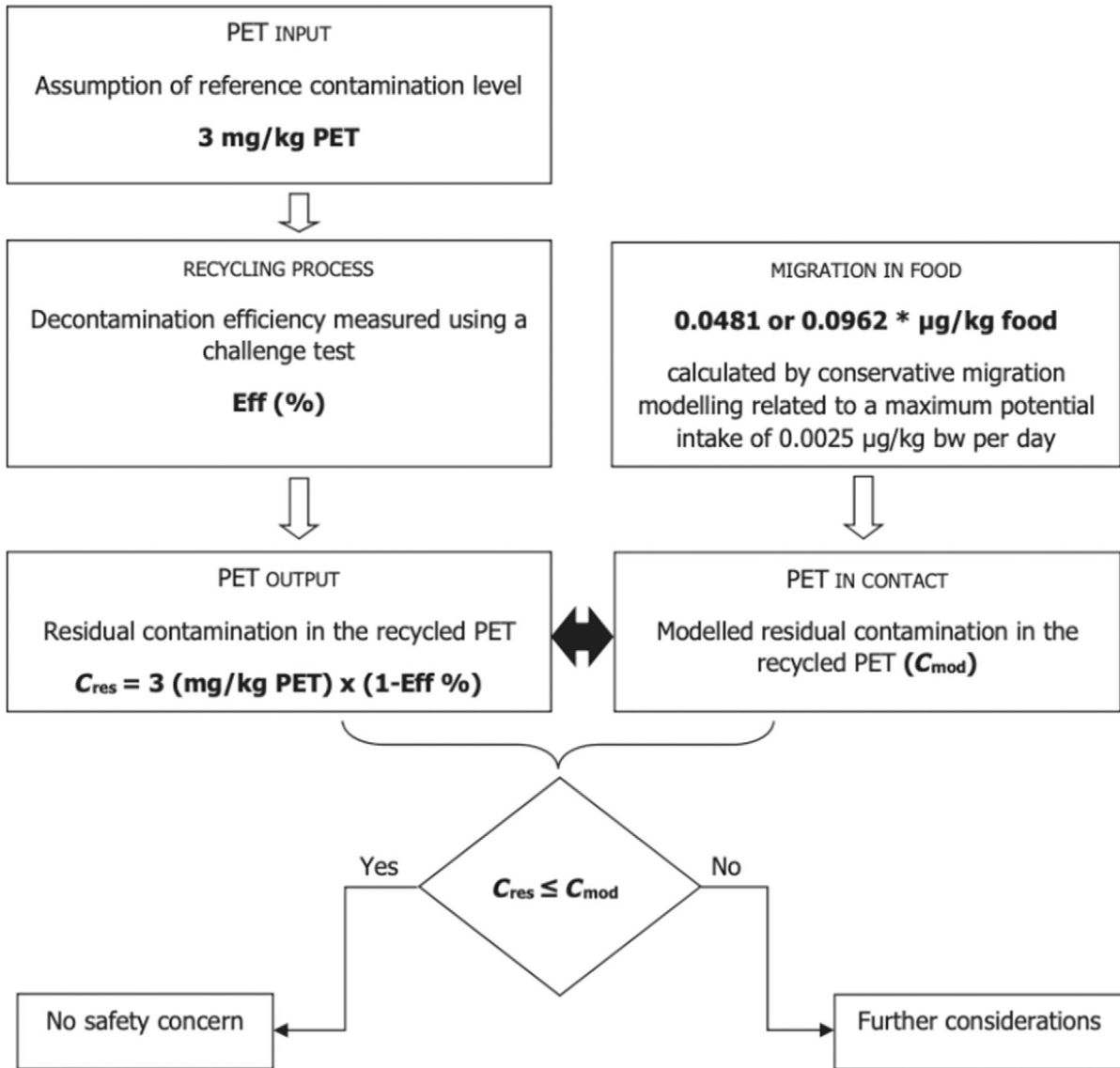
Parameter	Value
Intrinsic viscosity	0.65–0.83 dL/g
Moisture	≤ 20,000 mg/kg
Bulk density	250–500 kg/m ³
PVC	≤ 100 mg/kg
Polyolefins	≤ 200 mg/kg
PS and ABS	≤ 100 mg/kg
PC	≤ 50 mg/kg
PA and glue	≤ 4000 mg/kg
pH change	≤ 0.5

Abbreviations: ABS, acrylonitrile butadiene styrene; PA, polyamide; PC, polycarbonate; PS, polystyrene; PVC, poly(vinyl chloride).

¹²Technical dossier, section 'Characterisation of the input'.

APPENDIX B

Relationship between the key parameters for the evaluation scheme, based on the most conservative scenario A (EFSA CEP Panel, 2024)



*Depending on the molecular mass of the surrogate substance. The figures are derived from the application of the human exposure threshold value of 0.0025 µg/kg bw per day applying the factors of 5 and 10 related to the overestimation of modelling (most conservative Scenario A).

APPENDIX C

Table of operational parameters¹³

Although the operational parameters are reported for all the process steps, the critical steps and the corresponding parameters of the challenge test/process, considered for the evaluation of the process and for which it has been concluded that the process is safe, are highlighted in green.

The process should be operated at conditions at least as severe as the ones indicated in green in the table (e.g. lower pressures are more severe than higher, higher temperatures are more severe than lower, longer times are more severe than shorter, higher gas flows generally are more severe than lower).

The official enforcement control shall verify that the recycling plant is operating in a way that complies with its authorisation. Depending on the technology, some of the parameters are inter-related and changing one parameter to a more severe value may impact another parameter into a less severe value. Therefore, eventual deviations from the values of the parameters indicated as critical (marked in green in the table) should be demonstrated not impacting significantly on the safety assessment. The table does not necessarily report all the tolerances for the operational parameters.

	Process NGR LSP (RECYC328)												
	Step 2 (drying)				Step 3 (remelting in extruder)			Step 4 (Decontamination)*			Step 5 (granulation)		
	t (min)	P (mbar)	Gas flow rate (m ³ /h)	T (°C)	t (s)	P (mbar)	T (°C)	t (min)	P (mbar)	T (°C)	t (min)	P (mbar)	T (°C)
Challenge test (PA/4499b/20)	■	■	■	■	■	■	■	■	■	■	■	■	■
Process	■	■	■	■	■	■	■	■	■	■	■	■	■
	Batch				Continuous			Continuous			Continuous		
	Continuous				Continuous			Continuous			Continuous		

¹³Technical dossier, Sections 'Table of operating Parameters' and 'Recycling process'.

*Characteristics of the reactors in the challenge test and the industrial process.

	P:REACT 300 (challenge test)	P:REACT 600 (industrial process)	P:REACT 1200 (industrial process)	P:REACT 2000 (industrial process)	P:REACT 3000 (industrial process)
General					
Vertical part					
Horizontal part					