Initial Safety Report

Version 4: 19.12.2025

Post-consumer polypropylene (PP) buckets into new buckets

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Relevant for the recycling site:

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Table of Contents

Abstract

RE Plano has developed a recovery system for used PP food buckets from controlled sources as well as a super-clean process for the recycling of PP buckets. The process is based on decontamination of the sorted and washed PP flakes. The recyclate will be used for new buckets for food contact applications. The cleaning efficiency of the super-clean process was determined with a challenge test. The exposure assessment was carried out using migration modelling analogous to the EFSA assessment. Based on the results, the decontaminated PP recyclate can be used up to a proportion of 49% (milk products) and 32% (dry food), respectively, in new buckets for food contact applications without endangering the safety of the consumer.

General Information

RE Plano has developed a recovery system for used PP food buckets from controlled sources as well as a super-clean process for recycling PP buckets. The focus is on PP buckets which come from (fine) food producers, restaurants and canteens and were collected there by type. The PP buckets were in previous use exclusively in food applications. Therefore, collection takes place via a controlled collection system which is in compliance with Article 6 of Regulation 2022/1616. In addition, the manufacturers of the packaging are also part of the consortium so that the formulation of the PP buckets is known. In addition, the declarations of compliance of the PP buckets (in the first application) are available from the manufactures of the PP buckets. Also, the formulation of the PP buckets can be changed if problems arise during recycling cycles. The super-clean recycling process is based on a super-clean decontamination process with high cleaning efficiencies. After shredding, washing and decontamination of the collected PP buckets the recyclate should be used to produce new PP buckets for food contact applications.

Recycled PP buckets for use in production of new buckets for food contact applications have not been evaluated by the European Food Safety Authority yet. Therefore, according to Regulation 2022/1616 the use of recycled PP buckets in direct food contact applications can be considered as "Novel technology".

RE Plano acts as “Developer” for this Novel Technology.

Specific Information

Within this chapter the recycling process and the safety evaluation is described in detail. This chapter contains information about process steps and process parameters. The process parameters are fundamental to cleaning efficiency of the applied super-clean decontamination technology developed by RE Plano. The process parameters form part of the intellectual property of the technology manufacturer (= “Developer”) of the decontamination technology. Therefore, the process parameters should be kept confidential and must not be made accessible to the public domain. The confidential information is marked in red.

Characterisation of the Recycling Process

There are three main steps in the recycling plant, which are responsible for the safe recycling of PP buckets:

- Quality control (QC) of the input material (PP buckets from controlled sources e.g. (fine) food producers, restaurants, canteens, ...)
- Shredding and intense washing of the PP buckets

- Decontamination of the post-consumer material by use of [redacted] super-clean decontamination technology.

In the first step, the post-consumer PP container are ground to flakes and hot-washed with surfactants. The washing conditions are [redacted] for [redacted], followed by a rinsing step at room temperature. A colour sorting of the PP flakes is optional.

The washed flakes are reextruded to pellets at [redacted] with [redacted]. Subsequently, the pellets are further decontaminated [redacted] super-clean recycling process. In normal continuous operation the decontamination silo is fed and discharged at the same time with a [redacted]. For realization of the residence time ([redacted]) the filling level in the silo is kept constant. For the decontamination process the silo is purged from below with [redacted] and a temperature of [redacted]. The pellets are pre-heated by a heat-exchanger upstream to the silo to the target process temperature of [redacted]. The process parameters mentioned above result in a [redacted]. After the decontamination process, the pellets are cooled down to [redacted] by a pellet cooler downstream the silo.

A block diagram of the super-clean recycling process is shown in Figure 1.

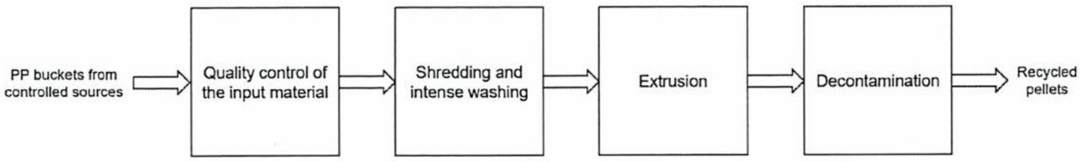

Figure 1: Block diagram of the super-clean recycling process

The cleaning efficiency of the super-clean technology was determined by use of a so-called Challenge Test (CT). The CT was performed with artificially contaminated PP material. The temperatures and pressure conditions within the CT are tried to be established as close as possible to the temperatures and pressures for the routine production mentioned above.

A Fraunhofer report [redacted] is available and applicable by request.

Characterisation of the Input Material

The PP buckets are exclusively used in the first life for packaging of food (e.g. milk products, dry food, ...). The PP buckets are collected at (fine) food producers, in the kitchens of the restaurants or canteens. Therefore, the recollected buckets were never contact with consumers, only with trained stuff of the restaurants or canteens. The collected PP buckets are therefore in compliance with article 6 of Regulation 2022/1616.

Input Contamination Levels

The input contamination level was determined by use of screening of PP flakes. Overall 20 samples of typical input materials for the industrial recycling process (washed PP flakes) were screened for substances. Each sample was analysed in triplicate. In addition, the corresponding output samples were analysed. Fraunhofer reports for each input/out pair are available containing all information about identification and semi-quantification of the investigated samples.

The investigated post-consumer PP samples were evaluated by different analytical fingerprint methods. Headspace gas chromatography as well as solvent extraction followed by gas chromatographic evaluation are suitable and complimentary methods to determine the differences in the input materials. By use of these two methods the most suitable recyclate sources can be qualified.

The analysed samples were very homogeneous and essentially showed the same substance peaks. The concentrations of the individual substance peaks were also very similar. The quantification was based on the extracts.

No evidence of contaminants due to improper storage or contamination during collection was found.

Calculation of the input contamination level: 60 samples of 1 g each were analysed. 1.0 g contains 51 individual PP flakes and it is assumed that there were never two flakes from one PP bucket in a 1 g sub-sample, then a total of 3060 individual PP buckets were analysed. No evidence of contaminants from storage of chemicals or other non-food items was found. The incidence is therefore <0.0327%. If one further assumes that a contamination with 100 mg/kg would occur, then the input contamination would be <0.0327 mg/kg.

Therefore, as a pragmatic approach an initial concentration of contaminants in PP buckets of 0.05 mg/kg was used within this document for the safety evaluation of rPP in PP buckets for food contact applications.

Determination of the Migration

<u>Description of the Methodology</u>

The cleaning efficiency is usually determined by a so-called challenge test by artificial contamination of the PP flakes.

Selection of the Surrogates

The surrogates were chosen in accordance with EU relevant criteria[1,2,3,4] such that they covered the whole spectrum of physical properties.

The surrogates correspond with the following four categories of organic compounds:

- high volatile and polar
- high volatile and non-polar
- low volatile and polar
- low volatile and non-polar

In addition, the surrogates used in the challenge test represent a variety of functional groups in order to reflect the different chemical and physical properties of real-life contaminants e.g. aliphatic and aromatic hydrocarbons, chlorinated hydrocarbons and carbonyl functional groups. Finally, the selection of surrogates also included the aspect of chemical stability under high temperature conditions as applied in PP extrusion and decontamination. From our experience from challenge tests the applied surrogates are stable under the applied process conditions. The applied surrogates used for the performance evaluation of the functional barrier are summarized in Table 1.

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[1] *Recycling of Plastics for Food Contact Use*, Guidelines prepared under the responsibility of the International Life Sciences Institute (ILSI) - European Packaging Task Force, 83 Avenue E. Mounier, B-1200 Brussels, Belgium, **1998**

[2] R. Franz, F. Bayer, F. Welle, Guidance and Criteria for Safe Recycling of Post Consumer Polyethylene Terephthalate (PET) into New Food Packaging Applications, EU Report 21155, ISBN 92-894-6776-2, Luxembourg **2004**.

[3] EFSA 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

[4] EFSA 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 **2024**, 22, 8879.

Table 1: Model contaminants for the challenge test

Substance	Mw[a]	Functional group	Properties
Toluene	92.1	Aromatic hydrocarbon	volatile, non-polar
Chlorobenzene	112.6	Aromatic hydrocarbon, halogen-containing	volatile, polar
Limonene	136.2	Aliphatic hydrocarbon	volatile, non-polar
Phenyl cyclohexane	160.3	Aromatic hydrocarbon	Low volatility, non-polar
Benzophenone	182.2	aromatic ketone	non-volatile, polar
Butyl salicylate	194.2	Aliphatic ester	non-volatile, non-polar
Methyl palmitate	270.5	Aliphatic ester	non-volatile, medium-polar
Diethylhexyl adipate DEHA	370.6	Aromatic ester	non-volatile, non-polar
Tris(ethylhexyl) trimellitate TEHTM	546.8	Aromatic ester	non-volatile, medium-polar

[a]Molecular weight in g/mol

Sample Materials

The following samples were investigated:

- Samples C: PP flakes, Input, contaminated (10 samples)
- Samples L: PP pellets, decontaminated after extrusion (7 samples)
- Samples Z: PP pellets, decontaminated after refresher (3 samples)

Experimentally Determined Concentrations of the Surrogates

The challenge test samples were analysed by gas chromatography after exhaustive extraction with dichloromethane. Example gas chromatograms of the dichloromethane extracts are shown in Figure 2 to Figure 5.

The surrogate concentrations determined in the investigated challenge test sample are summarised in Table 2.

This is only an excerpt from the challenge test results. The complete results are contained in the challenge test report.

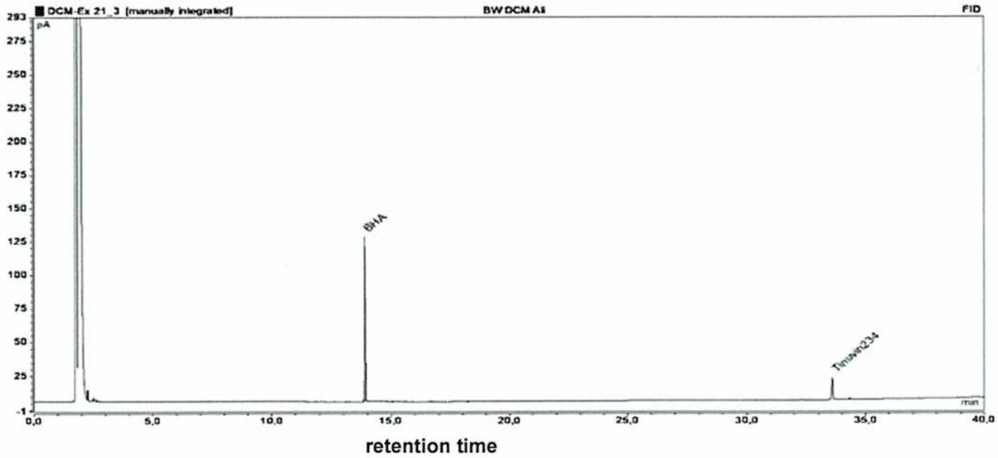

Figure 2: Gas chromatogram of the extract of solvent used for extraction (blind)

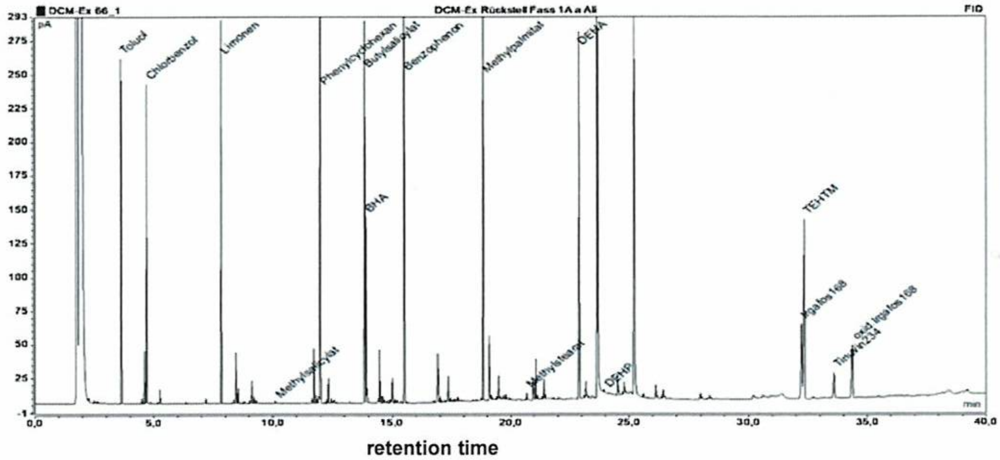

Figure 3: Gas chromatogram of the extract of sample C1

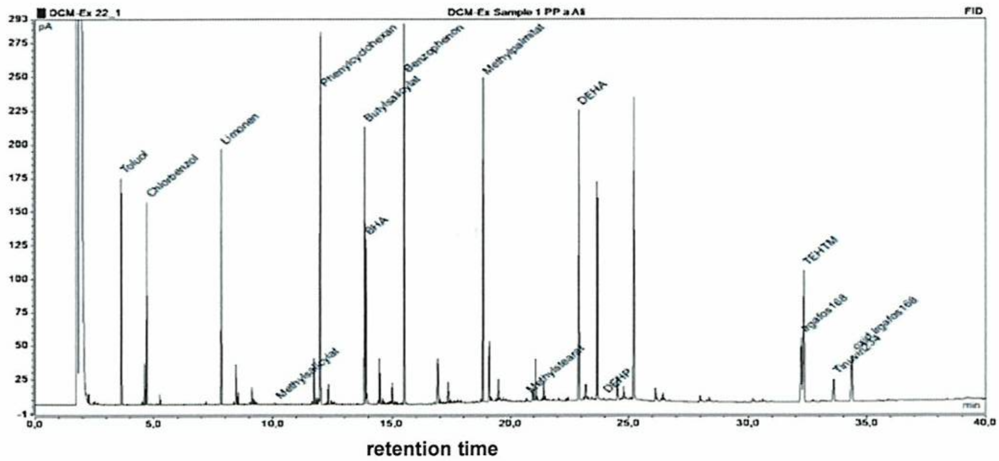

Figure 4: Gas chromatogram of the extract of sample L1

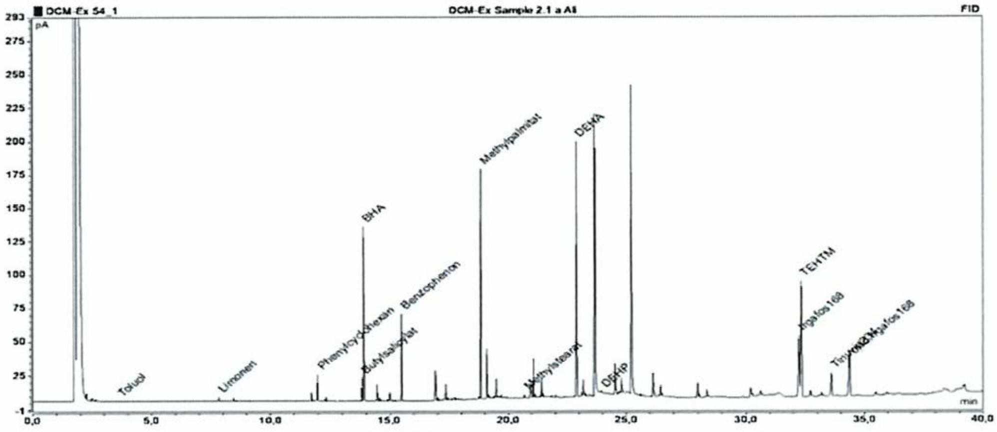

Figure 5: Gas chromatogram of the extract of sample Z2.1

Table 2: Summery of the concentrations of the surrogates in the challenge test

Sample	Concentration [mg/kg, ppm]								
	Toluene	Chloro-benzene	Limonene	Phenyl cyclo hexane	Benzo-phenone	Butyl salicylate	Methyl palmitate	DEHA	TEHTM
mean samples C	901.6 ±32.1	1201.0 ±52.8	1048.0 ±114.0	1030.0 ±179.9	1041.0 ±194.0	1131.1 ±207.3	943.6 ±190.0	992.4 ±173.6	921.6 ±193.2
mean samples L	620.3 ±12.5	828.2 ±22.9	848.9 ±56.8	935.0 ±73.7	1007.3 ±107.6	1065.2 ±114.1	967.4 ±134.3	1052.3 ±109.7	969.7 ±112.0
mean samples Z2	<0.1 (>99.9 %)	<0.1 (>99.9%)	16.3 ±0.6 (98.4%)	62.7 ±1.0 (93.9%)	230.7 ±5.8 (77.8%)	87.0 ±1.7 (92.3%)	665.1 ±5.0 (30.6%)	971.3 ±11.6 (2.1%)	873.3 ±9.9 (5.2%)

Determination of the Migration

Results from migration studies for the virgin buckets are available and applicable by request.

Intended Applications in Contact with Food

The intended application of the produced rPP is buckets for food contact e.g. PP buckets for food (e.g. milk products, dry food, ...) with storage conditions of up to 40 days at 8 °C (milk products) and 365 days at 25 °C (dry food).

Safety Evaluation of the Recycling Technology

Diffusion models provide a scientific tool for establishing a correlation between the migration into contact media and the corresponding concentration $C_{P,0}$ of a migrant (surrogates) in the final product of the super-clean recycling process. In this way maximum surrogate concentrations in PP can be established which would not lead to exceeding a certain migration value of interest.

Evaluation criteria for rPP buckets are not published by the European Food Safety Authority (EFSA). However, criteria for the evaluation of HDPE milk bottles[5] as well as criteria for mechanical recycled PET are available[4].

Scenario 1: Milk products:
A toddler with 12 kg b.w. consumes 80 g of milk products per kg body weight per day (960 g milk products per day). This results in a maximum migration of 0.0313 µg/kg. Due to the over-estimative character of the A_P migration prediction model by a factor at least of 2[5], the migration should be below of 0.0626 µg/kg.

Scenario 2: Dry food:
A toddler with 12 kg b.w. consumes 20 g of dry food per kg body weight per day (240 g dry food per day). This results in a maximum migration of 0.125 µg/kg. Due to the over-estimative character of the A_P migration prediction model by a factor at least of 2[5], the migration should be below of 0.250 µg/kg.

Using migration models, the maximum amount of substances of different molecular weights can be calculated using $A_P' = 13.1$ and $\tau = 1577$ K, which are the recommended modelling parameters for PP. The maximum concentrations C_{mod} of the applied surrogates were calculated for a food package with 1 l volume and with an inner surface area of 600 cm^2. The PP wall thickness in the standard applications is 220 µm. For worst-case considerations, a wall thickness of 300 µm was assumed. The calculation was done for a food with high solubility for the surrogates (partition coefficient $K_{Polymer/Food} = 1$ (good solubility) and K = 1000 (low solubility)) at conditions

[5]EFSA Scientific Opinion on the safety assessment of the processes 'Biffa Polymers' and 'CLRrHDPE' used to recycle high-density polyethylene bottles for use as food contact material. EFSA Journal **2015**, 13, 4016.

of 40 days at 8 °C (milk products) as well as 365 days at 25 °C (dry food). The density of PP was assumed to 0.92 g/cm³.

These calculated maximum concentrations correspond to the assumed migration limit of 0.0626 µg/kg and 0.250 µg/kg in food. In the first step, the concentrations in the bucket wall is calculated which corresponds to the migration limits of 0.0626 µg/kg and 0.250 µg/kg in food after storage for 40 days at 8 °C (milk products) as well as 365 days at 25 °C (dry food), respectively. The results are given in Figure 6 and Figure 7.

From the maximum concentrations in the bucket, the minimum cleaning efficiencies of the recycling process were calculated assuming a worst-case input concentration of 0.05 mg/kg. The results are visualized in Figure 8 to Figure 15.

As a result, the recyclate can therefore be used up to a proportion of 49% (300 µm, worst-case) and 49% (220 µm realistic case) in new buckets for milk products. For dry food, recyclate can be used up to a proportion of 32% (300 µm, worst-case) and 43% (220 µm realistic case). It is interesting to note, in case of low solubility of the surrogates in food 100% recyclate content is applicable for both milk products and dry food.

It is interesting to note, that maximum bucket wall concentrations above the initial contamination limit does not need any cleaning efficiency of the recycling process. This is the case if low solubility of the migrant in the foodstuff is assumed during migration (dashed lines in Figure 6 and Figure 7). Assuming good solubility, the limit is around 500 g/mol (milk products) and 750 g/mol (dry food), respectively.

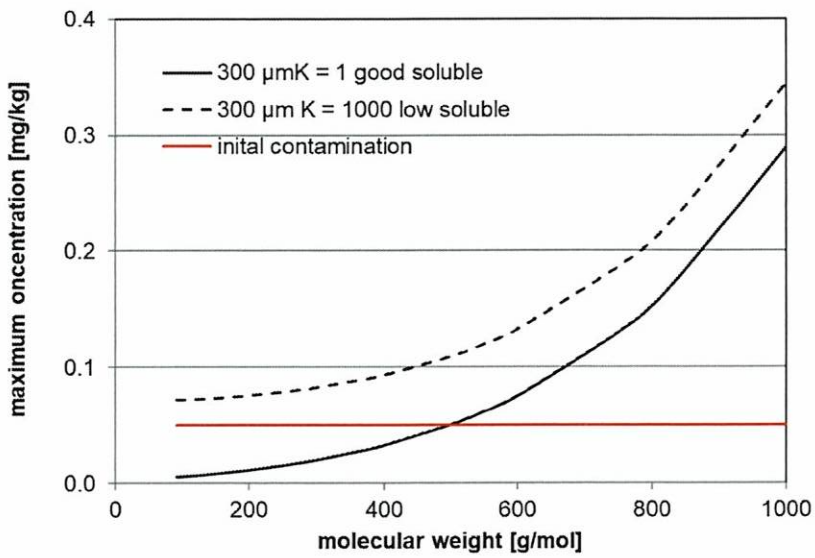

Figure 6: Maximum bucket wall concentrations which corresponds to the migration limit of 0.0626 µg/kg after storage for 40 days at 8 °C (milk products) for 300 µm (worst-case).

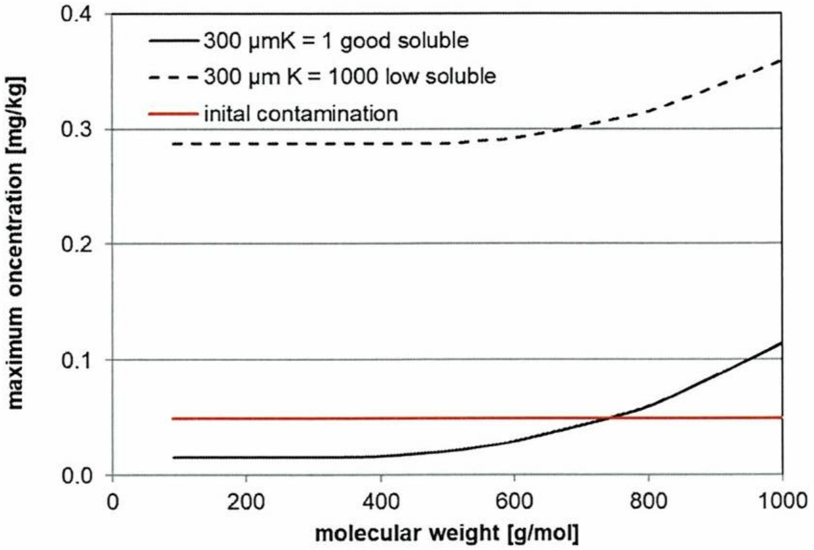

Figure 7: Maximum bucket wall concentrations which corresponds to the migration limit of 0.250 µg/kg after storage for 365 days at 25 °C (dry food) for 300 µm (worst-case).

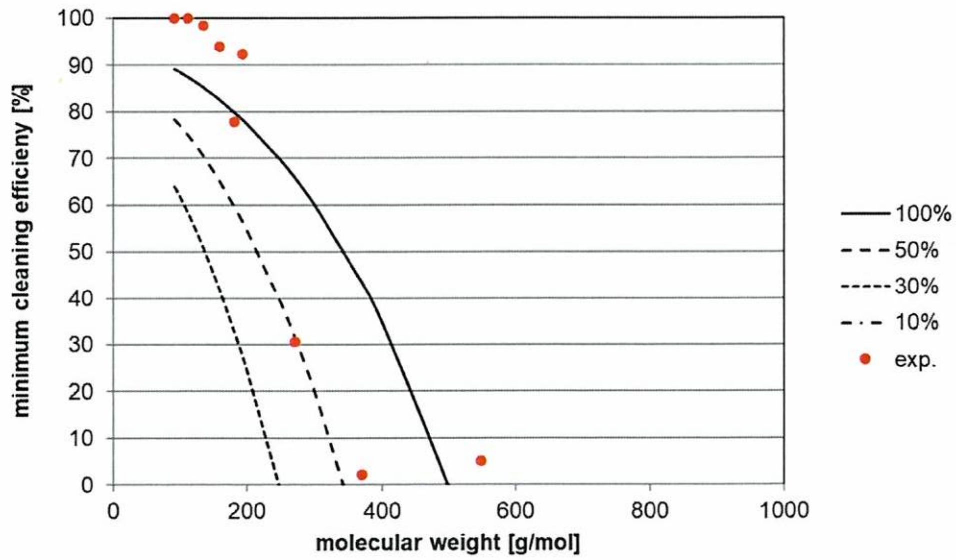

Figure 8: Minimum cleaning efficiencies of surrogates in the challenge test for a wall thickness of **220 µm (realistic wall thickness) and storage conditions of 40 days at 8 °C (milk products)**. lines: Minimum cleaning efficiency for 100%, 50% 30%, and 10% in the final food contact material, red dots: experimental data, calculated with **K = 1 (good solubility)**.

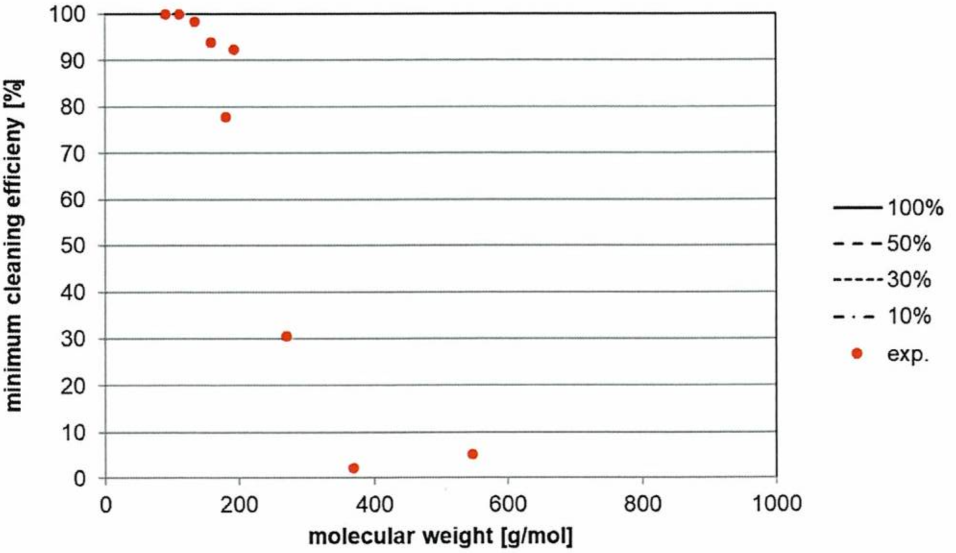

Figure 9: Minimum cleaning efficiencies of surrogates in the challenge test for a wall thickness of **220 µm (realistic wall thickness) and storage conditions of 40 days at 8 °C (milk products)**. lines: Minimum cleaning efficiency for 100%, 50% 30%, and 10% in the final food contact material, red dots: experimental data, calculated with **K = 1000 (low solubility)**. Remark: 100% recycled content no longer requires cleaning efficiency, so the lines are no longer visible.

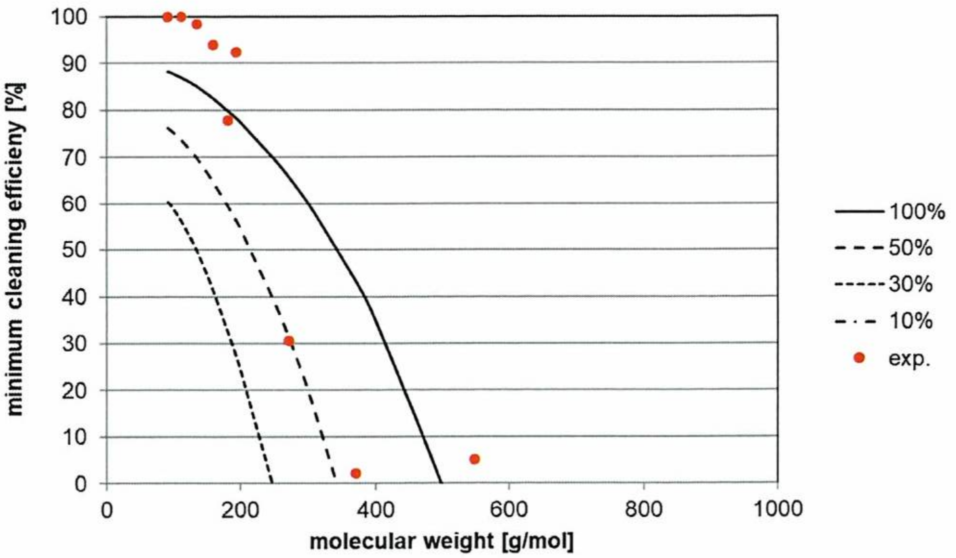

Figure 10: Minimum cleaning efficiencies of surrogates in the challenge test for a wall thickness of **300 µm (worst case wall thickness) and storage conditions of 40 days at 8 °C (milk products)**. lines: Minimum cleaning efficiency for 100%, 50% 30%, and

10% in the final food contact material, red dots: experimental data, calculated with **K = 1 (good solubility)**.

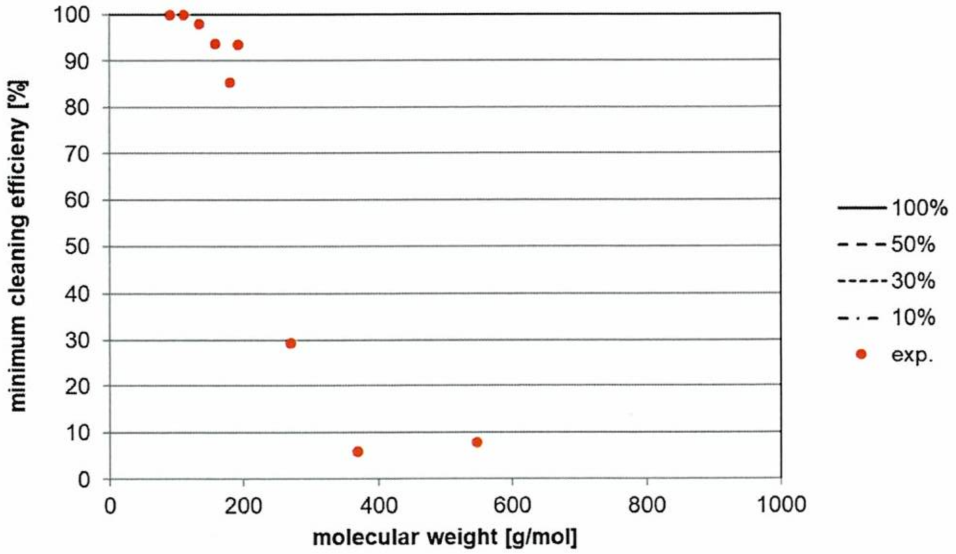

Figure 11: Minimum cleaning efficiencies of surrogates in the challenge test for a wall thickness of **300 µm (worst case wall thickness) and storage conditions of 40 days at 8 °C (milk products)**. lines: Minimum cleaning efficiency for 100%, 50% 30%, and 10% in the final food contact material, red dots: experimental data, calculated with **K = 1000 (low solubility)**. Remark: 100% recycled content no longer requires cleaning efficiency, so the lines are no longer visible.

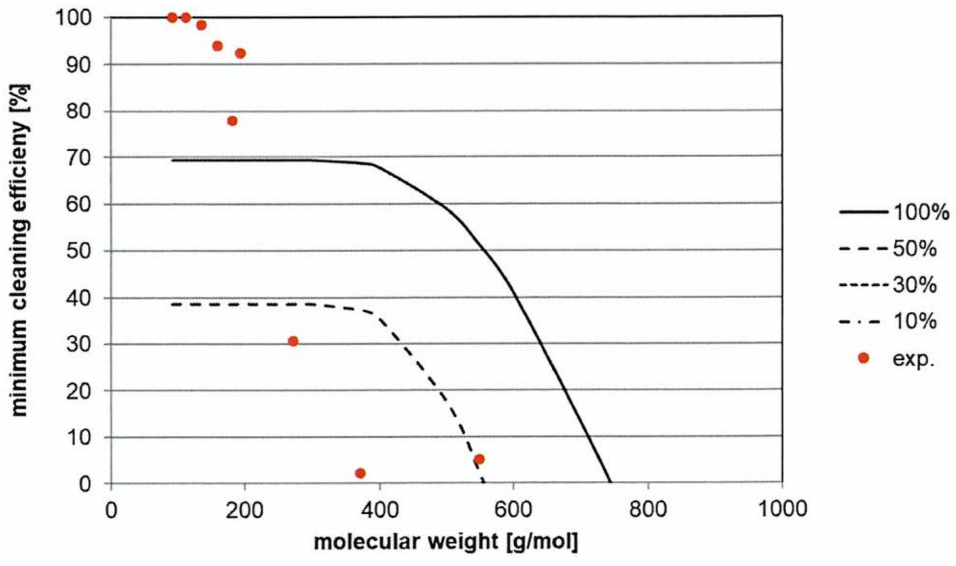

Figure 12: Minimum cleaning efficiencies of surrogates in the challenge test for a wall thickness of **220 µm (realistic wall thickness) and storage conditions of 365 days**

at 25 °C (dry food). lines: Minimum cleaning efficiency for 100%, 50% 30%, and 10% in the final food contact material, red dots: experimental data, calculated with **K = 1 (good solubility)**.

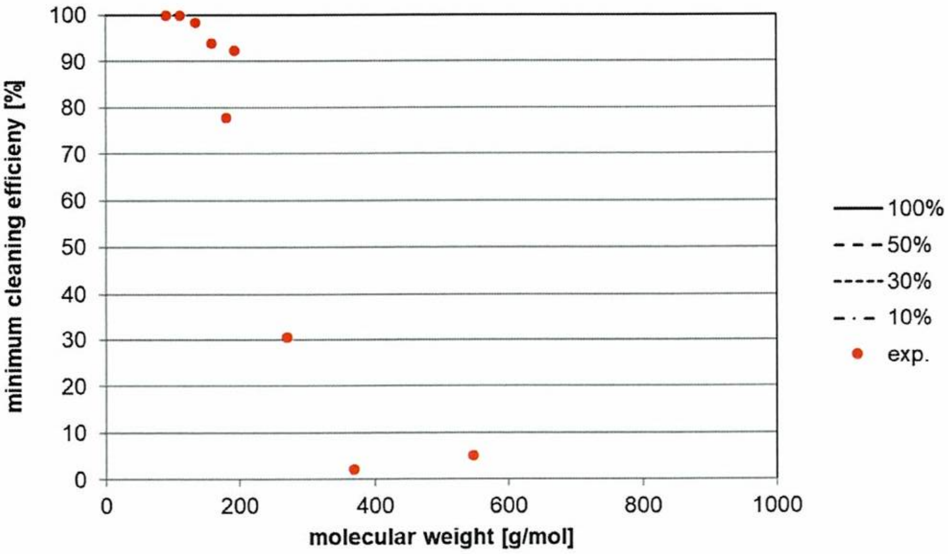

Figure 13: Minimum cleaning efficiencies of surrogates in the challenge test for a wall thickness of **220 µm (realistic wall thickness) and storage conditions of 365 days at 25 °C (dry food)**. lines: Minimum cleaning efficiency for 100%, 50% 30%, and 10% in the final food contact material, red dots: experimental data, calculated with **K = 1000 (low solubility)**. Remark: 100% recycled content no longer requires cleaning efficiency, so the lines are no longer visible.

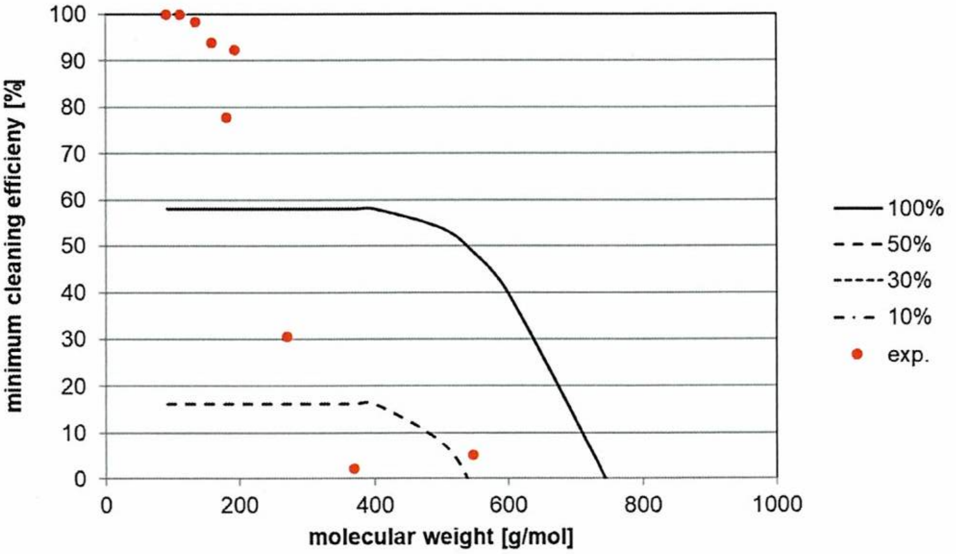

Figure 14: Minimum cleaning efficiencies of surrogates in the challenge test for a wall thickness of **300 µm (worst-case wall thickness) and storage conditions of 365 days at 25 °C (dry food)**. lines: Minimum cleaning efficiency for 100%, 50% 30%, and 10% in the final food contact material, red dots: experimental data, calculated with **K = 1 (good solubility)**.

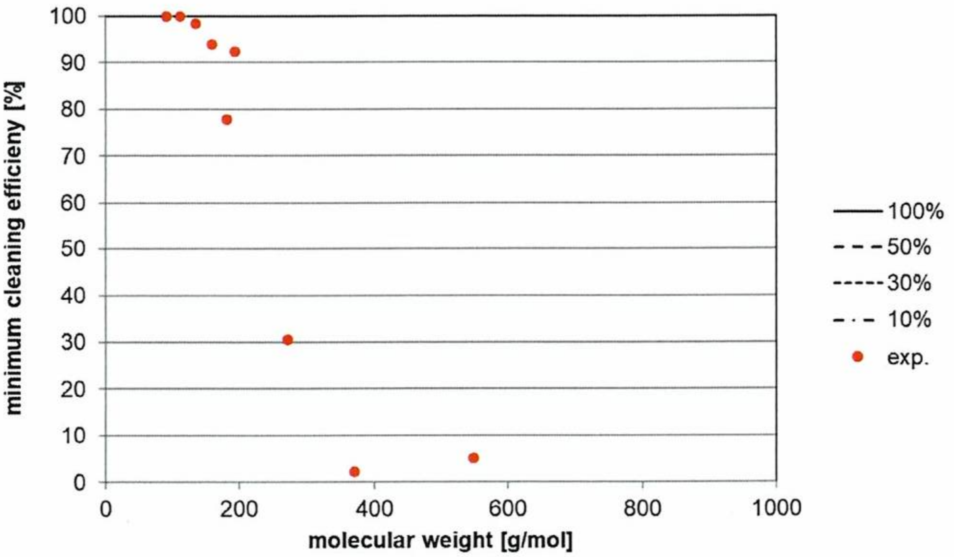

Figure 15: Minimum cleaning efficiencies of surrogates in the challenge test for a wall thickness of **300 µm (worst-case wall thickness) and storage conditions of 365 days at 25 °C (dry food)**. lines: Minimum cleaning efficiency for 100%, 50% 30%, and 10% in the final food contact material, red dots: experimental data, calculated with **K =**

1000 (low solubility). Remark: 100% recycled content no longer requires cleaning efficiency, so the lines are no longer visible.

Compliance with the Relevant Provisions on Food Contact Materials and Articles

From the data provided the following conclusions can be drawn:

- The investigated recycling technology is in a position to reduce the migration of potential contaminants from collected PP buckets to concentration levels which are in compliance with Article 3 of the EU Framework Regulation 1935/2004.
- The investigated recycling technology fulfils the requirements for the specific migration of the applied surrogates according to EU Regulation 10/2011.
- The investigated manufacturing process is in a position to fulfil the requirements of the GMP Regulation (EC) 2023/2006.

Due to the high temperature during PP recycling microbiological contamination is not a problem.

Decontamination installation operated for the development of the Novel Technology

The Novel Technology is (currently) relevant for the recycling site.

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Other lines or sites may be added to the list if these lines are providing the similar process and process conditions as described before. Updates will be given in the six months reports according to 2022/1616.

Proposed Evaluation Criteria

This chapter contains information about process steps and process parameters. The process parameters are fundamental to the cleaning efficiency. The process parameters form part of the intellectual property of the technology manufacturer of the recycling process. Therefore, the process parameters should be kept confidential. The confidential information is marked in red.

The following evaluation criteria are proposed:

- Temperature washing process: [redacted] for [redacted]
- Temperature extrusion process: [redacted]
- Temperature of the decontamination process: [redacted]
- Residence time of the decontamination process: [redacted]

Annex A

Experimental details

<u>Determination of the Surrogates in the PP samples</u>

For each test 1.0 g of PP material were covered with 10 ml of dichloromethane and stored for 3 days at 40 °C. The extracts were then analysed by GC/FID and GC/MS. Gas chromatograph: Agilent 6890, column: DB 1 - 30 m - 0.25 mm i.d. - 0.25 µm film thickness, temperature program: 50 °C (2 min), followed by heating at 10 °C/min to 340 °C (15 min), pre-pressure: 50 kPa hydrogen, split: 10 ml/min. Butylhydroxyanisole (BHA) and Tinuvin 234 were used as internal standards. Quantification was achieved by external calibration using standards of the surrogates in dichloromethane.

The detection limits were determined according to DIN 32645. The results are given in Table 3.

Table 3: Analytical detection limit of the surrogates in PP samples

Surrogate	Detection limit [mg/kg, ppm]
Toluene	0.1
Chlorobenzene	0.1
Limonene	0.1
Phenyl cyclohexane	0.1
Benzophenone	0.2
Butyl salicylate	0.3
Methyl palmitate	0.2
Diethylhexyladipate DEHA	0.3
Tris(ethylhexyl)trimellitate TEHTM	0.3