Initial Report on the Novel Technology

"INEOS STYROLUTION Twin Screw Degassing Extrusion"

According to Article 10(3) and Article 31(5) of the Commission Regulation (EU) 2022/1616

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This document contains confidential information which is marked in red throughout the text.

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1. Characterisation of the novel technology

The INEOS STYROLUTION super-clean recycling process, which began operating before the entry into force of Commission Regulation (EU) No. 2022/1616, comprises of the following main decontamination process steps:

- Step 1: Oversorting of available PS Bales (waste specification DSD 331; > 94% article content PS) Grinding of collected post-consumer PS containers into flakes followed by an intensive wash process and drying (remark: step 1 is made by the flake suppliers)

- Step 2: Re-extrusion of the washed flakes by using a twin screw extruder with vacuum degassing [redacted].

1.1 Description of the INEOS STYROLUTION Styrolution super-clean recycling process

INEOS STYROLUTION is buying washed flakes from the market. The flake suppliers are using state of the art oversorting and washing process parameters. In the first step, the container oversorting ensures that non PS articles are sorted out as well as non-food articles are sorted out in order to ensure that > 95% of all articles have food contact origin. Containers, labels and closures are then cut into flakes.

The PS flakes are further washed with hot washing processes. During such hot washing processes, typically [redacted] are used. To the washing solution, caustic soda at a concentration of [redacted] is added as well as surfactants. The residence time of the flakes in the washing line is [redacted].

The hot washing process is followed by rinsing with water and surface drying of the PS flakes. The flakes are sorted again with NIR technology in order to ensure that foreign materials from labels and closures that were formerly attached to the PS container are now taken out. After this final sorting step a PS content [redacted] achieved.

The washed flakes are re-extruded by use of the twin screw extruder with vacuum degassing. Potential contaminants are removed in the melt during this melt degassing [redacted]. The decontaminated melt is subsequently pelletized. The twin screw extruder design allows to control the parameters:

- Temperature
- Vacuum
- Residence time

which are determining the devolatilisation of volatile components from the polymer-matrix.

A flow chart of the investigated super-clean recycling process is shown in Figure 1.

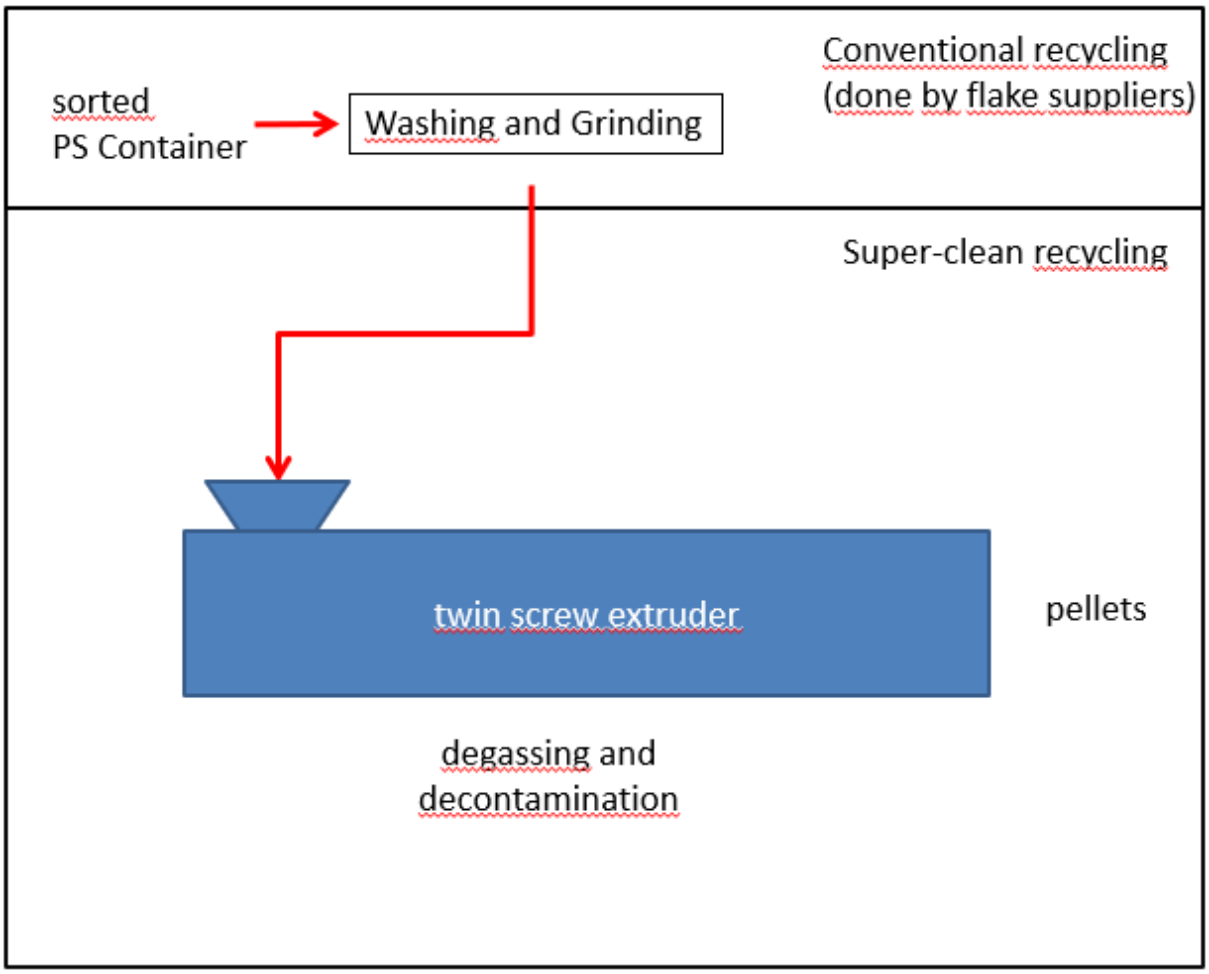

Fig. 1 Flow chart of the investigated super-clean recycling process

1.2 Input Material and characterisation

The investigated super-clean recycling process uses as a raw material source post-consumer PS trays and containers from green dot systems and curbside collections in Europe. Although we know that even non-food articles are typically manufactured with Food grade PS (see Welle, 2023), we limit the content of non-food articles to max 5%. This is ensured by oversorting either manually or by an automated system (e.g., "Gain" from Tomra) which performs object recognition and is trained for food containers. Table 1 contains data about the quality of the input material before super-clean recycling.

Table 1: Data about the quality of the input material of the super-clean recycling process (washed flakes before super-cleaning)

Parameter	Value
Moisture	<1%
PS flakes with printing content	<0.5%
PS flakes with glue content	<0.5%
Polyolefins content	<1%
Polyamide content	<0.5%
Metals content	<0.1%
Wood, paper, cellulose	<0.5%

1.3 Intended use of the recycled material

INEOS STYROLUTION is producing pellets which are intended for new food contact articles with a recyclate content of up to 100% (unless lower content is noted below).

Typical food contact applications for the INEOS Styrolution output materials (PS pellets) include containers for dairy products, trays for packaging food, and beverage cups:

- yogurt, milk rice and fresh cheese, storage conditions 40 d at 6 °C (cold filled yogurt)
- yogurt 8 hours at 40°C followed by 40 d at 6°C (yogurt fermented in the package)
- yogurt, milk rice and fresh cheese, storage conditions 1 h at 60 °C followed by 40 d at 6 °C (hot filled yogurt)
- trays for meat, fish or cheese, storage conditions 30 d at 6 °C
- trays for fruit or vegetables, storage conditions 30 d at 25 °C
- cups for cold drinks, storage conditions 1 d at 25 °C
- cups for hot drinks per day for an adult, 2 h at 70 °C (up to 50% rPS content).

2. Compliance with Article 3 of Regulation (EC) No 1935/2004

2.1 Characterisation of contaminant levels in the plastic input and the recycled plastics

Critical contaminants in post-consumer polymers might be chemicals from possible misuse of packaging containers, contaminants from non-food applications such as non-authorized additives as well as degradation products generated during recycling (Barthélémy et al. 2014).

Statistical data for the misuse of PS container for storage of household chemicals are not available to date in the scientific literature. Due to this reason, a so-called "misuse study" had been conducted by industry (Fraunhofer IVV report no. PA-2017-21 – conducted on behalf of Styrenics Circular Solutions (SCS) and property of SCS). In this study, 40 washed post-consumer PS flake samples obtained throughout Europe were analyzed to assess whether chemicals originating from the misuse of PS containers used to store solvents, household, or garden chemicals were present in the recycled polystyrene samples. Each sample (containing approximately 34.5 flakes/gram/sample) was analyzed 6 times. Overall, 8271 individual post-consumer PS flakes were analysed. No substances that would be associated with a misuse of the container (e.g., solvent, household chemical or garden chemical) were detected in the flake samples. This testing confirms that the incidence of misuse is less than 0.012%, and that recycled polystyrene containers are not likely to be used by consumers to store hazardous substances after the first food-use.

For comparison reasons, the incidence found for post-consumer PET bottles was 0.03% to 0.04%. Toluene (at a concentration of 6750 mg/kg in the contaminated flake) has been identified as an example of the sort of substances, which are most likely filled into these misused PET bottles. In terms of consumer behavior, PET bottles are much more suitable for storage of liquids, because the bottles can be re-sealed with a closure. PS cups or trays cannot be re-sealed, and are therefore not suitable for storage of liquid chemicals. In addition, solvents such as toluene dissolve PS and destroy the container. Therefore, the incidence for misuse of PS cups or trays for storage of hazardous chemicals is most likely much lower than that for PET, which was confirmed by the "misuse" study discussed above.

Because there was no evidence of misuse of the 8271 individual recycled PS flakes, the input concentration of misused chemicals cannot be directly determined from the study. However, using the incidence of contamination from this study, and the maximum sorption of surrogate contaminants from the surrogate challenge study, we can estimate the potential misuse concentration. That is, the maximum sorption of any of the surrogates (toluene, chlorobenzene, methyl salicylate, phenyl cyclohexane, benzophenone, and methyl stearate) was observed for methyl salicylate, at 1411 mg/kg. If we multiply this maximum sorption level by the worst-case incidence of contamination approximated in the misuse study (0.012%), we estimate that the contaminant concentration of recycled PS feedstreams is approximately 0.17 mg/kg (1411 mg/kg x 0.012% = 0.17 mg/kg). Even if we assume a misuse incidence five times higher (or a sorption level that is five times higher than what was observed in the surrogate challenge test), the worst-case input contamination would not exceed 1 mg/kg, the input contamination level for the rPS input stream used in the evaluation below.[1]

Other contamination, such as microbiological or viral contamination, can be excluded because of the high temperatures used to process the polymer (Barthélémy et al. 2014).

2.2 Determination of decontamination efficiency

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The decontamination efficiency was determined with a challenge test in collaboration with the Fraunhofer IVV. The challenge test was performed in a small production unit with a throughput of 24 kg/h and 100 kg of contaminated PS flakes. The contaminated flakes were given into the extruder intake zone and samples were drawn every 45 min. The temperature in the twin screw extruder during the whole challenge test was [redacted].

The Fraunhofer IVV report No. Pa-1406-21 (see Annex 1) contains all surrogate concentrations of the investigated samples, the sampling description, and analytical methods to determine the concentrations in the recycled plastic.

For the industrial process, the setup is close to the small production setup. The industrial extruder can thus compare in terms of heating zones, vacuum, temperature control, etc. The differentiator is the throughput which is higher. Good and predictable upscaling is one of the strengths of twin screw extrusion technology.

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2.3 Diffusion modelling

In a 2016 EFSA opinion, the panel provided recommendations on calculation of consumer exposure to substances originating from food-contact materials (EFSA CEF Panel, 2016). EFSA provided specific guidance on exposure scenarios for sensitive populations such as infants and toddlers for various categories of foodstuffs. As a pragmatic approach, the calculations included here demonstrate that dietary exposure is below 0.0025 µg/kg bw/day for an unknown contaminant possibly present, which is consistent with the approach used in the EFSA opinion on mechanically recycled PET (EFSA CEF Panel, 2011). A dietary exposure of 0.0025 µg/kg bw/day is the human exposure threshold value that has been used by EFSA for chemicals with structural alerts raising concern for potential genotoxicity.

[1] Similarly, if the worst-case concentration observed in the misuse study in PET (6750 mg/kg) is multiplied by the observed incidence of contamination in the PS study (0.012%), the input contamination level would be no more than 0.81 mg/kg, and thus the 1 mg/kg level assumed here would be considered worst case.

Generally, this threshold value is low enough to address concern over all toxicological effects. Thus, it is ensured that any unknown contaminant possibly present is treated in a conservative way.

In the present case, contact with category 1 foods can be excluded because the rPS is not intended to be used in packaging for human milk or infant formula or for water that is used to reconstitute powdered infant formula. Under category 3, which covers foods specifically intended for infants and toddlers, a consumption of 50 g/kg bw per day is indicated; however, for the specific category of interest to the novel technology developer, "fruit purée and dairy products (yoghurt, cheese preparations, milk-based dessert and puddings)," a consumption of 12.3 g/kg bw per day is indicated. For the tray applications, we have referred to the consumption pattern described in category 3 because it may include meals ready to eat. For this category, the level of consumption of 50 g/kg bw per day was indicated. For other foods, and foods consumed by the general population (i.e., category 4), the level of consumption of 20 g/kg bw per day is considered appropriate to cover the consumption by all population groups of foods. To cover use of the cold cups by toddlers, we have used the consumption pattern for category 2 (Milk, milk products and other non-alcoholic drinks e.g., fruit and vegetable juices) of 80 g/kg bw per day. For the hot cup application, we have limited the use to adults because toddlers (12 months to 3 years old) would not be expected to consume hot beverages from polystyrene cups. For this application, we have referred to food consumption category 4, for which the level of consumption of 20 g/kg bw per day is indicated. Typical body weights of 12 kg for toddlers and 60 kg for adults is indicated in the EFSA opinion.

Therefore, the following exposure scenarios are considered for the applications covered in this dossier:

Table 2: Intended Uses and Target Migration to Ensure Exposure < 0.0025 µg/kg bw/day

Application	rPS content	Representative Time / temperature scenarios	Food Consumption	Body weight	Daily consumption	Target migration in food
Yogurt and similar foods	100%	1 hr @ 60°C, + 40 days @ 6°C	12.3 g/kg bw/day	12 kg (toddler)	147.6 g	0.2 µg/kg
		8 hrs @ 40°C + 40 days @ 6°C				
		40 days @ 6°C				
Meat, poultry, fish, and cheese tray	100%	30 days @ 6°C	50 g/kg bw/day	12 kg (toddler)	600 g	0.05 µg/kg
Fruit and vegetable tray	100%	30 days @ 25°C	50 g/kg bw/day	12 kg (toddler)	600 g	0.05 µg/kg
Cold cups	100%	1 day @ 25°C	80 g/kg bw/day	12 kg (toddler)	960 g	0.03 µg/kg
Hot cups	50%	2 hrs @ 70°C	20 g/kg bw/day	60 kg (adult)	1200 g	0.125 µg/kg

The above-mentioned consumption data covers all packaging materials, not only rPS. For example, yoghurt is packed in other materials such as polypropylene; meat is also packed in PET trays. Thus, the consumption assessment here, assuming the food is packaged only in rPS, is conservative.

Diffusion model exaggerates migration from polystyrene

As noted in the EFSA opinion on the evaluation of mechanically recycled PET (EFSA CEF Panel, 2011) as well as the 2023 *Welle* article on recycling of post-consumer polystyrene packaging waste (Welle, 2023), the Piringer-based (i.e., A_P-based) diffusion modeling overestimates migration of substances from low diffusive polymers. Welle (2023) described testing that was conducted to determine the extent of this exaggeration in polystyrene. As noted in the table below, the extent of the overestimate for polystyrene is largely dependent on temperature (the extent of the overprediction of the A_P-based diffusion model increases as temperature decreases), but also influenced by both molecular weight and polarity. To represent contaminants of indeterminant volatility and polarity, we have used the lowest factor for the identified contaminants at the specific temperatures of interest (i.e., 2.86 for 60°C, 5.61 for 40°C, and 8.31 for room temperature conditions, and 14.2 for refrigerated conditions) in determining the minimum cleaning efficiencies needed for each of the use scenarios described below. (The factor nearest the specified temperature was used when applying these factors below. For example, for 25°C, the factor established for 20°C was used.)

Table 3: Over-Estimate Factors Compared to Experimental Migration (from *Welle* 2023)[2]

	Toluene **V, NP, (mw=92)**	**Chlorobenzene** **V, P, (mw=112)**	**Phenyl cyclohexane** **NV, NP (mw=160)**	**Benzophenone** **NV, P (mw = 182)**	**Methyl stearate NV, NP (mw = 298)**
60°C	4.77	2.86	93.2	29.3	28.6
40°C	11.8	5.61	213	47.5	64.0
20°C	22.9	8.31	568	125	>2940
5°C	20.8	14.2	456	271	>1130

<u>Scenario 1 (PS in yogurt cups: hot-filled, warm-fermented, and cold-filled; 100% rPS)</u>

There are three filling conditions considered for yogurt containers evaluated here. The first involves hot-filling of the yogurt or similar milk-based desserts (e.g., rice pudding). The food is expected to be filled at a temperature of approximately 60°C, rapidly cooled to refrigerated conditions, and held at refrigerated temperatures (6°C) for up to 40 days. The second fill condition involves fermenting the yogurt in the container at 40-45°C for up to 8 hours and subsequently cooling to refrigerated conditions and holding at refrigerated temperatures (6°C) for up to 40 days. Finally, the third condition involves merely filling and holding the yogurt at refrigerated temperatures (6°C) for up to 40 days. The packaging and use conditions noted here are representative of the intended use; somewhat different conditions of similar severity are subsumed by the calculations noted below.

As noted in section 2.1, the initial concentration of contaminants in food is assumed to be 1 mg/kg based on the incidence of contamination observed in a misuse study on recycled polystyrene collected throughout Europe. Because rPS may constitute up to 100% of the resin in yogurt containers, the calculations assume that the initial concentration of an indeterminate contaminant in the yogurt package will be 1 mg/kg.

The 2015 JRC Technical Report (Hoekstra, et al., 2015) provides the following estimate of diffusion coefficient (D_P^*) at a specified temperature (T, °K) for a substance with molecular weight M_r:

$$D_P^* = e^{(A_P^* - 0.1351 M_r^{\frac{2}{3}} + 0.003 M_r - \frac{10454}{T})}, \text{ where } A_P^* = A_P'^* - \frac{\tau}{T}.$$

[2] V = volatile; NV = nonvolatile; P = polar; NP = nonpolar; mw = molecular weight.

For high impact polystyrene, the JRC technical publication indicates that $A_P'^* = 1$, and $\tau = 0$.

To estimate the required cleaning efficiency for an indeterminate contaminant, we have modeled the migration that would result from diffusion of the contaminant using a nominal molecular weight of 100 Daltons, assuming an initial concentration in the recycled resin of 1 mg/kg. The target migration (0.2 µg-contaminant/kg-yogurt) is calculated to ensure that an exposure of 0.0025 µg-contaminant/kg bw/day will not be exceeded based on the 95th percentile of consumption of yogurt (and similar foods) of toddlers in Europe (12.3 g-yogurt/kg bw/day).[3] The results of the calculation, which are shown in the table below, demonstrate that the potential exposure to the contaminant will be less than 0.0025 µg/kg bw/day even if the recycling process does not reduce the contaminant concentration below 1 mg/kg (i.e., a cleaning efficiency [redacted] is required).

Table 4: Migration Results for Hot Filled Yogurt Cups

Contaminant molecular weight	mw = 100 Da
Migration Target, $<M>_{Target}$	0.2 µg/kg-food
Initial contaminant concentration	1 mg/kg
T_1	60°C (333°K)
Time	1 hour (3600 sec)
D_{P1}	4.64 x 10^{-11} cm^2/sec
$<M_1>$[4]	0.29 µg/kg
Adjustment Factor	2.86
$<M_1>_{adjusted}$	0.10 µg/kg
T_2	6°C (279°K)
Time	40 days (3,456,000 sec)
D_{P2}	1.06 x 10^{-13} cm^2/sec
$<M_2>$	0.23 µg/kg
Adjustment Factor	14.2
$<M_2>_{adjusted}$	0.016 µg/kg
$<M>_{Total} = (<M_1>_{adjusted} + <M_2>_{adjusted})$	0.116 µg/kg
Required Cleaning Efficiency	[redacted] (i.e., $<M>_{Total} \leq <M>_{Target}$

[3] See also Table 2 above;
$<M>_{Target}$ = 0.0025 µg-contaminant/kg bw/day ÷ 0.0123 kg-yogurt/kg bw/day = 0.2 µg/kg.

[4] The migration <M>, at time t (in seconds), is calculated using the approach described in the JRC Technical report, assuming Fickian diffusion, $M_t = 2Cpo\sqrt{\frac{D_P^* t}{\pi}}$. To estimate migration, the initial concentration (1 mg/kg) of the contaminant in food, density of HIPS (1.04 g/cm^3), and diffusion coefficient and time (in seconds) are used to estimate migration in grams per cm^2. To estimate the concentration in food, the standard EU cube, 1 kg contact 6 dm^2 (i.e., 600 cm^2) is used. Here, the M_t, in micrograms/cm^2 = 2 x $1e^{-6}$ x 1.04 g/cm^3 x (4.64 x 10^{-11} cm^2/sec x 3600 sec ÷ 3.14)$^{1/2}$ x 1,000,000 µg/g = 0.48 x 10^{-3} µg/cm^2. Expressing this as a concentration in food, we multiply by 600 cm^2/kg-food, which results in a concentration of 0.288 µg/kg. In cases where the food is expected to contact the finished plastic material at multiple different temperatures, the second phase of migration is calculated using the following equation: $M_{t_2} = \frac{2C_{P0}}{\sqrt{\pi}}\left[\sqrt{D_{P1}t_1 + D_{P2}t_2} - \sqrt{D_{P1}t_1}\right]$.

Likewise for the fermentation in the container, the following table summarizes the results:

Table 5: Migration Results for Yogurt Fermented in Cups

	mw = 100 Da
Migration Target, $<M>_{Target}$	0.2 µg/kg-food
Initial contaminant concentration	1 mg/kg
T_1	45°C (313°K)
Time	8 hours (28,800 sec)
D_{P1}	$1.05 \times 10^{-11} cm^2/sec$
$<M_1>$	0.39 µg/kg
Adjustment Factor	5.61
$<M_1>_{adjusted}$	0.069 µg/kg
T_2	6°C (279°K)
Time	40 days (3,456,000 sec)
D_{P2}	$1.06 \times 10^{-13} cm^2/sec$
$<M_2>$	0.22 µg/kg
Adjustment Factor	14.2
$<M_2>_{adjusted}$	0.016 µg/kg
$<M>_{Total} = (<M_1>_{adjusted} + <M_2>_{adjusted})$	0.083 µg/kg
Required Cleaning Efficiency	[redacted] (i.e., $<M>_{Total} \leq <M>_{Target}$

For cold filled yogurt, the following table summarizes the results:

Table 6: Migration Results for Cold Filled Yogurt Cups

	mw = 100 Da
Migration Target, $<M>_{Target}$	0.2 µg/kg-food
Initial contaminant concentration	1 mg/kg
T_1	6°C (279°K)
Time	40 days (3,456,000 sec)
D_{P1}	$1.06 \times 10^{-13} cm^2/sec$
$<M_1>$	0.43 µg/kg
Adjustment Factor	14.2
$<M>_{Total} = (<M_1>_{adjusted})$	0.03 µg/kg
Required Cleaning Efficiency	[redacted] (i.e., $<M>_{Total} \leq <M>_{Target}$

Under the same packaging conditions, the total migration decreases with increasing contaminant molecular weight as demonstrated in the table below. These calculations demonstrate that predicted migration remains below 0.2 µg/kg for all molecular weight contaminants for each of the three yogurt packaging scenarios. Because, as demonstrated in Table 7, the molecular weight calculations for the 100 dalton contaminant is worst case, we have not provided the calculations for other molecular weight contaminants here.

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Table 7: Summary of $<M>_{Total}$ for Yogurt Use Scenarios vs. Molecular Weight

	Molecular weight (Daltons)				
	100	200	300	400	500
Hot-filled	0.116 µg/kg	0.058 µg/kg	0.033 µg/kg	0.020 µg/kg	0.013 µg/kg
Fermentation	0.069 µg/kg	0.034 µg/kg	0.019 µg/kg	0.012 µg/kg	0.008 µg/kg
Cold-filled	0.030 µg/kg	0.015 µg/kg	0.008 µg/kg	0.005 µg/kg	0.003 µg/kg

Scenario 2 (PS in tray for meat, fish, poultry, and cheese; 30 days @ 6°C)

Recycled polystyrene may also be used in manufacture of trays for holding meat, fish, or cheese stored for a maximum of 30 days under refrigerated conditions (i.e., 6°C). As noted above, the initial concentration of contaminants in food is assumed to be 1 mg/kg, based on the incidence of contamination observed in a misuse study on recycled polystyrene collected throughout Europe.

To estimate the required cleaning efficiency for an indeterminate contaminant, we have modeled the migration that would result from diffusion of the contaminant using a nominal molecular weight of 100 Daltons, assuming an initial concentration in the recycled resin of 1 mg/kg. The target migration (0.05 µg-contaminant/kg-food) is calculated to ensure that an exposure of less than 0.0025 µg-contaminant/kg bw/day will not be exceeded based on the 95th percentile of consumption of solid foods by toddlers in Europe (50 g/kg bw/day).[5] The results of the calculation, which are shown in the table below, demonstrate that the potential exposure to the contaminant will be less than 0.0025 µg/kg bw/day even with a cleaning efficiency [redacted].

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Table 8: Migration Results for Trays for Meat, Fish, Poultry, Cheese

	mw = 100 Da
Migration Target, $<M>_{Target}$	0.05 µg/kg-food
Initial contaminant concentration	1 mg/kg
T_1	6°C (279°K)
Time	30 days (2,592,000 sec)
D_{P1}	1.06 x 10^{-13} cm^2/sec
$<M_1>$	0.37 µg/kg
Adjustment Factor	14.2
$<M>_{Total} = (<M_1>_{adjusted})$	0.026 µg/kg
Required Cleaning Efficiency	[redacted] (i.e., $<M>_{Total} \leq <M>_{Target}$

Scenario 3 (PS in Fruit and Vegetable Tray; 30 days @ 25°C)

Recycled polystyrene may also be used in manufacture of trays used to store whole fruit or vegetables (i.e., raw, uncut and unpeeled fruits and vegetables) for a maximum of 30 days at room temperature (25°C).

As noted above, the initial concentration of contaminants in food is assumed to be 1 mg/kg, based on the incidence of contamination observed in a misuse study on recycled polystyrene collected throughout Europe.

[5] $<M>_{Target}$ = 0.0025 µg-contaminant/kg bw/day ÷ 0.050 kg-solid foods/kg bw/day = 0.05 µg/kg.

To estimate the required cleaning efficiency for an indeterminate contaminant, we have modeled the migration that would result from diffusion of the contaminant using a nominal molecular weight of 100 Daltons, assuming an initial concentration in the recycled resin of 1 mg/kg.

A 2015 EFSA opinion on a different recycled resin evaluated the use of the recycled resin in the manufacture of trays for contact with whole fruits and vegetables including mushrooms (EFSA CEF Panel, 2015). In that opinion, EFSA noted that the intended use of trays to transport, store, and display whole fruits and vegetables (including mushrooms) at room temperature or below involved conditions under which migration was unlikely to occur, noting the solid-solid contact and small surface of contact. The EFSA opinion also noted that the Plastics Regulation (EU No. 10/2011) did not foresee use of migration tests to determine compliance of plastic packaging when used in contact with uncut and unpeeled fruits and vegetables. Subsequently, the Plastics Regulation was amended (EU Reg. No. 2016/1416 of 24 Aug. 2016) to add migration conditions for uncut and unpeeled fruits and vegetables. Specifically, Recital (31) of the regulation indicated that migration testing should be specified for these foods, but that the surface of fruits and vegetables are dry. The regulation also noted that food simulant E may overestimate migration and that a 10-fold correction factor should be applied to migration. Here, we will use diffusion modeling at room temperature conditions, and apply two correction factors: (a) factor (8.31) accounting for over-estimate of the AP diffusion model; and (b) factor (10) that is consistent with the adjustment indicated in the Plastics Regulation, Annex III, Table 2.

The target migration (0.05 µg-contaminant/kg-food) is calculated to ensure that an exposure of less than 0.0025 µg-contaminant/kg bw/day will not be exceeded based on the 95th percentile of consumption of solid foods by toddlers in Europe (50 g/kg bw/day).[6] The results of the calculation, which are shown in the table below, demonstrate that the potential exposure to the contaminant will be less than 0.0025 µg/kg bw/day even with a cleaning efficiency of [redacted].

Table 9: Migration Results for Fruit and Vegetable Trays

	mw = 100 Da
Migration Target, $\langle M \rangle_{Target}$	0.05 µg/kg-food
Initial contaminant concentration	1 mg/kg
T_1	25°C (298°K)
Time	30 days (2,592,000 sec)
D_{P1}	1.16 x 10^{-12} cm^2/sec
$\langle M_1 \rangle$	1.22 µg/kg
Adjustment Factor-1	8.31
Adjustment Factor-2	10
$\langle M \rangle_{Total} = (\langle M_1 \rangle_{adjusted})$	0.015 µg/kg
Required Cleaning Efficiency	[redacted] (i.e., $\langle M \rangle_{Total} \leq \langle M \rangle_{Target}$

Scenario 4 (Cold Drinking Cup; 1 day @ 25°C; 100% rPS)
Scenario 5 (Hot Drinking Cup, 2 hours @ 70°C; 50% rPS)

Recycled polystyrene may also be used in the manufacture of hot and cold drinking cups. To assess cold drinking cups, we have assumed a maximum temperature of 25°C held in the cup for up to one day. For hot drinking cups, we have assumed that the beverage will be held at up to 70°C for 2

[6] $\langle M \rangle_{Target}$ = 0.0025 µg-contaminant/kg bw/day ÷ 0.050 kg-solid foods/kg bw/day = 0.05 µg/kg.

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hours, with no heat treatment of the beverage in the container. (The beverage will not be held at 70°C, but rather will cool to ambient after the initial hot-fill; thus, the selection of migration conditions is likely exaggerative.) Both cup conditions are assessed below.

As noted above, the initial concentration of contaminants in food is assumed to be 1 mg/kg, based on the incidence of contamination observed in a misuse study on recycled polystyrene collected throughout Europe. The rPS may constitute up to 100% of the resin in cold cup applications, and thus, the calculations assume that the initial concentration of an indeterminate contaminant in the cold cup will be no more than 1 mg/kg. Because the rPS may constitute no more than 50% of the resin in hot cup applications, and the calculations assume that the initial concentration of an indeterminate contaminant in the hot cup will be no more than 0.5 mg/kg.

To estimate the required cleaning efficiency for an indeterminate contaminant, we have modeled the migration that would result from diffusion of the contaminant using a nominal molecular weight of 100 Daltons, assuming an initial concentration in the cold and hot cup applications of 1 mg/kg and 0.5 mg/kg, respectively. The target migration (0.03 µg-contaminant/kg-food for cold cups, 0.125 µg/kg for hot cups) is calculated to ensure that an exposure of less than 0.0025 µg-contaminant/kg bw/day will not be exceeded. The cold cup target is based on the 95th percentile of consumption of milk, milk products, and other non-alcoholic drinks (e.g., fruit and vegetable juices) by toddlers in Europe (80 g/kg bw/day), and the hot cup target is based on adult consumption pattern of foods of 20 g/kg bw/day.[7] The results of the calculation, which are shown in the table below, demonstrate that the potential exposure to the contaminate will be less than 0.0025 µg/kg bw/day even with a cleaning efficiency of [redacted].

Cold cup application, 100% rPS, 25°C for 1 day:

Table 10: Migration Results for Cold Cups

	mw = 100 Da
Migration Target, $<M>_{Target}$	0.031 µg/kg-food
Initial contaminant concentration	1 mg/kg
T_1	25°C (298°K)
Time	1 day (86,400 sec)
D_{P1}	1.16 x 10^{-12} cm^2/sec
$<M_1>$	0.22 µg/kg
Adjustment Factor	8.31
$<M>_{Total} = (<M_1>_{adjusted})$	0.027 µg/kg
Required Cleaning Efficiency	[redacted] (i.e., $<M>_{Total} \leq <M>_{Target}$

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[7] $<M>_{Target}$ = 0.0025 µg-contaminant/kg bw/day ÷ 0.080 kg-cold beverages/kg bw/day = 0.031 µg/kg
$<M>_{Target}$ = 0.0025 µg-contaminant/kg bw/day ÷ 0.020 kg-hot beverages/kg bw/day = 0.125 µg/kg.

Hot cup application, 50% rPS, 70°C for 2 hours:

Table 11: Migration Results for Hot Cups (50% rPS)

	mw = 100 Da
Migration Target, $<M>_{Target}$	0.125 µg/kg-food
Initial contaminant concentration	0.5 mg/kg
T_1	70°C (343°K)
Time	2 hours (7,200 sec)
D_{P1}	1.16 x 10^{-10} cm^2/sec
$<M_1>$	0.19 µg/kg
Adjustment Factor	2.86
$<M>_{Total} = (<M_1>_{adjusted})$	0.066 µg/kg
Required Cleaning Efficiency	[redacted] (i.e., $<M>_{Total} \leq <M>_{Target}$

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Cmod Estimates

Comparing the estimated migration to the targets above (which result in a maximum potential intake of 0.0025 µg/kg bw/day), we have derived the following Cmod based on the various use conditions discussed above:

Table 12: Cmod for intended uses covered by dossier

Application*	**Cmod for nominal 100 Da contaminant**
Yogurt – hot-filled	1.72 mg/kg
Yogurt – fermentation in container	2.40 mg/kg
Yogurt – cold-filled	6.66 mg/kg
Tray for Meat, Cheese, Fish, Poultry	1.92 mg/kg
Fruit and Vegetable tray	3.40 mg/kg
Cold Cup	1.16 mg/kg
Hot Cup (50% rPS)	1.11 mg/kg

*100 rPS unless otherwise noted

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As noted above, the 100 dalton contaminant represents a worst case because the diffusion through polystyrene will decrease as the molecular weight increases. Thus, because the Cres (1 mg/kg, [redacted] cleaning efficiency) is less than Cmod for all applications and for all foreseeable contaminants, there is no safety concern presented for the intended applications.

Conclusions

For all of the use scenarios described above, the estimated migration of contaminants is less than the target migration, ensuring that an exposure of less than 0.0025 µg-contaminant/kg bw/day will not be exceeded. This is the exposure threshold value for chemicals with structural alerts raising concern for potential genotoxicity. Generally, this threshold value is low enough to address all toxicological concerns. Thus, it is ensured that any unknown contaminant possibly present in the recycled polystyrene will not result in risk of harm to consumers consuming food out of the modelled containers.

3. Technology description

Different mandatory process steps define the process (Fig. 2).

1. Sorting of waste bales (which can be PS-enriched waste-bales from municipal sorting facilities) by material type (PS versus non-PS) using modern NIR-technology. For the PS-articles, Non Food contact articles are rejected by object recognition, Food contact articles are kept.

2. Shredding of the PS-food contact fraction to flakes. Washing of the flakes in different steps (pre-washing, intense washing with a caustic solution, rinsing with demineralized water). Drying of the washed flakes.

3. Sorting of the flakes using both NIR flakes analysers and sifters. This last step permits to purify the flakes to a PS-content of at least [redacted]. Film-like flakes from lids and sleeves are rejected due to wrong composition or weight (nota bene: lids and sleeves can in some cases be made of PET, aluminum, PP).

4. Decontamination step: Extrusion under vacuum of the dry PS fraction, consisting of at least [redacted] of PS.

5. Melt filtration and pelletisation. The pellets are the final product of the Novel Technology. The extrusion is done in a twin-screw extruder, characterized by well-controlled process parameters: residence time, temperature, vacuum, melt filtration. After granulation, the resulting pellets can be used in food contact applications.

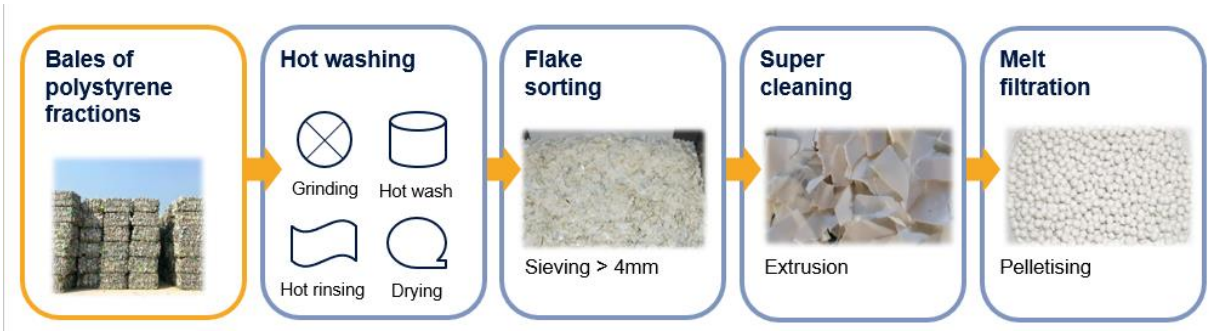

Figure 2. Block diagram of recycling process

4. Differentiation from other existing technologies

The development of the twin-screw extrusion technology to produce PS pellets from household waste to be used at up to 100% in food contact applications is a novel technology. Recycling of post-consumer PS packaging waste back into new packaging has not been established in Europe on an industrial scale to date (Welle, 2023). The only existing technologies to produce recycled plastics for food contact applications are the suitable technologies listed in Annex I of this regulation, which is PET recycling and closed loop recycling.

5. Proposed evaluation criteria

The novel technology developer proposes that the mechanically recycled polystyrene (PS) be assessed in a fashion similar to that utilized in the 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, 2011). That is, evaluation should apply the measured cleaning efficiency of the recycling process, obtained from a challenge test with surrogate contaminants at highly exaggerated levels, to a conservative reference contamination level for misuse contaminants in PS to calculate the residual concentration of contaminants in recycled PS (Cres). The resulting residual concentration for each contaminant is then compared to a modelled concentration in PS (Cmod). This Cmod is calculated using generally recognized conservative migration models and it corresponds to a migration which cannot give rise to a dietary exposure exceeding the threshold below which the risk to human health would be negligible. Therefore, when Cres is not higher than Cmod, it is considered that the process is able to produce an output which is not likely to be of safety concern for the defined conditions of use.

The following figure demonstrates the key parameters for the evaluation scheme:

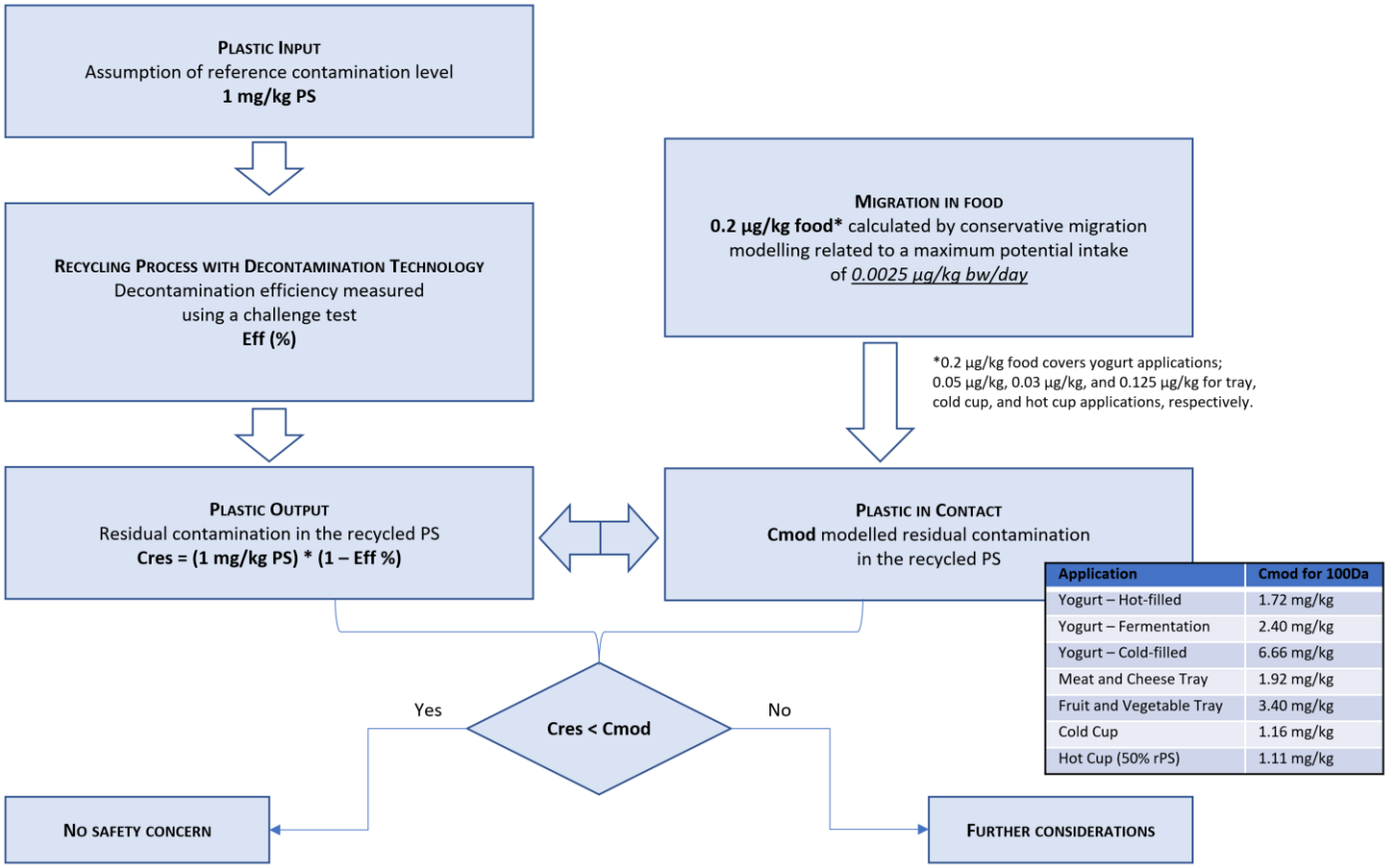

Figure 3: Relationship between key parameters for the evaluation scheme

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6. Decontamination installation operated for the development of the novel technology

The development of the decontamination technology is taking place at the [redacted]. This facility began operations before the entry into force of Commission Regulation (EU) No. 2022/1616.

7. References

Barthélémy, E.; Spyropoulos, D.; Milana, M.-R.; Pfaff, K.; Gontard, N.; Lampi, E.; Castle, L. Safety evaluation of mechanical recycling processes used to produce polyethylene terephthalate (PET) intended for food contact applications. Food Addit. Contam. Part A 2014, 31, 490–497.

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Franz, R.; Welle, F. Recycling of post-consumer packaging materials into new food packaging applications—Critical review of the European approach and future perspectives. Sustainability 2022, 14, 824.

Hoekstra, E.J.; Brandsch, R.; Dequatre, C.; Mercea, P; Milana, M.R.; Störmer, A.; Trier, X.; Vitrac, O.; Schäfer, A.; Simoneau, C.; JRC Technical Report: Practical guidelines on the application of migration modelling for the estimation of specific migration; EUR 27529 EN (2015). doi:10.2788/04517.

Welle, F. Recycling of Post-Consumer Polystyrene Packaging Waste into New Food Packaging Applications—Part 1: Direct Food Contact. Recycling 2023, 8, 26. https://doi.org/10.3390/recycling8010026

Annex 1

Fraunhofer IVV report No. Pa-1406-21

Fraunhofer IVV

Test Report

Determination of the cleaning efficiency of the INEOS polystyrene recycling technology

Client:	Ineos Styrolution Switzerland S.A. Avenue des Uttins 3 1180 Rolle Switzerland
Order No.:	Pa-1406a-21
Date of order:	12.02.2021
Samples:	01.03.2021
Date of the report:	14.03.2021

The results related to the investigated samples as received.

1 Aim of the Study

Aim of the study was the determination of the cleaning efficiency of the investigated polystyrene recycling process.

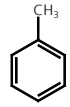
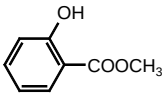
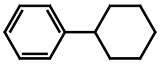
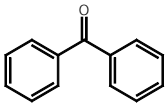
2 Sample Material

The cleaning efficiency is usually determined by a so-called challenge test by artificial contamination. For this purpose, polystyrene (PS) flakes were contaminated with the surrogates. Subsequently these artificial contaminated PS flakes were feed into the polystyrene recycling process.

For the challenge test 135 kg of washed PS flakes were provided by Huhtamaki. These flakes were contaminated at Fraunhofer IVV with the surrogates given in Table 1. Subsequently the flakes were shipped to Ineos. After the challenge test the company provided the samples given in Table 2.

The contamination of 100 kg of post-consumer PS flakes were achieved according to the following procedure: 100 kg of PS flakes were divided into 5 batches of 20 kg each. The 20 kg batches were sprayed with a solution of 20 ml toluene, 20 ml chlorobenzene, 20 ml phenyl cyclohexane, 20 ml methyl salicylate, 20 g benzophenone, 20 g methyl stearate. The barrels were sealed and store for 7 d at 50 °C with daily agitation. Subsequently the flakes were rinsed with 10% ethanol.

Table 1: Model contaminants for the challenge test

Surrogate	M_W[a]	Structure	Functional Group	Physical properties
Toluene	92.1		aromatic hydrocarbon	volatile, non-polar
Chlorobenzene	112.6	C_6H_5Cl	halogenated aromatic hydrocarbon	volatile, medium-polar
Methyl salicylate	152.2		aromatic ester	non-volatile, polar
Phenyl cyclo-hexane	160.3		aromatic hydrocarbon	non-volatile, non-polar
Benzophenone	182.2		aromatic ketone	non-volatile, polar
Methyl stearate	298.5	$CH_3(CH_2)_{16}COOCH_3$	aliphatic ester	non-volatile, polar

[a]Molecular weight in g/mol

Table 2: Challenge Test samples with contaminated flakes

sample	Description
C1 to C5	Contaminated and rinsed flakes drawn at Fraunhofer IVV
Sample 1	Input flakes contaminated, rinsed and vented, drawn at Ineos just before recycling
Sample 2	Input flakes contaminated, rinsed and vented, drawn at Ineos just before recycling
Sample 3	Input flakes contaminated, rinsed and vented, drawn at Ineos just before recycling
Sample 4	PS pellets, drawn at Ineos 13:50
Sample 5	PS pellets, drawn at Ineos 14:30
Sample 6	PS pellets, drawn at Ineos 15:15
Sample 7	PS pellets, drawn at Ineos 16:00
Sample 8	PS pellets, drawn at Ineos 16:45

3 Method

Each PS material sample was analyzed twice in the following way: 1.0 g of each PS sample was placed in a 10 ml glass vial. 10.0 ml acetone was given to the PS material and stored for 4 d at 60 °C. The extracts were analyzed by GC/FID. Gas chromatograph: HP 5890II, column: SE 10 - 30 m - 0.32 mm i.d. - 0.32 µm film thickness, temperature program: 40 °C (5 min), rate 15 °C min^{-1}, 240 °C (15 min), pressure: 50 kPa hydrogen, split: 10 ml min^{-1}. Quantification was achieved by external calibration using standard solution of the neat surrogates in 95% ethanol. The detection limits were determined according to DIN 32645. The results are given in Table 3.

Remark: Lower analytical detection limits are possible. Due to the high concentrations in the challenge test samples only higher concentrated standards were used, which results in higher detection limits, too.

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

surrogate	detection limit [ppm]
toluene	0.7
chlorobenzene	0.8
methyl salicylate	0.8
phenyl cyclohexane	0.5
benzophenone	0.1
methyl stearate	0.3

4 Results

4.1 Challenge Test

The surrogate concentrations determined in the investigated challenge test sample are given in Table 4. The gas chromatograms of the investigated samples are given in Figure 1 to Figure 9. Butylated hydroxyanisol (BHA, Retention time R_t = 8.5 min) and Tinuvin 234 (R_t = 24.2 min) were added as internal standards to the extracts.

The challenge test results show only a slight reduction of the concentrations of the artificially added surrogates.

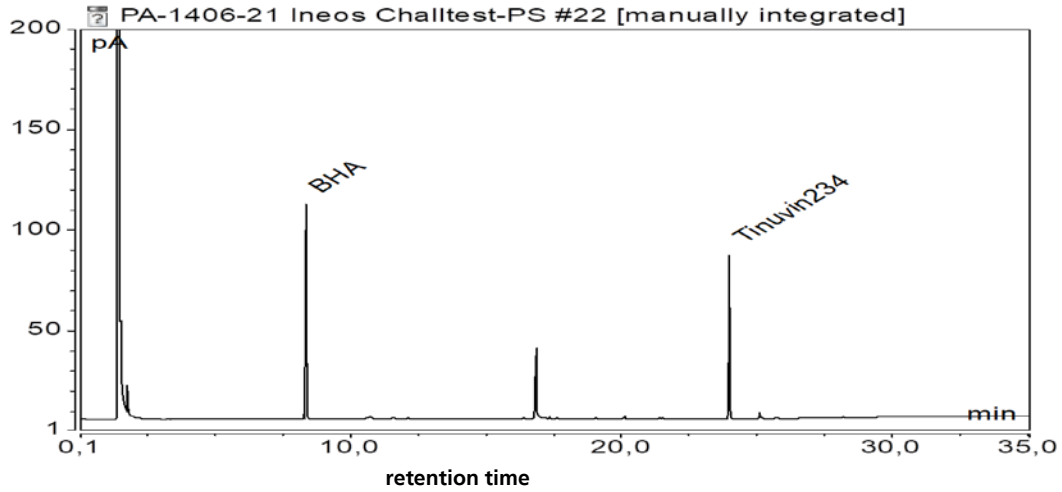


Figure 1: Gas chromatogram of the solvent used for extraction (blind value)

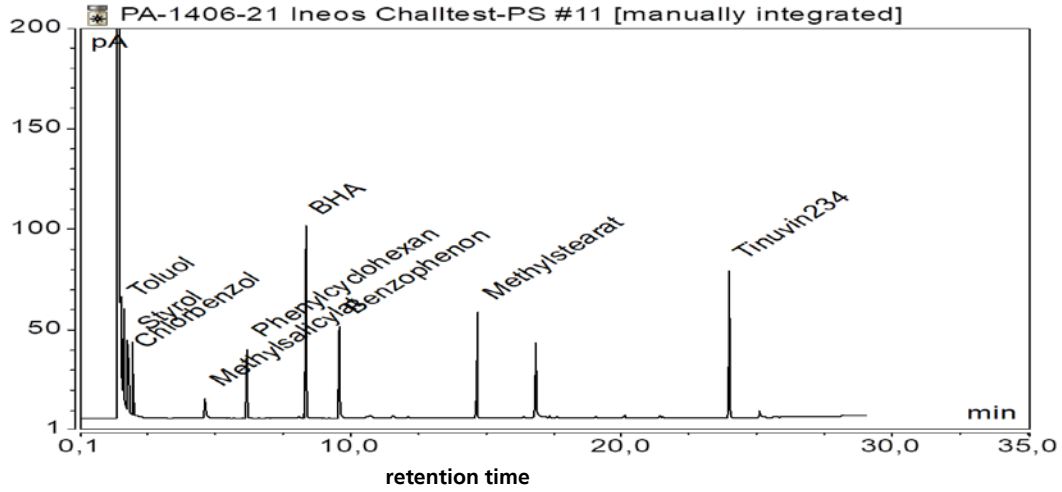


Figure 2: Gas chromatogram of a 20 ppm standard solution of the surrogates

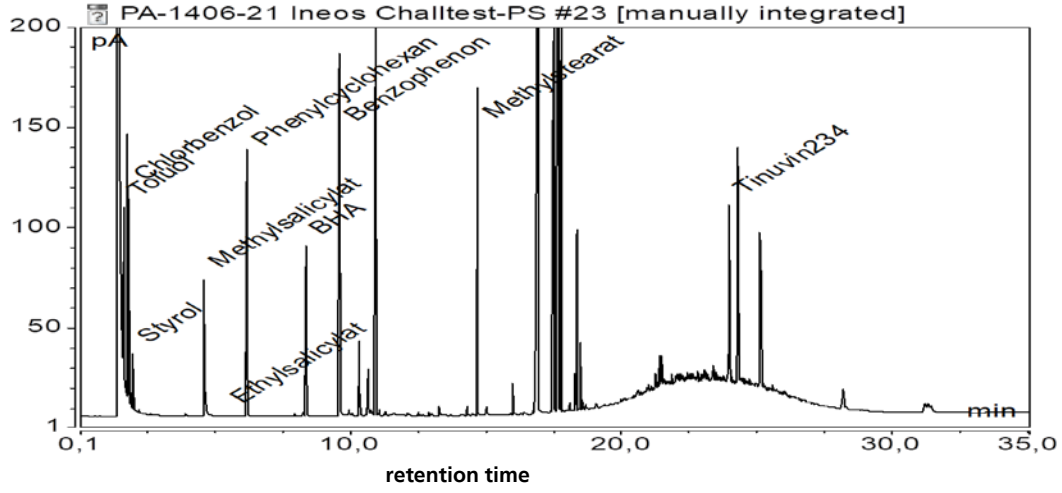


Figure 3: Gas chromatogram of the extract of sample C1 (as example for the contaminated and rinsed samples)

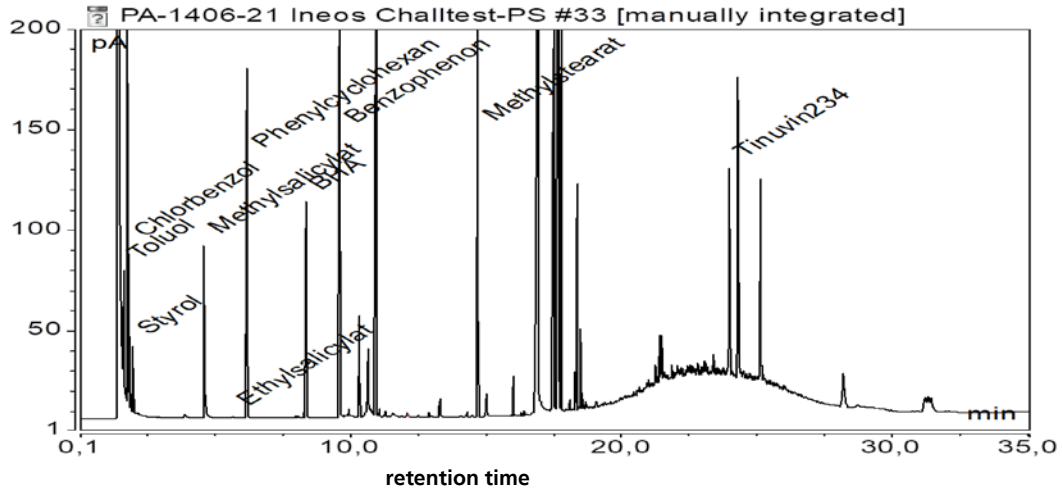


Figure 4: Gas chromatogram of the extract of sample 1 (as example for the contaminated, rinsed and vented samples drawn before recycling)

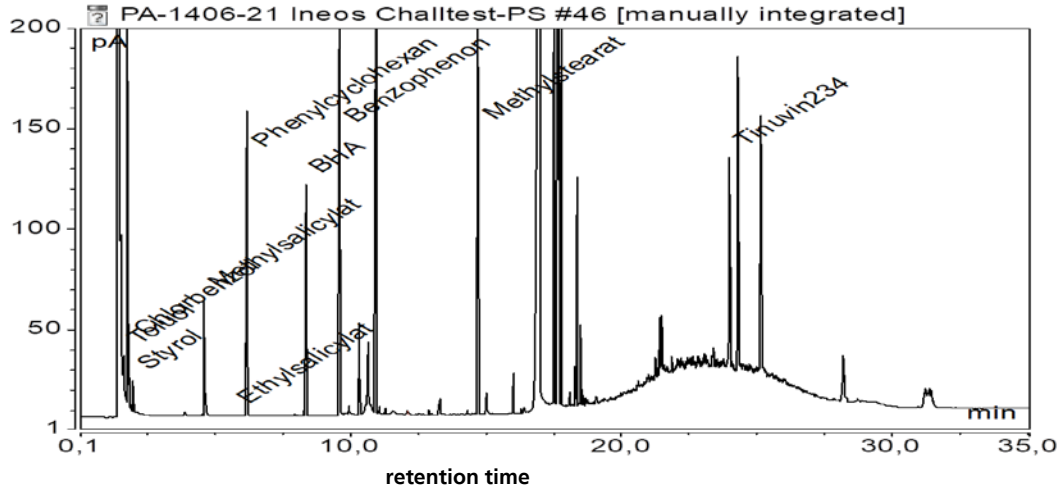


Figure 5: Gas chromatogram of the extract of sample 4

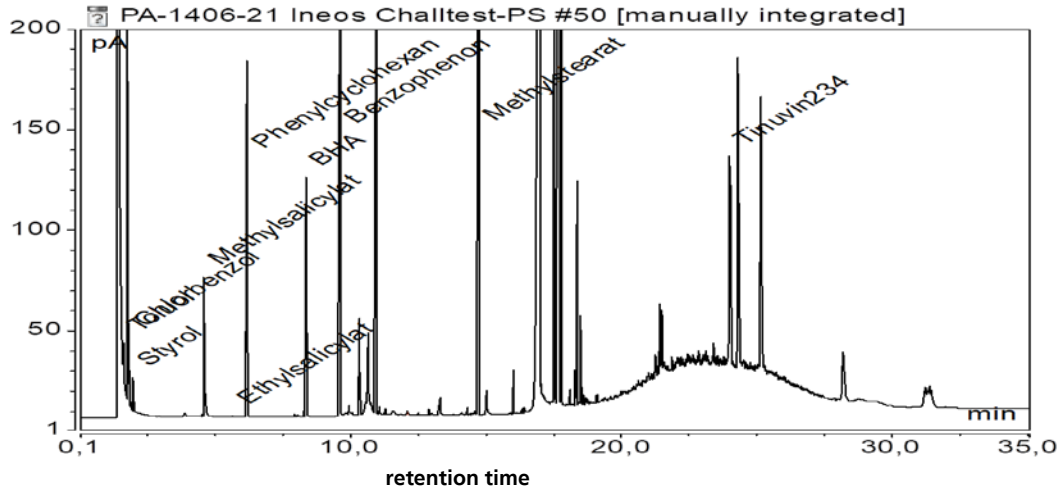


Figure 6: Gas chromatogram of the extract of sample 5

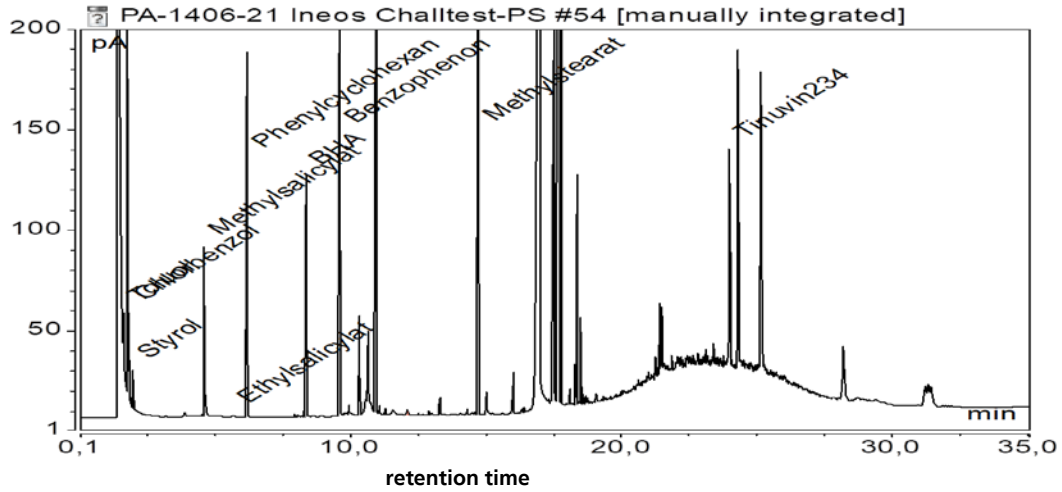


Figure 7: Gas chromatogram of the extract of sample 6

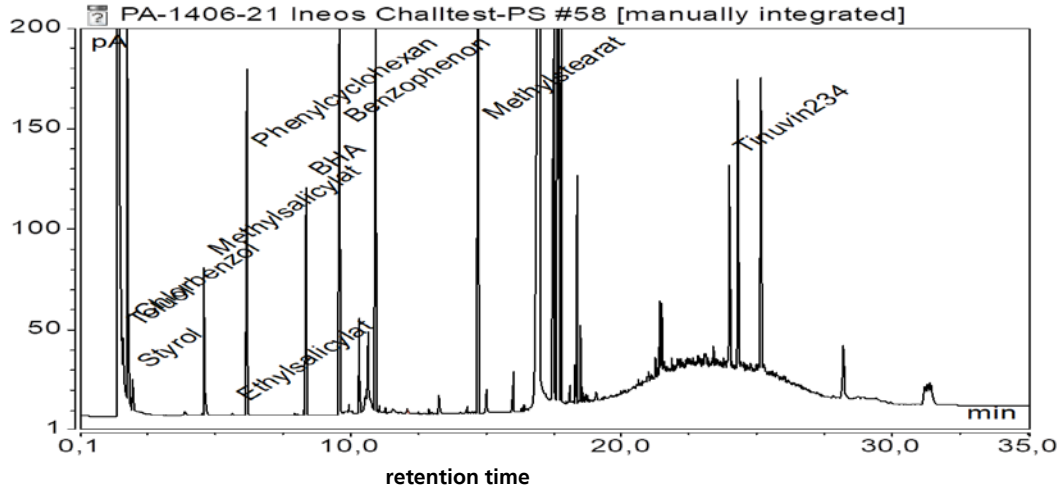


Figure 8: Gas chromatogram of the extract of sample 7

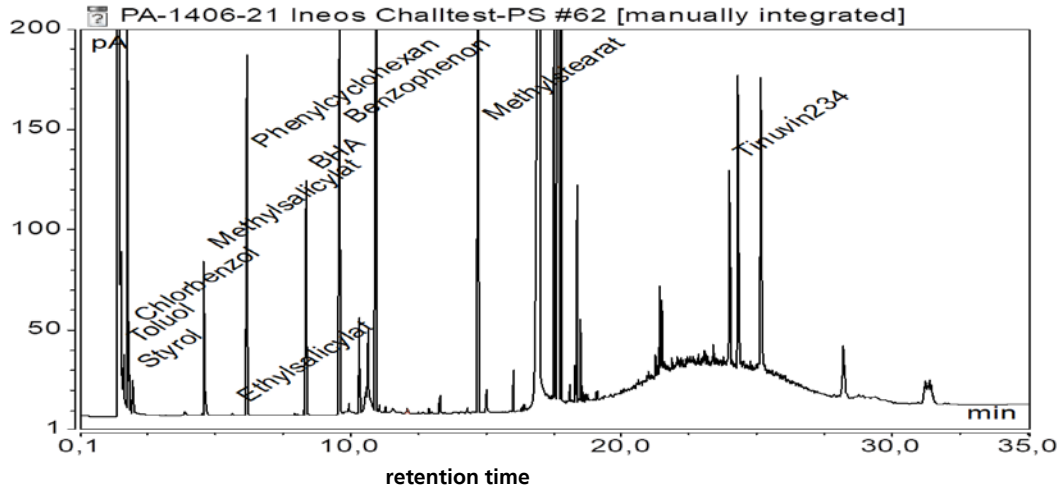


Figure 9: Gas chromatogram of the extract of sample 8

Table 4: Concentrations of the surrogates in the investigated PS samples

Sample	Concentration [mg/kg] (cleaning efficiency)					
	Toluene	Chloro-benzene	Methyl salicylate	Phenyl cyclohexane	Benzophenone	Methyl stearate
Sample C1	380.4	908.4	1219.2	906.5	761.5	593.0
Sample C2	387.3	884.6	1256.3	1100.3	1106.1	1094.9
Sample C3	335.9	792.7	1113.5	821.4	702.0	597.8
Sample C4	386.2	893.4	1330.5	1016.6	851.6	710.9
Sample C5	254.0	688.0	1359.7	1217.0	1113.8	1103.1
mean input C	348.7 ±57.1	833.4 ±93.1	1255.8 ±97.4	1012.4 ±156.0	907.0 ±192.8	820.0 ±259.1
Sample 1	248.6 ±8.9	655.9 ±23.2	1396.2 ±29.6	1148.5 ±10.9	982.9 ±49.5	854.8 ±70.2
Sample 2	276.6 ±6.5	704.6 ±32.8	1293.3 ±37.0	929.9 ±38.7	642.3 ±46.4	430.9 ±86.6
Sample 3	290.5 ±13.0	749.3 ±45.5	1411.5 ±116.6	1105.1 ±172.2	849.7 ±188.2	660.1 ±208.7
mean input 1-3	**271.9 ±21.3**	**703.3 ±46.7**	**1367.0 ±64.3**	**1061.1 ±115.7**	**824.9 ±171.7**	**648.6 ±212.2**
Sample 4	69.0 ±1.9	200.8 ±3.4	1027.9 ±33.6	1028.9 ±37.7	1105.9 ±25.8	1038.4 ±23.4
Sample 5	77.6 ±4.5	207.6 ±20.6	1119.6 ±49.8	1167.3 ±56.5	1278.4 ±52.7	1247.5 ±53.6
Sample 6	110.2 ±2.3	297.7 ±9.1	1274.9 ±34.4	1193.2 ±33.0	1116.3 ±20.8	1002.5 ±18.9
Sample 7	104.8 ±4.1	264.3 ±11.3	1239.1 ±45.6	1201.0 ±46.8	1182.2 ±40.4	1090.0 ±36.0
Sample 8	108.1 ±2.3	271.9 ±10.9	1280.0 ±34.9	1251.9 ±33.2	1264.9 ±30.3	1142.4 ±28.8
mean output 4-8	**93.9 ±19.2 (65.5%)**	**248.5 ±42.3 (64.7%)**	**1188.3 ±110.6 (13.1%)**	**1168.5 ±83.8 (0%)**	**1189.5 ±80.6 (0%)**	**1104.2 ±96.0 (0%)**