Fourth Report on the Novel Technology

"INEOS Styrolution Twin Screw Degassing Extrusion"

According to Article 13(4) of the Commission Regulation (EU) 2022/1616

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1. Description of the novel technology

The INEOS STYROLUTION super-clean recycling process for polystyrene (PS), which began operating before the entry into force of Commission Regulation (EU) No. 2022/1616, consists of the following main 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: Extrusion of the washed flakes using a twin screw extruder with vacuum degassing.

INEOS STYROLUTION is buying washed flake derived from post-consumer PS trays and containers from green dot systems and curbside collections in Europe. The flake suppliers use state of the art oversorting and washing processes. Oversorting ensures that non-PS and non-food articles are sorted out of the remaining recycled material to ensure that the feedstream consists of > 95% PS articles having food contact origin. After oversorting, the PS feedstock is then cut into flake.

The PS flakes are then washed using a caustic hot washing process that contains surfactants to assist in the removal of undesirable residues.

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 removed.

The washed flakes are then extruded using a twin screw extruder with vacuum degassing. Potential contaminants are removed during this melt degassing. The decontaminated melt is subsequently pelletized. The twin screw extruder design allows for control over the following critical decontamination parameters:

- Temperature
- Vacuum
- Residence time

The key components of the super-clean recycling process are shown in Figure 1.

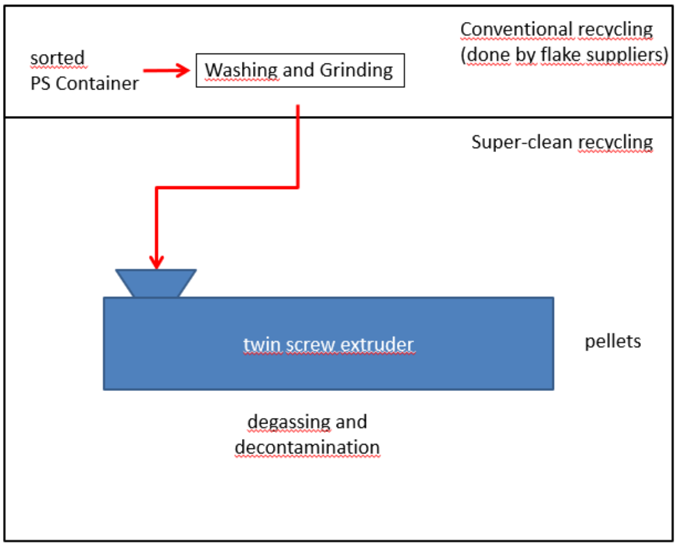

Fig. 1 Schematic of the investigated super-clean recycling process

The final pellets are intended for use in manufacturing new food contact articles with a recyclate content of up to 100%, including containers for dairy products, trays for packaging food, and beverage cups.

The novel technology developer has assessed the polystyrene (PS) recycling process 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). As discussed in the initial novel technology development report, the recycling process has been evaluated by applying the 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 an "allowable" concentration of each contaminant in the PS that is derived using diffusion modeling (Cmod) and by considering the conditions of use of the articles manufactured with recycled PS. Specifically, 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. Consistent with Commission Regulation (EU) 2022/1616, the notifier monitors substances in the input and output to ensure that contaminants that may be retained in the recycled output material are not expected to migrate to contacted food at levels that would present health or safety concerns.

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

INEOS STYROLUTION prepared an initial report on its novel polystyrene recycling technology in accordance with Article 10 of Commission Regulation (EU) No. 2022/1616. That report included extensive reasoning, scientific evidence, and studies that demonstrated that the recycled polystyrene produced under the INEOS STYROLUTION process complies with Article 3 of Regulation (EC) No. 1935/2004. The report summarized the results of a challenge test that was used to establish the decontamination efficiency of the process for commonly utilized surrogate contaminants. The initial report also included an industry study that evaluated the residual contaminant concentration in the recycled input based on samples of post-consumer PS flake samples obtained throughout Europe. This study demonstrated that a conservative estimate of contaminants in the input stream is unlikely to exceed 1 mg/kg. The initial report also included a migration estimate for contaminants based on various use scenarios for the applications under which the recycled PS will be marketed.

The initial report demonstrated that the cleaning efficiency for the INEOS STYROLUTION polystyrene recycling process was sufficient to ensure that an exposure of 0.0025 µg contaminant/kg bw/day would not be exceeded. The 0.0025 µg contaminant/kg bw/day exposure threshold value is the level that EFSA has determined is safe even for chemicals with structural alerts raising concern for potential genotoxicity. Generally, this threshold value is low enough to address all toxicological concerns. Thus, the initial report demonstrated that any unknown contaminant potentially present in the recycled polystyrene would not result in risk of harm to consumers consuming food packaged in the modelled applications.

INEOS STYROLUTION published its first semi-annual report in October 2023. The first report included sampling data demonstrating that although some impurities in the recycled PS output exceeded the 1 mg/kg assumed contaminant level, many of the substances are also present in virgin polystyrene. Additionally, several of the compounds were suspected to be artifacts of the analytical method used to analyze the samples, and likely were not true contaminants in the recycled plastic output. Based on the toxicity profiles of the detected substances and the expected migration of the detected substances to food, the first report demonstrated that the potential presence of the contaminants in the recycled PS did not present any health or safety concern, and the recycled PS may be considered compliant with Article 3 of Regulation (EC) No. 1935/2004.

As discussed in previous reports and below, INEOS Styrolution has refined the analytical methodologies used for the evaluation of contaminant chemicals in the recycled PS input and output to confirm that the observation of certain oxygenated species in prior analyses were attributable to decomposition of the test samples during analysis, rather than their actual presence in the recycled PS. In previous reports, this was primarily accomplished by sparging the headspace of Gas Chromatography (GC) vials with nitrogen in an attempt to avoid the oxygen-induced degradation of the samples. In addition to the nitrogen method, INEOS Styrolution has now used an additional analytical methodology, similar to the nitrogen method, by sparging the headspace of the GC vials with argon (argon method). The results of the analysis of samples analyzed with the nitrogen and argon sparge are compared in Table 5 below. As noted in the data, the similarities of the resulting identities and further reduced concentrations of certain substances found in samples analyzed under an argon atmosphere compared to the same samples analyzed in nitrogen, combined with similar levels of other expected impurities across analysis atmospheres, supports the hypothesis that the observation of certain analytes in early analyses may be attributable to reactions occurring during analysis, rather than contamination of the sampled plastic. In addition, the argon method is similar, if not, more effective method compared to that of the nitrogen method.

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

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

In a study conducted by the Fraunhofer Institute for Process Engineering and Packaging, the authors analyzed 49 washed post-consumer PS flake samples obtained throughout Europe 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 (Guazzotti and Welle 2025). Each sample (containing approximately 35.1 flakes/gram/sample) was analyzed 6 times. Overall, 10,310 individual post-consumer PS flakes were analysed. One substance, identified as α- and/or β-pinene, was detected in one rPS flake sample at a concentration of 16.9 mg/kg and was attributed to consumer misuse. The study authors assumed that only one flake in the 35.1 ± 7.0 flakes were contaminated with α- and/or β-pinene, the misuse concentration was calculated to be 475 - 711 mg/kg, which is a factor of 10 lower than the maximum concentration measured in PET. Additionally, the incidence of misuse was calculated to be no more than 0.0097% (1 ÷ 10,310), and thus, recycled polystyrene containers are not likely to be used by consumers to store hazardous substances after the first food contact-use.

For comparison, the incidence of misuse found for post-consumer PET bottles was 0.03% to 0.04%. Toluene (at a concentration of 6750 mg/kg in the contaminated PET flake) has been identified as an example of the sort of substances that 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.

Using the data from the Guazzotti and Welle study note above, the input concentration chemicals attributed to the misuse of the PS can be calculated by multiplying the “misuse” concentration level of 475 – 711 mg/kg by the incidence of contamination approximated in the misuse study (0.0097%). Thus, the contaminant concentration of recycled PS input is estimated to be no more than 0.1 mg/kg (711 mg/kg x 0.0097% = 0.069 mg/kg, or 0.1 mg/kg). Therefore, it would be conservative to assume a worst-case input contamination of the input flake is significantly less than the 0.5 mg/kg level assessed in previous reports of this novel technology development.

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).

3. List of substances in plastic input and recycled plastic output

Tables 1 through 4 below are lists of substances found in the plastic input (Table 1 and 3) and in the recycled polystyrene output (Table 2 and 4), sorted in descending order of the concentration in the sample. Tables 1 and 2 include data generated using the same analytical methodology (*i.e.*, nitrogen method) that was described in the second and third semi-annual reports prepared in April 2024 and October 2024, respectively. The data reported in Tables 3 and 4 were generated using a slightly modified analytical method (*i.e.*, argon method as discussed in Section 8 below) to demonstrate the efficiency and similarities between the nitrogen and argon methods which are used to minimize the oxidation and/or degradation of certain impurities during analysis.

The tentative identity of each substance was determined by matching the fragmentation pattern for each substance with a library of known compounds. The concentration of each substance was semi-quantified using calibration data for a limonene external standard. Substances identified with an asterisk (“*”) following the chemical name were quantified using external reference calibration data for that substance (rather than using the limonene standard).

Substances highlighted in blue were also identified in virgin polystyrene samples evaluated using the same analytical methods. Because these substances are present in virgin samples, they are not considered contaminants and are not further discussed in this report.

Table 1. Substances identified in source (INPUT)
Standard Analytical Method (nitrogen)

Chemical Name	CASRN	Ave. Conc. (ppm)
styrene*	100-42-5	126.37
ethylbenzene*	100-41-4	17.73
ethoxy ethene	109-92-2	14.27
1-propene	115-07-1	10.65
acetophenone*	98-86-2	8.33
isopropylbenzene	98-82-8	6.33
2-methyl-propene	115-11-7	6.01
limonene*	138-86-3	5.50
heptane	142-82-5	5.48
benzaldehyde	100-52-7	4.83
butylhodoxytoluene	128-37-0	4.74
4-methylcyclohexane-1-ol	589-91-3	3.91
succin dialdehyde	638-37-9	3.77
n-propylbenzene	103-65-1	3.70
styrene dimer		3.63
octanal	124-13-0	3.60
octene	111-66-0	3.31
1,2-dimethylbenzene	95-47-6	3.18
toluene	108-88-3	3.03
1-methyl-2-ethylbenzene	611-14-3	2.95
hexanal	66-25-1	2.75
not identified (potentially 2-methyl-3-pentanone)		2.73
dimethylfurane	625-86-5	2.57
2-methylpentane	107-83-5	2.44
1,4-dimethylbenzene	106-42-3	2.20
2-heptene-1-ol	33467-76-4	2.19
cyclohexane	110-82-7	2.15
2-ethylhexanol	104-76-7	2.08
nonanal	124-19-6	2.01
α-methylstyrene	98-83-9	1.90
not identified		1.82
DMSO		1.80
not identified		1.77
pentametylheptane	13475-82-6	1.71
benzene / 2-butanone (2.52)		1.60
dimethyl-ethyl-cyclohexane	1678-91-7	1.57
2-nonanone	821-55-6	1.53
cylohexane	110-82-7	1.49
not identified		1.45
2,2,4,6,6-pentamethylheptane	13475-82-6	1.43
phenol	108-95-2	1.40
dodecene	112-40-3	1.30
terpene (clear identification not possible)		1.29
not identified		1.26
terpenol (clear identification not possible)		1.21
(1-methylpropyl)benzene	135-98-8	1.20
undecanone	112-12-9	1.18
2-heptanone	110-43-0	1.10

Table 2. Substances identified in rPS (OUTPUT)
Standard Analytical Method (nitrogen)

Chemical Name	CASRN	Ave. Conc. (ppm)
styrene*	100-42-5	75.40
ethoxy ethene	109-92-2	11.35
ethylbenzene*	100-41-4	9.77
acetophenone*	98-86-2	6.90
propene	115-07-1	6.05
2-methyl-propene	115-11-7	5.04
limonene*	138-86-3	4.63
benzaldehyde	100-52-7	3.50
heptane	142-82-5	3.18
4-methylcyclohexane-1-ol	589-91-3	3.01
styrene dimer		2.99
octanal	124-13-0	2.71
isopropylbenzene	98-82-8	2.61
dimethylfurane	625-86-5	2.30
octene	111-66-0	2.23
not identified (potentially 2-methyl-3-pentanone)		2.07
toluene	108-88-3	1.82
DMSO		1.78
2-heptene-1-ol	33467-76-4	1.75
not identified		1.53
α-methylstyrene	98-83-9	1.47
terpene (clear identification not possible)		1.44
succin dialdehyde	638-37-9	1.41
2-ethylhexanol	104-76-7	1.41
1,2-dimethylbenzene	95-47-6	1.36
cyclohexane	110-82-7	1.34
hexanal	66-25-1	1.33
n-propylbenzene	103-65-1	1.32
not identified		1.20
1,4-dimethylbenzene	106-42-3	1.17
2-nonanone	821-55-6	1.16
nonanal	124-19-6	1.13
phenol	108-95-2	1.01
pentametylheptane	13475-82-6	0.63
2-methylpentane	107-83-5	0.61
2-ethylhexanol	104-76-7	0.07

Table 3. Substances identified in source (INPUT)

Modified Analytical Method (argon)

Chemical Name	CASRN	Ave. Conc. (ppm)
styrene*	100-42-5	168.22
ethylbenzene*	100-41-4	27.09
butylated hydroxytoluene	128-37-0	9.73
isopropylbenzene	98-82-8	6.67
d-limonene*	5989-27-5	5.30
benzene, propyl-	103-65-1	4.62
benzaldehyde	100-52-7	4.37
isobutene	115-11-7	3.61
m-xylene	108-38-3	3.57
toluene	108-88-3	3.53
2-propenal	67-63-0	3.34
1-octene	111-66-0	2.97
acetophenone*	98-86-2	2.47
anisole	100-66-3	2.36
acetic acid	64-19-7	2.32
not identified		2.27
benzene, 1-ethyl-4-methyl-	622-96-8	2.03
decane	124-18-5	1.94
2-nonanone	821-55-6	1.92
2-nonen-1-ol, (Z)-	41453-56-9	1.70
cyclopropane, octyl-	1472-09-9	1.59
isopropanol	67-63-0	1.57
cyclohexane, 1-methyl-4-(1-methylethyl)-, trans-	1678-82-6	1.56
cyclohexane	110-82-7	1.45
α-methylstyrene	98-83-9	1.43
oxalic acid, allyl decyl ester		1.30
octanal	124-13-0	1.27
1-ethyl-2,2,6-trimethylcyclohexane	71186-27-1	1.21
2-decanone	693-54-9	1.15
benzene, (1-methylpropyl)-	135-98-8	1.14
hydroxylamine, O-(3-methylbutyl)-	19411-65-5	1.13
phenol	108-95-2	1.11
undecane	1120-21-4	1.11
dodecane	112-40-3	1.05
dimers		/

Table 4. Substances identified in rPS (OUTPUT)

Modified Analytical Method (argon)

Chemical Name	CASRN	Ave. Conc. (ppm)
styrene*	100-42-5	86.86
ethylbenzene*	100-41-4	14.59
d-limonene*	5989-27-5	4.44
isobutene	115-11-7	3.44
benzaldehyde	100-52-7	3.17
isopropylbenzene	98-82-8	2.39
acetophenone*	98-86-2	1.74
acetic acid	64-19-7	1.69
1-octene	111-66-0	1.67
benzene, propyl-	103-65-1	1.59
2-nonen-1-ol, (Z)-	41453-56-9	1.55
m-xylene	108-38-3	1.41
2-propenal	67-63-0	1.39
2-decanone	693-54-9	1.34
anisole	100-66-3	1.24
decane	124-18-5	1.22
2-nonanone	821-55-6	1.20
hydroxylamine, O-(3-methylbutyl)-	19411-65-5	1.20
butylated hydroxytoluene	128-37-0	1.19
cyclohexane, 1-methyl-4-(1-methylethyl)-, trans-	1678-82-6	1.16
benzene, (1-methylpropyl)-	135-98-8	1.13
toluene	108-88-3	1.06
α-methylstyrene	98-83-9	1.01
isopropanol	67-63-0	< 1
cyclohexane	110-82-7	< 1
benzene, 1-ethyl-4-methyl-	622-96-8	< 1
phenol	108-95-2	< 1
octanal	124-13-0	< 1
undecane	1120-21-4	< 1
1-ethyl-2,2,6-trimethylcyclohexane	71186-27-1	< 1
cyclopropane, octyl-	1472-09-9	< 1
dodecane	112-40-3	< 1
oxalic acid, allyl decyl ester		< 1
hexanal		< 1
dimers		/

Table 5 includes a comparison of results from testing on three OUTPUT samples (tested in triplicates) using the two analytical methods, listing those substances that were found in common between the two sample sets. This table demonstrates that the nitrogen and modified argon analytical methods produce similar levels of each compound. In some cases, some of the compounds that may have been oxidated or degradation compounds in the resin were not detected in the modified analytical approach. As discussed in Section 8, the modified argon method accurately represents the levels of impurities in the recycled samples, and this method will be used in future analyses.

Table 5: Standard vs. Modified output analytical method

Sample (Nitrogen Method)	**Ave. Conc. (ppm)**	**Sample (Modified Argon Method)**	**Ave. Conc. (ppm)**
Compound Identification		**Compound Identification**	
isobutene	5.74	isobutene	3.44
cyclohexane	1.34	cyclohexane	<1
toluene	1.82	toluene	1.06
hexanal	1.33	hexanal	<1
octene	2.38	1-octene	1.67
ethylbenzene*	9.77	ethylbenzene*	14.59
1,2-dimethylbenzene (o-xylene)	1.25	m-xylene	1.41
styrene*	75.40	styrene*	86.86
isopropylbenzene	2.86	isopropylbenzene	2.39
benzaldehyde	4.19	benzaldehyde	3.17
n-propybenzene	1.12	n-propybenzene	1.59
phenol	1.34	phenol	<1
α-methylstyrene	1.47	α-methylstyrene	1.01
octanal	5.61	octanal	<1
limonene*	4.63	d-limonene*	4.44
acetophenone*	6.90	acetophenone*	1.74
2-nonanone	1.16	2-nonanone	1.20
nonanal	1.13	2-nonen-1-ol, (Z)-	1.55
styrene dimer	2.78	dimers	/

4. List of contaminating materials regularly present in the plastic input

As discussed in INEOS STYROLUTIONS' previous reports, the waste stream from which source material is obtained consists of PS trays and containers from green dot systems and curbside collection systems in Europe. The waste may originally contain non-food articles such as:

- Video cassettes
- Flower pots
- Hangers
- CD covers
- Clip closures (*e.g.*, freezer bags including metal wire and PS)

These materials are sorted out of the waste stream such that the input material consists predominantly of PS used in contact with food. The specifications for the input to the decontamination process are as follows:

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

5. Analysis of the most likely origin of the identified contaminants

As noted above, testing has demonstrated that many of the substances found in the recycled PS are also found in samples of virgin PS. These substances are generally found at similar concentrations in both virgin and recycled samples.

Several other substances (e.g., limonene) are flavoring substances that may be associated with foods that were stored in the plastic packaging that was in the source material. Other substances could be present in the input and output material from their use as components of the packaging (e.g., labels, printing inks, adhesives, etc.) that was recycled. The levels of these substances are relatively low and are comparable to the levels in other packaging materials.

The utilization of modified analytical techniques, *i.e.*, headspace sampling of contaminants/ impurities in PS flakes in both nitrogen and argon atmospheres, for the analysis of potential contaminants in the recycled material supports the hypothesis that certain substances found when PS samples are analyzed in standard analytical methods (e.g., air) results from the decomposition of the analyzed material, and are not expected to be present in the recycling input or output streams. As noted above, the argon method provides similar and accurate information when compared to the nitrogen method concerning potential contamination of the PS input and output streams. A constituent analysis of the recycled PS will be performed under an inert atmosphere (*i.e.*, argon method) moving forward.

6. Measurement or estimation of the migration levels to food of contaminants present

The migration of the contaminants present in the output (recycled polystyrene) were determined using diffusion modeling following the same approach for the various applications covered by the first three reports submitted on this novel technology.

That is, the Piringer-based (i.e., A_P-based) diffusion model was used to estimate migration of the various substances. Because the A_p model exaggerates migration from polystyrene, the migration values were adjusted using the temperature correction factors established by Welle (2023).[1] As noted in the initial report, the correction factors for polystyrene depend on temperature (the extent of the overprediction of the A_P-based diffusion model increases as temperature decreases), but are also influenced by both molecular weight and polarity. We have used the factor developed for toluene at the specific temperatures of interest (i.e., 4.77 for 60°C, 11.8 for 40°C, 22.9 for room temperature conditions, and 20.8 for refrigerated conditions) in determining the estimated migration for each of the contaminants in the various use scenarios for the recycled PS.[2] That is, applications considered here include packaging for yogurt and similar foods (following three different packing scenarios), meat and cheese tray

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[1] 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.

[2] As noted above, substances that have been identified in virgin polystyrene resin (and at levels that are similar to that found in the virgin samples) have been excluded from this analysis.

applications, fish boxes, fruit and vegetable tray applications, hot and cold cup applications. The migration values for each contaminant and under each use scenario are reported in Table 6.

Table 6: Calculated migration for substances under various recycled PS use scenarios

			Predicted migration (μg/kg-food)					
Substance Name	**CASRN**	**Conc. in rPS (ppm)**	**Yogurt[3]**	**Meat/ Cheese Tray**	**Fish Boxes**	**Fruit/ Vegetable Tray[4]**	**Cold Cups**	**Hot Cups**
limonene*	5989-27-5	4.44	0.24	0.06	0.03	0.02	0.03	0.45
benzaldehyde	100-52-7	3.17	0.21	0.05	0.03	0.02	0.03	0.41
acetic acid	64-19-7	1.69	0.17	0.04	0.02	0.01	0.02	0.33
1-octene	111-66-0	1.67	0.11	0.03	0.01	0.01	0.01	0.20
12-nonanol	41453-56-9	1.55	0.08	0.02	0.01	0.01	0.01	0.15
12-propenal	67-63-0	1.90	0.19	0.05	0.03	0.01	0.03	0.37
2-decanone	693-54-9	1.34	0.06	0.02	0.01	0.00	0.01	0.12
anisole	100-66-3	1.24	0.08	0.02	0.01	0.01	0.01	0.16
decane	124-18-5	1.22	0.06	0.02	0.01	0.00	0.01	0.12
2-nonanoe	821-55-6	1.20	0.06	0.02	0.01	0.00	0.01	0.12
O-3-methylbutyl-hydroxylamine	19411-65-5	1.20	0.08	0.02	0.01	0.01	0.01	0.16
BHT	128-37-0	1.19	0.04	0.01	0.00	0.00	0.01	0.07
1-methyl-4-1-methylethyl-cyclohexane	1678-82-6	1.16	0.06	0.02	0.01	0.00	0.01	0.11
sec-butylbenzene	135-98-8	1.13	0.06	0.02	0.01	0.00	0.01	0.12
α-methylstyrene	98-83-9	1.01	0.06	0.02	0.01	0.00	0.01	0.12

We have concluded that the weight of the evidence indicates that the compounds listed in Table 6 are not genotoxic. Thus, migration can exceed the EFSA-established threshold value for genotoxic compounds 0.0025 μg/kg bw/day without presenting a health or safety concern.[5] A dietary exposure of 1.5 μg/kg bw/day, which is the human exposure threshold value that has been used by EFSA for Cramer Class III compounds, has been used to assess the safety. Using the same exposure scenarios described in the initial report, including the consumption patterns and assumed body weights described in Table 7 (below), we have calculated the migration levels in foods that will result in exposures to the listed substances of no more than 1.5 μg/kg bw/day under each of the use scenarios.

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[3] The hot-filled yogurt packaging condition (60°C for 1 hour, followed by 40 days at 6°C) was found to be the worst case migration condition, and the migration estimate for only that packaging condition is included in this table.

[4] Consistent with the initial report, migration to raw, uncut/unpeeled fruit and vegetables was divided by a 10-fold correction factor as an estimate to this type of food. Prior EFSA opinions noted that the use of trays to transport, store, and display whole fruits and vegetables at room temperature or below involved conditions under which migration was unlikely to occur, noting the solid-solid contact and small surface of contact.

[5] No health or safety concerns are presented from exposures to potentially mutagenic or genotoxic substances at dietary exposures below the genotoxic threshold. Therefore, comprehensive toxicity reviews of substances that may be present in the rPS where diffusion modeling indicates extremely low migration (i.e., that results in a dietary exposure below 0.0025 μg/kg bw/day) were not conducted.

Table 7: Intended uses and target migration to ensure exposure < 1.5 µg/kg bw/day

Application	rPS content	Representative Time / temperature scenarios	Food Consumption	Body weight	Daily consumption	Acceptable migration in food[6]
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	122 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	30 µg/kg
Fish boxes	100%	10 days @ 5°C	50 g/kg bw/day	12 kg (toddler)	600 g	30 µg/kg
Fruit and vegetable tray	100%	30 days @ 25°C	50 g/kg bw/day	12 kg (toddler)	600 g	30 µg/kg
Cold cups	100%	1 day @ 25°C	80 g/kg bw/day	12 kg (toddler)	960 g	18.8 µg/kg
Hot cups	100%	2 hrs @ 70°C	20 g/kg bw/day	60 kg (adult)	1200 g	75 µg/kg

As demonstrated in Tables 6 and 7, the estimated migration of the contaminants in the recycled PS processed with the INEOS STYROLUTION novel technology is well below the acceptable migration level noted above (and in most cases less than 1/100th of the level), and clearly these contaminants in the recycled PS do not present any health or safety concern.

Conclusions

For all of the use scenarios described above, the estimated migration of substances in the recycled polystyrene results in a dietary exposure below the relevant toxicity threshold for each of the substances. Thus, substances that may possibly be present in the recycled polystyrene will not result in risk of harm to consumers consuming food out of the modelled containers.

7. Description of the applied sampling strategy

The technology developer operates a single recycling facility employing the novel technology. Consistent with Article 13(1) of Commission Regulation (EU) No. 2022/1616, samples from each batch of input flake from the source material and the corresponding batch of the decontaminated plastic output are collected. Each lot size is between 7 and 25 metric tons.

To date, twenty-two (22) production batches have been processed using this novel technology (three of which were produced since the last report) and each of these batches were sampled and analyzed using the described analytical methods. Replicate samples of each batch were analyzed.

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[6] Example calculation:

$\langle M \rangle_{\text{Target}}$ = 1.5 µg-contaminant/kg bw/day ÷ 0.0123 kg-yogurt/kg bw/day = 122 µg/kg.
$\langle M \rangle_{\text{Target}}$ = 0.0025 µg-contaminant/kg bw/day ÷ 0.0123 kg-yogurt/kg bw/day = 0.20 µg/kg.

8. Description of the analytical procedures and methods used

Although the analysis methodology used for the identification and quantification of potential contaminants and impurities in the recycled PS is significantly similar to the methodology that was described in the previous semi-annual reports, one important sampling modification has been introduced for certain of the samples evaluated to further understand the source of potential contaminants in the PS feedstream. This minor, but important, difference is the sparging of the headspace of GC vials with argon prior to analysis for the purposes of minimizing any oxygen-induced degradation of the samples during the analysis. Indeed, comparing the results obtained for the output of ethoxy ethene, when no precaution was taken (e.g. high levels (43.886 ppm and 38.692 ppm in Reports 1 and 2, respectively) were noted for ethoxy ethene when the analysis was completed under the standard air method). Switching to the nitrogen method resulted in a reduction of ethoxy ethene to 4.45 ppm (Report 3). However, no ethoxy ethene was detected when the samples were analyzed using the argon method. The current report contains the results from the two slightly different methods used to analyze the samples of the input and output materials. The “nitrogen method” is the same as was described in the previous semi-annual reports (Reports 2 and 3). The “argon method” which is first introduced in this report, will continue to be modified for optimal assessment of future samples.

The importance of the use of the “argon method” and its similarity to the “nitrogen method” was established via analysis of same samples using both nitrogen and argon.

Nitrogen Method

As described in Reports 2 and 3, samples of the input and output material are screened for volatile substances using the nitrogen method.

Argon Method

Analysis of samples using the argon method is conducted in a significantly similar manner to that described in previous reports for the nitrogen method. Samples of the input and output material are screened for volatile substances using a modification of the accredited Fraunhofer IVV Method 1.334:2021-11. The only significant difference is in the variation of the heating ramps. Here, a slower heating ramp was employed allowing for a better resolution of the peaks. Similar to the nitrogen method, for each test, approximately 1.0 g of sample material is weighed, placed in a headspace vial and sparged with argon to remove excess oxygen, and analyzed by headspace GC/FID. Quantification of benzene, ethylbenzene, styrene, limonene and acetophenone was achieved by external calibration.

Identification of other substances in the input and output material was conducted using mass spectrometry. Specifically, a Perkin Elmer Clarus GC-MS-System with electrospray ionization (EI), in full scan mode with mass range m/z 35-300 was used for the analysis. The identification of the substances found was performed by comparison with the NIST spectra library (NIST/EPA/NIH Mass Spectral Library 2017). Confirmation of the suggested spectra by analysis of a respective standard was not performed, so these compounds are considered tentatively identified. Other than benzene, ethylbenzene, styrene, limonene and acetophenone, which were quantified based on the external calibration, quantification of the other substances was performed using the limonene external standard.

The analytical methodology was useful in identifying low molecular weight substances (i.e., less than 300 Daltons). Higher molecular weight substances would not be expected to migrate at any significant level from recycled PS because it is a relatively low diffusive polymer.

Comparison of Nitrogen and Argon Methods

As noted above, the nitrogen and argon methods are similar except the argon method has a slower heating ramp. A comparison of the impurity/contaminant profiles of recycled PS when assessed separately under nitrogen and argon atmospheres demonstrates that the argon method results in the identification of similar substances and further refines the analysis of samples by improving the removal of excess oxygen that may detrimentally impact contaminant identification and/or quantification. Because the use of argon sparging to reduce oxygen-induced reactions should allow for a more precise assessment of the chemical profile of the recycled PS, the “argon method” will be used for analysis of residues in recycled PS moving forward.

9. Analysis and explanation of discrepancies

No discrepancies have been observed between the contaminant levels expected in the input and output of the installation and its decontamination efficiency. The data above supports a finding that the decontamination process adequately removes contaminants from the waste stream.

10. Discussion of the differences with previous reports

As discussed in Section 8, a minor modification to the analytical methodology now exclusively uses an argon sparge of the headspace vial to remove excess oxygen which may interfere with the identification and quantification of the analytes. Future reports will employ the argon method.

11. References

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