Second 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 now taken out.

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.

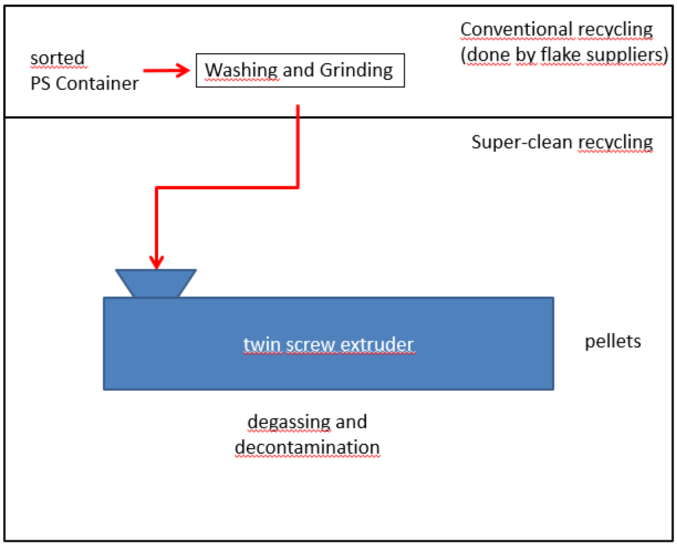

Fig. 1 Schematic of the investigated super-clean recycling process

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 semiannual 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 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. 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. The results of the analysis of samples analyzed with and without the nitrogen sparge are compared in Table 5 below. The reduced concentrations of certain substances found in samples analyzed under a nitrogen atmosphere compared to the same samples analyzed in air, 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.

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).

Statistical data assessing the frequency of misuse of food-contact PS containers for the storage of household chemicals are not currently available in the scientific literature. Accordingly, a so-called "misuse study" had been conducted by industry (Fraunhofer IVV report no. PA-2017-21 and PA-1770-23 – conducted on behalf of Styrenics Circular Solutions (SCS) and property of SCS). In this study, 49 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 35.1 flakes/gram/sample) was analyzed 6 times. Overall, 10,310 individual post-consumer PS flakes were analysed. No substances that were associated with the misuse of a container (e.g., solvent, household chemical or garden chemical) were detected in the flake samples. This testing supports that the incidence of misuse is expected to be less than 0.0097% (< 1/10,310), and that 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.

Because there was no evidence of misuse of the 10,310 individual recycled PS flakes analyzed, the input concentration chemicals attributed to the misuse of the PS 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 concentration of contaminants in a recycled PS feedstream resulting from the presence of misused PS containers therein. That is, the maximum sorption of any of the surrogate contaminants (toluene, chlorobenzene, methyl salicylate, phenyl cyclohexane, benzophenone, and methyl stearate) into PS observed after the intentional contamination of PS flake was observed for methyl salicylate, at 1,411 mg/kg. If we multiply this maximum sorption level by the incidence of contamination approximated in the misuse study (0.0097%), we estimate that the contaminant concentration of recycled PS feedstreams is approximately 0.14 mg/kg (1,411 mg/kg x 0.0097% = 0.14 mg/kg). Therefore, it would be conservative to assume a worst-case input contamination of the input flake of no more than 0.5 mg/kg, or half of that considered in the initial report.

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 (Tables 1 and 3) and in the recycled polystyrene output (Tables 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 that was described in the first annual report prepared in October 2023. The data reported in Tables 3 and 4 were generated using a modified analytical method (discussed in Section 8 below) 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 (air)

Chemical Name	CASRN	Ave. Conc. (ppm)
styrene*	100-42-5	100.80
ethoxy ethene	109-92-2	38.391
2-methyl-1-propene (isobutene)	115-11-7	24.278
acetophenone*	98-86-2	12.39
iso-propanol	67-63-0	12.045
ethylbenzene*	100-41-4	11.86
beta-myrcene	123-35-3	8.171
Limonene*	138-86-3	7.47
1-methyl-4-(1-methylethyl)-cyclohexene	5502-88-5	5.899
benzaldehyde	100-52-7	5.890
alpha-pinene	80-56-8	5.587
(1-methylethyl)-benzene	98-82-8	5.251
4-ethenyl cyclohexene	100-40-3	4.348
octanal	124-13-0	4.041
1-heptene	592-76-7	3.833
1-(methylpropyl)benzene	135-98-8	3.693
dimethylsulfide	624-92-0	3.171
2,2,4,6,6-pentamethylheptane	13475-82-6	3.118
toluene	108-88-3	3.029
heptanal	111-71-7	3.027
1-hydroxy-2-propanone	116-09-6	2.998
2,4-dimethylfurane	3710-43-8	2.971
styrene dimer		2.869
hexanal	66-25-1	2.539
2-methylpentane	107-83-5	2.497
heptane	142-82-5	2.485
unidentified		2.430
unidentified		2.344
2-methylpentanone	565-69-5	2.312
1-pentanol	71-41-0	2.308
1,3-dimethylbenzene	108-38-3	2.278

Table 2. Substances identified in rPS (OUTPUT)

Standard Analytical Method (air)

Chemical Name	CASRN	Ave. Conc. (ppm)
styrene*	100-42-5	70.69
ethoxy ethene	109-92-2	38.692
2-methyl-1-propene (isobutene)	115-11-7	21.637
acetophenone*	98-86-2	13.63
iso-propanol	67-63-0	11.944
beta-myrcene	123-35-3	8.463
ethylbenzene*	100-41-4	8.04
benzaldehyde	100-52-7	6.345
alpha-pinene	80-56-8	5.827
1-methyl-4-(1-methylethyl)-cyclohexene	5502-88-5	5.764
Limonene*	138-86-3	5.43
(1-methylethyl)-benzene	98-82-8	4.482
octanal	124-13-0	4.086
1-heptene	592-76-7	3.739
1-(methylpropyl)benzene	135-98-8	3.553
3-methylbutanal	590-86-3	3.332
2,4-dimethylfurane	3710-43-8	3.265
4-ethenyl cyclohexene	100-40-3	3.171
heptanal	111-71-7	2.986
1-hydroxy-2-propanone	116-09-6	2.884
dimethylsulfide	624-92-0	2.764
styrene dimer		2.739
2,2,4,6,6-pentamethylheptane	13475-82-6	2.640
unidentified		2.535
toluene	108-88-3	2.459
hexanal	66-25-1	2.383
2-methylpentanone	565-69-5	2.333
heptane	142-82-5	2.276
nonanal	124-19-6	2.263
1-decene	872-05-9	2.246
2-methylpentane	107-83-5	1.954

Table 3. Substances identified in source (INPUT)

Modified Analytical Method (nitrogen)

Chemical Name	CASRN	Ave. Conc. (ppm)
styrene*	100-42-5	81.35
ethylbenzene*	100-41-4	10.95
ethoxy ethene	109-92-2	7.143
2-methyl-1-propene (isobutene)	115-11-7	6.279
acetophenone*	98-86-2	5.45
limonene*	138-86-3	3.55
1,3-propandiol	504-63-2	3.340
acetic acid	64-19-7	3.027
styrene dimer		2.877
2-propenylbenzene	300-57-2	2.824
(1-methylethyl)-benzene	98-82-8	2.761
1-ethyl-2-methyl-benzene	611-14-3	2.435
n-propylbenzene	103-65-1	1.912
cyclohexane	110-82-7	1.820
1,3-dimethylbenzene	108-38-3	1.778
unidentified		1.749
hexanal	66-25-1	1.673
tert-butylbenzene	98-06-6	1.607
toluene	108-88-3	1.606
n-hexane	110-54-3	1.438
1-octene-3-one	4312-99-6	1.396
2-heptanone	110-43-0	1.360
1-octanol	111-84-5	1.356
linalool	78-70-6	1.220
2-nonanone	821-55-6	1.214
1-decene	872-05-9	1.175
2-methylpentane	107-83-5	1.103
dodecane	112-40-3	1.076
1,3,5-trimethylbenzene	108-67-8	1.004
alpha-methylstyrene	98-83-9	1.003
1-heptene	592-76-7	0.995

Table 4. Substances identified in rPS (OUTPUT)

Modified Analytical Method (nitrogen)

Chemical Name	CASRN	Ave. Conc. (ppm)
styrene*	100-42-5	49.00
ethoxy ethene	109-92-2	5.858
ethylbenzene*	100-41-4	5.70
acetophenone*	98-86-2	4.55
1-methyl-4-(1-methylethyl)-cyclohexene	5502-88-5	4.195
2-methyl-1-propene (isobutene)	115-11-7	3.874
benzaldehyde	100-52-7	3.622
iso-propanol	67-63-0	3.223
styrene dimer		2.777
2-propenylbenzene	300-57-2	2.686
4-ethenyl cyclohexene	100-40-3	2.622
beta-myrcene	123-35-3	2.455
2,6-dimethyl-4-heptanone	108-83-8	2.304
acetic acid	64-19-7	2.150
octanal	124-13-0	2.057
limonene*	138-86-3	2.05
(1-methylethyl)-benzene	98-82-8	2.042
1-ethyl-2-methyl-benzene	611-14-3	1.755
cyclohexane	110-82-7	1.651
1,3-propandiol	504-63-2	1.566
n-propylbenzene	103-65-1	1.482
2-nonanone	821-55-6	1.426
tert-butylbenzene	98-06-6	1.358
hexanal	66-25-1	1.356
1,3-dimethylbenzene	108-38-3	1.251
toluene	108-88-3	1.249
linalool	78-70-6	1.107
2-butanone	78-93-3	1.020
1-decene	872-05-9	1.008
unidentified		0.989
1,3,5-trimethylbenzene	108-67-8	0.982

Table 5 includes a comparison of the results from testing on a single sample using the two analytical methods. This table demonstrates that many of the compounds that were suspected to be artifacts of the analytical method (from oxidation or degradation of compounds in the resin during analysis) were not detected in the modified analytical approach. As discussed in Section 8, the modified method more accurately represents the levels of impurities in the recycled samples, and this method will be used in future analyses.

Table 5: Standard vs. Modified Analytical Method[1]

Sample (Standard Method) **Compound Identification**	**Ave Conc. (ppm)**	**Sample (Modified Nitrogen Method)** **Compound Identification**	**Ave Conc. (ppm)**
styrene	75.602	styrene	78.130
ethoxy ethene	32.470	ethoxy ethene	6.430
2-methyl-1-propene (isobutene)	21.111	2-methyl-1-propene (isobutene)	4.714
iso-propanol	10.300	iso-propanol	3.223
ethylbenzene	10.238	ethylbenzene	9.844
beta-myrcene	9.348	beta-myrcene	2.455
benzaldehyde	6.064	benzaldehyde	3.622
alpha-pinene	5.382	alpha-pinene	--
(1-methylethyl)-benzene	4.584	(1-methylethyl)-benzene	2.784
1-methyl-4-(1-methylethyl)-cyclohexene	4.117	1-methyl-4-(1-methylethyl)-cyclohexene	4.195
octanal	4.032	octanal	2.057
1-heptene	3.253	1-heptene	--
styrene dimer	3.159	styrene dimer	3.225
4-ethenyl cyclohexene	3.152	4-ethenyl cyclohexene	2.622
dimethylsulfide	2.941	dimethylsulfide	--
heptanal	2.879	heptanal	--
2,4-dimethylfurane	2.760	2,4-dimethylfurane	--
1-hydroxy-2-propanone	2.742	1-hydroxy-2-propanone	--
1-(methylpropyl)-benzene	2.647	1-(methylpropyl)-benzene	--
hexanal	2.560	hexanal	1.356
2,2,4,6,6-pentamethylheptane	2.531	2,2,4,6,6-pentamethylheptane	--
2,6-dimethyl-4-heptanone	2.428	2,6-dimethyl-4-heptanone	2.304
2-methylpentane	2.334	2-methylpentane	--
toluene	2.092	toluene	1.397
heptane	2.074	heptane	--
2-nonanone	2.000	2-nonanone	1.426
2-methyl-3-pentanone	1.968	2-methyl-3-pentanone	--
linalool	1.830	linalool	1.107
1-decene	1.768	1-decene	--

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:

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[1] Unlike the Tables 1-4 above, the levels of styrene, ethylbenzene, benzene, and acetophenone reported in Table 5 were semi-quantified based on the limonene calibration standard (rather than an external reference standard).

- 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, alpha pinene, various aldehydes) 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 air and nitrogen atmospheres, for the analysis of potential contaminants in the recycled material provides support for the previously stated hypothesis that certain substances found when PS samples are analyzed in air result from the decomposition of the analyzed material, and are not expected to be present in the recycling input or output streams. Therefore, in order to obtain the most accurate information concerning potential contamination of the PS input and output streams, a constituent analysis of the recycled PS will be performed under an inert atmosphere moving forward. The reduced levels of these substances upon analysis under an inert atmosphere also supports the prior conclusion that the concentration of contaminants resulting from misuse of the PS feedstock material is exceedingly low. In fact, the majority of substances observed in analyses of the PS input and output streams were also found at similar, and in some cases higher, concentrations in virgin PS.

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 two 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).[2] 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.[3] That is, applications considered here include packaging for yogurt and similar foods (following three different packing scenarios), meat and cheese tray 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.

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[2] 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.

[3] 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.

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[4]**	**Meat/ Cheese Tray**	**Fish Boxes**	**Fruit/ Vegetable Tray[5]**	**Cold Cups**	**Hot Cups (50% rPS)**
acetophenone	98-86-2	4.55	0.28	0.07	0.04	0.02	0.04	0.52
1-methyl-4-(1-methylethyl)-cyclohexene	5502-88-5	4.19	0.22	0.06	0.03	0.02	0.03	0.42
2-methyl-1-propene (isobutene)	115-11-7	3.87	0.41	0.10	0.06	0.03	0.06	0.78
benzaldehyde	100-52-7	3.62	0.25	0.06	0.03	0.02	0.03	0.46
iso-propanol	67-63-0	3.22	0.33	0.08	0.04	0.02	0.04	0.62
4-ethenyl cyclohexene	100-40-3	2.62	0.17	0.04	0.02	0.01	0.02	0.33
beta-myrcene	123-35-3	2.46	0.13	0.03	0.02	0.01	0.02	0.25
2,6-dimethyl-4-heptanone	108-83-8	2.30	0.12	0.03	0.02	0.01	0.02	0.23
acetic acid	64-19-7	2.15	0.22	0.05	0.03	0.02	0.03	0.42
octanal	124-13-0	2.06	0.12	0.03	0.02	0.01	0.02	0.22
limonene	138-86-3	2.05	0.11	0.03	0.01	0.01	0.02	0.21
1-ethyl-2-methyl-benzene	611-14-3	1.76	0.11	0.03	0.01	0.01	0.01	0.20
cyclohexane	110-82-7	1.65	0.13	0.03	0.02	0.01	0.02	0.25
1,3-propandiol	504-63-2	1.57	0.14	0.03	0.02	0.01	0.02	0.26
n-propylbenzene	103-65-1	1.48	0.09	0.02	0.01	0.01	0.01	0.17
2-nonanone	821-55-6	1.43	0.07	0.02	0.01	0.01	0.01	0.14
tert-butylbenzene	98-06-6	1.36	0.07	0.02	0.01	0.01	0.01	0.14
hexanal	66-25-1	1.36	0.10	0.02	0.01	0.01	0.01	0.18
1,3-dimethylbenzene	108-38-3	1.25	0.08	0.02	0.01	0.01	0.01	0.16
linalool	78-70-6	1.11	0.05	0.01	0.01	0.00	0.01	0.10
2-butanone	78-93-3	1.02	0.09	0.02	0.01	0.01	0.01	0.18
1-decene	872-05-9	1.01	0.05	0.01	0.01	0.00	0.01	0.10
unidentified[6]		0.99	0.05	0.01	0.01	0.00	0.01	0.09
1,3,5-trimethylbenzene	108-67-8	0.98	0.06	0.01	0.01	0.00	0.01	0.11
1-pentanol	71-41-0	0.98	0.08	0.02	0.01	0.01	0.01	0.15
1-octene-3-one	4312-99-6	0.98	0.06	0.01	0.01	0.00	0.01	0.11
1-ethyl-2-methyl-benzene	611-14-3	0.93	0.06	0.01	0.01	0.00	0.01	0.11
2-heptanone	110-43-0	0.91	0.06	0.01	0.01	0.00	0.01	0.11
alpha-pinene	80-56-8	0.66	0.04	0.01	0.01	0.00	0.00	0.07

For the substances identified in Table 6 with a migration that results in a dietary exposure greater than 0.0025 µg/kg bw/day (the EFSA-established threshold value for genotoxic compounds),[7] we have concluded that the weight of the evidence indicates that these compounds are not genotoxic. Therefore, a dietary exposure of 1.5 µg/kg bw/day, which is the human exposure threshold value that has been

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[4] 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.

[5] 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.

[6] Based on the retention time of this unidentified compound in the GC/MS analysis, we have assigned a molecular weight of 150 daltons, which is consistent with other identified compounds that elute in that retention time range.

[7] 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.

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.

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[8]
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.

6.1 Revision to Intended Conditions of Use

Fish Boxes

The use of recycled PS in manufacturing fish boxes is a new application covered by this report. INEOS/Styrolution's customers may use recycled PS to manufacture boxes (i.e., coolers) that are used to transport edible fish. The boxes would typically be filled with water and/or ice in addition to the fish, and the water/ice is discarded before preparation of the fish for consumption. Thus, migration of potential contaminants from the recycled PS may occur to the water/ice, further diminishing the potential for human consumption through the fish.

Recycled PS may be used at levels up to 100% in the manufacture of fish boxes, which are intended for use for no more than 10 days at 5°C. Because these parameters are the same or less severe than those listed for the preceding use (i.e., meat, poultry, fish, and cheese trays), the migration of potential

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[8] Example calculation:

$<M>_{Target}$ = 1.5 µg-contaminant/kg bw/day ÷ 0.0123 kg-yogurt/kg bw/day = 122 µg/kg.
$<M>_{Target}$ = 0.0025 µg-contaminant/kg bw/day ÷ 0.0123 kg-yogurt/kg bw/day = 0.20 µg/kg.

contaminants from the fish box application is considered to be subsumed by the meat, poultry, fish, and cheese tray application.

Hot Cup

The hot cup application has been raised from a maximum use level of 50% recycled PS to 100% recycled PS. This change has been reflected in the safety analysis above.

Cmod Estimates

Consistent with the proposed evaluation criteria discussed in the initial novel technology notification report, we have derived the following Cmod based on the various use conditions discussed above:

Table 8: 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
Fish Boxes	1.92 mg/kg
Fruit and Vegetable tray	3.40 mg/kg
Cold Cup	1.16 mg/kg
Hot Cup	0.56 mg/kg

*All applications consider use of 100% recycled PS

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 (0.5 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 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 10 and 15 metric tons. To date, twelve production batches have been processed using this novel technology (nine of which were produced since the last report) and each of these batches were sampled and analyzed using at least one of the methods described below. Replicate samples of each batch were analyzed.

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 report, 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 nitrogen prior to analysis for the purposes of minimizing any oxygen-induced degradation of the samples during the analysis. As the significance of this procedure had not yet been established at the outset of contaminant sampling addressed by this report, the current report contains results from the two slightly-different methods used to analyze samples of the input and output material. The “air method” is the same as was described in the previous semi-annual report. The “nitrogen method” which is first introduced in this report, will be utilized for the assessment of future samples.

The importance of the use of the “nitrogen method” was established via analysis of similar samples using both air and nitrogen and the analysis of additional samples of virgin resin using the nitrogen method.

Air Method

Samples of the input and output material are screened for volatile substances using the accredited Fraunhofer IVV Method 1.334:2021-11. For each test, approximately 1.0 g of sample material is weighed, placed in a headspace vial, 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.

Nitrogen Method

Analysis of samples using the “nitrogen method” is conducted in a significantly similar manner to that described above for the “air method.” The only significant difference is that the headspace of the GC vials containing the samples is sparged with nitrogen prior to analysis to remove excess oxygen that may detrimentally impact contaminant identification and/or quantification. The conduct of the remainder of the analysis is essentially identical to that described above.

Comparison of Air and Nitrogen Methods

As noted above, a comparison of the impurity/contaminant profiles of recycled PS when assessed separately under nitrogen and air atmospheres supports the previous hypothesis that excess oxygen in the headspace of sample vials leads to oxidation and/or degradation of certain impurities/contaminants and a corresponding inaccurate representation of the chemical profile of the recycled PS. For example, when assessed under an inert atmosphere, the concentration of 1-hydroxy-2-propanone is not detected using nitrogen method, but present at approximately 2.7 ppm using the standard method in air. The minimization of unintentional reactions by assessment of the samples under nitrogen also results in reductions in the estimated levels of such substance as ethoxy ethene and benzaldehyde. Because the use of nitrogen sparging to reduce oxygen-induced reactions should allow for a more precise assessment of the chemical profile of the recycled PS, the “nitrogen 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 2.1, the misuse study referenced in the initial report has been updated to reflect additional samples of rPS. This revised information supports that contaminants attributed to misuse are not expected to exceed 0.5 mg/kg.

The specifications in Section 4 above were revised to conform to EFSA’s recent draft guidance on evaluation of post-consumer recycled polyethylene terephthalate (PET) recycling processes.[9]

In Section 6, a new application (fish boxes) has been added to the intended applications of use. Additionally, the use level of recycled PS in the fabrication of cups intended to hold hot beverages has been increased to 100% rPS.

As discussed in Section 8, a minor modification to the analysis methodology (the nitrogen method) used for the identification and quantification of contaminants/impurities was introduced to address the potential for the previous method (the air method) to introduce irregularities/error into the analysis. Future reports will employ the nitrogen method.

11. References

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.

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[9] Public Consultation Detail (1) (europa.eu).