VERSALIS RECYCLED POLYSTYRENE (rPS) DECONTAMINATION TECHNOLOGY

NOVEL TECHNOLOGY

DATA MONITORING REPORT

Report required by Article 13 of Regulation (EU) 2022/1616

Data

31/01/2026

The data presented in this report are based on the measurements performed by a third-part laboratory, which was contracted by Versalis S.p.A. The data provided is property of Versalis S.p.A. and cannot be copied, reproduced, or distributed without the prior written consent. Versalis S.p.A. is not responsible nor liable for any errors or inaccuracies that may have occurred during the measurement process by third-part laboratory. The data are provided for informational purposes only and do not constitute any endorsement or recommendation by Versalis S.p.A.

versalis

TABLE OF CONTENTS

1) Introduction

Versalis S.p.A. notified the Novel Technology "Recycled Polystyrene (rPS) Decontamination Technology" as "developer" under the Regulation 2022/1616 on 7th December 2023.

Recyclers using Versalis S.p.A. Novel Technology will produce pellets of decontaminated rPS suitable to be used up to 100% in food packaging applications in direct contact with food, as virgin material.

The enclosed report provides a summary of the data forthcoming from the monitoring, based on the latest information from the installation using the novel technology. During the reporting period, the industrial installation implementing the novel technology was temporarily shut down in order to carry out engineering modifications and optimization activities aimed at improving plant efficiency and operability. Critical process parameters (temperature, residence time, pressure/vacuum) remain within the validated operational window defined during the challenge test, ensuring that previously demonstrated decontamination efficiency remains unchanged.

Consequently, no new rPS batches were produced during this time frame.

Although no production data were generated, the monitoring activity has been ensured through:

- the evaluation and consolidation of data collected in previous monitoring periods,
- the verification that no modifications affecting the critical decontamination steps and process parameters have been introduced,
- the extension and refinement of the exposure assessment through the introduction of additional application scenarios and updated modelling approaches.

On this basis, it is considered that the previously generated experimental data, obtained under conditions representative of the industrial process, remain valid and applicable to the current configuration of the installation.

This report therefore provides an extended assessment of the safety of the recycled material under additional exposure scenarios.

2) Brief description of the novel technology - Art. 13 (5a)

Polystyrene is a well-suited material for mechanical recycling, however recycling in food contact applications is not yet possible, mainly due to lack of availability of processes able to fulfil the EFSA requirements for recycled plastics in direct food contact. This novel technology overcomes this limit, allowing the use up to 100% rPS in food packaging (direct contact).

The Versalis S.p.A. decontamination Novel Technology, thanks to a proprietary special design of some items and properly managing process parameters, is able to clean efficiently recycled polystyrene (rPS) and so to reduce all contaminants below the target level required for direct food application.

All collection and pre-processing requirements as per Article 6 of Regulation (EU) 2022/1616 are satisfied in the recycling process.

The input material consists of PS objects (mainly containers and trays) from separate collection (e.g. kerbside, post-industrial, etc.), so called post-consumer PS. A high share (95% min) of food contact origin is obtained by accurate sorting. The traceability will be ensured by fulfilling the EN norm 15343 “Plastics - Recycled Plastics - Plastics recycling traceability and assessment of conformity and recycled content”.

The PS waste is fed into a transport belt, where metals and non-PS-containing articles (such as PET, polyolefins, etc.) are sorted out by standard near infrared (NIR) technology. This sorted PS stream is then sent to the shredder, which reduces the size of the articles to flakes. The following steps comprises typically a density separation and an hot washing, followed by rinsing. After the washing step, the flakes are mechanically and thermally dried to bring the water level down to virtually 0%.

The novel technology has been proven by extensive decontamination tests in pilot scale set-up.

The recycling process includes the following steps:

• Step 1: Grinding of post-consumer PS into flakes followed by an intensive washing process and drying.

• Step 2: Melting by extrusion with degasing of such rPS flakes and polymer melt filtration.

• **Step 3: Decontamination of the polymer melt (Novel Technology based on Versalis proprietary design).**

• Step 4: polymer melt feeding system to rPS filtration and pelletizing system.

3) Summary of the reasoning on the capability of the novel technology and the recycling process to manufacture recycled plastic materials and articles that comply with Article 3 of Regulation (EC) No 1935/2004 – Art. 13 (5b)

Versalis and the Fraunhofer-Institute IVV have been working together on the evaluation of the cleaning efficiency of this decontamination process using the Versalis' rPS Decontamination Technology.

The cleaning efficiency was experimentally verified with tests performed into an appropriate pilot scale set-up, using virgin polystyrene intentionally contaminated with high concentrations of model substances (surrogates) according to the principles recommended by European Guidelines and US FDA. The so-called challenge test was performed to study the efficiency of proprietary decontamination process. All relevant process parameters of pilot scale set-up are representative of the industrial plant process.

To evaluate the risk for the consumer, EFSA defined an evaluation procedure, which is based on the following parts:

a) Concentration of potential contaminants in post-consumer polymers

b) Exposure scenario of the consumer

c) Cleaning efficiencies of the Versalis' rPS Decontamination Technology.

The points a) and b) can be taken directly from [1]. The point c) is the core of the Novel Technology and its efficiency should be evaluated with respect to the minimum cleaning efficiencies calculated by Welle in the above-mentioned Article.

The cleaning efficiency of the process for each of the applied surrogates, was calculated according to:

$$Cleaning\ efficiency = \left(1 - \frac{concentration\ after\ recycling}{concentration\ before\ recycling}\right) * 100\%$$

In details:

a) Input contamination levels

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. Other contamination, such as microbiological or viral contamination, can be excluded because of the high temperatures used to process the polymer.

Regarding the input contamination in recycled flakes (rPS) before decontamination processes, scientific literature studies on misuse or contamination levels from substances from the first use of the package are rare. However, hints for misused substances were not found in any investigated samples to date. This is expected since PS containers, in contrast to PET bottles, typically cannot be re-sealed, and PS as polymer is less chemically resistant, rendering it less suitable for storage of chemicals. A low incidence of misuse and a low sorption rate will result in (very) low initial concentrations of potential contaminants in washed PS flakes, which is the input stream of decontamination process. In the absence of such a determination for PS, the use of the misuse rate of PET bottles (3–4 per 10,000) would appear to be a conservative approach so, as a pragmatic approach, the same input concentration as for PET of 3 mg/kg has been assumed for the safety evaluation of recycled PS.

b) Exposure scenario of the consumer

In the previous two Data Monitoring Reports the exposure scenario considered is for toddlers with 10 kg body weight (most conservative approach). The migration scenario for calculations is reported in [1] and are reported in the Table 1 below:

Table 1: Values for food consumption and maximum storage temperatures

Scenario	Application	Food Consumption per Day	Maximum Storage Time and Temperature	Exposure (Maximum Migration Value)	Maximum Migration with Overestimation Factor 5
1	Cold-filled yogurt	250 g	40 d at 6°C	0.1 µg/kg	0.5 µg/kg
2	Hot-filled yogurt	250 g	2 h at 70°C followed by 40 d at 6°C	0.1 µg/kg	0.5 µg/kg
3	Trays for meat, fish or cheese	150 g	30 d at 6°C	0.167 µg/kg	0.835 µg/kg
4	Trays for food and vegetables	500 g	30 d at 25°C	0.05 µg/kg	0.25 µg/kg
5	Cups for cold drinks	750 mL	1 d at 25°C	0.033 µg/kg	0.167 µg/kg
6	Cups for hot drinks	750 mL	2 h at 70°C	0.033 µg/kg	0.167 µg/kg

In order to extend the range of application scenarios of the decontamination technology, on 01/07/2025 Versalis formally submitted, under identification protocol ID 1fb7830c-b91d-4c21-917d-733de6f6c518 (as reported on Versalis' website, document named "Newer r-PS - Extension of exposure scenarios"), a request for the extension of the use of the same technology to broader application scenarios, characterized by different assumptions of daily food intake and different contact conditions (time and temperature).

The newly defined scenarios are reported below:

- **Scenario 7**: 150 g/day; hot filling at 95 °C for 10 minutes; storage for 18 months (540 days) at 25 °C.
- **Scenario 8**: 150 g/day; storage for 12 months (365 days) at 25 °C.
- **Scenario 9**: 150 g/day; storage for 6 months (180 days) at 25 °C.
- **Scenario 10**: 500 g/day; storage for 10 days at 40 °C.
- **Scenario 11**: 250 g/day; storage for 80 days at 8 °C.
- **Scenario 12**: 250 g/day; storage for 10 days at 40 °C.
- **Scenario 13**: 250 g/day; storage for 12 months (365 days) at 25 °C.
- **Scenario 14**: 500 g/day; storage for 12 months (365 days) at 25 °C.
- **Scenario 15**: 1000 g/day; storage for 10 days at 40 °C.
- **Scenario 16**: 250 g/day; hot filling at 95 °C for 10 minutes; storage for 18 months (540 days) at 25 °C.

- **Scenario 17**: 500 g/day; hot filling at 95 °C for 10 minutes; storage for 18 months (540 days) at 25 °C.

Unlike scenarios 1 to 6 (e.g. trays for food and vegetables, cold-filled yogurt, etc., see Table 1), these scenarios are not limited to a specific application case but are defined in a more general way. In particular, with respect to the estimation of the Maximum Safe Concentration (MSC) (as explained in Chapter 7, point b), the equation used does not depend on the application case. Consequently, it is possible to release this variable and apply the equation to any type of food, taking into account only time, temperature, and daily food intake parameters.

These scenarios therefore widen the assessment perimeter by including several combinations of storage conditions (time and temperature) and daily consumption levels.

c) Cleaning efficiency of the decontamination process (Novel Technology)

The calculated minimum cleaning efficiencies of the recycling process, used in the previous two Data Monitoring Reports, for the applications and food consumption data can be taken from [1] and are reported in the Table 2 below.

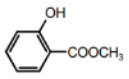
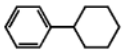
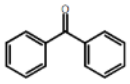
Table 2: Minimum cleaning efficiency

Application	Minimum Cleaning Efficiency				
	Toluene	Chlorobenzene	Phenyl Cyclohexane	Benzophenone	Methyl Stearate
Cold-filled yogurt	64.0%	57.2%	39.9%	30.4%	0%
Hot-filled yogurt	80.0%	75.1%	66.5%	61.3%	24.5%
Trays for meat, fish or cheese	30.6%	17.6%	0%	0%	0%
Trays for food and vegetables	93.7%	92.5%	89.4%	87.8%	76.2%
Cups for cold drinks	76.9%	72.6%	61.5%	55.4%	13.0%
Cups for hot drinks	91.9%	90.4%	86.5%	84.5%	69.7%

The surrogates were chosen in accordance with EU relevant criteria and US FDA recommendations such that they covered the whole spectrum of physical properties and represent the different chemical and physical properties of real-life contaminants.

From theoretical considerations on migration of such substances, the molecular weight represents the major parameter important for the selection of the surrogates. It is well established [1] that chemicals with a molecular weight up to approximately 400 Dalton are the most relevant ones for migration from PS. Substances with a molecular weight higher than 400 Dalton have an extremely low migration potential due to their low diffusivity in PS.

Table 3: Surrogate selection

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

The contamination procedure and the analyses of the real quantities of surrogates added are reported on Versalis' website, document named "Newer rPS Petition Summary, attachment 1: Fraunhofer Institute Report". The decontaminated polymer samples were then sent back to Fraunhofer Institute for analyses of residual surrogates.

The data, reported into Attachment 1 "Fraunhofer IVV Test Report" (available on Versalis' website), compared with the minimum cleaning efficiencies, show that the Novel Technology, as Versalis rPS Decontamination Technology, is able to clean efficiently rPS

and so to reduce all contaminants below the target level required for direct food application, thus demonstrating the suitability of the Decontamination Novel Technology.

Starting from this Data Monitoring Report, the exposure scenarios are widened. The comparison between the data, reported into Attachment 2 “Fraunhofer IVV Test Report” (available on Versalis’ website), and the minimum cleaning efficiencies, show that the Novel Technology, as Versalis rPS Decontamination Technology, is also able to clean efficiently rPS and so to reduce all contaminants below the target level required for direct food application for each single new scenario (from 7 to 17).

From the data provided in this document the following conclusions can be drawn:

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

4) List of all substances with a molecular weight below 1000 Dalton found in the plastic inputs to each of the decontamination installations and in the recycled plastic output thereof – Art. 13 (5c)

During the period subject to this data monitoring, no rPS batches were produced, as the manufacturing plant was temporarily shut down for the implementation of engineering modifications.

5) List of contaminating materials regularly present in the plastic input – Art. 13 (5d)

The washed and dried PS flakes have a >95% purity regarding food PS. Typical PS flake specifications after conventional recycling (washing and sorting) are given in the Table 4 below (PS non-food < 5%).

The waste may originally contain non-food articles, these materials are sorted out of the waste stream, such that the input material consist predominantly of PS used in contact with food. The specification for the input to the decontamination process are as follows:

Table 4: List of contaminating materials

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

The waste material is tracked according to EN 15343 standard and analysed according UNI 10667/10 standard in order to determine the amount of PS in the input material. In Annex 2 a typical production certificate of decontaminated PS (rPS) is reported as an example.

6) Analysis of the most likely origin of the identified contaminants referred to in points (c) and (d). – Art. 13 (5e)

During the period subject to this data monitoring, no rPS batches were produced, as the manufacturing plant was temporarily shut down for the implementation of engineering modifications.

7) Measurement or estimation of the migration levels to food of contaminants present in the recycled plastic materials and articles – Art. 13 (5f)

a) Approach followed for the determination of the target values

To evaluate the risk for the consumer, European Food Safety Authority (EFSA) defined an evaluation procedure, which is based on the Exposure scenario of the consumer.

The exposure of the consumer is calculated from the daily food consumption of the relevant consumer groups (e.g., infants, toddlers, or adults) and the migration of potential contaminants from the recyclate-containing packaging material into food. The migrated amount is typically not experimentally determined but predicted by use of diffusion modelling. For example, EFSA uses the so-called A_P prediction model for the evaluation of the migrated amount of the surrogates into food. This A_P model over-estimates the real migration into food [2].

Therefore, it is essential to reduce the contaminants' concentration to values below the limits, where the limits are the values that would cause excessive migration of the contaminant from the package, prepared using the treated recycled polymer, into the food products.

Such limits are described in detail in article by F. Welle [1], where it is given a summary of the evaluation of safety as provided by the European Food Safety Authority (EFSA). The latter was based on the Threshold of Toxicological Concern (TTC) Concept [3]. The TTC approach was used by EFSA for safety evaluation of other plastics such as recycled PET. In particular, for PET reference is made to EFSA CEF Panel [4].

Up to now, EFSA did not produce similar documentation for vinyl aromatic based polymers, such as polystyrene (PS) and rubber reinforced vinyl aromatic polymers (such as HIPS).

In absence of specific information on vinyl aromatic based polymers, it was assumed the same TTC concept of recycled PET.

To facilitate the application of the TTC approach, Kroes et al. [5] proposed a decision tree which has since been modified. The TTC decision tree presented in [6] is based on the EFSA and WHO [3].

In case of potential DNA-reactive mutagens and/or carcinogens contaminants, the assumed scenario is that, according to the TTC concept [6], an exposure of 0.0025 µg of a substance per kg body weight per day is not critical to human health.

On the other hand, for all substances for which the TTC value is known [2], [5], [6], this has been assumed as the value to be considered for the determination of the MSEC.

It is specified that the MSEC value reported in Table 8 has been determined by multiplying the TTC value by the weight of the toddler, which is 10 kg.

b) Evaluation of the migrated amount of the surrogates into food

There are different possible scenarios and applications for post-consumer in direct food contact. For the evaluation of the migrated amount of surrogates into food it has been assumed the same exposure scenarios used by F. Welle (see Table 2 at page 7 of [1]) as reported in Table 1 and the new exposure scenarios reported into Attachment 2 "Fraunhofer IVV Test Report" (available on Versalis' website).

The computation was carried out following the European Technical Report "Practical Guidelines on the Application of Migration Modelling for the Estimation of Specific Migration" [2] with particular reference to the analytical solution to the diffusion equation at section 9.1 and the ranges of parameters for the applicability of the migration model for PS, HIPS and SBS as reported at section "3.2.2 Polystyrenes", Table 2, and in particular it has been chosen as Ap'*=1.0 and tau=0 (i.e., the data for HIPS) and the diffusion coefficients it has been estimated by equations 1 and 2 as reported at section 3.1 of [2].

In addition, the following parameters have been defined according to what it is reported in [1]: the maximum safe concentration (MSC) is the concentration of contaminant in the plastic package that would lead to an intake of the contaminant, by a toddler of 10 kg of

body weight, corresponding to the maximum safe exposure of the contaminant (MSEC). MSC represents the maximum safe concentration of contaminant that must be present in the packaging in order not to exceed the maximum permissible migration threshold into food.

$$\mathrm{MSC} = \frac{\mathrm{OEF}\cdot\mathrm{MSEC}}{\mathrm{FC}} \cdot \frac{\mathrm{K_{pf}}\cdot\rho_F}{\rho_P \cdot \left[\frac{1}{1+\alpha} - 2\cdot\alpha\cdot\sum_1^n \frac{\exp\left(-q_n^2 \cdot \frac{D_P(T,MW)}{d_P{}^2}\cdot t\right)}{1+\alpha+\alpha^2\cdot q_n^2}\right]} \quad (1)$$

Following the indications disclosed in the articles of EFSA [2] and of F. Welle [1], the MSC was computed by analytically solving the previously cited diffusion equation (EU Report 27529, section 9.1, equations 3 and 7) [2]. More precisely, such equations derive from equation 4.37 of Crank [7] (at page 57).

Where, OEF is the overestimation factor, FC the food consumption per day, $\mathrm{K_{pf}}$ the partition coefficient, ρ_F the food density, ρ_P the polymer density, $\alpha = V_F/(\mathrm{K_{pf}}\cdot A\cdot d_P)$ where A is the food-plastic interface area, V_F the food volume, d_P is the plastic thickness, $D_P(T, MW)$ is the diffusion coefficient, computed with constants $A_p{}'^*$=1.0 and $\tau = 0$, and MW the molecular weight of the contaminant, in Dalton:

$$D_P(T, MW) = D_P{}^* = exp\left(A_p{}'^* - \frac{\tau}{T} - 0.1351\cdot MW^{2/3} + 0.003\cdot MW - \frac{10454}{T}\right) =$$
$$exp\left(1.0 - 0.1351\cdot MW^{2/3} + 0.003\cdot MW - \frac{10454}{T}\right) \quad (2)$$

with T in Kelvin.

The number of terms n in the series was chosen to be at least 100 (minimum 100 terms, but even more in case the subsequent term would change MCE by more than 0.01%).

Finally, Q_n are the non-zero positive roots of the following equation (3) eq. 4.38 [7], reported also as equation 5 in EFSA report, section 9.1 [2]:

$$tan(\mathrm{q_n}) = -\alpha \cdot \mathrm{q_n} = -55.6 \cdot \mathrm{q_n} \quad (3)$$

The roots can be computed solving:

$$f(\mathrm{q_n}) = tan(\mathrm{q_n}) + \alpha \cdot \mathrm{q_n} = 0 \quad (4)$$

with high degree of precision by numerical methods. The Newton-Raphson algorithm was used, with maximum error tolerance on both abscissas $\mathrm{q_n}$ and ordinates $f(\mathrm{q_n})$ equal to 0.0001.

For the evaluation of MSC of each contaminant, according to [1], it was assumed that the following parameters are constant for any applications and for any contaminants:

- the human being is the toddler of 10 kg of weight
- OEF is the overestimation factor is = 5
- $\mathrm{K_{pf}}$ the partition coefficient is = 1.0
- ρ_F the food density is = 1000 kg/m^3
- ρ_P the polymer density is = 1040 kg/m^3
- $\alpha = \mathrm{V}_F/(\mathrm{K_{pf}} \cdot \mathrm{A} \cdot \mathrm{d}_P) = 55.6$ where A is the food-plastic interface area (0.06 m^2), V_F the food volume (0.001 m^3), d_P is the plastic thickness (0.0003 m)

Table 5: Values for food consumption and maximum storage temperatures (as in Table 1)

Application	Food Consumption (FC) per Day	Maximum Storage Time and Temperature
Cold-filled yogurt	250 g	40 d at 6 °C
Hot-filled yogurt	250 g	2 h 70 °C followed by 40 d at 6°C
Trays for meat, fish or cheese	150 g	30 d at 6 °C
Trays for food and vegetables	500 g	30 d at 25 °C
Cups for cold drinks	750 ml	1 d at 25 °C
Cups for hot drinks	750 mL	2 h at 70 °C

It is clarified that the estimation of the diffusion coefficient was performed outside the parameter ranges defined for the applicability of the migration model. This approach is justified by the fact that the diffusion coefficient estimated using equations 1 and 2 satisfies the condition $Dp \leq Dp^*$ stipulated by the Guideline, ensuring that the migration is conservatively overestimated.

c) Application example of equation (1)

Instead of the analytical solution, to compute MSC, F. Welle [1] used a finite element solvent software AKTS SML.

In this paragraph, is reported a comparison between the results obtained by solving equation (1), applying the analytical resolution developed by Versalis' R&D, and those obtained by F. Welle [1] by solving the same equation with finite element solvent software.

The comparison was done considering the same contaminants used by F. Welle, that are potential DNA-reactive mutagens and/or carcinogens contaminants, and for which the TTC value is 0.0025 µg of a substance per kg body weight per day.

Replacing into the MSC equation (1) the following parameters reported at points from 1 to 9, for the application "Trays for food and vegetables", which is the most demanding in terms of max migration, the following final equation is obtained:

$$\mathrm{MSC} = \frac{(5)\cdot\left(2.5\cdot 10^{-11}\,\frac{\mathrm{kg_C}}{\mathrm{day}}\right)}{\left(0.5\,\frac{\mathrm{kg_F}}{\mathrm{day}}\right)} \cdot \frac{1.0\cdot 1000\,\frac{kg}{m^3}}{1040\,\frac{kg}{m^3}\cdot\left[\frac{1}{1+55.6} - 2\cdot 55.6\cdot\sum_1^n \frac{\exp\left(-\mathrm{q_n^2}\cdot\frac{\mathrm{D_P}(T,MW)}{(3\cdot 10^{-3})^2 m^2}\cdot 30\ day\cdot 86400\ s/day\right)}{1+55.6+55.6^2\cdot \mathrm{q_n^2}}\right]}$$

Where:

1. $\alpha = \mathrm{V}_F/(\mathrm{K_{pf}}\cdot \mathrm{A}\cdot \mathrm{d}_P) = 55.6$ where A is the food-plastic interface area (0.06 m^2), V_F the food volume (0.001 m^3), d_P is the plastic thickness (0.0003 m)
2. $\mathrm{D_P}(T, MW)$ is the diffusion coefficient, computed with constants $\mathrm{A_p}'$=1.0 and $\tau = 0$, and MW the molecular weight of the contaminant, in Dalton
3. T is the temperature storage of food in Kelvin = 298.15 K
4. t is the storage time of food in seconds = $30\ day\cdot 86400\,\frac{s}{day} = 2592000\ s$
5. MSEC is the maximum safe exposure to contaminants per day = $2.5\cdot 10^{-11}\ \mathrm{kg_C/day}$
6. FC is the food consumption per day = $0.5\ \mathrm{kg_F/day}$
7. $\mathrm{K_{pf}}$ is the partition coefficient = 1.0
8. ρ_F is the food density = 1000 kg/m^3
9. ρ_P is the polymer density = 1400 kg/m^3

The MSC values obtained with equation (1) are the following:

- ✓ Toluene: 0.190 $mg/kg_{PLASTIC}$
- ✓ Chlorobenzene 0.225 $mg/kg_{PLASTIC}$
- ✓ Methyl salicylate 0.300 $mg/kg_{PLASTIC}$
- ✓ Phenyl cyclohexane 0.317 $mg/kg_{PLASTIC}$
- ✓ Methyl stearate 0.367 $mg/kg_{PLASTIC}$
- ✓ Benzophenone 0.715 $mg/kg_{PLASTIC}$

Comparing the results obtained with those in [1], can observe a slight difference, only for Benzophenone, equal to an error of 0.4%.

d) State of art of the migration of styrene monomer and oligomers from polystyrene food contact materials to foods

Styrene dimers and trimers, which are also residual materials produced during polymerization, have come under scrutiny due to conflicting reports suggesting they may or may not exhibit estrogenic activity [8], [9].

Currently, the rate at which styrene dimers and trimers transfer from food packaging into food is unclear. For this reason, additional work was performed to determine as correct as possible the coefficients relevant to styrene dimers and trimers in the polymer matrix.

The calculation of the diffusion and partition coefficients made with the model described gives quite high and unexpected values.

Thus, due to their estimated low water solubilities (0.86–120 mg l^{-1} at 25°C for the dimers and 0.0013–0.00092 mg l^{-1} at 25°C for the trimers) compared with the styrene monomer (310 mg l^{-1} at 25°C) and increased molecular size (MW = 196–312 Dalton for the dimers/ trimers versus 104 Dalton for the monomer), their diffusion coefficients are expected to be lower than that of the styrene monomer at approximately 3.0×10^{-13} cm^2 s^{-1} [10]. It was decided to evaluate the Diffusion coefficient starting from experimental data available in scientific and toxicological literature.

e) Evaluation of the migration of styrene dimers and trimers

The results reported in the FDA report [11] indicate that the migration of styrene dimers and trimers in food is significantly limited by the low value of the diffusion coefficient and the high value of the partition coefficient. Further literature from F. Welle reiterates the same concepts [12]. Starting from the article by Genualdi et al. [11], to ensure an even greater level of detail, more accurate information relating to the migrations of styrene

dimers and trimers could be introduced into the model. In particular, the partition coefficient and the diffusion coefficient of equation (1) could be modified according to the values obtained from experimental trials, so that the previously determined MSC values for the dimers and trimers of styrene, can be reconsidered and made more consistent with real data.

The diffusion coefficients were determined by Genualdi et al. [11] by analyzing different polystyrene (PS) applications, used in the manufacture of food contact materials (FCMs), and subjecting them to a migration test in three different food simulants: 10% ethanol, 50% ethanol, and 95% ethanol. Among the food contact materials (FCMs) analyzed, four were HIPS materials, along with one XPS, one EPS, and one GPPS. To achieve this objective, new calculations were performed using equation (1), both for the dimers and trimers of styrene, with the aim of determining the MSC values through more representative diffusion and partition coefficients.

Referring to the values of diffusion and partition coefficients reported by Genualdi et al. in Table 3 and 4 of [11] and using:

1. the human being is the toddler of 10 kg of weight
2. an overestimation factor (OEF) equal to 1
3. ρ_F the food density equal to 1000 kg/m^3
4. ρ_P the polymer density equal to 1040 kg/m^3
5. the food-plastic interface area (A) equal to 0.06 m^2
6. the food volume (V_F) equal to 0.001 m^3
7. the plastic thickness (d_P) equal to 0.0003 m
8. the same exposure scenarios indicated in [1]
9. the MSEC values related to the dimers and trimers of styrene [2], [5], [6].

The new MSC values have been determined. The calculations take into account only the results related to HIPS materials, which were obtained using 95% ethanol as the food simulant at 40°C, as this condition represents the worst-case scenario.

For the newly defined scenarios described above, and based on Tables 3 and 4 of [11], the following values were applied for the calculation of the MSC across all scenarios, as

they represent the most conservative assumptions from a risk assessment perspective, i.e. the worst-case scenario.

Table 6: Partition and Diffusion coefficients used for scenarios 6÷17

	1,3-Diphenylpropane	Styrene Dimers	Styrene Trimers
K	1.10E+04	2.00E+04	1.80E+05
D_p [m^2/s]	3.53E-18	4.43E-19	3.10E-20

f) Evaluation of the migration of styrene -acrylonitrile dimers and trimers

As already reported in point d) for styrene oligomers, also in the case of styrene–acrylonitrile oligomers the migration calculation performed using the previously described model (Equation 1) yields unrealistic MSC values when the diffusion coefficient calculated using Equation 2 is applied.

Indeed, several studies [13], [14] experimentally demonstrate that the migration of styrene–acrylonitrile oligomers from SAN/ABS articles into food is generally very low. Under realistic use conditions (hot beverages, alcoholic media, fatty foods), safety limits (TTC) are not exceeded.

For this reason, the scientific work of [13] investigating SAN and ABS polymers widely used in food contact materials, was used as reference. The study aimed to identify and quantify oligomers, mainly dimers and trimers, and to evaluate their migration into food. Thanks to the experimental tests conducted by the authors, it was possible to determine a realistic diffusion coefficient for styrene–acrylonitrile oligomers.

In particular, by knowing the concentration of styrene–acrylonitrile trimers (SAn_2 and S_2An) present in the initial material (SAN 5) [13] and the final amount of styrene–acrylonitrile trimers migrated into the food simulant (20% EtOH), the diffusion coefficient was calculated using Fick's second law.

This approach is highly conservative for several reasons:

- The temperature at which Kubicova's [13] experiments were conducted was higher than the storage temperatures foreseen in all 17 scenarios considered; therefore, the determined coefficient is significantly more conservative than the actual one.
- All tests were repeated three times, and migration progressively decreased from the first to the third test.

It should be noted that in study [13] the choice of the 20% EtOH simulant was dictated by the fact that simulants containing 50% ethanol do not provide reliable results. Such simulants tend to significantly overestimate real migration, as demonstrated in [13], [14], [15], and may alter the material, rendering it unsuitable for realistic SAN and ABS testing. The increased migration observed in alcoholic simulants is related to polymer swelling: in study [14], acrylonitrile diffusion coefficients in SAN at 40 °C were measured in different alcoholic solutions, showing a much higher diffusion coefficient in 50% ethanol (5.2×10^{-11} cm^2/min) compared to water (1.2×10^{-11} cm^2/min) because of swelling effect of polymer in 50% ethanol.

Similarly, study [15] reported significant ABS swelling when in contact with ethanol solutions ≥50%, while negligible swelling was observed upon contact with milk, cream, and olive oil. For these reasons, simulants containing ethanol ≥50% are not suitable for migration testing at 70 °C on SAN and ABS.

Once the diffusion coefficient was determined, and considering styrene–acrylonitrile trimers as Cramer Class III, the maximum concentration (MSC) of styrene–acrylonitrile trimers in the plastic for the different scenarios was defined using the Equation (1).

However, the described approach is not applicable to styrene–acrylonitrile dimers due to the lack of analogous literature data. As reported in [16], the mass ratio between acrylonitrile dimers and trimers formed during oligomer production is approximately 1:20 (w/w), indicating that dimers represent a minor fraction of extractable oligomers. This evidence is consistent with Kubicova's [13] findings and confirms the difficulty in estimating styrene–acrylonitrile dimer migration, whose concentrations are often below instrumental detection limits. Therefore, for styrene–acrylonitrile dimers, the diffusion

coefficient was estimated using Equation (2), analogously to what was already adopted for other contaminants.

g) Migration level evaluation

During the reporting period, no new measurements of migration levels from recycled materials into food were performed, due to the absence of produced batches.

The evaluation of migration has therefore been carried out through:

- established diffusion modelling approaches,
- application of EFSA-recognised methodologies (TTC concept),
- extension of exposure scenarios (Scenarios 7–17),
- use of experimentally derived parameters from literature and previous studies.

The assessment includes:

- previously generated analytical concentrations from monitoring data,
- updated modelling of migration behaviour under expanded time/temperature and consumption conditions,
- refined diffusion and partition coefficients for key contaminants (e.g. styrene oligomers and styrene–acrylonitrile oligomers).

The results confirm that, under all considered scenarios, including worst-case assumptions, the concentration of potential contaminants in the recycled material remains below the maximum safe concentration (MSC).

Therefore, even in the absence of new experimental data, the migration assessment remains robust and conservative, and the conclusions on safety are maintained.

For the assessment of the new exposure scenarios introduced in the present monitoring report, these scenarios were applied to the values reported in Table 4 of the First Six-Monthly Monitoring Report (January 2025) to evaluate the compliance of the batches

manufactured at that time under the newly introduced scenarios. The results are reported in Table 7.

For most of the contaminants reported in Table 7 and Table 8, to calculate MSC, the MSEC (TTC) values are taken from [17] and from [18].

It must be underlined that in the in Table 7 and Table 8 for the contaminants: Butylated Hydroxytoluene (BHT), Toluene, Ethylbenzene, 1,3-Dimethyl Benzene, Dioctyl Phthalate, Dioctyl Adipate, Dioctyl Terephthalate and Acetyltributylcitrate the following assumption has been done to calculate MSC:

- Butylated Hydroxytoluene (BHT, FCM 315, Ref. No 46640 of Annex I of Reg. (UE) 10/2011): in this case, according to [2], the SML value was used instead of MSEC (TTC) approach, as highlighted by * in Table 8. The used SML value is 3 mg/kg, as indicated by Reg. (UE) 10/2011.
- Toluene: in this case, according to [19], the SML value has used instead of MSEC (TTC) approach, as highlighted by * in Table 8. The used SML value is 1.2 mg/kg.
- Ethyl Benzene: in this case, according to [19], the SML value was used instead of MSEC (TTC) approach, as highlighted by * in Table 8. The used SML value is 0.6 mg/kg.
- 1,3-Dimethyl Benzene: in this case, according to [19], the SML value was used instead of MSEC (TTC) approach, as highlighted by * in Table 8. The used SML value is 1.2 mg/kg.
- Dioctyl Adipate (FCM 207, Ref. No 31920 of Annex I of Reg. (UE) 10/2011): in this case, according to [17], the SML value was used instead of MSEC (TTC) approach, as highlighted by * in Table 8. The used SML value is 18 mg/kg, as indicated by Reg. (UE) 10/2011.
- Dioctyl Terephthalate (FCM 798, Ref. No 92200 of Annex I of Reg. (UE) 10/2011): in this case, according to [17], the SML value was used instead of MSEC (TTC) approach, as highlighted by * in Table 8. The used SML value is 60 mg/kg, as indicated by Reg. (UE) 10/2011.

- Acetyltributylcitrate (FCM 138, Ref. No 93760 of Annex I of Reg. (UE) 10/2011): in this case, according to [17], the SML value was used instead of MSEC (TTC) approach, as highlighted by * in Table 8. The used SML value is 60 mg/kg, as indicated by Reg. (UE) 10/2011.

Furthermore, for the following contaminants: styrene dimers, styrene trimers and 1,3-Diphenylpropane, indicated in Table 7 and Table 8 with **, starting from the article by Genualdi et al. [11], to ensure an even greater level of detail, more accurate information relating to the migrations of styrene dimers and trimers, could be introduced into the model. In particular, the partition coefficient and the diffusion coefficient of equation (1) (reported in Paragraph 7) could be modified according to the values obtained from experimental trials, so that the previously determined MSC values for the dimers and trimers of styrene, can be reconsidered and made more consistent with real data (see paragraph 7 point e) for more details).

Instead, for the styrene-acrylonitrile trimers indicated in Table 7 and Table 8 with ***, starting from the article by Kubicova et al. [13], to ensure an even greater level of detail, more accurate information relating to the migrations of styrene-acrylonitrile trimers, could be introduced into the model. In particular the diffusion coefficient of equation (1) (reported in Paragraph 7) could be modified according as described in 7 point f.

Table 7: Assessment of batch compliance under the newly introduced exposure scenarios based on data from the First Six-Monthly Monitoring Report (January 2025).

Occourrency	MW [g/mol]	Substance type	Substance	CAS Number	Origin	Typical/NIAS	Output Maximum Concentration [ppm]	MSC Scenario 6	MSC Scenario 10	MSC Scenario 14	MSC Scenario 16
43	208	Non Volatiles	[2.2]Paracyclophane	1633-22-3	Styrene Dimer	Typical		329.00	194.00	74.00	122.00
43	106	Volatiles	1,3-Dimethyl benzene	108-38-3	Feedstock Contaminant	Typical	1.00	1947.00	765.00	294.00	242.00
43	196	Non Volatiles	1,3-Diphenylpropane	1081-75-0	Styrene Dimer	Typical	21.60	742**	520**	345**	680**
43	120	Volatiles	1-Methylethylbenzene	98-82-8	Polymerization Product	Typical	0.79	3627.00	2134.00	819.00	1348.00
43	220	Non Volatiles	Butylated Hydroxytoluene (BHT)	128-37-0	Food additive (E321)	NIAS		10590.00	4161.00	1596.00	1313.00
43	210	Non Volatiles	C14H14N2	*Brute formula*	Styrene Acrylonitrile Trimer (An2S)	Typical	32.00	7025**	962**	159**	262**
43	174	Non Volatiles	Dimethyl Adipate	627-93-0	Additive: Ink solvent	NIAS	32.80	5297.00	3122.00	1198.00	1971.00
43	391	Non Volatiles	Dioctyl Phthalate	117-81-7	Additive: Plasticizer	NIAS	45.20	5176.00	2034.00	780.00	641.00
43	106	Volatiles	Ethylbenzene	100-41-4	Polymerisation product	Typical	13.00	973.00	383.00	147.00	121.00
43	240	Non Volatiles	Heptadecane	629-78-7	Additive: mineral oil	Typical	18.00	7952.00	4677.00	1794.00	2951.00
43	212	Non Volatiles	Pentadecane	629-62-9	Additive: Mineral oil	Typical	57.10	6743.00	3966.00	1522.00	2503.00
43	120	Volatiles	Propylbenzene	103-65-1	Polymerization product	Typical	1.80	3627.00	2134.00	819.00	1348.00
43	104	Volatiles	Styrene	100-42-5	Monomer	Typical	109.00	3199.00	1883.00	723.00	1190.00
43	210	Non Volatiles	Styrene Acrylonitrile Trimer (An2S)	*Oligomer*	Polymerization product	Typical	53.00	7025***	962***	159***	262***
43	271	Non Volatiles	Styrene Acrylonitrile Trimer (AnS2)	*Oligomer*	Polymerization product	Typical	58.00	11869***	1626***	269***	443***
43	208	Non Volatiles	Styrene Dimers	Mixture	Polymerisation product	Typical	131.00	742**	1177**	658**	1285**
43	312	Non Volatiles	Styrene Trimers	Mixture	Polymerisation product	Typical	1943.00	31661**	7238**	5481**	10855**
43	157	Non Volatiles	Styrene-Acrylonitrile Dimers	*Mixture*	Polymerization product	Typical	2.90	237.00	139.00	53.00	88.00
43	92	Volatiles	Toluene	108-88-3	Polymerization product	Typical	1.30	1735.00	682.00	262.00	216.00
41	84	Volatiles	Cyclohexane	110-82-7	Polymerization product	Typical	0.21	2704.00	1591.00	611.00	1006.00
40	136	Volatiles	D-Limonene	5989-27-5	Post-consumer	NIAS		4085.00	2403.00	923.00	1518.00
39	106	Volatiles	Benzaldehyde	100-52-7	Degradation/Oxidation	Typical		3251.00	1913.00	735.00	1209.00
38	222	Volatiles	Hexamethylcyclotrisiloxane	541-05-9	Additive: silicone oil	Typical		358.00	211.00	81.00	133.00
37	371	Volatiles	Decamethylcyclopentasiloxane	541-02-6	Additive: silicone oil	NIAS	0.29	787.00	463.00	177.00	292.00
33	120	Volatiles	1,2,3-Trimethylbenzene	526-73-8	Polymerization product	NIAS	0.31	181.00	107.00	41.00	67.00
33	120	Volatiles	Acetophenone	98-86-2	Degradation/Oxidation	NIAS		3627.00	2134.00	819.00	1348.00
32	130	Volatiles	2-Ethyl-1-hexanol	104-76-7	Degradation/Plasticizer	NIAS		3909.00	2300.00	883.00	1453.00
32	74	Volatiles	2-Methyl-2-Propanol	75-65-0	Washing & cleaning products	NIAS		124.00	73.00	28.00	46.00
32	120	Volatiles	Dimethoxydimethylsilane	1112-39-6	Additive: silicone oil	Typical	0.40	181.00	107.00	41.00	67.00
29	170	Volatiles	2,2,4,6,6-Pentamethylheptane	13475-82-6	Additive: Mineral oil	NIAS		5170.00	3041.00	1167.00	1920.00
28	100	Volatiles	Hexanal	66-25-1	Fragrances	NIAS	0.47	3097.00	1822.00	700.00	1152.00
26	70	Volatiles	2-Pentene, (Z)-	627-20-3		NIAS		2381.00	1401.00	539.00	886.00
26	56	Volatiles	Acrolein	107-02-8		NIAS	0.80	623.00	366.00	141.00	232.00
26	60	Volatiles	Methyl formate	107-31-3		NIAS	0.40	2161.00	1272.00	489.00	805.00
25	142	Volatiles	Decane	124-18-5	Additive: Mineral oil	Typical		4265.00	2509.00	963.00	1585.00
25	74	Volatiles	Methyl methoxyacetate	6290-49-9		NIAS		124.00	73.00	28.00	46.00
25	156	Volatiles	Undecane	1120-21-4	Additive: Mineral oil	Typical		4704.00	2767.00	1062.00	1747.00
22	86	Volatiles	Pentanal	110-62-3	Fragrances	NIAS		2752.00	1619.00	622.00	1024.00
21	61	Volatiles	o-Ethylhydroxylamine	624-86-2		NIAS		109.00	64.00	25.00	41.00
20	142	Volatiles	Nonanal	124-19-6	Fragrances	NIAS		4265.00	2509.00	963.00	1585.00
19	72	Volatiles	Butanal	123-72-8	Flavour	NIAS		2426.00	1428.00	549.00	903.00
10	60	Volatiles	Acetic acid	64-19-7	Degradation/Plasticizer	Typical		2161.00	1272.00	489.00	805.00
7	128	Volatiles	Octanal	124-13-0	Fragrances	NIAS		3852.00	2266.00	870.00	1432.00

Table 8: Maximum migration level and maximum safe concentration of all the substance found in the output batches

					Scenario 6: Cup for hot drinks, 750 ml hot drinks per day for a toddler, storage for 2 h at 70 °C		Scenario 10: Packaging for solid and liquid food, 500 g per day for a toddler, 10 d at 40 °C		Scenario 14: Packaging for solid and liquid food, 500 g per day for a toddler, 12 months (365 d) at 25 °C		Scenario 16: Packaging for solid and liquid food, 250 g per day for a toddler, hot filling at 95 °C for 10 min, stored 18 months (540 d) at 25 °C	
Type of substance	**Contaminants**	**MW [g/mol]**	**CAS Number**	**MSEC (TTC) value per Toddler (10 kg) [µg/day] [2], [5], [6], [13], [14]**	**Max migration [mg/kg foodstuff]**	**MSC: Max safe concentration in the PS packaging [mg/kg]**	**Max migration [mg/kg foodstuff]**	**MSC: Max safe concentration in the PS packaging [mg/kg]**	**Max migration [mg/kg foodstuff]**	**MSC: Max safe concentration in the PS packaging [mg/kg]**	**Max migration [mg/kg foodstuff]**	**MSC: Max safe concentration in the PS packaging [mg/kg]**
Non-Volatile	[2.2]Paracyclophane	208	1633-22-3	15	0.1	329	0.15	194	0.15	74	0.3	122
Volatile	1,2,3-Trimethylbenzene	120	526-73-8	15	0.1	181	0.15	107	0.15	41	0.3	67
Volatile	1,3-Dimethyl benzene	106	108-38-3	*	1.2 (SML)	1947	1.2 (SML)	765	1.2 (SML)	294	1.2 (SML)	242
Non-Volatile	1,3-Diphenylpropane	196	1081-75-0	15	0.03	742**	0.03	520**	0.03	345**	0.06	680**
Volatile	1-Methylethylbenzene	120	98-82-8	300	2	3627	3	2134	3	819	6	1348
Volatile	2,2,4,6,6-Pentamethylheptane	170	13475-82-6	300	2	5170	3	3041	3	1167	6	1920
Volatile	2-Ethyl-1-hexanol	130	104-76-7	300	2	3909	3	2300	3	883	6	1453
Volatile	2-Methyl-2-Propanol	74	75-65-0	15	0.1	124	0.15	73	0.15	28	0.3	46
Volatile	2-Pentene, (Z)-	70	627-20-3	300	2	2381	3	1401	3	539	6	886
Volatile	Acetic acid	60	64-19-7	300	2	2161	3	1272	3	489	6	805
Volatile	Acetophenone	120	98-86-2	300	2	3627	3	2134	3	819	6	1348
Volatile	Acrolein	56	107-02-8	90	0.6	623	0.9	366	0.9	141	1.8	232
Volatile	Benzaldehyde	106	100-52-7	300	2	3251	3	1913	3	735	6	1209
Volatile	Butanal	72	123-72-8	300	2	2426	3	1428	3	549	6	903
Non-Volatile	Butylated Hydroxytoluene (BHT)	220	128-37-0	*	3 (SML)	10590	3 (SML)	4161	3 (SML)	1596	3 (SML)	1313
Non-Volatile	C14H14N2	210	*Brute formula*	15	0.1	7025**	0.15	962**	0.15	159**	0.3	262**
Volatile	Cyclohexane	84	110-82-7	300	2	2704	3	1591	3	611	6	1006
Volatile	Decamethylcyclopentasiloxane	371	541-02-6	15	0.1	787	0.15	463	0.15	177	0.3	292
Volatile	Decane	142	124-18-5	300	2	4265	3	2509	3	963	6	1585
Volatile	Dimethoxydimethylsilane	120	1112-39-6	15	0.1	181	0.15	107	0.15	41	0.3	67
Non-Volatile	Dimethyl Adipate	174	627-93-0	300	2	5297	3	3122	3	1198	6	1971
Non-Volatile	Dioctyl Phthalate	391	117-81-7	*	0.6 (SML)	5176	0.6 (SML)	2034	0.6 (SML)	780	0.6 (SML)	641
	Dioctyl Adipate	371	103-23-1	*	18 (SML)	141326	18 (SML)	55520	18 (SML)	21290	18 (SML)	17506
	Dioctyl Terephthalate	391	6422-86-2	*	60 (SML)	517640	60 (SML)	203353	60 (SML)	77977	60 (SML)	64116
	Acetyltributylcitrate	402	77-90-7	*	60 (SML)	544683	60 (SML)	213976	60 (SML)	82048	60 (SML)	67464
Volatile	D-Limonene	136	5989-27-5	300	2	4085	3	2403	3	923	6	1518
Volatile	Ethylbenzene	106	100-41-4	*	0.6 (SML)	973	0.6 (SML)	383	0.6 (SML)	147	0.6 (SML)	121
Non-Volatile	Heptadecane	240	629-78-7	300	2	7952	3	4677	3	1794	6	2951
Volatile	Hexamethylcyclotrisiloxane	222	541-05-9	15	0.1	358	0.15	211	0.15	81	0.3	133
Volatile	Hexanal	100	66-25-1	300	2	3097	3	1822	3	700	6	1152
Volatile	Methyl formate	60	107-31-3	300	2	2161	3	1272	3	489	6	805
Volatile	Methyl methoxyacetate	74	6290-49-9	15	0.1	124	0.15	73	0.15	28	0.3	46
Volatile	Nonanal	142	124-19-6	300	2	4265	3	2509	3	963	6	1585
Volatile	Octanal	128	124-13-0	300	2	3852	3	2266	3	870	6	1432
Volatile	o-Ethylhydroxylamine	61	624-86-2	15	0.1	109	0.15	64	0.15	25	0.3	41
Non-Volatile	Pentadecane	212	629-62-9	300	2	6743	3	3966	3	1522	6	2503
Volatile	Pentanal	86	110-62-3	300	2	2752	3	1619	3	622	6	1024
Volatile	Propylbenzene	120	103-65-1	300	2	3627	3	2134	3	819	6	1348
Volatile	Styrene	104	100-42-5	300	2	3199	3	1883	3	723	6	1190
Non-Volatile	Styrene Acrylonitrile Trimer (An2S)	210	*Oligomer*	15	0.1	7025***	0.15	962***	0.15	159***	0.3	262***
Non-Volatile	Styrene Acrylonitrile Trimer (AnS2)	261	*Oligomer*	15	0.1	11869***	0.15	1626***	0.15	269***	0.3	443***
Non-Volatile	Styrene Dimers	208	*Mixture*	15	0.03	742**	0.03	1177**	0.03	658**	0.06	1285**
Non-Volatile	Styrene Trimers	312	*Mixture*	15	0.03	31661**	0.03	7238**	0.03	5481**	0.06	10855**
Non-Volatile	Styrene-Acrylonitrile Dimers	157	*Mixture*	15	0.1	237	0.15	139	0.15	53	0.3	88
Volatile	Toluene	92	108-88-3	*	1.2 (SML)	1735	1.2 (SML)	682	1.2 (SML)	262	1.2 (SML)	216
Volatile	Undecane	156	1120-21-4	300	2	4704	3	2767	3	1062	6	1747

8) Detailed description of the applied sampling strategy – Art. 13 (5g)

The sampling strategy is different between input flakes and decontaminated final product.

For the input a sample of 0,5 Kg is sampled after Step 1. For the output decontaminated material, a sample of 50 g is collected every 2 ton of rPS produced. By taking into account the flow rate of the plant (about 4 t/h) a sample of 50 g is collected every 30 minutes of production. Because a lot of rPS is consisting of 100 ton of material, 2500 g of rPS are collected. The collected samples of each single rPS output batch are mixed together to form a mean sample.

Consistent with Art. 13 (1) of regulation 2022/1616, sample of each input batches and their resultant output batches were collected.

During the period subject to this data monitoring, no rPS batches were produced, as the manufacturing plant was temporarily shut down for the implementation of engineering modifications.

9) Detailed description of the analytical procedures and methods used – Art. 13 (5h)

Samples of PS input batches and corresponding output batches were labelled for traceability purposes and shipped in clear and hermetically sealed containers. The analytical procedures and method used for the analysis of the samples as well as their limits of detection and quantification are summarized. Analysis of organic substances is done through a non-targeted screening of volatile and non-volatile substances with two different methods. These techniques are very versatile and are employed in a wide range of industries and research areas to identify, quantify, and characterize volatile and non-volatile compounds in plastic/polymer samples.

Determination of volatile substance (except for styrene and ethylbenzene)

Introduce 1g of flakes (for input batch analysis) or 1g of granules (for output batch analysis) into a 10mL headspace vial with a cap equipped with a perforable silicone/PTFE septum. 5-10 µL of a methanol solution of internal standard, i.e. chlorobenzene, at approximately 3000 ppm are added. The sample is thermostatated at 125 °C for 30 minutes and then injected into GC-MS.

Instrumentations: HP6890 GC interfaced to HP5975 MS with EI source and single quadrupole analyzer, equipped with SSL injector, FID detector and HTA 300HT headspace autosampler

Chromatography column: Mega-JXR 25m x 0.25mm x 1.50µm (or equivalent)

Thermostatation: 125 °C for 30 minutes

Injector T: 260 °C

Injection volume: 1 ml

Injection technique: split 30:1

Column flow (He): 0.8 mL/min (constant flow mode)

Temperature ramp: initial isotherm at 40 °C for 3 minutes, then T ramp (2 °C/min) up to 70 °C, isotherm at 70 °C for 5 minutes, then T ramp (2 °C/min) up to 160 °C, isotherm at 160 °C for 20 minutes, then T ramp (2 °C/min) up to 250 °C, isotherm at 250 °C for 5 minutes

T transfer line: 260 °C

Response factor 1 is given with respect to the internal standard for all compounds.

Determination of volatile substance (styrene and ethylbenzene)

The determination of styrene and ethylbenzene (volatile compound) is performed using Versalis internal method. Please refer to Annex 4 for the detailed procedure.

Determination of non-volatile compounds

0,5g of flakes (for input batch analysis) or 0,5g of granules (for output batch analysis) are dissolved with 3 mL of an internal standard solution in $CHCl_3$ (di-butyl phthalate at approximately 15 ppm, for foreign substances, and n-C16 at approximately 50 ppm, for oligomers), then precipitates with 8 mL of EtOH under mechanical stirring. The resulting solution is filtered through 0.45 μm pore syringe filters and injected into the GC (for quantitative purposes) or GC-MS (for qualitative purposes).

Instrumentation: GC Thermo Trace 1300, equipped with on-column injector and FID detector and TriPlus autosampler

Chromatography column: HP-1 25m x 0.320mm x 0.52μm (or equivalent)

Injection technique: Cold-On-Column

Injection volume: 1 μL

Column flow (H_2): 2 mL/min for 1 minute, then flow ramp (0.2 mL/min) up to 4.2 mL/min (programmed flow mode)

Temperature ramp: initial temperature at 60 °C, then T ramp (40 °C/min) up to 160 °C, isotherm at 160 °C for 5 minutes, then T ramp (8 °C/min) up to 325 °C, isotherm at 325 °C for 5 minutes.

T detector: 330°C

Response factor 1 is given with respect to the internal standard for all compounds

10) Analysis and explanation of any discrepancies observed between contaminant levels expected in the input plastic and in the output of the installation and its decontamination efficiency – Art.13 (5i)

During the period subject to this data monitoring, no rPS batches were produced, as the manufacturing plant was temporarily shut down for the implementation of engineering modifications.

11) Discussion of the differences with previous published reports - Art. 13 (5j)

During the period subject to this data monitoring, no rPS batches were produced, as the manufacturing plant was temporarily shut down for the implementation of engineering modifications.

Given that:

- no modifications affecting the critical process steps have been introduced,
- operating principles and process parameters remain unchanged,

no deviations from the previously established decontamination performance are expected.

It is confirmed that all information reported in the previous six-monthly reports, as well as the content described in Chapters 1 to 6 of the present document, remains unchanged. The only modification concerns the scenarios indicated in Chapter 3, points b) and c), which, as previously described, have been extended up to Scenario 17, as detailed above.

In particular, as reported in Attachment 2 “Fraunhofer IVV test report 08/05/2025”, annexed to the previous application submitted on 01/07/2025, all the scenarios analysed above can be considered safe up to 100% recycled material.

With regard to the measurement and estimation of contaminant migration levels from plastics into food, the adopted approach is the same as that described in Chapter 7, points a), b), and c), naturally applied to the newly defined scenarios. Consequently, Table 8 has been updated to report the new migration values for scenarios 6, 10, 14, and 16, which represent the scenarios of greatest commercial interest.

For the evaluation of styrene dimers and trimers migration, as indicated in Chapter 7, point e), diffusion and partition coefficients reported in Tables 3 and 4 of reference [11] were used. Specifically, the same coefficients were applied to all scenarios, as they represent a worst-case assumption.

In the Table 9 below, the average concentration values (both for input and output) of all identified substances in the rPS produced batches during the first, second and third monitoring periods are reported. It is important to note that the values have been considered in the worst-case scenario, meaning that when the contaminant concentration is lower than the LoQ (Limit of Quantification), the concentration is assumed to be equal to the LoQ, which is 1 ppm for non-volatile contaminants and 0.2 ppm for volatile contaminants. When the concentration is n.d. (not determinable), the concentration of each contaminant is assumed to be equal to 0.1 ppm (LoD, Limit of Detection).

Table 9. Average concentration (both for Input and Output) of the substance found in rPS produced Lots in the First, Second and Third Monitoring period.

			First Data Monitoring Report		Second Data Monitoring Report		Third Data Monitoring Report	
Substance	**MW [g/mol]**	**CAS Number**	**Average Input Concentration [ppm]**	**Average Output Concentration [ppm]**	**Average Input Concentration [ppm]**	**Average Output Concentration [ppm]**	**Average Input Concentration [ppm]**	**Average Output Concentration [ppm]**
[2.2]Paracyclophane	208	1633-22-3	1.00	1.00	1.03	1.01	-	-
1,2,3-Trimethylbenzene	120	526-73-8	0.44	0.14	0.57	0.19	-	-
1,3-Dimethyl benzene	106	108-38-3	1.58	0.18	1.66	0.24	-	-
1,3-Diphenylpropane	196	1081-75-0	13.37	9.89	8.23	3.74	-	-
1-Methylethylbenzene	120	98-82-8	2.03	0.25	1.98	0.32	-	-
2,2,4,6,6-Pentamethylheptane	170	13475-82-6	1.73	0.11	1.53	0.11	-	-
2-Ethyl-1-hexanol	130	104-76-7	3.53	0.11	5.41	0.10	-	-
2-Methyl-2-Propanol	74	75-65-0	0.94	0.12	1.11	0.10	-	-
2-Pentene, (Z)-	70	627-20-3	0.38	0.11	0.41	0.10	-	-
Acetic acid	60	64-19-7	0.29	0.11	0.96	0.15	-	-
Acetophenone	120	98-86-2	1.17	0.13	1.52	0.13	-	-
Acrolein	56	107-02-8	6.12	0.13	7.97	0.10	-	-
Benzaldehyde	106	100-52-7	0.54	0.17	0.65	0.17	-	-
Butanal	72	123-72-8	0.27	0.12	0.34	0.10	-	-
Butylated Hydroxytoluene (BHT)	220	128-37-0	1.00	1.00	1.01	1.01	-	-
C14H14N2	210	*Brute formula*	16.53	11.44	23.88	26.81	-	-
Cyclohexane	84	110-82-7	2.23	0.13	1.36	0.12	-	-
Decamethylcyclopentasiloxane	371	541-02-6	1.07	0.17	1.27	0.16	-	-
Decane	142	124-18-5	0.49	0.11	0.82	0.10	-	-
Dimethoxydimethylsilane	120	1112-39-6	0.54	0.19	0.61	0.15	-	-
Dimethyl Adipate	174	627-93-0	29.90	7.92	1.00	1.00	-	-
Dioctyl Phthalate	391	117-81-7	25.13	14.60	48.89	3.71	-	-
Dioctyl Phthalate	371	103-23-1	n.a.	n.a.	1.00	1.00	-	-
Dioctyl Terephthalate	391	6422-86-2	n.a.	n.a.	43.49	4.66	-	-
Acetyltributylcitrate	402	77-90-7	n.a.	n.a.	79.49	2.60	-	-
D-Limonene	136	5989-27-5	2.67	0.12	6.88	0.14	-	-
Ethylbenzene	106	100-41-4	17.44	3.62	10.18	5.04	-	-
Heptadecane	240	629-78-7	17.13	8.28	1.27	1.29	-	-
Hexamethylcyclotrisiloxane	222	541-05-9	1.59	0.16	1.89	0.16	-	-
Hexanal	100	66-25-1	1.63	0.17	2.21	0.14	-	-
Methyl formate	60	107-31-3	7.55	0.11	13.04	0.10	-	-
Methyl methoxyacetate	74	6290-49-9	0.70	0.12	0.49	0.12	-	-
Nonanal	142	124-19-6	0.43	0.11	0.59	0.10	-	-
Octanal	128	124-13-0	0.30	0.10	0.37	0.10	-	-
o-Ethylhydroxylamine	61	624-86-2	0.67	0.10	1.15	0.10	-	-
Pentadecane	212	629-62-9	46.87	37.28	6.94	1.03	-	-
Pentanal	86	110-62-3	0.57	0.13	0.84	0.12	-	-
Propylbenzene	120	103-65-1	2.35	0.33	2.40	0.64	-	-
Styrene	104	100-42-5	145.79	70.05	108.31	63.41	-	-
Styrene Acrylonitrile Trimer (An2S)	210	*Oligomer*	35.33	8.93	46.37	22.54	-	-
Styrene Acrylonitrile Trimer (AnS2)	271	*Oligomer*	37.66	16.90	13.99	7.75	-	-
Styrene Dimers	208	*Mixture*	274.95	89.14	307.43	113.31	-	-
Styrene Trimers	312	*Mixture*	2085.35	1346.60	1505.91	1259.99	-	-
Styrene-Acrylonitrile Dimers	157	*Mixture*	4.53	1.35	1.58	3.46	-	-
Toluene	92	108-88-3	1.87	0.55	2.79	0.73	-	-
Undecane	156	1120-21-4	0.65	0.10	0.74	0.10	-	-

From the results reported in Table 9 it can be observed that the average concentrations of the substances (both for input and output) are absolutely comparable. Therefore, no significant variations are observed.

Based on the available data and assessment described in this report, the following conclusions can be drawn:

- during the present reporting period, no production batches were generated due to the temporary shutdown of the plant for engineering modifications. However, it

has been verified that no changes affecting the critical decontamination steps or process conditions have been implemented. Therefore, the previously obtained decontamination performance remains representative of the current process.

- the extension of the exposure scenarios (Scenarios 7–17), together with the updated migration modelling approach and the use of experimentally derived diffusion and partition coefficients for relevant contaminants, further confirms the robustness and conservativeness of the safety assessment.
- the evaluation performed, based on established EFSA methodologies (TTC concept and migration modelling), indicates that the concentration of potential contaminants in the recycled material would remain below the maximum safe concentration (MSC) for all considered scenarios, including worst-case conditions.

The monitoring activity will continue in future reporting periods once production is resumed, in order to further confirm the consistency of the process performance and the compliance of the recycled material.

Annex 1 – Analytical results on each single produced batches

During the period subject to this data monitoring, no rPS batches were produced, as the manufacturing plant was temporarily shut down for the implementation of engineering modifications.

Annex 2 – Typical production certificate of decontaminated PS (rPS)

Forever PLAST	GENERAL SUMMARY FOR DECONTAMINATED MATERIALS	MD079 Rev.00 LUGLIO 2024
BATCH NUMBER	L4-2024-00373	
FOREVER PLAST MATERIAL NAME	REFENCE PS AIR SER.FOREVER	
VERSALIS MATERIAL NAME	REFENCE PS AIR_SERIES FOREVER	
STARTING PRODUCTION DATE	13/12/2024	
ENDING PRODUCTION DATE	14/12/2024	
DATE OF ISSUE	13/12/2024	
CHECK CRITICAL PARAMETERS (DECONTAMINATION VESSEL STEP; AVERAGE VALUES)		
CRITICAL PARAMETERS	VALUES FOUND	LIMITS
RESIDENCE TIME INTO DECONTAMINATION UNIT	14	15 - 30 minutes Min.10'
MELT TEMPERATURE	242	240°C - 270°C Min 230°C
DECONTAMINATION VESSEL PRESSURE	3	1 - 5 Torr Max.10 Torr
CHECK WASHING PARAMETERS (WASHING STEP ON FLAKES; AVERAGE VALUES)		
PARAMETERS	VALUES FOUND	LIMITS
WATER ENTERING TEMPERATURE IN THE WASHING TANK	DAY1: 58,4 - DAY2: 58,2	>50°C
WATER ENTERING DENSITY IN THE WASHING TANK	DAY1: <1,01 - DAY2: <1,01	<1,020 g/cm^3
INFORMATION MATERIALS USED (EXTRUSION STEP)		
PLACE	MATERIAL	BATCH
DOSER 1 FLAKE/GRANULE 1		
DOSER 1 FLAKE/GRANULE 2		
DOSER 1 FLAKE/GRANULE 3		
DOSER 2 FLAKE/GRANULE 1	PS BOOSTER EDISTIR	PS-2024-00286
DOSER 2 FLAKE/GRANULE 2		
DOSER 2 FLAKE/GRANULE 3		
DOSER 3 FLAKE/GRANULE 1	PS MACINATO DA BALLE EUROPA	PSMI-2024-12-0001
DOSER 3 FLAKE/GRANULE 2		
DOSER 3 FLAKE/GRANULE 3		
INFORMATION MATERIALS USED (EXTRUSION STEP)		
PS BOOSTER	VIRGIN MATERIAL	
	% USE: 25	
PS MACINATO DA BALLE EUROPA	FLAKES RECYCLATED MATERIAL ACCORDING ISO 10667-10	
	% USE: 75	
DATA FROM FLAKES (ACCORDING POINT 4 VERSALIS PETITION)		
PARAMETERS	VALUES FOUND	LIMITS
MOISTURE (Note 2)	<1,00	<1%
TOTAL QUOTE OF POLYOLEFINS (Note 1)	0,27	<1%
POLYAMIDE CONTENT (Note 1)	0,00	<0,5%
PRESENCE OF WOOD, PAPER, CELLULOSE	0,00	<0,5%

WASTE INFORMATION (ACCORDING TABLE 1 EN 15343)		
ORIGINS	Material type/form	PS / varius
	Product type	Trays, cups, yogurt pot
	Type of waste	Post user
	Supplier identification	See table "INFORMATION ON THE FORMS USED"
	Date (delivered in Forever Plast)	See table "INFORMATION ON THE FORMS USED"
	History of waste	No contatct with hazardous substances
LOGISTICS	Collection	Varius trasporter/Truks
	Sorting	Dedicated area
	Batch size,identification and marking	15 - 30 TON; identified location
	Pre tretment	Washing, grinding
	Storage	Outside
TEST CARRIED OUT BEFORE PROCESSING	UNI 10667-10 (on flakes)	
PROCESS PARAMETERS	See "CHECK WASHING PARAMETERS"	
TEST CARRIED OUT AFTER PROCESSING	UNI 10667-10 (on granules)	
INTENDED (SUITABLE) APPLICATION	Cold-filled yogurt;Hot-filled yogurt;Trays for meat, fish or cheese;Trays for food and vegetables;Cups for cold drinks;Cups for hot drinks	

INFORMATION ON THE FORMS USED (LOT OF BALES WITH WHICH THE FLAKE IS PRODUCED; ACCORDING TABLE 1 EN 15343)		
FORMS NUMBER	SUPPLIER IDENTIFICATION	DATE (DELIVERED IN FOREVER PLAST)
REF. 208692	SUPPLIER 1	24/07/2024
REF. 219940	SUPPLIER 2	10/09/2024
REF. 333978	SUPPLIER 3	21/10/2024
DUF 589616/2023	SUPPLIER 4	30/10/2024

VERIFICATION OF THE CONTENT OF MATERIAL SUITABLE FOR FOOD CONTACT - TEST PERFORMED ON 50Kg OF BALES
ALL THE FORMS USED ARE FOUND SUITABLE (QUATITY OF FOOD MATERIAL >=95%)

REQUIRED CHARACTERISTICS OF PLASTIC WASTE (ACCORDING EN 15347)	
BATCH SIZE	15 - 30 Ton
COLOUR	Mixed colours
FORM OF WASTE	Mixed forms
HISTORY OF WASTE	No contatct with hazardous substances
MAIN POLYMER PRESENT	Polystyrene
OTHER POLYMER PRESENT	Polyethylene, Polypropylene
PACKAGING	Pressed and strapped bales

QUOTE OF POLYOLEFINS DETECTED (ON GRANULES)		
PARAMETERS	VALUES FOUND	LIMITS
PE CONTENT (Note 1)	0,10%	N.A.
PP CONTENT (Note 1)	0,00%	N.A.
TOTAL QUOTE OF POLYOLEFINS (Note 1)	0,10%	N.A.

PRESENCE OF OTHER (VISUAL ANALYSIS ON GRANULES)		
PARAMETERS	PRESENCE	LIMITS
PRESENCE OF METALLIC SPLINTERS	N0	N.A.
PRESENCE OF WOOD, PAPER, CELLULOSE	N0	N.A.

RESULTS ON GRANULES (ACCORDING UNI 10667-10)		
PARAMETERS	VALUES FOUND	LIMITS
PS CONTENT, COMPATIBLE ELASTOMERS (NOTA3)	97,64	95% - 100%
TOTAL ASH CONTENT	2,26	0 %- 4%
IZOD	3,34	1,8Kj/m^2 - 8Kj/m^2

Note 1
THERMAL SCANNING with DSC 20°/min in NITROGEN 50ml/min
Note2
TYPICAL MOISTURE VALUE OF THE MATERIAL AT THE INLET OF THE EXTRUDER
Note 3
100-(ASH CONTENT+TOTAL POLYOLEFINS)

Annex 3 – Decontaminated PS (rPS) Lot identification

Versalis Refence PS lot consists of 100 tons of homogeneous material. The homogeneity of the product is guaranteed by continuous e repeated mixing of input flakes and mixing in homogenizing storage silos before bagging of the final Revive PS. For purpose of tracing and quality identification of Versalis Refence PS each Lot will be subject to the following actions:

• Identification with a unique tracing number,

• Identification of a sample representative of the Lot (see Paragraph 8)

Each batch of Versalis Refence PS is identified with an 11-digit alphanumeric code as described below:

Lot: AA BBBB CCCCC

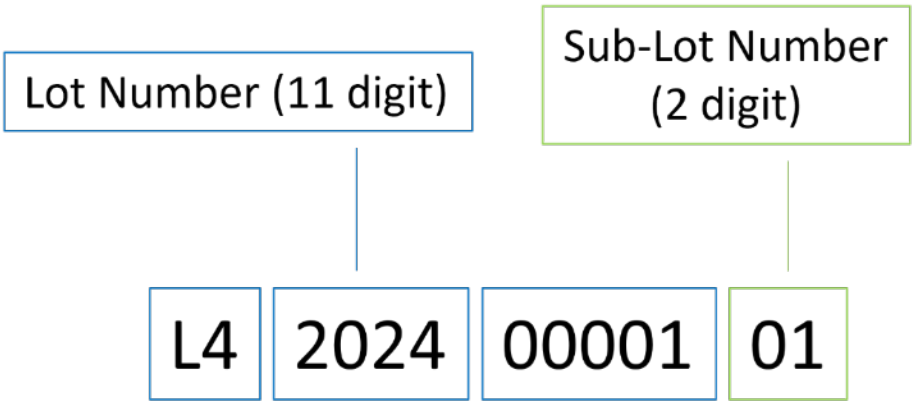
where:

AA: Foreverplast Production Line

BBBB: Year of production

CCCCC: progressive production number

In order to allow optimal management of goods handling, each lot may be further divided into sub-lots which identify the individual trucks. Below is a representation of the Lot and sub-lot:


Lot Number (11 digit)
Sub-Lot Number (2 digit)
L4
2024
00001
01

Annex 4 –Styrene and Ethylbenzene determination in input and output batches

1.0 Scope of the method

Determination of styrene and ethylbenzene amount by gas chromatographic analysis in polymer samples.

2.0 Principle of the method

The analysis is carried out according to the internal standard method by adding a known amount of cyclohexanone (internal standard) to the sample dissolved in 1:1 THF-acetone solution. The mixture is injected direct into the gaschromatograph. Styrene and ethylbenzene are identified on the chromatograph through their retention time. Their quantities are determined by comparing their areas with the area of the internal standard.

3.0 Interference

None.

4.0 Appartus

- AGILENT 8890 gaschromatograph having the following characteristics:
  - FID detector
  - Capillary column, internal diameter 0.32 – 0.50 mm, length 20 - 30 m
  - Stationary phase Carbowax 20M, film 0.4 – 1.0 µ thick
- 10 µl microsyringe

- 10 ml vials
- Device to open vials

5.0 REAGENTS

- Pure tetrahydrofuran (THF) hydroquinone stabilized.
- Pure cyclohexanone.
- Acetone pure reagent grade.
- nitrogen, hydrogen, air.
- Standard cyclohexanone in vial.

6.0 Procedure

6.1 Sample solution

Pour in a vial 0.3 - 0.4 g of sample exactly weighed; add 5 ml of standard sample (cyclohexanone solution) and weigh exactly. Calculate cyclohexanone amount in mg.

$$CY\text{-}ONE = STD \times P$$

where:

CY-ONE = cyclohexanone per g of solution

P = added solution, g

Put the vial under mechanical stirring to dissolve polymer.

6.2 Operating conditions

Set the chromatograph as follows:

- Temperature program: 90 °Cx4' – 4 °C/minute raise until 120 °Cx0'. Then 45 °C/minute raise until 200 °Cx0'.
- Chamber temperature 95 °C
- Injector temperature 220°C
- Detector temperature 240°C
- Helium (column I.D. 0.53 mm) 3 ml/min
- N2 make-up 30 ml/min
- H2 pressure 35 ml/min
- Air 350 ml/min
- Split 1:40
- Electrometer x0

6.3 Preparation of the Internal Standard Solution

Solution A preparation

Weighing on an analytical balance in a 100 ml flask, 0.5 g of propionitrile (**pPRN**) and 15 g of cyclohexanone (**pCY-ONE**). Add a solution of acetone / THF 1:1 until the volume of the flask is reached and record the final weight (**pTOT, A**).

Solution B preparation

Take about 1.5 g of solution A (**pA**) in an open vial and place it in a 1000 ml flask. Add a solution of acetone / THF 1:1 until the volume of the flask is reached and record the weight of solvent added (**pTOT, B**).

The cyclohexanone, in mg/g of solution, and and propionityle, µg/g of solution, concentrations are calculated by means of the following formulas:

$$\frac{\mu g}{g}\ \text{PRN (SOL B)} = \frac{(\text{pPRN}*1000000*\text{pA})}{(\text{pTOT,A}*\text{pTOT,B})}$$

$$\frac{mg}{g}\ \text{CY-ONE (SOL B)} = \frac{(\text{pCY-ONE}*1000*\text{pA})}{(\text{pTOT,A}*\text{pTOT,B})}$$

On the base of sample nature, it is necessary to calculate the correction factors, compared with the standard. Prepare an exactly weighed solution containing all the components usually present in the sample, in which each component has the same concentration of a typical polymer sample.

Internal standard is added and the resulting solution is injected.

The correction factors are calculated as follows:

$$CF_i = \frac{A_R}{A_i} * \frac{P_i}{P_R}$$

where:

A_r = standard peak area

A_i = i component peak area

P_i = weight of i component in the solution, g

P_r = weight of standard in the solution, g

6.4 Performance of the analysis

Sample 0,5–1.0 µl by means of a micro-syringe and inject in the gas-chromatographer.

Plot the chromatogram.

7.0 Expression of the results

The styrene or ethylbenzene content in the sample is given by the following formula:

$$X\% = \frac{P_s \cdot A_x \cdot CF \cdot 100}{A_s \cdot P_c}$$

where:

X % = Styrene or ethylbenzene amount in the polymer, %wt

A_s = standard peak area

P_s = standard weigh in solution

Pc = weight of the sample

CF = correction factor of the component

References

[1] Welle F., “Recycling of post-consumer polystyrene packaging waste into new food packaging applications-Part 1: Direct food contact,” *Recycling,* vol. 8, no. 1, p. 26, 2023.

[2] E. J. Hoekstra and et al., “Practical guidelines on the application of migration modelling for the estimation of specific migration,” *Publications Office,* 2015.

[3] E. a. W. (. F. S. A. a. W. H. Organization), «Review of the Threshold of Toxicological Concern (TTC) approach and development on new TTC decision tree,» *EFSA Supporting Publications,* vol. 13, n. 3, 2016.

[4] E. a. F. a. P. A. EFSA Panel on food contac materials, «Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food,» *EFSA Journal,* vol. 9, n. 7, 2011.

[5] R. Kroes and et al., “Threshold of toxicological concern for chemical substances present in the diet: A practical tool for assessing the need for toxicity testing,” *Food and Chemical Toxicology,* vol. 38, no. 2-3, pp. 255-312, 2000.

[6] S. J. More and et al., “Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment,” *EFSA Journal,* vol. 17, no. 6, 2019.

[7] J. Crank, The Mathematics of Diffusion, 2nd Ed. ed., Oxford: Clarendon Press, 1975, pp. 56-59.

[8] K. Ohno, “Assessment of styrene oligomers eluted from polystyrene-made food containers for estrogenic effects in in vitro assays,” *Food and Chemical Toxicology,* vol. 39, no. 12, p. 1233–1241, 2011.

[9] K. Ohyama,, F. Nagai and Y. Tsuchiya, “Certain styrene oligomers have proliferative activity on MCF-7 human breast tumor cells and binding affinity for human estrogen receptor,” *Environental Health Perspective,* vol. 109, no. 7, pp. 699-703, 2001.

[10] P. Murphy,, D. MacDonald and T. Lickly, “Styrene migration from general-purpose and high-impact polystyrene into food-simulating solvents,” *Food and Chemical Toxicology,* vol. 30, no. 3, pp. 225-232, 1992.

[11] S. Genualdi, P. Nyman and T. Begley, “Updated evaluation of the migration of styrene monomer and oligomers from polystyrene food contact materials to foods and food simulants,” *Food Additives and Contaminants-Part A,* vol. 31, no. 4, pp. 723-733, 2014.

[12] F. Welle, “Diffusion Coefficients and Activation Energies of Diffusion of Organic Molecules in Polystyrene below and above Glass Transition Temperature,” *Polymers,* vol. 13, no. 8, p. 1317, 2021.

[13] M. Kubicova, E. P. S. Säger, C. Hug, S. Hofmann e T. Simat, «Styrene-acrylonitrile-copolymer and acrylonitrile-butadiene-styrene-copolymer: a study on extractable and migratable oligomers,» *Food Additives & Contaminats: Part A,* vol. 39, n. 2, pp. 397-414, 2022.

[14] H. Yoshida e Y. K. R. Yoshida, «Anealing effect of migration of acrylonitrile monomer from styrene-acrlylonitrile copolymer,» *Sen'i Gakkaishi,* vol. 38, n. 11, pp. 45-52, 1982.

[15] V. Guazzotti, A. Ebert, A. Gruner e F. Welle, «Migration from acrylonitrile butadiene styrene (ABS) polymer: swelling effect of food simulants compared to real foods,» *Journal für Verbraucherschutz und Lebensmittelsicherheit ,* vol. 16, n. 1, pp. 19-33, 2021.

[16] A. Ferrando, G. Goffredi, P. Cantini e E. Bencini, «Identification of cis- and trans-1-phenyl-2-cyanocyclobutane in the thermal copolymerization of styrene,» *Eur. Polym J.,* vol. 32, n. 7, pp. 899-908, 1996.

[17] EFSA, «Chemical hazards,» [Online]. Available: https://www.efsa.europa.eu/en/microstrategy/openfoodtox. [Consultato il giorno 8 10 2024].

[18] T. Database, «Downloads,» [Online]. Available: https://toxtree.sourceforge.net/download.html. [Consultato il giorno 11 11 2024].

[19] E. union, «Opinion on certain aromatic hydrocarbons present in food (expressed on 20/1/1999),» [Online]. Available: https://food.ec.europa.eu/document/download/7b8ca290-dfe9-4b05-82d5-0ff8a07ab2aa_en?filename=sci-com_scf_out24_en.pdf. [Consultato il giorno 10 11 2024].