NOVEL TECHNOLOGY:

VERSALIS RECYCLED POLYSTYRENE (r-PS) DECONTAMINATION TECHNOLOGY

SUMMARY

ARTICLE 10.1

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ARTICLE 10.2

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Novel Technology summary – "Recycled Polystyrene (rPS) Decontamination Technology"
Versalis notifies the novel technology "Recycled Polystyrene (rPS) Decontamination Technology as "developer" under the Regulation 2022/1616. Recyclers using Versalis 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. 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.
The Versalis novel Decontamination Technology, thanks to a proprietary special design of some items and properly managing process parameters, as temperature, pressure and residence time, is able to clean efficiently recycled polystyrene (r-PS) and so to reduce all contaminants below the target level required for direct food application. 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 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

1. FOREWORDS

Versalis notifies the novel technology "Recycled Polystyrene (rPS) Decontamination Technology" as "developer" under the Regulation 2022/1616.

Recyclers using Versalis 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 **process parameters, design of equipment** and **process scheme** form part of Versalis intellectual property, therefore, they should be kept **confidential**.

This document has been written following the requirements for the development of a novel technology as reported in Regulation 2022/1616 with particular reference to Article 10.

Versalis points out that the present document contains confidential information owned by Versalis. These information must be not disclosed and they are included between red marked sentences.

2. CHARACTERIZATION OF THE NOVEL TECHNOLOGY (ART. 10.3.A)

Polystyrene (here below as "PS") 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 that are capable to clean the polymer to a grade that fulfils 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).

In the case of PET super-clean recycling processes, EFSA concluded that non-food PET containers should not be intentionally used as feedstock input, and that the non-food fraction should not exceed 5% of the input material (EFSA, 2011)[1]. Due to the comparable low diffusion behavior of PET and PS, the 5% value might be also applicable for PS.

For the scope of the present work 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 automatic sorting, complemented with manual sorting if required.

The typical recycling process includes the following steps:

- Step 1: Grinding of post-consumer PS into flakes followed by, purification of PS stream, hot water washing process and drying of the final flakes,
- Step 2: Melting by extrusion with degassing 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.

The Decontamination section, mentioned in step 3, is composed by…**CONFIDENTIAL INFORMATION**.
The system will works in **CONFIDENTIAL INFORMATION**.
The polymer optimal residence time to reach the required decontamination efficiency is **CONFIDENTIAL INFORMATION**

Typical food contact applications are trays and containers for yogurt, cheese, meat, fruits and vegetables, ecc.

The main final applications addressed by Versalis Novel technology are:

- 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

The storage conditions will depend on the final application and are listed in paragraph 3, b.

Versalis Novel Technology has been designed to allow rPS to be used in all food contact applications where currently it is used virgin PS material, also foamed articles.

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

As required by Art. 10.3.b, there are no relevant deviations from the requirements set out in Articles 6 (except Art. 6.1.a), 7 and 8 of the Regulation. In deviation from Art. 6(1a), the technology may be applied also to industrial waste originating only from materials and articles manufactured in accordance with Reg. 10/2011 or recycled plastic materials and articles manufactured in accordance with Reg. 2022/1616.

3. SCIENTIFIC EVIDENCE AND STUDIES ABOUT THE DECONTAMINATION TECHNOLOGY (ART. 10.3.C)

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[1] and US FDA[2]. The so-called challenge test was performed to study the efficiency of proprietary Decontamination process. All relevant process parameters as the residence time, temperature and vacuum profiles 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 the Article "Recycling of Post-Consumer Polystyrene Packaging Waste into New Food Packaging Applications—Part 1: Direct Food Contact" published by F. Welle in 2023[3]. The point c) is the core of the Novel Technology that is notified in this document and its efficiency should be evaluated respect to the minimum cleaning efficiencies calculated by Welle in the above-mentioned Article.
In details:

a) <u>Input contamination levels</u>

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[3]. Other contamination, such as microbiological or viral contamination, can be excluded because of the high temperatures used to process the polymer[3].
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 PS recyclates[3].

b) <u>Exposure scenario of the consumer</u>

The exposure scenario considered is for toddlers with 10 kg body weight (most conservative approach). The migration scenario for calculations is reported too in Welle's Article[3] and are reported in the Table below:

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

c) <u>Cleaning efficiency of the decontamination process (Novel Technology)</u>

The calculated minimum cleaning efficiencies of the recycling process for the applications and food consumption data can be taken too from Welle's Article[3] and are reported in the Table below.

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 decontamination process shall be considered as safe if the experimental decontamination efficiencies will be equal or greater than the calculated minimum cleaning efficiencies as reported above.

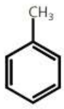
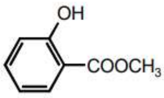
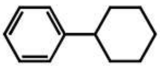
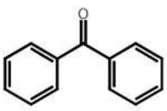
The surrogates were chosen in accordance with EU relevant criteria and US FDA recommendations such that they covered the whole spectrum of physical properties and represent the different chemical and physical properties of real-life contaminants[3,4,5,6]. The surrogates correspond with the following four categories of organic compounds:

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

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

In addition, the surrogates used in the challenge test represent a variety of functional groups in order to reflect the different chemical and physical properties of real-life contaminants e.g. aliphatic and aromatic hydrocarbons, chlorinated hydrocarbons and carbonyl functional groups.

From migration theoretical considerations, the molecular weight represents the major parameter important for the selection of the surrogates. It is well established that chemicals with a molecular weight up to approximately 300 g mol^{-1} are the most relevant ones for migration from PS. Substances with a molecular weight >300 g mol^{-1} have an extremely low migration potential due to their low diffusivity in PS.

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 pressure/temperature profiles as well as the residence times… **CONFIDENTIAL INFORMATION.**

The contamination procedure and the analyses of the real quantities of surrogates added are reported in Attachment 1 “Fraunhofer IVV test report”. The decontaminated polymer samples were sent to Fraunhofer Institute for analyses of residual surrogates. The results are reported in test report, Attachment 1 “Fraunhofer IVV test report”.

The same decontamined polymer samples have been also analyzed by Mantova Research Center Analytical Chemistry Laboratory, finding results in accordance with the report in Attachment 1 “Fraunhofer IVV test report”. This is the evidence that the labs are perfectly aligned.

The cleaning efficiency of the process for each of the applied surrogates, was calculated according to Equation 1.

$$\text{Eq. 1: } Cleaning\ efficiency = \left(1 - \frac{surrogate\ concentration\ after\ recycling}{surrogate\ concentration\ before\ recycling}\right) 100\%$$

The data, reported into Attachment 1 “Fraunhofer IVV Test Report” and compared to 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 Technology.
Therefore, the experimental observations deriving from the challenge test are as follow are:

- the lower the pressure into the decontamination vessel, the greater the decontamination efficiency
- the diffusivity of each species decreases as the molecular weight increases; the higher the temperature of the molten polymer, the greater the diffusivity of the contaminants to be removed
- for obtaining high efficiencies it is necessary to manage the melt polymer flow rate and residence time inside the decontamination system to decrease the contaminants concentration.

The combination of temperatures and residence times ensures efficient decontamination of the polystyrene without degrading it (i.e., not appreciable reduction in molecular weight).

As explained above, the applied residence times, temperatures and vacuum conditions are essential for the cleaning efficiency. Therefore, these parameters are controlled and logged by a data system… **CONFIDENTIAL INFORMATION.**

4. DESCRIPTION OF TYPICAL RECYCLING PROCESS USING THE TECHNOLOGY (ART. 10.3.D)

As already mentioned, the typical 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 technology)**
- Step 4: polymer melt feeding system to rPS filtration and pelletizing system

A scheme of the recycling process is shown in the Figure below… **CONFIDENTIAL INFORMATION.**

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

Regarding the input material, a control and management system will be adopted to ensure that 95% of the input material is constituted by PS originated from food packaging.

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 sorting of waste starts from waste bales, which consist of articles from household waste. Due to a first sorting step at municipalities, these waste bales contain mainly PS articles. At the recycling facility, 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 a 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 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 below (PS non-food < 5%).

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

5. SUITABILITY OF THE RECYCLING TECHNOLOGY AND COMPLIANCE WITH THE RELEVANT PROVISIONS ON FOOD CONTACT MATERIALS AND ARTICLES

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

- The recycling process and the novel technology thereof is 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.

6. DIFFERENCES FROM EXISTING TECHNOLOGIES (ART. 10.3.E)

The technology has not been subject to a decision on its suitability. Due to the state of the implementation of Regulation 2022/1616, the extent to which it differs from any other technology cannot been known at the time of the notification.

According to our knowledge, currently there is no rPS grade suitable for direct food contact; this technology overcomes this limit, allowing the use up to 100% rPS in food packaging (direct contact).

7. SUMMARY OF EVALUATION CRITERIA (ART. 10.3.F)

Proposed evaluation criteria for decontamination section are the following process parameters… **CONFIDENTIAL INFORMATION.**

These parameters will be reported in the compliance monitoring summary sheet established in accordance with Article 26 of Regulation (EU) 2022/1616.

8. LIST OF DECONTAMINATION INSTALLATIONS (ART. 10.3.G)

The first Versalis Decontamination system, at full scale level, is currently under Engineering Procurement & Construction (EPC) phase. The recycler Forever Plast S.p.A. will install the above mentioned industrial equipment in its factory, located in via IV Novembre, 58/C – 25030 Lograto (BS), by July 1st 2024.

The present novel technology is quite flexible in terms of flowrate.
Equipment with nominal capacity from 500 kg/h to 7000 kg/h will be proposed to the market.

References

1. EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids). 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 J. 2011, 9, 2184.

2. https://www.fda.gov/FoodGuidances - Use of Recycled Plastics in Food Packaging (Chemistry Considerations): Guidance for Industry, July 2021

3. 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

4. Points to Consider for the Use of Recycled Plastics in Food Packaging: Chemistry Considerations, US Food and Drug Administration, Center for Food Safety and Applied Nutrition, (HFF-410), 1992, 200 C Street SW, Washington, DC 20204; internet: URL: http://vm.cfsan.fda.gov/~dms/opa-cg3b.html [July 2000]

5. Guidance for Industry: Use of Recycled Plastics in Food Packaging: Chemistry Considerations. HFS-275, Washington, DC: US Food and Drug Administration, Center for Food Safety and Applied Nutrition, 2006

6. Guidelines for the Safe Use of Recycled Plastics for Food Packaging Applications, Plastics Recycling Task Force Document, National Food Processors Association, The Society of the Plastic Industry, Inc., 1995

ATTACHMENT 1: FRAUNHOFER IVV TEST REPORT