NOVEL TECHNOLOGY:
VERSALIS RECYCLED HIGH-DENSITY POLYETHYLENE (r-HDPE) DECONTAMINATION TECHNOLOGY

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Novel Technology summary – "Recycled High-Density Polyethylene (r-HDPE) Decontamination Technology"
Versalis notifies the novel technology "Recycled High-Density Polyethylene (r-HDPE) Decontamination Technology" as "developer" under the Regulation 2022/1616. Recyclers using Versalis novel technology will produce pellets of decontaminated r-HDPE suitable to be used in food packaging applications in direct contact with food, according to the application-specific recycled content limits supported by the safety evaluation shown in the following. High-density polyethylene is a well-suited material for mechanical recycling, however recycling in food contact applications requires a validated process able to fulfil EFSA requirements for recycled plastics in direct food contact.

The notified technology comprises the melt-decontamination step and the associated melt-transfer, control, monitoring, diversion and segregation functions required to ensure that only material processed within the validated operating window may be designated for food-contact use. Collection, sorting, grinding, washing and drying are upstream pre-treatment operations and remain mandatory prerequisites governed by a quality-assurance system. Melt filtration, extrusion, pelletizing and any downstream post-treatment shall be operated under documented conditions that do not compromise the validated decontamination performance.

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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 high-density polyethylene (r-HDPE) and so to reduce contaminants below the target level required for the intended direct food contact applications, when used according to the application-specific recycled content limits defined. The input material consists of HDPE objects (mainly bottles and closures/caps) from separate collection (e.g. curbside), so called post-consumer HDPE. A high share of food contact HDPE is obtained by the selection of the proper source and 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 HDPE into flakes followed by an intensive washing process and drying; an optional flake-sorting step can be used to improve flake quality.
- ✓ Step 2: Melting by extrusion with degassing of such r-HDPE 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 r-HDPE filtration and pelletizing system.

1. FOREWORDS

Versalis notifies the novel technology "Recycled High-Density Polyethylene (r-HDPE) Decontamination Technology" as "developer" under the Regulation 2022/1616.

Recyclers using Versalis Novel technology will produce pellets of decontaminated r-HDPE suitable to be used in food packaging applications in direct contact with food, according to the conditions of use and maximum recycled content justified by the evaluation.

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 originally contains confidential information owned by Versalis. This confidential information have been omitted and replaced by confidentiality placeholders.

2. CHARACTERIZATION OF INPUT MATERIAL

The input to the Novel Decontamination Technology consists of washed and dried post-consumer High-Density Polyethylene (here below as "HDPE") flakes derived from materials and articles manufactured in accordance with applicable EU food-contact legislation. Eligible feedstock includes mono-material HDPE bottles and closures/caps previously used for food contact. The feedstock shall originate from qualified and traceable sources.

The assessment covers input materials derived from HDPE articles obtained from separate collection of municipal waste, including UK milk-bottle streams.

Representative articles include bottles, mainly milk bottles, and caps from PET bottles.

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So, the present assessment covers:

- ✓ HDPE bottles, mainly milk bottles, derived from UK separate collection of municipal waste.
- ✓ HDPE caps and closures, mainly from PET bottles, derived from separate collection of municipal waste.

For post-consumer HDPE derived from UK milk-bottle streams, EFSA stated that the sorting process results in at least 99 % of HDPE bottles having been previously used in food applications[ii].

For mechanically recycled PET, EFSA has concluded that non-food PET containers should not be intentionally introduced into the input and that the non-food fraction should not exceed 5% (EFSA, 2011)[i]. This PET-specific benchmark can be transferred to HDPE caps that are derived from PET bottles. So, the present notification applies the consideration that for HDPE caps derived from municipal separate-collection streams, more than 99% HDPE shall be compliant with Regulation (EU) No 10/2011 and more than 95% food-contact articles shall be contained.

Compliance shall be demonstrated through source qualification, sorting performance, sampling and documented quality controls.

Table 1 summarizes the feedstock characteristics for each collection scenario (i.e: HDPE closures and caps derived from separate collection of municipal waste and HDPE bottles, mainly milk bottles, derived from UK separate collection of municipal waste), in particular with regards to the proportion of HDPE food-contact articles.

Type of collection	**Example of food-contact articles**	**Content of food-contact articles (%)**
UK separate collection of municipal waste	bottles, mainly milk bottles	>99%
Separate collection of municipal waste	Caps and closures, mainly from PET bottles	>95%

Table 1: *Feedstock characteristics for different collection scenario.*

For post-consumer HDPE derived from UK milk-bottle streams, EFSA used a reference contamination level of 0.5 mg/kg[ii]. As the present assessment encompasses also food-contact HDPE input streams derived from HDPE caps and closures from separate collection of municipal waste, an initial contamination level of 3 mg/kg was additionally considered for this stream. In fact EFSA used 3 mg/kg as reference contamination level in the input of a PET recycling process[i] so, as a pragmatic approach, the same input concentration has been assumed for the safety evaluation of HDPE recyclates derived from caps and closures, as the source of the waste is the same of the one considered for PET recycling.

The safety conclusions and maximum recycled-content percentages are therefore application-specific and depend on the selected initial contamination assumption.

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The input material to the Novel Decontamination Technology is produced from waste bales or qualified HDPE streams. After initial sorting at municipalities or qualified sorting facilities, the material is sorted at the recycling facility using near-infrared (NIR) and/or other sorting technologies, integrated with manual sorting where necessary, to remove metals, non-HDPE polymers and other foreign materials. The selected HDPE articles are shredded or ground into flakes, subjected to density separation where applicable, hot washed, rinsed, and mechanically and thermally dried. An optional flake-sorting step may be included after washing and drying to further remove non-target materials and improve the purity of the HDPE flake stream. These operations remove labels, adhesives, dirt, product residues, non-target materials and other surface contaminants, yielding washed, dried and, where applicable, flake-sorted HDPE flakes suitable for the subsequent melt-decontamination step.

In case of caps derived from PET bottles recycling, the steps of sorting, shredding and hot washing are usually managed together for caps and bottles, separation between the polyolefin material and PET are then made by gravity after washing. The polyolefin flakes so separated and dried can be further purified through flakes sorting in order to improve the flakes quality, suitable for the subsequent melt-decontamination step.

The approved input specification to the Novel Decontamination Technology defines acceptance limits for polymer composition, food-contact origin, moisture, foreign materials, visible contamination and evidence of misuse. PVC, PET, PP, PS, polyamide, multilayer structures, metals, paper, wood, labels, adhesives and other foreign materials are controlled by documentary review, sorting and, where appropriate, analytical verification. Each delivery is uniquely identified and traceable to its collection or aggregation source and is subject to documentary verification, visual inspection and a statistically justified sampling plan. Non-conforming deliveries are rejected, segregated or subjected to an approved corrective treatment. The washed and dried flakes to be fed to the Novel Decontamination Technology shall comply with the approved input specification, reported in Table 2:

Parameter	value
PE content	>99%
Moisture	<1%
PP content	<1%
PET content	<1%
PS content	<0.5%
PVC content	<0.5%
Polyamide content	<0.5%

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Metals content	<0.1%
Wood, paper, cellulose	<0.5%

Table 2: *Input specification to the Novel Decontamination Technology.*

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

HDPE is a well-suited material for mechanical recycling, however recycling in food contact applications is challenging and requires 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 of r-HDPE in food packaging for direct contact applications according to the conditions and maximum recycled content supported by the safety evaluation.

The overall typical recycling process includes thus the following steps:

- ✓ Step 1 (pre-treatment): Grinding and purification of the post-consumer HDPE stream, followed by hot washing, rinsing and drying of the flakes; an optional flake-sorting step can be used to improve flake quality.
- ✓ Step 2 (pre-treatment): Extrusion melting with degassing and melt filtration.
- ✓ **Step 3 (Novel Decontamination Technology based on Versalis proprietary design): Decontamination of the polymer melt.**
- ✓ Step 4 (post-treatment): Transfer of the decontaminated polymer melt to final filtration and pelletizing.

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

Typical food contact applications where the decontaminated HDPE could be used are milk bottles, beverage closures/caps, containers and trays for dairy products, beverages, meat, fruits and vegetables, and other solid or liquid food applications under the conditions supported by the safety evaluation.

The main final applications addressed by Versalis Novel technology are:

- ✓ milk bottles;
- ✓ closures/caps for mineral water bottles;
- ✓ closures/caps for softdrink bottles;
- ✓ packaging for solid and liquid food, refrigerated storage;
- ✓ packaging for solid and liquid food, short-term room temperature storage;
- ✓ other HDPE food contact articles subject to application-specific evaluation.

Application case “closures/caps for softdrink bottles” is of reference also for caps/closure for any other liquid food/beverage bottles, given the daily food consumption as referred in paragraph 4.

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The storage conditions and the maximum recycled content allowed in the relevant packaging are listed in paragraph 4 and will depend on the input material and the selected final application.

Versalis Novel Technology has been designed to allow r-HDPE to be used in food contact applications where HDPE is currently used as virgin material, within the application-specific recycled content limits demonstrated by the safety evaluation.

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.

4. 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 Versalis' r-HDPE Decontamination Technology. The cleaning efficiency was experimentally verified with tests performed into an appropriate pilot scale set-up, using virgin HDPE intentionally contaminated with high concentrations of model substances (surrogates) according to the principles recommended by European Guidelines[i] and US FDA[iii]. 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' r-HDPE Decontamination Technology.

Regarding point a), i.e. the contamination level of recycled HDPE flakes before the decontamination process, a specific initial contamination level is defined for each feedstock scenario considered in this assessment. The selected values are derived from available EFSA reference criteria[ii], relevant scientific literature[iv] and conservative assumptions intended to account for the expected variability of the input streams.

The point b) is based on the EFSA criteria established for post-consumer HDPE milk bottles, mineral water bottle caps, and soft-drink bottle caps[i,v]. Additional scenarios were considered according to the specific applications of interest to the applicant.

The point c) is the core of the Novel Technology that is notified in this document, and its efficiency should be evaluated with respect to the minimum cleaning efficiencies calculated for the intended applications.

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

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generated during recycling. Other contamination, such as microbiological or viral contamination, can be excluded because of the high temperatures used to process the polymer[vi].
Regarding the contamination level of recycled HDPE flakes prior to the decontamination process, the following assumptions have been considered:

- 0.5 mg/kg, in accordance with the EFSA reference contamination level established for post-consumer r-HDPE for the UK milk bottle scenario[i];
- for HDPE caps and closures, mainly from PET bottles, derived from separate collection of municipal waste, a conservative initial contamination level of 3 mg/kg has been considered. In fact, regarding the input contamination in recycled HDPE flakes before decontamination processes, scientific literature studies on misuse or contamination levels from substances from the first use of the package are rare. In the absence of a robust determination for HDPE, considering also that these HDPE articles originate from the same collection, sorting, and recycling streams as post-consumer PET bottles, the utilization 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 HDPE recyclates.

b) Exposure scenario of the consumer

The exposure scenarios considered are presented in Table 3. Specifically, the table includes the following applications and associated contact conditions:

- ✓ milk bottles (15 days at 5 °C);
- ✓ closures for mineral water bottles (365 days at 25 °C);
- ✓ closures for soft-drink bottles (365 days at 25 °C);
- ✓ packaging for solid and liquid foods (40 days at 6 °C);
- ✓ packaging for solid and liquid foods (10 days at 20 °C).

To develop a more general approach, some scenarios have been evaluated at a certain Maximum Storage Time and Temperature, based on different food consumption per day.

For each exposure scenario, Table 3 reports the specific application, the concentration of potential contaminants in input (which depends on the selected input to the Novel Decontamination Technology, as indicated in point a)), the geometrical characteristics used in modelling, the reference consumer group and corresponding body weight, the daily food consumption, the exposure threshold expressed as the maximum allowable migration level, and the maximum estimated migration level calculated using an overestimation factor of 2.

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Application	Concentration of potential contaminants in input	Geometrical characteristics used in modelling	Specific Food Consumption per Day	Reference consumer group	Daily Food Consumption	Maximum Storage Time and Temperature	Exposure (Maximum Migration Value)	Maximum Migration with Overestimation Factor 2
Milk bottles	0.5 mg/kg	1 L package; 6 dm² internal surface	90 g/ kg bw day	Toddler	-	15 d at 5 °C	0.03 µg/kg[i]	**0.06 µg/kg[i]**
Closures for mineral water bottles	3 mg/kg	1 L bottle; closure inner surface area 3.2 cm²; closure thickness 1250 µm	260 g/ kg bw day	Infant / 5 kg bw	1300 ml/day	365 d at 25 °C	0.0095 µg/kg	**0.019 µg/kg**
Closures for softdrink bottles	3 mg/kg	1 L bottle; closure inner surface area 3.2 cm²; closure thickness 1250 µm	80 g/ kg bw day	Toddler / 12 kg bw	960 ml/day	365 d at 25 °C	0.0313 µg/kg	**0.0626 µg/kg**
Packaging for solid and liquid food — refrigerated	3 mg/kg	1 L package; 6 dm² internal surface; wall thickness 300 µm	80 g/ kg bw day	Toddler / 12 kg bw	960 ml/day	40 d at 6 °C	0.0313 µg/kg	**0.0626 µg/kg**
Packaging for solid and liquid food — refrigerated	3 mg/kg	1 L package; 6 dm² internal surface; wall thickness 300 µm	29.2 g/ kg bw day	Toddler / 12 kg bw	350 ml/day	40 d at 6 °C	0.086 µg/kg	**0.171 µg/kg**
Packaging for solid and liquid food — refrigerated	3 mg/kg	1 L package; 6 dm² internal surface; wall thickness 300 µm	20.8 g/ kg bw day	Toddler / 12 kg bw	250 ml/day	40 d at 6 °C	0.120 µg/kg	**0.240 µg/kg**

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Application	Concentration of potential contaminants in input	Geometrical characteristics used in modelling	Specific Food Consumption per Day	Reference consumer group	Daily Food Consumption	Maximum Storage Time and Temperature	Exposure (Maximum Migration Value)	Maximum Migration with Overestimation Factor 2
Packaging for solid and liquid food — short-term ambient	3 mg/kg	1 L package; 6 dm^2 internal surface; wall thickness 300 µm	80 g/ kg bw day	Toddler / 12 kg bw	960 ml/day	10 d at 20 °C	0.0313 µg/kg	**0.0626 µg/kg**
Packaging for solid and liquid food — short-term ambient	3 mg/kg	1 L package; 6 dm^2 internal surface; wall thickness 300 µm	29.2 g/ kg bw day	Toddler / 12 kg bw	350 ml/day	10 d at 20 °C	0.086 µg/kg	**0.171 µg/kg**
Packaging for solid and liquid food — short-term ambient	3 mg/kg	1 L package; 6 dm^2 internal surface; wall thickness 300 µm	20.8 g/ kg bw day	Toddler / 12 kg bw	250 ml/day	10 d at 20 °C	0.120 µg/kg	**0.240 µg/kg**

Table 3: *Exposure scenarios considered in the present document. The evaluated scenarios include different contaminants concentrations in input, different daily food consumption, different applications and relevant associated contact conditions.*

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	MW (Da)	Milk Bottle - 0.5 mg/kg Toddler	Closures for mineral water - 3 mg/Kg Infant 5 kg	Closures for softdrinks - 3 mg/Kg Toddler 12 kg	Packaging for solid and liquid food, 40 days at 6 °C (960 ml - Toddler 12 kg) - 3 mg/kg	Packaging for solid and liquid food, 40 days at 6 °C (350 ml - Toddler 12 kg) - 3 mg/kg	Packaging for solid and liquid food, 40 days at 6 °C (250 ml - Toddler 12 kg) - 3 mg/kg	Packaging for solid and liquid food, 10 days at 20 °C (960 ml - Toddler 12 kg) - 3 mg/kg	Packaging for solid and liquid food, 10 days at 20 °C (350 ml - Toddler 12 kg) - 3 mg/kg	Packaging for solid and liquid food, 10 days at 20 °C (250 ml - Toddler 12 kg) - 3 mg/kg
toluene	92	98.98%	98.33%	94.50%	99.87%	99.65%	99.51%	99.88%	99.66%	99.52%
chlorobenzene	113	98.80%	98.33%	94.50%	99.86%	99.63%	99.48%	99.88%	99.66%	99.52%
limonene	136	98.58%	98.33%	94.50%	99.85%	99.59%	99.42%	99.87%	99.65%	99.50%
phenyl cyclohexane	160	98.34%	98.33%	94.50%	99.83%	99.54%	99.35%	99.86%	99.63%	99.47%
benzophenone	182	98.08%	98.33%	94.49%	99.81%	99.47%	99.26%	99.85%	99.60%	99.43%
butyl salicylate	194	97.92%	98.33%	94.48%	99.79%	99.44%	99.21%	99.84%	99.57%	99.40%
methyl palmitate	271	96.76%	98.19%	94.02%	99.68%	99.12%	98.77%	99.77%	99.37%	99.12%
DEHA	371	94.60%	97.44%	91.54%	99.47%	98.54%	97.96%	99.62%	98.96%	98.54%
TEHTM	548	88.34%	94.54%	81.96%	98.85%	96.86%	95.59%	99.18%	97.76%	96.85%
Uvinul T150	823	68.46%	85.21%	51.13%	96.89%	91.51%	88.08%	97.78%	93.93%	91.48%

Table 4: *Calculated minimum cleaning efficiencies of the recycling process required for the scenarios listed in Table 3.*

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

The calculated minimum cleaning efficiencies of the recycling process required for the applications and food consumption data have been calculated by Fraunhofer-Institute IVV and are reported in Table 4.

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. 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 a major parameter important for the selection of the surrogates. The high molecular weight substances were the most challenging substances for the investigated super-clean recycling process. Therefore, the selected surrogate set includes substances from 92.1 g/mol up to 823.1 g/mol, covering volatile and non-volatile, polar and non-polar substances relevant for HDPE evaluation.

Substance	Mw (g/mol)	Functional groups	Properties
Toluene	92.1	Aromatic hydrocarbon	Volatile, non-polar
Chlorobenzene	112.6	Aromatic hydrocarbon, halogen-containing	Volatile, polar
Limonene	136.2	Aliphatic hydrocarbon	Volatile, non-polar
Phenylcyclohexane	160.3	Aromatic hydrocarbon	Low volatility, non-polar
Benzophenone	182.2	Aromatic ketone	Low volatility, polar
Butyl salicylate	194.2	Aliphatic ester	Non-volatile, non-polar
Methyl palmitate	270.5	Aliphatic ester	Non-volatile, medium-polar
Diethylhexyl adipate (DEHA)	370.6	Aliphatic ester	Non-volatile, medium-polar
Tris(ethylhexyl) trimellitate (TEHTM)	546.8	Aromatic ester	Non-volatile, medium-polar
Ethylhexyl triazone (Uvinul T150)	823.1	Aromatic ester	Non-volatile, medium-polar

Table 5: *Surrogates used in the challenge test, representing a variety of functional groups, different polarities and volatile/non-volatile behavior.*

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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 analysis of residual surrogates. The results are reported in test report, Attachment 1 "Fraunhofer IVV test report". Data referred to sample 14, Sample 23A and Sampe 23B are representative of the above-defined process parameters.

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 in Attachment 1, "Fraunhofer IVV Test Report", and compared with the minimum required cleaning efficiencies, demonstrate that the Novel Technology, as Versalis r-HDPE Decontamination Technology, is capable of efficiently decontaminating post-consumer r-HDPE, reducing contaminants to levels below the target concentrations established for the evaluated direct food-contact applications in the scenario referred to the application "Closures for soft drinks". For applications for which the target level is not fully achieved, the recycled material may nevertheless be used at a proportion not exceeding the application-specific recycled content derived from the assessment and reported in Attachment 1. This limitation ensures that the relevant migration and exposure criteria are met.
These results therefore demonstrate the suitability of the Novel Decontamination Technology for the intended applications within the corresponding application-specific limits.
Therefore, the experimental observations deriving from the challenge test are as follows:

- ✓ 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 vacuum, temperatures and residence times ensures efficient decontamination of the high-density polyethylene without causing unacceptable degradation of the polymer properties (i.e., not appreciable variation in molecular weight nor in melt index and density).

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

The maximum recycled content for the different scenarios reported above have been calculated by Fraunhofer-Institute IVV and are summarized in Table 6.

Application	Concentration of potential contaminants in input [mg/kg]	Storage Conditions	Food Consumption (g/kg bw day)	Maximum Recycled Content (%)
Milk bottles	0.5	15 days at 5 °C	90	83%

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Application	Concentration of potential contaminants in input [mg/kg]	Storage Conditions	Food Consumption (g/kg bw day)	Maximum Recycled Content (%)
Closures for mineral water	3	365 days at 25 °C	260	39%
Closures for soft drinks	3	365 days at 25 °C	80	100%
Packaging for solid and liquid food	3	40 days at 6 °C	80	8%
Packaging for solid and liquid food	3	40 days at 6 °C	29.2	22%
Packaging for solid and liquid food	3	40 days at 6 °C	20.8	32%
Packaging for solid and liquid food	3	10 days at 20 °C	80	6%
Packaging for solid and liquid food	3	10 days at 20 °C	29.2	16%
Packaging for solid and liquid food	3	10 days at 20 °C	20.8	23%

Table 6: *Maximum recycled content for the different scenarios listed in Table 3.*

The evaluations reported in Table 6 show that, once the relevant conditions of use are fixed — namely contact time, contact temperature, food type or simulant, reference consumer group, polymer thickness, diffusion assumptions and initial contamination level — the maximum recycled content may be treated as a parametric variable depending on the daily food consumption.
In particular, for the same reference consumer group, the same decontamination performance (i.e. same process parameters of the decontamination device), the same initial contamination level, the same food-contact conditions and the same wall thickness, the migration and the resulting recycled content in the final article scale with the daily food consumption associated with the relevant consumer scenario.

Therefore, the maximum allowable recycled content derived for one reference scenario reported in Table 6 may be extrapolated to the same application, when characterized only by a different daily food consumption, provided that the relevant use conditions remain equivalent.

Under these assumptions, the following proportionality can be applied:

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$$RC_{max,ref} \times C_{ref} = RC_{max,new} \times C_{new}$$

where:

- ✓ $RC_{max,ref}$ is the maximum recycled content validated for reference scenario and reported in Table 6; it must be lower than 100%;
- ✓ C_{ref} is the daily food consumption assumed for the consumer scenario in the reference condition, reported in Table 3;
- ✓ $RC_{max,new}$ is the maximum recycled content to be calculated for the same reference scenario but with a different daily food consumption;
- ✓ C_{new} is the different daily food consumption assumed for the consumer scenario in the same reference condition.

Consequently, the maximum recycled content applicable to a scenario characterized by a daily food consumption C_{new} can be calculated as the minimum between 100% and the application of the previous correlation, i.e.:

$$RC_{max,new} = MIN\left(100\%;\ RC_{max,ref} \times \frac{C_{ref}}{C_{new}}\right)$$

The correlation allows the maximum recycled content to be adjusted in a transparent way as a function of the daily food consumption.

The above correlation should be regarded as a conservative scaling approach. Its use is appropriate only when the same polymer, the same decontamination process, the same contaminant profile, the same initial contamination assumption, the same contact conditions and the same wall thickness are maintained.

Hereafter a calculation example:

Reference scenario (last case of table 6):

Food Consumption (g/kg bw day): 20.8 (C_{ref})
Maximum recycled content: 23% ($RC_{max,ref}$)

New scenario:

Application: Packaging for solid and liquid food
Concentration of potential contaminants in input [mg/kg]: 3
Storage Conditions: 10 days at 20 °C
Food Consumption (g/kg bw day): 41.6 (500 g/day for a 12 kg toddler) (C_{new})

Maximum recycled content for new scenario :

($RC_{max,ref}$)=23% x (20.8 / 41.6) = 11.5 %

Furthermore it can be noted that daily assumption is connected to the specific typology of food. As a general approach we may refer to 95th percentile consumption as per EFSA Food Consumption Database (available online: https://www.efsa.europa.eu/en/data-report/food-consumption-data).

Such database is constantly updated with new surveys; as reference, in the below Table 7 we report the updated data for some food typology.

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Chronic Food Consumption Grams per day (g/day) - Consumers only EFSA Food Consumption Database*		Toddlers**
Milk and dairy products	Dairy dessert and similar	200 gr/day
Milk and dairy products	Fermented milk or cream	337 gr/day
Milk and dairy products	Cheese	166 gr/day
Coffee, cocoa, tea and infusions	Hot drinks and similar (coffee, cocoa, tea and herbal infusions)	354 gr/day
Fruit and fruit products	Processed fruit products	151 gr/day

*EFSA Food Consumption Database. Available online: https://www.efsa.europa.eu/en/data-report/foodconsumption-data .

** Food consumption considered: the maximum of 95th percentile with regards to the following Countries: Italy (survey 2017, 2018), Germany (survey 2006,2007), France (survey 2014), Spain (survey 2012, 2013), Belgium (survey 2002), Netherland (survey 2012), Portugal (survey 2015).

Table 7: *Food Consumption per day as calculated based on 95th percentile consumption as per EFSA Food Consumption Database.*

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Hereafter we report a calculation example related to the consumption of “Processed fruit products”:

Reference scenario (sixth case of table 6):

Food Consumption (g/kg bw day): 20.8 (C_{ref})
Maximum recycled content: 32% ($RC_{max,ref}$)

New scenario:

Application: Packaging for solid and liquid food
Concentration of potential contaminants in input [mg/kg]: 3
Storage Conditions: 40 days at 6 °C
Food Consumption (g/kg bw day): 12.6 (151 g/day for a 12 kg toddler) (C_{new})

Maximum recycled content for new scenario :

($RC_{max,ref}$)=32% x (20.8 / 12.6) = 52.8 %

5. 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 (pre-treatment): Grinding and purification of the post-consumer HDPE stream, followed by hot washing, rinsing and drying of the flakes; an optional flake-sorting step can be used to improve flake quality.
- ✓ Step 2 (pre-treatment): Extrusion melting with degassing and melt filtration.
- ✓ **Step 3 (Novel Technology based on Versalis proprietary design): Decontamination of the polymer melt.**
- ✓ Step 4 (post-treatment): Transfer of the decontaminated polymer melt to final filtration and pelletizing.

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

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

For each production batch, representative input samples to the Novel Decontamination Technology and output samples produced with the Novel Decontamination Technology shall be collected according to a written sampling plan. Samples should be sealed and combined into representative batch composites. Each delivery shall be uniquely identified and traceable to the collection or aggregation source. Acceptance shall include documentary verification, visual inspection and a statistically justified sampling plan.

Regarding the input material, a control and management system will be adopted to ensure that the input material to the Novel Decontamination Technology is constituted by HDPE originating mainly from food packaging.

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The control plan shall cover, as applicable: polymer composition, non-food articles, PP, PET, PS, PVC and PA content, metals, paper/cellulose/wood, moisture and evidence of misuse. Non-conforming deliveries shall be rejected, segregated or subjected to an approved corrective treatment.

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 or qualified HDPE streams, which consist of articles from household waste and/or food contact streams. Due to a first sorting step at municipalities or at qualified sorting facilities, these waste streams contain mainly HDPE articles. At the recycling facility, the HDPE waste is fed into a transport belt, where metals and non-HDPE-containing articles (such as PET, PP, PS, PVC, paper, multilayer articles, etc.) are sorted out by standard near infrared (NIR) technology and/or other sorting technologies. This sorted HDPE stream is then sent to the shredder, which reduces the size of the articles to flakes. The following steps comprise typically density separation and hot washing, followed by rinsing. After the washing step, the flakes are mechanically and thermally dried to reduce the residual moisture to the limit established in the approved input specification. Optionally, a flake-sorting step can be used to improve flake quality.

In case of caps derived from PET bottles recycling, the steps of sorting, shredding and hot washing are usually managed together for caps and bottles, separation between the polyolefin material and PET are then made by gravity after washing. The polyolefin flakes so separated and dried can be further purified through flakes sorting in order to improve the flakes quality, suitable for the subsequent melt-decontamination step.

The HDPE flakes shall comply with the approved input specification.

Regarding the output material, a control and management system will be adopted to ensure the quality of the produced material. Routine internal controls shall include, as applicable, volatile screening, color, melt-flow rate or viscosity, moisture and pellet quality. Periodic testing by competent external laboratories shall include non-targeted screening covering volatile, semi-volatile and non-volatile. The monitoring frequency shall be justified by feedstock variability, process capability and trend data and shall be increased following deviations or changes.
Known substances detected in output shall be assessed with respect to Regulation (EU) No 10/2011, restrictions or scientifically justified toxicological thresholds. Unknown substances detected in output shall be treated as measured residual concentrations and compared with an appropriate modelled or toxicological threshold. Recurrent unknowns shall trigger identification work and source investigation.

6. 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 are capable to reduce the migration of potential contaminants from post-consumer HDPE to concentration levels which are in compliance with Article 3 of Regulation (EC) 1935/2004 for the evaluated applications and recycled content limits.
- ✓ 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.

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

The technology has not been subjected 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 the availability of r-HDPE grades suitable for direct food contact is very limited; this technology allows the use of r-HDPE in food packaging (direct contact) under the evaluated conditions.

8. 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.

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

The first Versalis Decontamination system for r-HDPE, at full scale level, will be listed in this section when the installation details are finalized. The recycler, site address, nominal capacity and implementation date will be communicated when available.

The present novel technology is quite flexible in terms of flowrate.
Equipment with nominal capacity from 500 kg/h to 5000 kg/h will be proposed to the market.

References

[i] 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.

[ii] Scientific Opinion on the safety assessment of the processes 'Biffa Polymers' and 'CLRrHDPE' used to recycle high-density polyethylene bottles for use as food contact material, EFSA J. 2011; 13(2):4016.

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

[iv] F. Welle, Recycling of post-consumer HDPE bottle caps into new caps for food contact, Recycling, 2025, 10(6), 197; https://doi.org/10.3390/recycling10060197.

[v] Scientific Guidance on the criteria for the evaluation and on the preparation of applications for the safety assessment of post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food, EFSA J. 2024, 22, 8879.

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

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ATTACHMENT 1: FRAUNHOFER IVV TEST REPORT

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