Technical dossier for the Veolia Plastics rHDPE recycling process to produce recycled high-density polyethylene intended to be used for the manufacture of materials and articles in contact with food

Recycling process name: Veolia Plastics rHDPE

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1. Administrative data

1.1. Applicant information

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Recycling process name:	Veolia Plastics rHDPE
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1.2. Public summary

The Veolia Plastics rHDPE recycling process is designed to transform post-consumer HDPE packaging previously used for food back into food contact HDPE, referred to as rHDPE, using decontamination technology that remove contaminants that may be incidentally introduced into HDPE from its previous use or during collection and sorting processes.

The main decontamination step involves heating washed HDPE flakes in a vacuum chamber to just below the melting temperature of HDPE to degassing and allow for the escape of volatile substances, over a period of time.

The overall decontamination efficiency of both steps has a high efficacy, as demonstrated by a challenge test using surrogate materials representing a wide variety of chemical properties.

Figure 1: Schematic of the decontamination technology
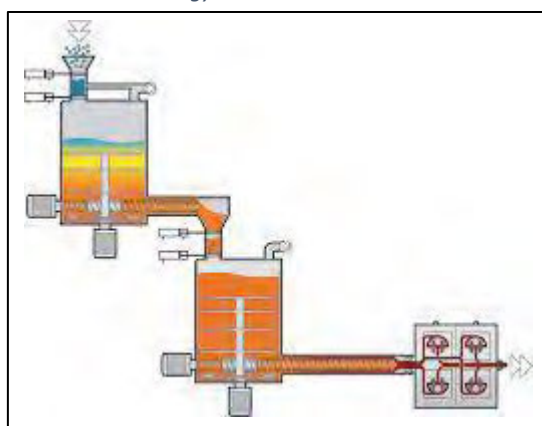
The full recycling process begins with the collection of post-consumer waste from kerbside collections or recycling schemes. Recycling collections are sorted at MRFs or PRFs which purify recyclates producing high purity HDPE bales. HDPE bales are received at the Veolia Plastics recycling facility which are then sorted further using automated bottle sorting technology and purified to a nominal 99% food-use HDPE packaging using manual sorting.

The sorted materials are granulated and washed using a hotwash process, combined with caustic soda and surfactants to remove residues and adhered labels. A sink float system is incorporated which allows the efficient removal of objects with densities greater than 1 g/cm^3, providing a high purity HDPE washed flake material. The washed flakes are sorted further to remove coloured closures, leaving a natural-coloured flake for the decontamination process.

The feedstock for the decontamination process has been characterised for both physical and chemical properties to understand the performance requirements needed for the decontamination process for the intended use of manufacturing HDPE milk bottles. The harmful contamination observed in washed HDPE flakes has been calculated to be less than 0.024 mg/kg, determined by a large GC-MS solvent extraction survey of approximately 200,000 flakes combined with the statistical approach of Principal Component Analysis.

The coupling of the reference contamination rate of 0.024 mg/kg and the decontamination efficiency allows for the concentration estimation of low abundance substances which cannot be identified by conventional analytical methods. Migration modelling has been employed to provide a severe over estimation of migration for the milk bottle application. Considerations have also been made for toddler scenarios where infants consume a relatively high volume of milk relative to their body mass.

NIAS testing on rHDPE included both headspace and organic exhaustive extraction identification and quantification by GC-MS.

The safety criteria used for the safety evaluation of the Veolia Plastics rHDPE process is based on the Threshold of Toxicological Concern (TTC) approach, with the genotoxic exposure threshold of 0.0025 µg/kg bw/day being the critical target to be sure there is negligible risk to both adult and toddler consumers.

2. Technical dossier

2.1. Recycling process

2.1.1. Process flow chart

Figure 2: Veolia Plastics process flow diagram

2.1.2. Short written process description

2.1.2.1. Input materials

Materials received from suppliers are inspected visually before accepting the material, to ensure it is of an appropriate polymer type and purity. Each input batch received from a supplier is uniquely identifiable and further purity assessments performed.

2.1.2.2. Material sorting

At the recycling facility, input batches of HDPE have a further sorting step. The method of sorting is by positively selecting white and natural HDPE using a ▮▮▮▮▮ NIR-visible bottle sorter, followed by hand-picking removal of non-food HDPE materials. The objective of the material sorting process is to achieve

a high purity accept stream for the next manufacturing stage, where at least 99% of the HDPE is food packaging (99% food grade HDPE), and that the remaining balance of material is post-consumer material manufactured with food grade HDPE resins.

[REDACTED]

[REDACTED]

2.1.2.4. Washing

A washing process is essential for the recycling of post-consumer packaging, to wash off labels and surface residues of its previous use or incidental contamination from the collection and sorting processes. The HDPE flakes are washed using a solution of sodium hydroxide, detergent, and antifoam. The washing cycle has a controlled concentration of additives, throughput, residence time and temperature to provide a consistent washing quality.

Following the wash, the flake is separated from solution up an inclined auger, which falls into a friction separator, which spins off residual wash solution, pulped papers, and fines. After the friction separator the is one final rinsing step which has a counter current flow of water to rinse off residues.

The rinsed flakes then pass through a large sink-float tank where HDPE flakes will float, and higher density polymers or impurities will sink. When the HDPE flake reaches the end of the sink-float tank it is separated off the surface into another drying unit purposed for water removal.

[REDACTED]

[REDACTED]

2.1.2.6. Decontamination

The decontamination process used at Veolia Plastics is a Vacurema Advanced manufactured by Engineering Recycling Maschinen und Anlagen GmbH, also known as EREMA. There are three decontamination unit installations.

The principle of the decontamination process is to heat HDPE flake under vacuum using friction from internal stirring paddles in one chamber (referred to as the KT), then cascading the pre-heated flakes into another chamber (referred to as the reactor) with tight temperature and residence time control under vacuum. [REDACTED]

[REDACTED]

The Vacurema includes a melt degassing section under vacuum which allows semi-volatiles to be extracted from the molten HDPE. After degassing, the melt passes through a filter to remove contaminants which do not melt under the extruder conditions such as foils, then is pelletised.

2.1.3. Detailed process description

2.1.3.1. Input materials

Materials received from suppliers are inspected visually before accepting the material, to ensure it is of an appropriate polymer type and purity. Each input batch received from a supplier is uniquely identifiable and further purity assessments performed. At least 10 kg of each input batch is sampled and categorised to determine the approximate concentration of HDPE packaging, and how much of the HDPE packaging was previously used for food purposes. The data collected is used to evaluate supplier performance and ensure that the material sorting process is adequately resourced to achieve the target accept purity. Further detail on the source of the materials is provided in Section 2.2.1.

Figure 3: HDPE input bale labelled with a unique identifier

2.1.3.2. Material sorting

At the recycling facility, input batches of HDPE have a further sorting step. The method of sorting is by positively selecting white and natural HDPE using a ▇▇▇▇ NIR-visible bottle sorter, followed by hand-picking removal of non-food HDPE materials. The objective of the material sorting process is to achieve a high purity accept stream for the next manufacturing stage, where at least 99% of the HDPE is food packaging (99% food grade HDPE), and that the remaining balance of material is post-consumer material manufactured with food grade HDPE resins.

Food packaging would include, but not limited to:

- Milk bottles
- Milkshake bottles
- Chewing gum tubs
- Ice cream containers
- Yoghurt drink bottles
- Vitamin bottles

- Fruit juice bottles
- Vinegar containers
- Salt bottles
- Pancake powder bottles
- Hot chocolate powder bottles
- Weight gain powder containers

Figure 5: Examples of food use and non-food use HDPE packaging

Food use HDPE	Non-food use HDPE

For the hand sorting method, prior use of material is identified either by the labels, the definitive package shape or other printed decoration. Throughput speeds are set accordingly to the purity of inputs into the sorting stage, the target purity out of the sorting stage, and the number of personnel available to remove the appropriate quantity of non-food HDPE packaging.

The purified HDPE stream then moves on to the granulation step, with the rejected fraction being sent to a bunker for baling, which is no longer used by the Veolia Plastics food grade recycling process.

Figure 7: Rejected material from the sorting process, rich in non-food HDPE items

The purity of the accept material is assessed frequently to ensure the purity is meeting the minimum target of 99% food grade HDPE. Two methods of assessment are used, where there is a frequent, hourly assessment by counting the number of non-food articles exiting the manual sorting step over 5 minutes to estimate the non-food concentration, and a 10 kg physically sorted sample performed daily. A measurement system study has been performed to determine the equivalence of the two test methods, where correction factors such as article mass and detection rate are applied to the count method to estimate the purity. The higher frequency of testing provides information on the stability of the quality out of the sorting process and prompting corrective action.

Figure 8: HDPE articles following automated and manual sorting step, which is sampled frequently to determine its composition

In general, the sorting processes available at the recycling facility can purify a 90% food grade HDPE stream to 99% food grade HDPE at 3 tonnes per hour, with additional precautions available such as reducing throughput or feedstock blending to remove or dilute non-food HDPE items from feedstocks.

In accordance with EU Regulation No. 2023/2006 on Good Manufacturing Practises (GMP), corrective action plans are available and initiated to address non-conformances, which outlines how to manage and correct non-conforming materials.

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███

Figure 13: Unwashed HDPE flakes entering the washing process

2.1.3.7. Washing

A washing process is essential for the recycling of post-consumer packaging, to wash off labels and surface residues of its previous use or incidental contamination from the collection and sorting processes. The washing process installed at the recycling facility was manufactured and installed by ████████████████████, world leaders in recycling solutions.

The HDPE flakes are washed using a solution of sodium hydroxide, detergent, and antifoam. The washing cycle has a controlled concentration of additives, throughput, residence time and temperature to provide a consistent washing quality. The washing conditions to produce cleaned HDPE flakes are:

- ████████% sodium hydroxide (w/w)
- Washing temperature of ██████ °C
- Residence time of ████████ minutes.

The detergent and antifoam are used within the washing process to improve the cleaning performance. Such washing additives are used within the food industry processed which the addition rate has been optimised for the recycling process. In theory, washing additives can be altered so long as the cleaning performance is satisfactory, which can be assessed by colour measurement of outputs and chemical residue analysis by GC-MS. The additives currently in use at Veolia Plastics are:

████████████████████████████
████████████████████████████

The essential monitoring parameters in line with GMP are:

- Sodium hydroxide strength
- Detergent dosage
- Residence time
- Temperature
- Water consumption
- Throughput rate
- Hotwash blowdowns

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Following the wash, the flake is separated from solution up an inclined auger, which falls into a friction separator, which spins off residual wash solution, pulped papers, and fines.

After the friction separator the is one final rinsing step which has a counter current flow of water to rinse off residues.

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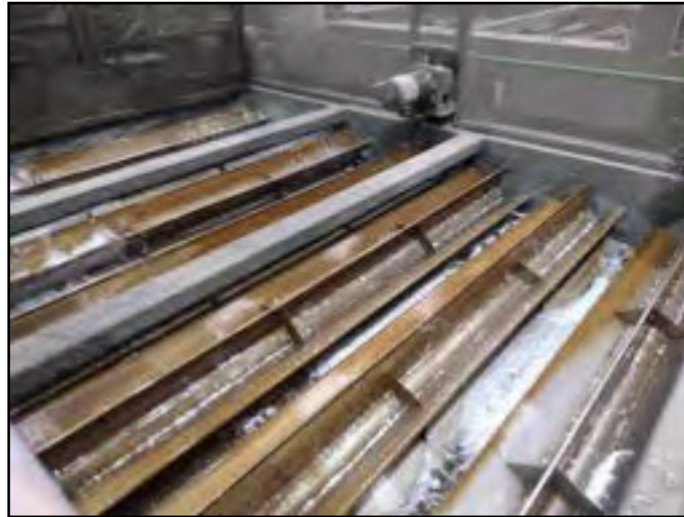████████████████████████████████████

Figure 16: Rinsing unit

The rinsed flakes then pass through a large sink-float tank where HDPE flakes will float, and higher density polymers or impurities will sink. Paddles gently move the flakes across the surface of the water, with resubmerging with each rotation to maximise separation.

Figure 17: Sink floatation tank

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Figure 19: HDPE washed flakes

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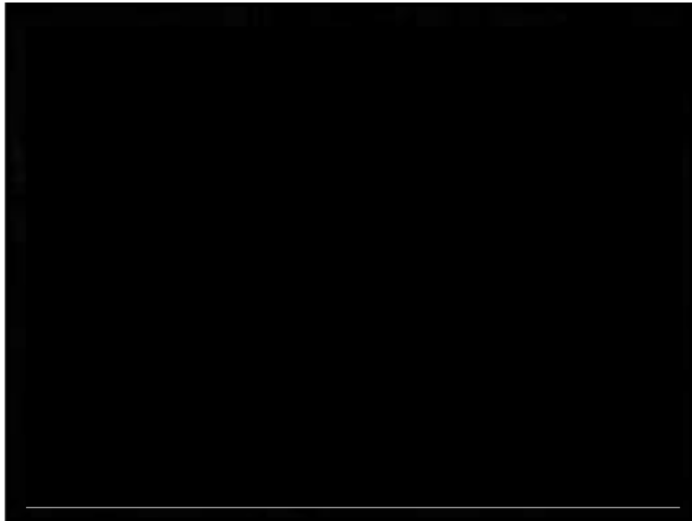
Figure 21: Coloured HDPE flake by-product

[image: coloured HDPE flakes]

Figure 22: Washed and sorted HDPE flakes

[image: washed and sorted HDPE flakes]
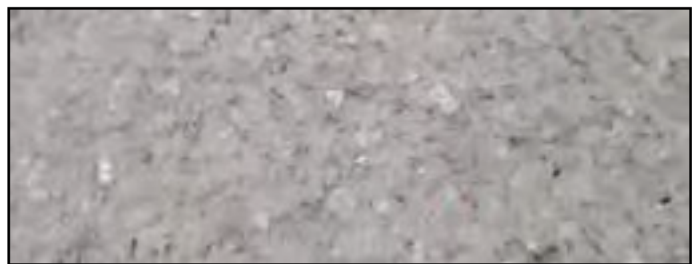
2.1.3.9. Decontamination

The decontamination process used at Veolia Plastics is a Vacurema Advanced manufactured by Engineering Recycling Maschinen und Anlagen GmbH, also known as EREMA. There are three decontamination unit installations, one Vacurema 1716 TE and two Vacurema Advanced 1716 TE systems. The principal differences between the two models are software-based, where the Vacurema

1716 TE was installed in 2008 and the Vacurema Advanced 1716 TE systems were installed in 2013/2014.

Figure 23: Vacurema 1716 TE, installed in 2008

The principle of the decontamination process is to heat HDPE flake under vacuum using friction from internal stirring paddles in one chamber (referred to as the KT), then cascading the pre-heated flakes into another chamber (referred to as the reactor) with tight temperature and residence time control under vacuum. ███

Figure 24: Schematic of the Vacurema 1716 TE system
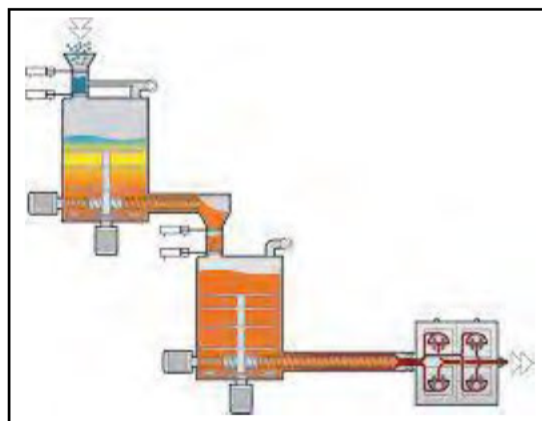
The Vacurema includes a melt degassing section under vacuum which allows semi-volatiles to be extracted from the molten HDPE. After degassing, the melt is passed through a filter to remove contaminants which do not melt under the extruder conditions such as foils, then is pelletised. The pelletisation occurs directly on the die face, with immediate cooling and transportation in water. The pellets are approximately 5 mm in diameter, with a height of 2 mm. The pellet is dewatered across a

vibrating table, then finally a centrifuge. The throughput rate of the process is automatically measured by the Vacurema weigh scales before being sent to the product storage vessel.

The Vacurema systems have online monitoring of temperature, pressures, motor loading and weight scales, so that it can self-regulate to achieve the target parameters optimised to manufacture food contact rHDPE. The essential operating parameters are:

- KT temperature
- KT pressure
- KT fill (loading)
- Reactor temperature
- Reactor pressure
- Reactor fill (loading)
- ███████████████████████
- Degassing temperature
- Degassing pressure
- Throughput rate

Other essential operating parameters for quality aspects are:

- Melt filter pressures
- Melt filter specifications
- Water bath temperature

Due to the online monitoring of the Vacurema, alarms will activate if parameters are outside of tolerance, and additional to that, it will automatically divert material away from recipe compliant storage vessels.

There are also sampling valve attached to the end of the Vacurema process which take a small portion of the output frequently, approximately 50 g every 4 minutes, which a composite sample is taken hourly for quality control testing.

Figure 25: Output recycled HDPE pellets

2.2. Characterisation of the input

2.2.1. Material sources

Materials for the recycling process come from two primary of sources. The plastic waste typically originates from municipal waste or other food businesses where it was only intended and used for contact with food.

When originating from municipal sources, it is subject to separate collection from any other waste, or it is collected with other recycled fractions of municipal waste containing plastic, metal, paper, or glass. The municipal collection businesses are licensed waste operators which have accredited quality assurance systems to make sure the collection system is not likely to contain hazardous substances and that the collection of waste, and its sorting processes, minimise the contamination of plastics under its custody.

Each waste operator or carrier has a legal duty to record the movement of waste materials between collection, treatment, or storage sites, and that they have authorisation from regulators to treat or sort the materials subject to a permit, which also provides a system of traceability of the source at the first stage of sorting after collection. To balance the need of traceability and the commercial sensitivity of the suppliers of a MRF or PRF, the quality system requires a declaration from its suppliers, stating:

- that they operate a system of traceability where the source of inputs to generate its outputs are known;
- that the sources are only from municipal waste, deposit return schemes, or from food retail, or other food businesses where it was only intended for contact with food;
- if originating from a municipal source, it is collected separately from any other waste, or it is collected with other recycled fractions of municipal waste;
- should its suppliers provide sorted wastes from unsorted municipal collections or non-food businesses, that it has procedures in place to prevent its inclusion into the recycled material supplied to the recycling facility.

Recyclate collections are sorted at MRFs or PRFs by automatic sorting into single streams of recyclable materials. MRFs will take comingled recyclates and separate materials in different material types typically being plastic, metals, paper, and glass. MFRs may also sort plastics in a similar operation to PRFs, where plastics are separated into polymer type and colour, and some instances where food packaging and non-food packaging are separated.

HDPE food packaging is manufactured according to EU Regulations No. 1935/2004 and 10/2011, and EU Directive 94/62/EC. Based on a survey of HDPE producers and converters, nearly all HDPE resins used for packaging applications comply to EU regulations and directives.

The quality assurance system has the requirement of assessing its suppliers prior to the reception of goods. Assessments include certification to ISO 9001 quality management system requirements, environmental permit, or waste broker or dealer licence if necessary.

Scrap materials from manufacturers of HDPE packaging would also be a suitable material source. Input materials would not include materials from outside the category of food packaging. For example, automotive plastics, chemical containers, waste electrical and electronics plastics would not be included as these may contain significant levels of additives unsuitable for food contact applications.

Food use HDPE containers from deposit return or recycling schemes would be a suitable input source for the recycling process. Given the nature of such collection systems, the incidental contamination of the packaging would be very low in comparison to conventional municipal collections. As such, washing processes using materials from deposit schemes could be made more resource efficient, with a potential to lower the sodium hydroxide strength and washing temperature.

2.2.2. Sorting process input materials

Materials received from suppliers are visually inspected before accepting the material, to ensure it is of an appropriate polymer type and purity. Each input batch received from a supplier is uniquely identifiable and further purity assessments performed. At least 10 kg of each input batch is sampled and categorised to determine the approximate concentration of HDPE packaging, and how much of the HDPE packaging was previously used for food purposes. The data collected is used to evaluate supplier performance and ensure the material sorting process is adequately resourced to achieve the target accept purity.

The recycling facility originally had the ability to recycle comingled HDPE and PET, however the facility currently focuses on the use of pre-sorted HDPE inputs. Some of the suppliers of HDPE have different sorting strategies therefore it is not always appropriate to have a single specification for input material. There is a generic target specification of HDPE required, such as approximate concentrations of natural, white, and coloured HDPE as examples, as well as suitable bale size and packing. Frequent suppliers have individual specifications designed during the supplier evaluation phase, to determine the typical quality consistency.

There are procedures in place that if the input batch does not meet the expected requirements of the supplier, that the batch is visually and physically quarantined to prevent its inadvertent use, then the batch is either returned to the supplier, or suitably treated to meet the minimum requirement of 99% food grade HDPE with extra resourcing or precautions.

The food packaging is typically used in contact with oily and fatty foods. There will be substances found in virgin plastic packaging when it is produced, which should already be at acceptable levels for food contact applications in accordance with EU Regulations No 10/2011. Such intentionally and unintentionally added substances could be:

- Oligomers from polymerisation of propylene
- Antioxidants and their breakdown products
- Lubricants
- Pigments
- Stabilisers

Non-food HDPE packaging largely consists of laundry bottles and personal care bottles, such as shower gel and shampoo bottles. Input material types to avoid include those from outside post-consumer packaging, for example, automotive plastics, chemical containers, and construction plastics.

2.2.3. Sorting process input material history

Between January 2021 and June 2022, the average natural and white food use HDPE measured entering the recycling facility was 90.4%. Natural and white HDPE packaging from non-food uses represents approximately 6.2% of the feedstock, which calculates that 93.6% of natural and white bottles are food-use HDPE packaging.

Figure 28: Graphic of the average composition of materials supplied to Veolia Plastics
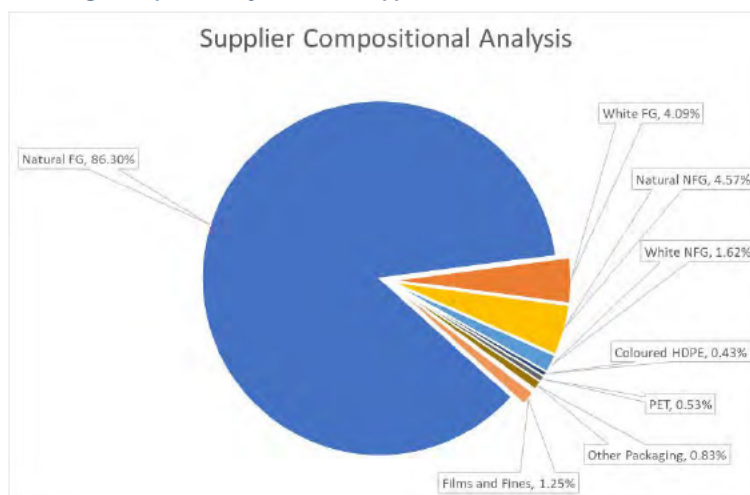

Table 1: Average composition of materials supplied to Veolia Plastics

Category	% (w/w)
Natural FG	86.30%
White FG	4.09%
Heavy Food FG	0.01%
Natural NFG	4.57%
White NFG	1.62%
Misuse FG	0.01%
Coloured HDPE	0.43%
Carbon Black HDPE	0.02%
PET	0.53%
Other Packaging	0.83%
Other Non-packaging	0.16%
Ferrous	0.05%
Non-ferrous	0.14%
Films and Fines	1.25%

2.2.4. Washing process input material history

Between January 2021 and June 2022, involving over 300 analyses of 10 kg samples, the average food use proportion of the natural and white fractions of inputs into the washing process was 98.6%. The proportion of food use is simply the mass of natural and white food use HDPE containers divided by the mass of all natural and white HDPE containers. Non-natural and non-white HDPE items are excluded from the food use fraction calculation as there are recycling process steps incorporated to remove those fractions, such as a sink-float tank to remove metals and sinking polymers, and flake colour sorting to remove coloured HDPE. Identifying if a natural or white HDPE flake was from food or non-food is extremely difficult, hence why food use measurements are made on bottle forms. There are other indirect means of estimating food use purity such as the melt flow rate of pellets, where the recycling facility does not adjust the melt flow values significantly away from those of milk bottle grades, which are around 0.7 g/10 min, where those used in non-food blow moulding applications are approximately 0.4 g/10 min.

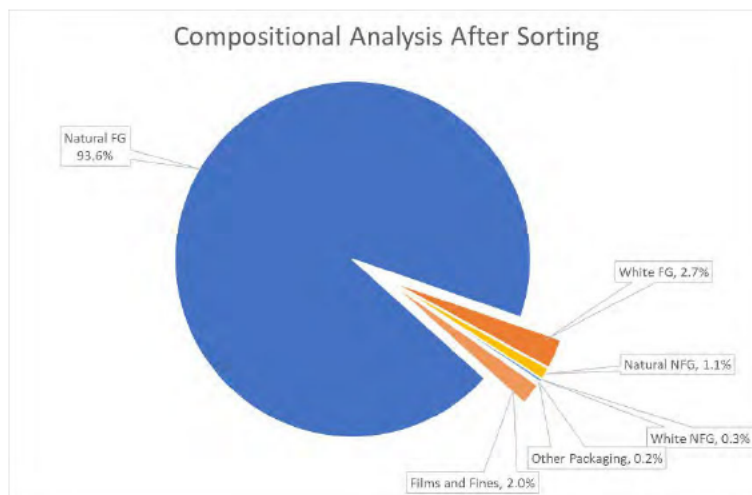*Figure 29: Graphic of the average composition of materials after the Veolia Plastics sorting process*

Table 2: Average composition of materials after the Veolia Plastics sorting process

Category	% (w/w)
Natural FG	93.6%
White FG	2.7%
Heavy Food FG	0.0%
Natural NFG	1.1%
White NFG	0.3%
Misuse FG	0.0%
Coloured HDPE	0.0%
Carbon Black HDPE	0.0%
PET	0.0%
Other Packaging	0.2%
Other Non-packaging	0.0%
Ferrous	0.0%
Non-ferrous	0.0%
Films and Fines	2.0%

There is a misuse FG category for analysis, for recording instances of misuse on HDPE bottles. Identifiable cases of misuse are those which appear contaminated internally with non-milk substances, such as paint. Between January 2021 and June 2022, a total of 0.4955 kg was placed into the misuse FG category from 14,194 kg of samples from bale suppliers, resulting in a rate of 0.0035% or 1 in 28,500 bottles prior to the sorting process. In the same period, no misuse bottles were found in 3,532 kg of samples following the sorting process. This suggests that the misuse rate could be as low as 0.001% or 1 in 100,000 (one 35 g misuse bottle in 3,500 kg of samples).

As well as a weighed sample of HDPE to measure the portion of HDPE into the washing process, there is also a more frequent counting measurement of non-food use natural and white containers into the washing process. The measurement system has been developed to enable more frequent assessments of purity. The counting method has been found to require a multiplication factor on the number of non-food bottles counted within 5 minutes along with an average mass of a non-food use bottles estimated. The multiplication factor currently applied is 3.8 and 48 g per bottle, with standard throughput of 3,000 kg/hr and an incoming food use purity of 90%.

Between February 2021 and June 2022, when the count method was introduced, the average food use HDPE purity is assessed to be 99.0%. During this period there have been nearly 3,800 assessments made.

Figure 30: Chart of the purity of HDPE following the Veolia Plastics sorting process assessed by counting the number of non-food bottles observed in 5 minutes
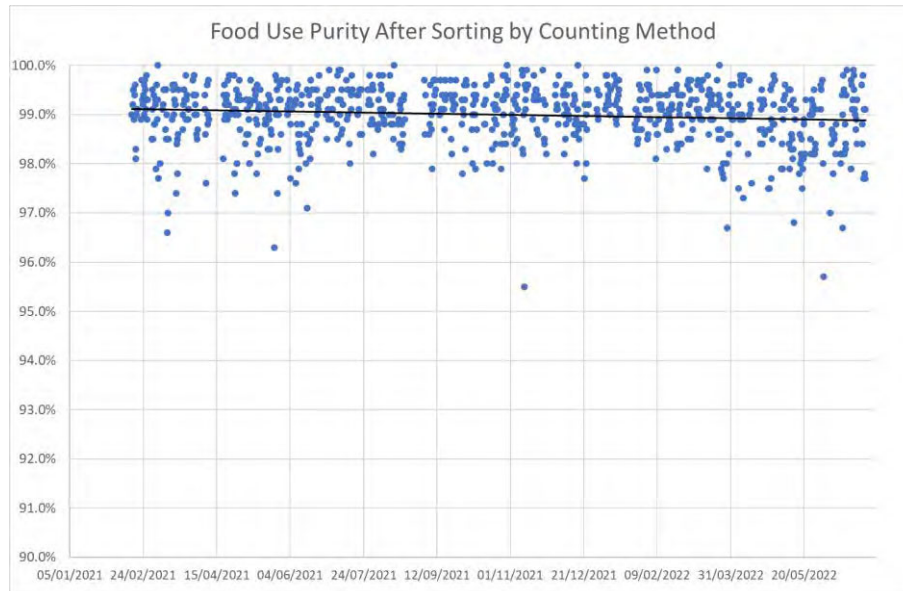
An individual batch of recycled HDPE will consist of many food use purity count assessments, where the average value of the manufacturing period will represent the entire batch. The target purity for a batch is greater than 99% food use (less than 1% non-food use) for the intention of producing a milk bottle manufactured from 100% recycled HDPE; the essential property being that the milk bottle does not contain more than 1% material from non-food use HDPE. Restrictions on the blending of recycled HDPE with virgin HDPE are placed on the output batches if the 99% purity is not achieved as a control measure. For example, if the purity was calculated to be 98%, the blend is limited to no more than 50% with virgin HDPE, resulting in the final milk bottle containing no more than 1% material from non-food use HDPE. Figure 31 shows the average purity of individual batches, where the blend usage is currently restricted to a standard of 40% rHDPE for customers, resulting in the lower limit of 97.5% for food use purity.

Figure 31: Average of the individual purity assessments made for each output batch of rHDPE
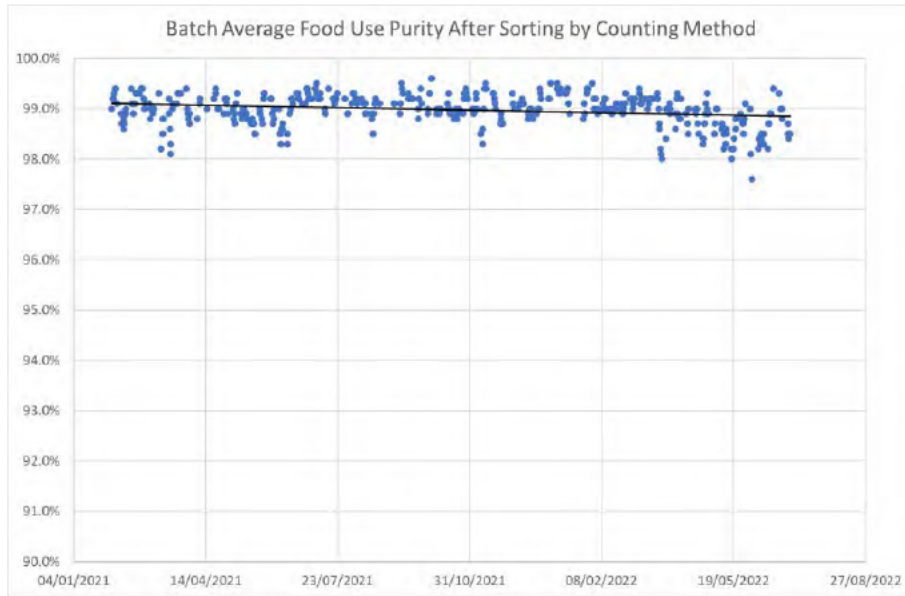
2.2.5. Decontamination process input materials

The dried washed flakes are subjected to flake sorting process steps to purify the flake so that at least 99% of the flakes are HDPE. ██████████████████████████████████████ ██ ████████████████████ The volatile contamination content, specifically limonene, of the flake entering the decontamination process is evaluated at least once every 30 tonnes.

2.2.6. Decontamination process input material history

2.2.6.1. Flake composition

Based on sampling data of HDPE flakes entering the decontamination process, 99.6% of the flakes entering are either natural or white HDPE, with or without adhered labels. The proportion of adhered labels is approximately 2.2%, where approximately 20% of the mass is label, resulting in 0.6% label residue overall. The washing process is effective at removing inks from labels, therefore unlaminated labels appear white the flake colour sorters. The amount of ink residues traversing to the decontamination process is low for the case of adhered labels, although some adhesive layers evidently still enter the decontamination process.

Figure 32: Graphic of the composition of washed HDPE flakes
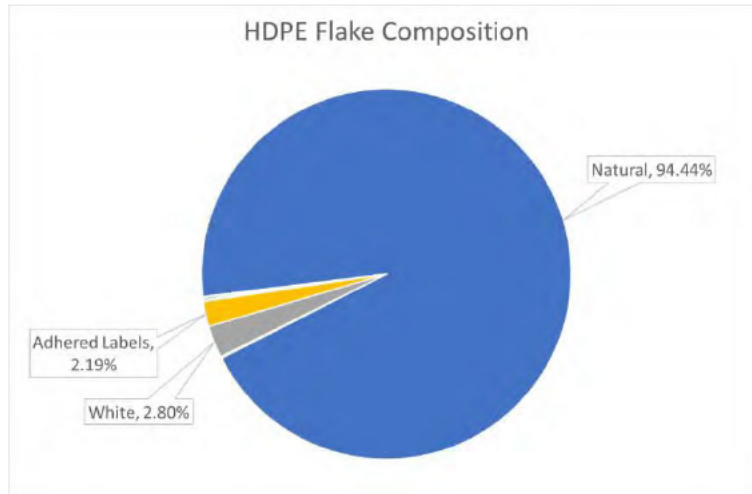
Table 3: Table of the composition of washed HDPE flakes

Category	% (w/w)
Natural	94.44%
Coloured	0.14%
White	2.80%
Adhered labels	2.19%
Loose labels	0.16%
Flake with glue	0.18%
Carbon black	0.01%
Foil	0.01%
Film	0.02%
Others	0.04%

2.2.6.2. Flake properties

Table 4: Typical properties of HDPE flakes

Property	Value
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2.2.6.3. Chemical contaminants

Substances may be introduced into the HDPE materials at various stages of its lifetime. It will begin with the manufacture of polyethylene packaging resins where additives, designed predominantly for food applications may be added. The manufacture of articles may also introduce substances in the form of processing aids or NIAS from addition of other recycled materials.

Once the container has been filled with the product, either food or non-food, the migration process begins, for both packaging substances migrating to the product, and the product migrating to the packaging. The consumer is likely to dispose of the container once the product has been consumed, however there could be an occasion where the consumer may find an alternative use for the container before disposing of it, providing an opportunity of packaging being contaminated with an unexpected substance.

Municipal collection, handling and sorting systems provide the opportunity for residues of one recyclable container to encounter other containers, potentially transferring contaminants. Washing aids are used to clean the materials in a recycling facility in a solution which will wash many millions of flakes giving the opportunity of leaving a residue on each flake passing through the system.

Finally, the materials from a decontamination process will be melt filtered and extruded at temperatures which may see degradation products formed, especially from additives such as antioxidants.

Figure 33: Sources of contamination
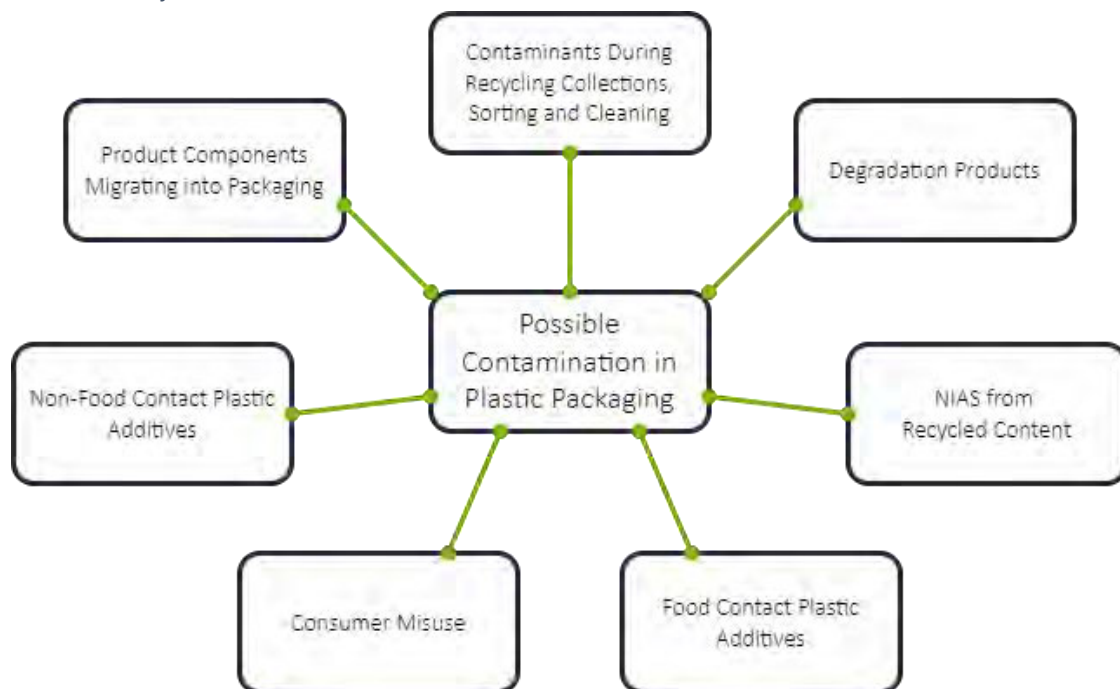
The majority of contamination entering the decontamination stage is controlled by effective sorting of materials and the washing stage, removing the bulk of non-food contact containers and washing away the surface residues of previous use or incidental contamination. Annex 1 provides detail on some ingredients found in non-food use packaging, which may be present within the washed flake since sorting systems are not 100% effective. A significant proportion of HDPE packaging found in supermarkets is used for storage of either food products, personal care cosmetic products or home cleaning products, with some uses found in garden and pest control products. The cosmetic goods are

a range of leave-on or wash-off products meaning the cosmetic goods will need to be safe for consumer use in the first instance therefore generally low risk through the decontamination process.

The ingredients of the non-food products are generally in the TTC classifications of Cramer Class I, II and III. There are substances observed fitting the organophosphate and carbamate classes. When surveying non-food product ingredients, no ingredients were found to be considered as carcinogenic and however there are ingredients labelled as toxic to reproduction or currently under investigation for endocrine disrupting properties. Such ingredient found to be reprotoxic was tebuconazole identified in a slug pellets HDPE bottle, with butyl methoxydibenzoylmethane found in suncream, and methylparaben found in a skin moisturiser HDPE bottle which are currently being assessed for endocrine disrupting properties. Hence, non-food use bottles are removed from the sorting process with great emphasis on garden or pest control products.

2.2.6.4. Reference contamination level

A reference contamination level for an unknown contaminant potentially present in the input of a PET recycling process was based on experimental data of an EU survey, the FAIR-CT98-4318 project (Franz, 2004). In this survey, performed in the framework of a European project, thousands of collected PET bottles were examined. Post-use residual substances were identified and quantified, and the level (severity) and the frequency of misused bottles were determined. For HDPE, Fraunhofer IVV carried out a survey based on the same approach as the FAIR project with the exception that it was carried out in the UK only (Welle, 2005) which is described in Annex 2. In each survey, the headspace of 600 to 700 conventionally recycled flake samples of PET and HDPE were analysed by GC-FID. The analytical data obtained was interpreted by the use of Principal Component Analysis (PCA), to identify statistical outliers within a large data set.

For the HDPE study, Fraunhofer IVV identified a single outlier sample and the investigation concluded that there were 2 unknown substances with approximate concentrations of 130 and 40 mg/kg for the sample containing 50 flakes. It had been assumed that a single flake contributed to the amount observed in the sample, therefore the contamination within the single flake was calculated to be up to 6,500 mg/kg. The number of flakes sampled by GC-FID for the entire study was estimated to be 24,000. Because 2 unknown substances were identified in 24,000 flakes, the misuse rate was extrapolated to 2 in 24,000, resulting in a rate of 0.008% of bottles. The reference contamination for HDPE was used by EFSA by multiplying the concentration of the unknown 6,500 mg/kg by the misuse rate of 0.008%, generating a contamination reference of 0.5 mg/kg for the CLRrHDPE and Biffa Polymers safety assessments.

Veolia Plastics performed a similar study to that performed by Fraunhofer IVV over two periods, 2018 and 2021, detailed in Annex 4. In these studies, GC-MS was adopted rather than GC-FID, which allowed for identification of substances observed in chromatograms which was not possible for the Fraunhofer IVV studies without using standards. Additional to this, solid phase extraction using tetrahydrofuran was used instead of measuring the volatiles by headspace. This provides further information on semi volatile substances that may be present in washed HDPE flakes.

Because recycled plastics are evaluated against carcinogenic and mutagenic TTC criteria of 0.0025 µg/kg bw/day, the aim of the study was to identify if such class of substances exist within the HDPE washed flakes. This is believed to add additional information not available in surveys for PET and HDPE, where substances like toluene, xylene, limonene and dodecane which are Cramer Class I substances, are used to set a carcinogenic reference.

The study was performed on HDPE washed flakes sampled from the Veolia Plastics process used to manufacture rHDPE. Between December 2017 and August 2018, 93 washed flake samples were extracted and analysed, then a further 40 samples were Between March 2021 and June 2021. The entire study represented approximately 200,000 flakes or items of packaging.

Using the same approach as Fraunhofer IVV, retention time windows were established, and abundances summed for each window.

Figure 34: Retention time windows of chromatograms
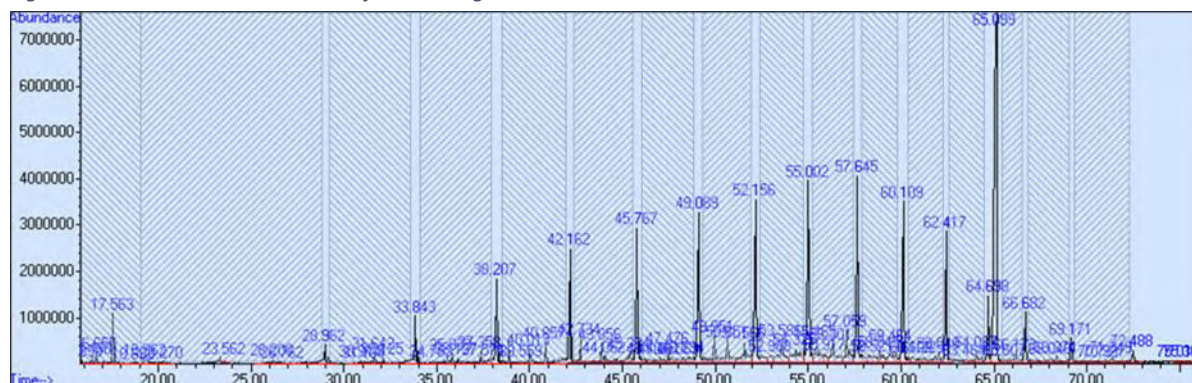
The Mahalanobis distances were calculated for each sample from the entire set of observations as the test for outlier samples. Several samples were identified as outliers as shown in Figure 34, where the green vertical line represents the Mahalanobis critical value.

Figure 35: Outlier diagnostics plot
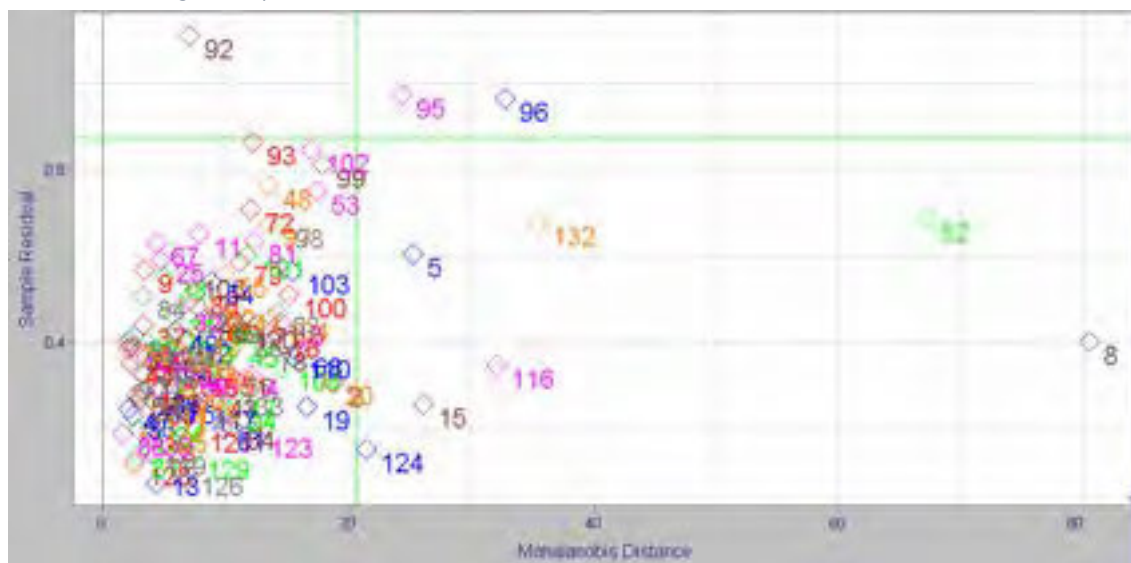
Each outlier sample was investigated to determine the cause of it being an outlier. The substances observed were isoamyl laurate, bis(2-ethylhexyl) terephthalate, isopropyl palmitate, palmityl oleate, stearyl oleate, Irgafos 168, and 1,3,5-triphenylcyclohexane. All the substances observed in the outlier samples are either Cramer Class I, or III substances, with no alerts for mutagenicity. All substances are likely to be present from either the mis-selection of cosmetic non-food packaging, a plasticiser within an adhered label or a polystyrene impurity.

Table 5: Summary of substances found in outlier samples

Substance - CAS No	Toxicological classification	Sample	Concentration mg/kg
Isoamyl laurate 6309-51-9	Cramer Class I 1,800 µg/person/day	5	61
Bis(2-ethylhexyl) terephthalate 6422-86-2	Cramer Class I 1,800 µg/person/day	8 15	105 25
Isopropyl palmitate 142-91-6	Cramer Class I 1,800 µg/person/day	52	420
Palmityl oleate 22393-86-8	Cramer Class I 1,800 µg/person/day	95	5
Stearyl oleate 17673-49-3	Cramer Class I 1,800 µg/person/day	95	5
Irgafos 168 31570-04-4	Cramer Class III 90 µg/person/day	96	2.8
1,3,5-Triphenylcyclohexane 28336-57-4	Cramer Class III 90 µg/person/day	116 124 132	30 14 15

Since the PCA study had not identified any outliers containing harmful substances in the category of mutagenic, the chemometric data was screened in further granular detail. The additional method applied for the screening involved tabulating the best mass spectral matches for each peak on the GC-MS chromatogram of all samples. Approximately 1,470 unique assignments were made by the library search, with the lowest semi-quantifiable peak observed to be 0.2 mg/kg. None of the 1,470 substance had mutagenic or carcinogenic hazards associated with them. The median concentration of all peaks detected is expected to be representative concentration when an incident of misuse occurs, being 3.2 mg/kg diluted across 225 flakes, therefore a single flake may be contaminated up approximately 720 mg/kg on average. The reference contamination level could be established by assuming that the frequency is 1 in 133 samples at a peak concentration of 3.2 mg/kg, or alternatively expressed as 1 in 30,000 bottles at a peak of 720 mg/kg, resulting in an average background rate of 0.024 mg/kg.

Using the misuse rate assessed in the material characterisation (Section 2.2.4) following the sorting process of 1 in 100,000 (0.001%) coupled with the median concentration of substances found in the GC-MS study at 720 mg/kg, the background contamination rate could be as low as 0.0072 mg/kg. The GC-MS study is being extended to confirm if the presence of a DNA-reactive substance is less frequent than 1 in 100,000 by analysing more washed flakes, due for completion in April 2023.

There were some substances observed which are currently under assessment for endocrine disrupting properties summarised in Table 6 below. Such substances are subject to their own Tolerable Daily Intakes (TDIs) which is addressed in Section 2.7 along with the assessment of the DNA-reactive background contamination rates of the experimentally determined 0.024 mg/kg, and the projected 0.0072 mg/kg.

Table 6: Detect substances currently under assessment for endocrine disrupting properties

CAS No	Occurrence	Study average mg/kg	Maximum mg/kg	Identity
96-76-4	66	0.12	3.9	2,4-DTBP
77-94-1	18	0.05	2.5	Tributylcitrate
128-37-0	11	1.92	9.9	BHT
1222-05-5	7	0.81	2.3	Galoxolide
1506-02-1	1	0.02	7.2	Tonalid
131-57-7	1	0.34	3.2	Benzophenone-3
80-54-6	1	0.01	0.9	Lilal

2.3. Determination of the decontamination efficiency of the recycling process

A challenge test was performed in 2022 using the decontamination equipment at Veolia Plastics. The full challenge test report is in Annex 5. The feedstock for the challenge test was prepared at Veolia Plastics where two 50 L drums, each containing 5 kg washed HDPE flakes, were contaminated with surrogate chemicals as described in Table 7. In one drum (A) approximately 100 g of toluene and chlorobenzene were dissolved in 2.5 L isopropanol (IPA), and the other drum (B) contained 100 g phenylcyclohexane, benzophenone, eicosane, benzyl butyl phthalate and sucrose octaacetate in 2.5 L IPA. The drums were sealed and heated to 40 °C for 14 days, with periodic rolling. After the soaking period the IPA was drained, and flake allowed to evaporate to dryness. The challenge test was performed using the entire batch of surrogates prepared, combined together on the challenge test date. The challenge test lasted for approximately 5 hours using typical washed HDPE flakes as the makeup feedstock. Sampling of output materials occurred every 15 minutes to determine the concentration profile of surrogates.

Table 7: Surrogates used for challenge testing

Substance	M_r	Polarity	Amount g	% (w/v)	Mixture
Toluene	92.1	Non-polar	102.1	4.1%	A
Chlorobenzene	112.6	Polar	100.0	4.0%	A
Phenylcyclohexane	160.3	Non-polar	111.7	4.5%	B
Benzophenone	182.2	Polar	100.0	4.0%	B
Eicosane	282.6	Non-polar	93.8	3.8%	B
Benzyl butyl phthalate	312.4	Polar	100.6	4.0%	B
Sucrose Octaacetate	678.6	Polar	100.0	4.0%	B

2.3.1. Operating parameters

Table 8: Challenge test operating parameters

Parameter	Value	
Throughput	▮▮▮	kg/hr
KT temperature	▮▮▮	°C
KT pressure	▮	mBar
KT fill level	▮▮▮▮▮	
Reactor temperature	▮▮▮	°C
Reactor pressure	▮	mBar
Reactor fill level	▮▮▮▮▮	
	▮▮	
	▮▮▮	
	▮▮▮	
Degassing temperature	▮▮▮	°C
Degassing pressure	▮	mBar

2.3.2. Decontamination efficiency

The concentration of surrogates was determined by extraction of 5 g of pellets with 20 mL tetrahydrofuran (THF) over a period of 3 days at 60 °C, in triplicate. The concentration of substances within the surrogate flakes was determined by extraction of 100 g of flakes in 400 mL THF over a period of 3 days at 60 °C. As well as determining the concentration of surrogates in the contaminated and flake and pellets, portions of the feedstock were sampled for determination of surrogates in the background. The total surrogate mass was determined by multiplying the concentration at each sampling interval by the quantity of feedstock used in the period, summarised in Table 9.

Table 9: Challenge test decontamination efficiency

Surrogate	Surrogate input g	Feedstock input g	Total input g	Total output g	Decontamination
Toluene	27.9	0	27.9	0	100%
Chlorobenzene	23.2	0	23.2	0	100%
Phenylcyclohexane	46.3	0	46.3	4.4	90.5%
Benzophenone	35.1	3.1	38.2	23.6	38.2%
Eicosane	64.2	36.4	100.6	103.6	0%
Benzyl butyl phthalate	32.0	0	32.0	40.1	0%
Sucrose octaacetate	33.6	0	33.6	42.5	0%

It is important to note that the mass of eicosane, benzyl butyl phthalate and sucrose octaacetate observed in the output material was higher than what was theoretically placed into the decontamination process. This suggests that either the input concentration is underestimated, or the output concentration is overestimated, in either case resulting in an underestimation of the

decontamination performance. The concentration profiles of benzyl butyl phthalate and sucrose octaacetate show that there little to no presence in the feedstock of HDPE therefore unlikely to be caused by interference of the feedstock. Assuming the decontamination efficiency is truly 0% for benzyl butyl phthalate and sucrose octaacetate, the total masses of the input surrogate may be underestimated by 20% for benzophenone, benzyl butyl phthalate and sucrose octaacetate. Also, the profiles show that the concentrations did not return back to original background levels, however the decontamination chambers were completely emptied at the end of the trial due to lack of feed. This also means there was no diluting makeup feedstock in the last two hours of the test.

Figure 36: Phenylcyclohexane CT profile
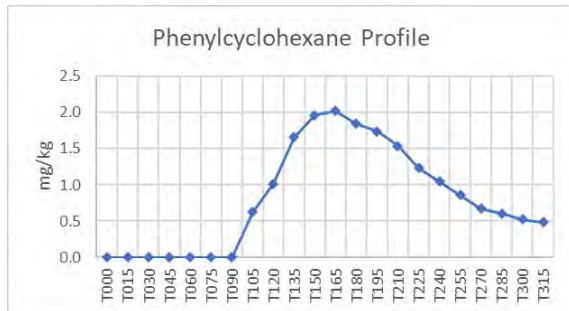
Figure 37: Benzophenone CT profile
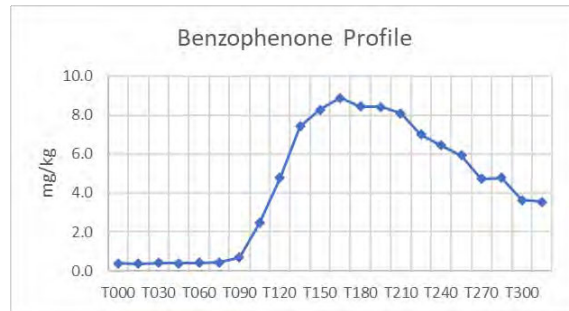
Figure 38: Eicosane CT profile
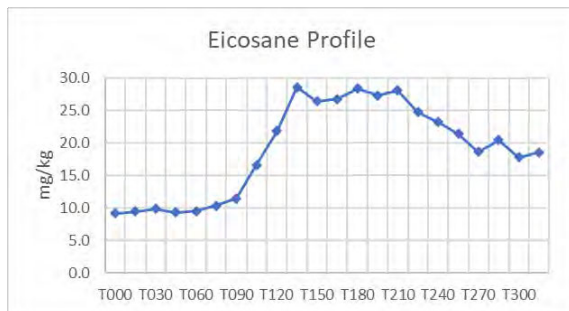
Figure 39: Benzyl butyl phthalate CT profile
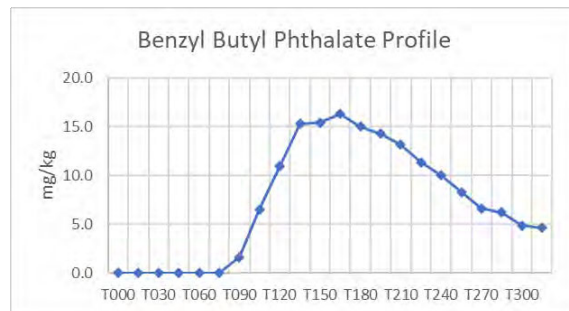
Figure 40: Sucrose octaacetate CT profile
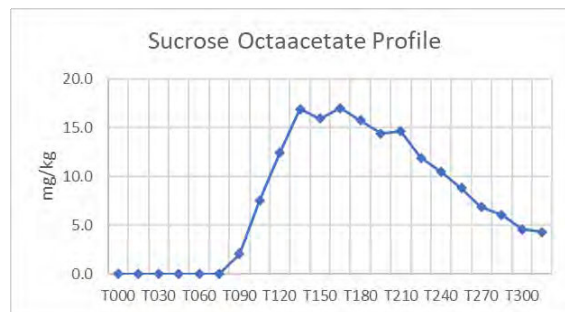
In comparison to previous challenge tests performed in 2010 and 2015, the decontamination performance of phenylcyclohexane has increased from approximately 60% to 90% and the peak concentration time shifted from 75 minutes to 165 minutes. Benzophenone had a slight improvement from approximately 25% to 38%. Both toluene and chlorobenzene were undetected in the output therefore a very high decontamination rate. Historical challenge test analytical reports are found in Annex 6, Annex 7 and Annex 8.

The low decontamination rates for benzophenone, eicosane and benzyl butyl phthalate are likely due to the boiling points of the substances being 305, 343 and 370 °C respectively, in comparison to those of toluene, chlorobenzene and phenylcyclohexane being 111, 132 and 238 °C.

The migration of surrogates following the challenge test has been assessed and summarised in Table 10 using simulation parameters given in Table 11 assuming an article made from 100% rHDPE at 5 °C for 15 days, using a conservative partition coefficient representing fatty food. The modelling software used is Safe Food Packaging Portal 3 (SFPP3) licensed by INRA\Olivier Vitrac, using the Piringer formula to calculate diffusion coefficients.

Table 10: Challenge test migration evaluation

Surrogate	Mw	Peak concentration mg/kg	Migration mg/kg
Toluene	92	< 0.1	<0.00119
Chlorobenzene	113	< 0.1	<0.00102
Phenylcyclohexane	160	2.1	0.0153
Benzophenone	182	9.3	0.0587
Eicosane	283	30.0	0.105
Benzyl butyl phthalate	312	17.0	0.0513
Sucrose Octaacetate	679	17.4	0.011

Table 11: Challenge test migration modelling parameters

Parameter	Value
Surface area	600 cm^2
Food volume	1 L
Layer thickness	0.3 mm
Polymer density	0.96 g/cm^3
Food density	1 g/cm^3
Food/packaging coefficient	1
Temperature	5 °C
Duration	15 days
Diffusion coefficient calculation	Piringer

The combination of the reference contamination level and decontamination performance is addressed in Section 2.7, where the food application is also considered when assessing the dietary exposure to consumers.

2.4. Characterisation of the recycled plastic

2.4.1. Physical properties

Several properties for the recycled HDPE intended for food contact use summarised in Table 12, along with the typical specification agreed with customers published on certificates of analysis (Annex 3). Properties such as melt flow rate and density are largely controlled by the grades of HDPE resin used in packaging manufacturing, therefore have the potential to deviate over time influenced by packaging manufacturers. Colour properties are largely controlled by the recycler however effects can be observed from industry pigment reduction initiatives.

Table 12: Typical properties of recycled HDPE from the Veolia Plastics recycling process

Property	Value	Specification
Pellets per 5 g	▉	▋
Diameter (mm)	▋	▋
Melt flow rate 2.16 kg (g/10min)	▉	▉
Density (g/cm^3)	▉	▉
L*	▉	▋
a*	▉	▋
b*	▉	▋

Figure 41: Veolia Plastics rHDPE melt flow rate with 2.16 kg loading
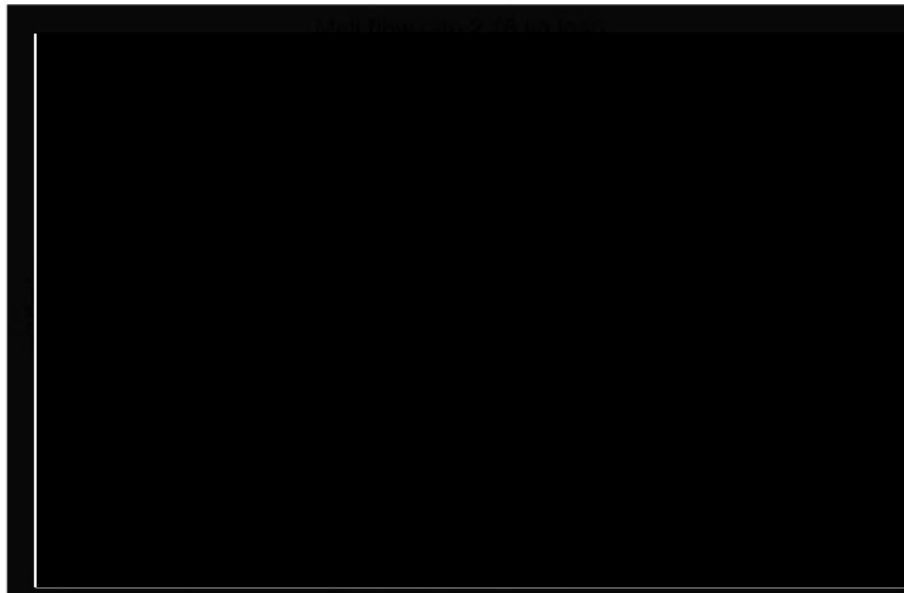
Figure 42: Veolia Plastics rHDPE density
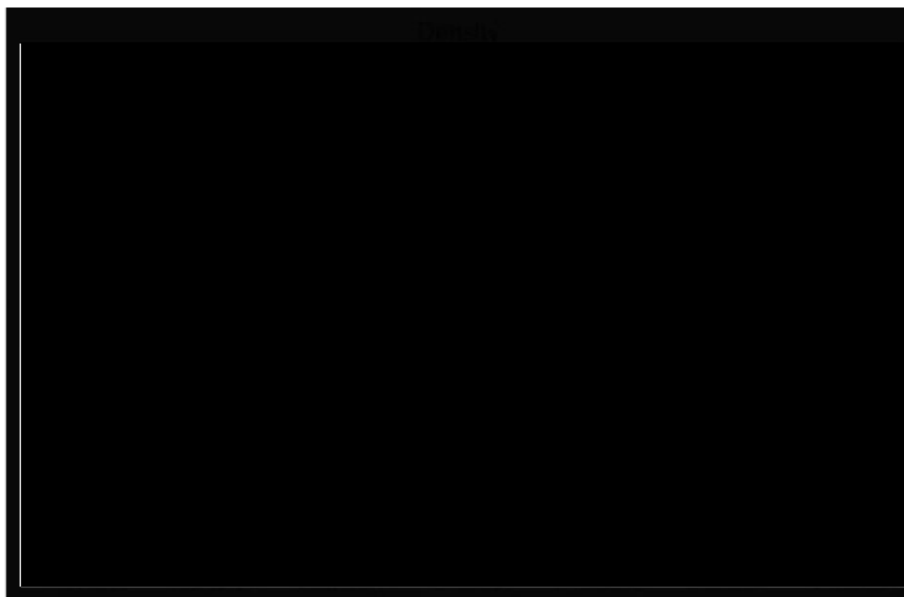
Figure 43: Veolia Plastics rHDPE L* colour value

2.4.2. Non-intentionally added substances

Recycled HDPE materials were screened for NIAS substances to understand the components which may be commonly found in the output material. Recycled HDPE pellets are routinely analysed by GC-MS headspace at Veolia Plastics using a method involving incubating 1 g of pellets at 120 °C pellets for 90 minutes, with an example chromatogram shown in Figure 44. The volatile activity is very low with a key volatile indicator of limonene being less than 0.5 mg/kg. The headspace data shows that the Vacurema process is relatively effective at removing semi volatile substances up to and including hexadecene (RT 10.4 min), with a molecular weight of 224 g/mol and a boiling point of 275 °C.

The recycled HDPE pellets were subject to THF solvent extraction during the chemometric study of washed HDPE flakes. Figure 45 is an example GC-MS chromatogram of the solvent extraction of rHDPE, with identification and semi quantification results in Table 13. The majority of substances found were oligomers, hydrocarbons and fatty acids, falling into Cramer Class I. The oxidised form of Irgafos 168

is has the highest concentration of approximately 500 mg/kg. The key substance identified in the extractions was Bis(2-ethylhexyl) phthalate (BEHP) found at a concentration of approximately 2 mg/kg. BEHP is regarded as an endocrine disruptor as well as being toxic to reproduction. The impact of the presence of BEHP is evaluated in Section 2.7, combining migration modelling and consumption factors to estimate exposure.

Figure 44: GC-MS headspace chromatogram of rHDPE in comparison to virgin HDPE
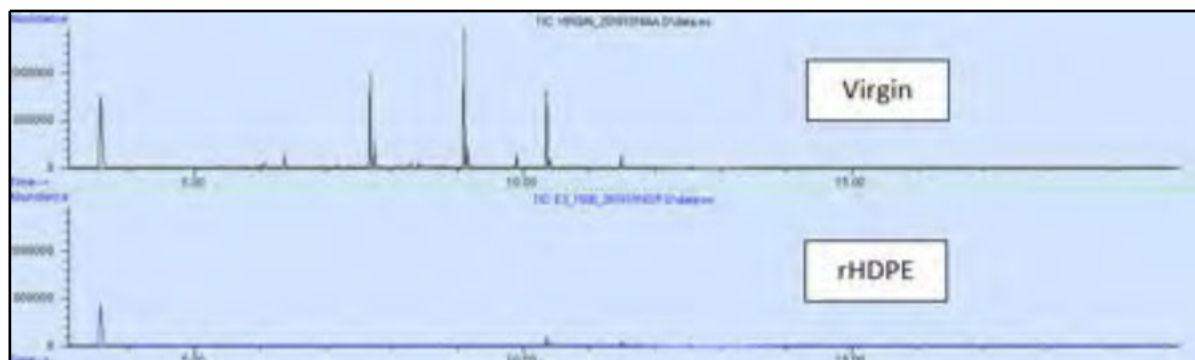
Figure 45: GC-MS chromatogram of rHDPE THF extraction
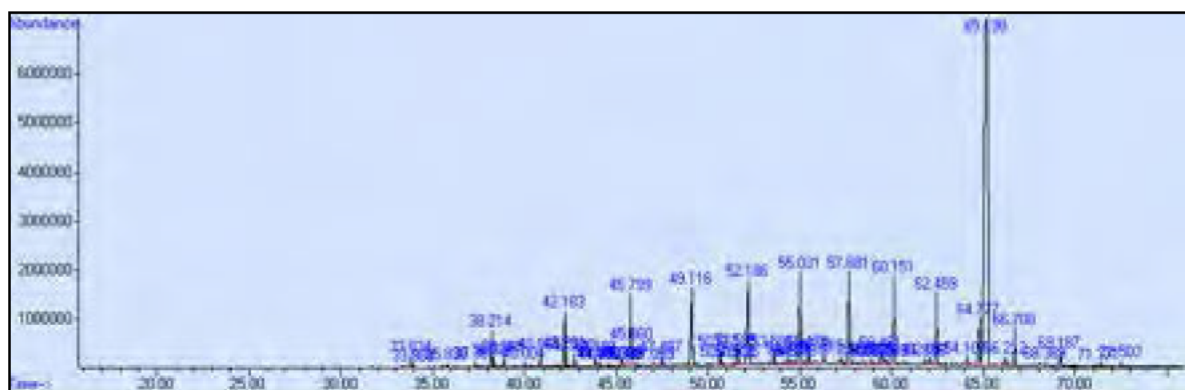
Table 13: Substances identified in THF extraction of rHDPE

RT	CAS	Name	Warnings	Cramer Class	Concentration mg/kg
33.83	629-73-2	1-Hexadecene	-	I	3.1
33.98	544-76-3	Hexadecane	-	I	1.0
35.82	6259-76-3	n-Hexyl salicylate	-	I	1.1
37.35	101-86-0	Hexylcinnamaldehyde	-	II	1.2
38.2	112-88-9	1-Octadecene	-	I	13.2
38.32	593-45-3	Octadecane	-	I	2.3
38.88	110-27-0	Isopropyl myristate	-	I	3.4
40	36653-82-4	1-Hexadecanol	-	I	2.1
40.86	82304-66-3	7,9-Di-tert-butyl-1-oxaspiro[4.5]deca-6,9-diene-2,8-dione	-	III	4.3
42.18	3452-07-1	1-Eicosene	-	I	24.9
42.26	112-95-8	Eicosane	-	I	3.5
42.74	142-91-6	Isopropyl palmitate	-	I	3.4
43.85	112-92-5	1-Octadecanol	-	I	4.1
44.05	629-94-7	Heneicosane	-	I	1.2
44.13	112-62-9	Methyloleate	-	I	1.3
45.21	544-35-4	Ethyl linoleate	-	I	0.7
45.31	111-62-6	Ethyl oleate	-	I	1.6

RT	CAS	Name	Warnings	Cramer Class	Concentration mg/kg
45.39	109-43-3	Dibutylsebacate	-	I	1.5
45.8	1599-67-3	1-Docosene	-	I	34.6
45.86	629-97-0	Docosane	-	I	5.3
47.06	77-90-7	Tributylacetylcitrate	-	III	0.7
47.49	638-67-5	Tricosane	-	I	2.9
49.12	10192-32-2	1-Tetracosane	-	I	49.9
50.66	629-99-2	Pentacosane	-	I	4.2
50.76	55194-81-5	Capryl palmitate	-	I	1.3
51.51	117-81-7	BEHP	ED Repr. 1B	I	1.8
51.59	3896-11-5	Bumetrizole	-	III	5.2
51.73	13945-76-1	Lauryl laurate	-	I	1.6
52.19	18835-33-1	1-Hexacosene	-	I	56.5
53.59	593-49-7	Heptacosane	-	I	3.9
54.33	6422-86-2	DOTP	-	I	2.5
54.57	22412-97-1	Tetradecyl laurate	-	I	2.0
54.81	112-84-5	Erucamide	-	III	1.3
55.03	18835-34-2	1-Octacosene	-	I	59.9
55.48	111-02-4	Squalene	-	I	4.1
56.32	630-03-5	Nonacosane	-	I	2.4
57.24	42232-29-1	Dodecyl palmitate	-	I	2.3
57.68	18435-53-5	1-Triacontene	-	I	58.0
58.86	630-04-6	Hentriacontane	-	I	1.6
59.03	915-05-9	b-Sitosterolacetate	-	III	1.6
59.35	57-88-5	Cholesterol	-	III	2.5
59.49	17673-49-3	Stearyl oleate	-	I	4.7
59.73	4536-26-9	Myristyl palmitate	-	I	1.9
60.15	18435-55-7	1-Dotriacontene	-	I	50.8
61.84	83-46-5	b-Sitosterol	-	III	2.2
62.06	540-10-3	Cetyl palmitate	-	I	2.9
62.46	61868-12-0	1-Tetratriacontene	-	I	36.3
64.11	22393-86-8	Cetyl oleate	-	I	5.5
64.78	61868-14-2	1-Hexatriacontene	-	I	25.7
65.19	95906-11-9	Irgafos 168 (oxidised)	-	III	501.4
66.21	3687-45-4	Oleyloleate	-	I	4.7
66.71	61868-16-4	1-Octatriacontene	-	I	14.4
69.19	61868-18-6	1-Tetracontene	-	I	6.5
71.37	621-71-6	Caprin	-	I	1.4
72.5	21807-60-3	1-Dotetracontene	-	I	3.4

2.4.3. Migration performance

Overall migration testing was performed on Veolia Plastics rHDPE with the full laboratory report given in Annex 9. The overall migration testing conditions were 40 °C for 10 days (OM2) much more severe than chilled conditions, and the choice of food simulant was D1 (50% v/v ethanol) which represents

milk. The migration was observed to be 0.9 mg/cm^2. This means that the resins could be suitable for certain food types for long-term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to a temperature T where 70 °C ≤ T ≤ 100 °C for a maximum of t = 120/2^((T-70)/10) minutes.

Specific migrations were performed on the rHDPE materials from the challenge test of 2009 described in Annex 8, where the pellets were transformed into milk bottles manufactured from 100% rHDPE. The analytes for the specific migration study were phenylcyclohexane, benzophenone and methyl stearate. The migration conditions were 20 °C for 10 days in 50% v/v ethanol. A comparison is made in Table 14 of the residual concentration with the experimental migration and modelled migration concentrations. The modelled migration is assuming a surface area food ratio of 15.4 dm^2/kg and a layer thickness of 250 µm, for 10 days at 20 °C, which shows migration modelling significantly overestimates migration; a factor of 5 for benzophenone.

Table 14: Specific migration testing performed on challenge test materials

Surrogate	Residual concentration mg/kg	Experimental migration mg/kg	Modelled migration mg/kg
Benzophenone	6.3	0.042	0.208
Phenylcyclohexane	1.2	0.003	0.041
Methyl stearate	11.7	n.d.	0.337

An accelerated migration test is performed at Veolia Plastics for each output batch of material. The conditions are 55 °C for 4 hours in 50% v/v ethanol which is equivalent to the 20 °C 10 days test using the Arrhenius equation in EU Regulation 10/2011. Substances that monitored are those which have been observed to migrate to a concentration above 10 µg/kg, historically being limonene, dodecane, α-hexylcinnamaldehyde, n-hexyl salicylate, 2-ethylhexyl benzoate, dibutyl sebacate, isopropyl myristate, Irgafos 168 and Irganox 1076. Although Irgafos 168 in its oxidation form is an organophosphate, EFSA has the opinion that the combination of the phosphite and phosphate form are not of safety concern below a food concentration of 10 mg/kg (EFSA, 2017).

Table 15: Basic statistics specific migrations of 474 batches between February 2021 and June 2022 using the accelerated migration testing method

Substance	Mean µg/kg	Maximum µg/kg	SML µg/kg	Toxicological classification
Limonene	4.1	16.4	-	Cramer Class I 1800 µg/person/day
Dodecene	2.0	7.4	50	Cramer Class I 1800 µg/person/day
α-Hexylcinnamaldehyde	15.8	91.6	-	Cramer Class II 540 µg/person/day
n-Hexyl salicylate	23.8	68.0	-	Cramer Class II 540 µg/person/day
2-Ethylhexyl benzoate	1.8	47.9	-	Cramer Class I 1800 µg/person/day
Dibutyl sebacate	30.4	157.4	60,000	Cramer Class I 1800 µg/person/day
Isopropyl myristate	20.6	140.2	-	Cramer Class I 1800 µg/person/day
Irgafos 168 (oxidised)	5.1	38.5	6,000*	Organophosphate 18 µg/person/day
Irganox 1076	81.8	179.8	6,000	Cramer Class II 540 µg/person/day

* Phosphite form   Test surface area: 21 cm^2, simulant volume: 35 mL

Figure 46: Typical accelerated migration GC-FID chromatogram
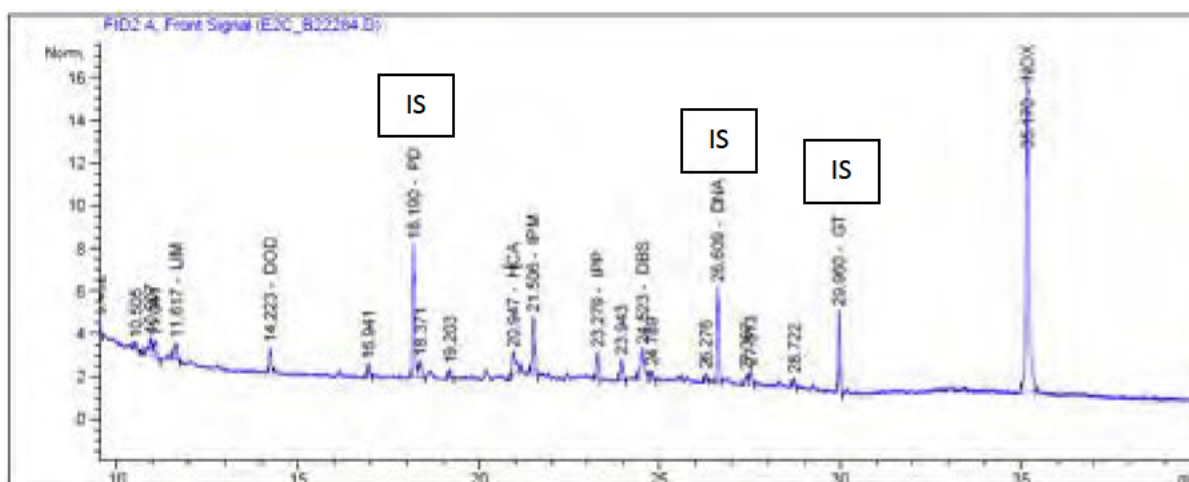
Specific migrations were performed on challenge test materials from 2014 to understand the migration behaviour of phenylcyclohexane, benzophenone and methyl stearate at 5 °C, 25 °C, and 40 °C using 95% (v/v) ethanol for 10 days, with results summarised in Table 16. Specific migrations were also performed at 25 °C for 10 days using various simulants of 3% (w/v) acetic acid, 10% (v/v) ethanol, 50% (v/v) ethanol and 95% (v/v) ethanol. Results from the simulants study, show that the 95% ethanol simulant has the highest concentration of all simulants, therefore the data from the 95% ethanol experiment would be the most appropriate for comparison to migration modelling.

Table 16: Experimental migrations on surrogate materials using 95% ethanol at various temperatures for 10 days

Surrogate	Migration at 5 °C µg/kg	Migration at 25 °C µg/kg	Migration at 40 °C µg/kg
Phenylcyclohexane	21.6	131.0	301.1
Benzophenone	0.0	245.9	442.7
Methyl stearate	0.0	15.8	116.2

Table 17: Experimental migrations on surrogate materials using various simulants at 25 °C for 10 days

Surrogate	Migration into 3% w/v acetic acid µg/kg	Migration into 10% v/v ethanol µg/kg	Migration into 50% v/v ethanol µg/kg	Migration into 95% v/v ethanol µg/kg
Phenylcyclohexane	0.0	8.0	102.8	131.0
Benzophenone	133.8	98.0	169.4	245.9
Methyl stearate	0.0	0.0	0.0	15.8

Table 18: Modelled migrations at various temperatures using standard parameters in Table 11.

Surrogate	Migration at 5 °C µg/kg	Migration at 25 °C µg/kg	Migration at 40 °C µg/kg
Phenylcyclohexane	85.4	198	199
Benzophenone	133	356	356
Methyl stearate	143	474	496

Table 18 show migrations based on modelling parameters used to assess rHDPE reflected in Table 11; the residual concentration of phenylcyclohexane, benzophenone and methyl stearate were determined to be 11.7, 21.1 and 29.2 mg/kg respectively from challenge tests performed in 2014. Comparisons of Table 16 and Table 18 show that the migration can be overestimated by a significant factor of at least 4 for the case of phenylcyclohexane, and that factor drastically increases with molecular weight, with benzophenone and methyl stearate undetected at 2 µg/kg, suggesting an overestimation factor of at least 50, providing evidence that migration of high molecular weight substances is significantly inhibited by cold temperatures.

2.4.4. Sensory performance

In 2009, milk bottles were manufactured with 50% rHDPE derived from the Vacurema process, and taste assessments were performed on the milk stored in the milk bottles (Annex 10 and Annex 11). The conclusions from the study were that there was no significant difference between bottles manufactured from virgin HDPE or rHDPE, for skimmed, semi-skimmed or whole milk.

2.4.5. Ames testing

Guidance from ILSI Packaging Materials Task Force (ILSI, 2015) suggests that in-vitro bioassays can be used as a tool for assisting risk assessments for NIAS found in food contact materials. It can be used to provide a toxicological evaluation of migrating substances from food contact materials. OFI, based in Austria, are project leads into the development of a miniaturised Ames test suitable for identifying mutagenic activity in recycled food contact materials called Migratox. Veolia Plastics rHDPE was

selected for evaluation using the method developed in the project, with the results and detail of the method provided in Annex 15.

The test method involved exposing 10 g of pellets to 100 mL of 50% ethanol at 20 °C for 10 days, then the volume of simulant was reduced by a factor of 300 under slight heat and vacuum. The residue is mixed with DMSO and added to the bioassay. The bioassays use two different Salmonella Typhimurium strains to identify both frameshift and point mutations, and further discrimination using liver enzymes to mimic other biological interactions with substances. The bacteria strains have deactivated histidine synthesis genes, which mutagenic substances could potentially reverse and reactivate. The plates are placed into incubation for 2-3 days where after, an indicator is added to detect if histidine has been produced.

Migration testing at 20 °C for 10 days covers all durations at frozen and chilled storage conditions. The results of the Ames testing had shown no genotoxic activity for rHDPE, as summarised in Table 19.

Table 19: Ames testing results

Strain (Enzyme)	Result (LOD) µg/L
TA98 (- S9)	< LOD (4.7)
TA98 (+ S9)	< LOD (0.9)
TA100 (- S9)	< LOD (1.8)
TA100 (+ S9)	< LOD (3.7)

As shown in Table 16 of Section 2.4.3, the migration of a substance like phenylcyclohexane at 5 °C is a factor of 5 times lower than that of 25 °C, and a much higher factor for larger migrants. Therefore, the concentration of mutagenic substances at chilled conditions are expected to be much lower than the limit of detection concentration of 0.9 µg/L from an exposure performed at 20 °C.

2.5. Intended application in contact with food

The primary application for rHDPE will be used for packaging chilled milk. HDPE milk bottles are generally stored in a refrigerated environment at 5 °C, with a shelf life of approximately 2 weeks. HDPE milk bottles come in a variety of volumes, typically measured in units of pints. The most common volume is approximately 4 pints, with 1, 2 and 6 pints also available on the market. The surface area to volume ratio does vary with each format, and typically ranges from 3 dm^2/kg for higher volumes to 6 dm^2/kg for lower volumes. The thickness of the milk bottle wall is found to be approximately 0.3 to 0.5 mm thick.

Typical serving suggestions are approximately 200 mL, therefore the milk storage cycle is naturally very low in duration, consumed over a period of a couple days. The consumption rate of milk can be quite high in certain demographics. The NHS England recommends that infants should consume breast milk for at least the 6 months of life, with the alternative being infant formula. Whole milk is not recommended until after 12 months, where the infant should have at least 350 mL of milk per day. Based on WHO UK Child Growth Standards a 12-month-old infant may weigh between 7 and 13 kg, therefore the consumption rate is expected to be approximately 50 mL/kg bw/day.

Other foreseen applications would also be for chilled drinks products such as fruit juices, in similar formats to milk, as well as chilled milkshake bottles. Reusable water bottles are another desirable application for rHDPE, which are thick-walled approximately 2 mm and expected to remain at room temperature.

In all applications, the ability to manufacture a 100% recycled content container is desirable, however it is understood that the collection systems may not be able to sustain such usage. It is expected that there will be at least 30% rHDPE mixed with virgin for most applications, with the upper usage level expected to be approximately 50%.

2.6. Compliance with the relevant provisions on food contact materials and articles

The information provided on the rHDPE material have been evaluated to be compliant with Article 3 general requirements of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food. Based on the intended use of the material, it is not expected to:

- Endanger human health;
- Bring about unacceptable change in the composition of the food;
- Bring about a deterioration in the organoleptic characteristics.

Recycled materials are manufactured according to Commission Regulation (EC) No 2023/2006 on good manufacturing practice. This technical dossier provides the Quality Assurance System framework on GMP for Veolia Plastics in Section 2.8.

It is understood that the recycling facility provisionally complies with the conditions of novel technology within Commission Regulation (EC) No 2022/1616, where:

- The quality of the plastic input has been characterised;
- The plastic input has originated from collection processes compliant with EU Regulation 2022/1616 Article 6.
- A challenge test has been performed to demonstrate that the process is able to reduce any contamination of the plastic input to a concentration that does not pose risk to human health;
- The quality of the recycled plastic has been characterised to ensure compliance with Article 3 of Regulation (EC) No 1935/2004;
- Conditions of use have been established for the use of the recycled material.

In 2007, the WRAP food grade HDPE recycling process, which is based upon the Vacurema decontamination technology, received a Letter of Non-Objection from the US Food and Drug Administration (Annex 12). The letter contains the opinion that the recycling technology is suitable for manufacturing milk bottles containing up to 50% rHDPE.

In 2015, EFSA published an opinion on the safety of Vacurema technology to produce food contact HDPE (EFSA, 2015), where it was determined that originally that the process does not satisfy criteria set for HDPE following the same principle as for recycled PET. However, the CEF Panel emphasised that the uncertainties arising from the lack of sufficient scientific knowledge and the consequent conservatism of the selected criteria could allow the conclusion that a process is safe when criteria are met but do not allow a conclusion to be reached on the safety of the processes when the criteria are not met. Consequently, additional data was required to reduce the uncertainties hence additional chemical analysis was performed on the feedstock to the decontamination equipment.

The HDPE recycling process has been established within the UK since 2008, with two major suppliers providing thousands of tonnes of recycled HDPE to the market within the last 14 years. It's estimated that approximately 1.5 billion milk bottles are produced each year in the UK containing some rHDPE, therefore since establishing rHDPE recycling nearly 20 billion bottles have entered the UK market. Over the years there have been no product recalls regarding the safety of rHDPE bottles; a practical measure of the safety of the material.

2.7. Process analysis and evaluation

2.7.1. Identification of critical steps

2.7.1.1. Sorting

The sorting process achieved at least approximately 99% food use HDPE packaging sourced from the UK, reducing the risks of non-authorised additives and processing aids used in non-food use HDPE materials. Of the 1% non-food use HDPE materials, most of the articles will be manufactured from HDPE that use additives which compliment FDA and EU food contact regulations. The substances within the non-food containers have been found to be of relatively low toxicity, apart from exceptions of garden and pest control products, that form a very small proportion of non-food packaging. Where batches do not meet the 99% food use criteria, the blend rates are limited and documented on certificates of analysis, so that the customers are aware of the restriction, and that the final food contact article shall not contain more than 1% of HDPE derived from non-food use materials.

2.7.1.2. Washing

The decontamination process has been evaluated based upon the use of an approximate feedstock of 99% food use HDPE which is also influential to the setting of reference contamination level in HDPE. As the reference contamination study was performed on washed 99% food use HDPE flakes, it is essential that residues on and within the washed flakes remains comparable to or better than the study. The washing conditions of the flakes in the reference contamination study are:

- ▉▉▉% sodium hydroxide (w/w);
- Washing temperature of ▉▉▉ °C;
- Residence time of ▉▉▉▉ minutes.

To encourage washing process optimisation and resource efficiency, it would be appropriate to deviate from the reference washing process parameters if it can be demonstrated that output washed flakes are cleaner than those produced using the reference washing conditions. Washing performance criteria would need to include both physical and chemical monitors to conclude if an improvement has been made.

2.7.1.3. Flake sorting

The flake sorting step is not such a critical step for the performance with respect to food safety, as emphasis should be placed upon article sorting and washing processes to maximise contamination removal, including labels. The flake sorting is likely to be critical to product quality and aesthetic performance, such as colour control, therefore it is still an essential step to have specifications of the outputs.

2.7.1.4. Vacurema decontamination

Table 20: Vacurema critical parameters

Parameter	Value
Throughput	██████████
KT temperature	███████
KT pressure	█████
Reactor temperature	███████
Reactor pressure	██████
	█████
████████████	████████
	██████████
Degassing temperature	███████
Degassing pressure	█████

The first stage of the Vacurema decontamination (KT) is to heat the material to just below the melting temperature of HDPE under a vacuum to draw off volatiles. The material should reach at least ██ °C with a vacuum pressure ██████ mBar, which were the operating parameters during the challenge test summarised in Table 8 in Section 2.3. The fill level is also an important parameter to standardise the residence time within both chambers.

The second stage of the Vacurema decontamination (reactor) subjects the material to consistent temperature between █████ °C under vacuum with pulsed injections of water to assist the mobilisation of volatiles out of the chamber. ██

The final step is to degas the melt with a temperature between ███████ °C with a vacuum pressure ██████ mBar.

The effect of operating at lower temperatures, higher pressures and lower fill levels is expected to have a reduction in the removal of contaminants, as boiling points for some materials have not been achieved and the kinetic energy of molecules within the polymer has reduced. A higher pressure in the vacuum system will have the effect of increasing the boiling point of substances marginally.

2.7.2. Background contamination rate

The contamination within the feedstock into the decontamination process has been measured by multiple methods. To begin with, the rate of misuse has been characterised at bottle level on the feedstock into the recycling process as described in Section 2.2.3. This data collected provides information of the rate of identifiable misuse such as a milk bottle contaminated with a paint or soil with oil-like substances. The proportion of materials falling into the category of misuse was observed to be 0.006% (1 in 16,700), from a collective study of over 14,000 kg of input materials over the period of January 2021 and June 2022. The same assessment was carried out on materials exiting the sorting process, entering the washing process, where no bottles were identified in 3,500 kg of samples. A single milk bottle weights approximately 35 g therefore the rate of a misused bottle could be as low as 1 in 100,000 (0.001%) bottles entering the washing process due to the efficiencies of the automatic and manual sorting.

To verify the 1 in 100,000 contamination rate, washed HDPE flakes were analysed by GC-MS to search for harmful carcinogenic and mutagenic residues. The solvent extraction of approximately 30,000 flakes did not show presence of any carcinogenic or mutagenic substances with semi quantitative detection limit in the order of 1 mg/kg. To add a degree of conservatism, median concentration of substances observed in the study, oligomers included, was selected at the potential concentration level of a carcinogenic or mutagenic substance, calculated to be 720 mg/kg per flake. These findings resulted in a particular harmful contamination rate less than 0.024 mg/kg.

Coupling the median concentration finding of 720 mg/kg with the potential misuse rate of 1 in 100,000 the background contamination rate could be as low as 0.007 mg/kg. For clarification, this background contamination rate only refers to DNA-reactive substances and does not represent the concentration of Cramer Class I, II, III, organophosphates or carbamates. The concentration of such substances has been identified in organic NIAS testing of rHDPE pellets, discussed in Section 2.4.2 (Table 13).

2.7.3. Decontamination rate

The decontamination rate is extremely high for volatile substances, regardless of polarity, with a reasonable effectiveness on substances with molecular weights approximately 160 g/mol or boiling points around 250 °C. The decontamination rate of higher molecular weight materials with boiling points approximately 300 °C begin to reduce significantly, with little effectiveness at 350 °C.

The decontamination rate of the high molecular weights may not need to be as high, given diffusion into and out of the polymer reduces with increased molecular weight. Therefore, it is essential to characterise and quantify the contamination found within the feedstock to the decontamination process. Applying the various decontamination efficiencies to the background contamination rate will determine the residual contamination left within the pellet which is summarised in Table 21.

Table 21: Decontamination efficiencies applied to background contamination rate

Surrogate	Decontamination efficiency	Background 0.024 mg/kg		Background 0.007 mg/kg	
		Initial µg/kg	Residual µg/kg	Initial µg/kg	Residual µg/kg
Toluene	100%	24	0	7	0
Phenylcyclohexane	90%	24	2.4	7	0.7
Benzophenone	38%	24	14.9	7	4.34
Benzyl butyl phthalate	0%	24	24	7	7

2.7.4. Migration modelling

Migration modelling has been used to simulate how much migration there could be from the milk bottle packaging to milk. The modelling parameters chosen are those selected by EFSA when it published the original opinion of CLRrHDPE detailed in Table 22. The simulation results in Table 23 indicate that the highest migration could be approximately 0.1 µg/kg for a reference contamination level of 0.024 mg/kg, and 0.03 µg/kg for a reference contamination level of 0.007 mg/kg.

Table 22: Standard modelling parameters

Parameter	Value
Temperature	5 °C
Duration	15 days
K_{fp}	1
rHDPE	100%
Area	6 dm^2
Food	1 kg
Thickness	300 μm
Layer density	0.96 g/cm^3

Table 23: Migration modelling of residual contamination

Surrogate	Mw	Background 0.024 mg/kg		Background 0.007 mg/kg	
		Residual μg/kg	Migration μg/kg	Initial μg/kg	Migration μg/kg
Phenylcyclohexane	160	2.4	0.0175	0.7	0.0051
Benzophenone	182	14.9	0.0941	4.34	0.0274
Benzyl butyl phthalate	312	24	0.0724	7	0.0211

2.7.5. Consumer exposure

Taking into account the intended uses of milk and milk products, the toddlers' exposure scenario considering a consumption of 90 g/kg bw/day the dietary exposure for each surrogate can be estimated for comparison to the threshold of 0.0025 μg/kg bw/day. It should be noted that the EFSA use a negligible risk threshold for DNA-reactive substances of 0.15 μg/person/day, whereas the US FDA use a threshold of 1.5 μg/person/day (0.025 μg/kg bw/day), with no toddler scenarios for consideration.

As shown in Table 24, the recycling process may very well be capable of producing a milk bottle manufactured from 100% if the contamination level of DNA-reactive substances is less than 0.007 mg/kg, and certainly meets the US FDA threshold of regulation of 1.5 μg/person/day (0.025 μg/kg bw/day). Using the US FDA HDPE consumption factor of 0.13, migration of 0.1 μg/kg (highest migration observed in Table 24) and food consumption of 3 kg/person/day, the estimated daily intake would 0.04 μg/person/day, a factor of 37.5 below the threshold.

Table 24: Consumer exposure concentrations

Surrogate	Background 0.024 mg/kg		Background 0.007 mg/kg	
	Migration μg/kg	μg/kg bw	Migration μg/kg	μg/kg bw
Phenylcyclohexane	0.0175	0.00158	0.0051	0.00046
Benzophenone	0.0941	0.00847	0.0274	0.00247
Benzyl butyl phthalate	0.0724	0.00651	0.0211	0.00190

Since the background contamination study had not identified any DNA-reactive substances in the feedstock down to 0.024 mg/kg, the contamination study is being continued to confirm the projected concentration of 0.007 mg/kg.

Ames testing did not show any mutagenic activity from a contact temperature of 20 °C for 10 days, using a test method with limits of detection in the order of 1 μg/L. Although the limit of detection does not necessarily demonstrate that consumer exposure to mutagenic substances is below 0.0025 μg/kg bw, it has demonstrated it is less than 0.1 μg/kg bw. Also, there is conservatism in the exposure via this method as migration testing was performed at 20 °C rather than 5 °C, where it has been shown that the migration concentration of some substances could increase by at least a factor of 5 in Section 2.4.3, meaning the exposure concentration could be much lower than 0.02 μg/kg bw.

There is a high degree of conservatism in the use of parameters used in migration modelling. Starting with the contact duration of 15 days, the mean contact duration is expected to be approximately 5 days, with a couple days spent in transit and storage, a few days in fridge storage in the household. The migration is also exaggerated because the food contact surface reduces with the consumption of milk over time. Generally, it is expected that infants would consume milk from the higher volume packages, given the high volume consumed within a day, therefore a surface area to food ratio is more likely to be 3 – 4 dm^2/kg.

BEHP was observed in the NIAS screening of rHDPE at a concentration of approximately 2 mg/kg. Because it was observed after the decontamination process, there is no decontamination efficiency to apply. Migration modelling of BEHP using the standard modelling parameters in Table 22 resulted in a food concentration of 4.12 μg/kg. The exposure rate was calculated to be 0.371 μg/kg bw/day. EFSA is considering establishing a group-TDI of 50 μg/kg bw/day (EFSA, 2019), concerning multiple phthalates, expressed as DEHP equivalents. On this basis the rHDPE will be suitable for producing a milk bottle from 100% rHDPE.

2.8. Quality assurance system

Veolia Plastics has a quality management system (QMS) in place (Annex 13). The scope of the QMS system includes the manufacture and distribution of recycled plastics intended for food contact use. Within this system there is control of documented information to ensure that the requirements of ISO 9001 are met, and that suitable information is recorded to demonstrate the effectiveness of the system. Key procedures in place provide descriptions and objectives of processes along with criteria established to meet regulatory or customer requirements. Such procedures included are:

- Control of documentation
- Control of raw material and suppliers
- Control of processing ingredients and suppliers
- Control of use of raw materials
- Sorting process SOP
- Washing process SOP
- Flake sorting process SOP
- Vacurema process SOP
- Product packaging and storage
- Product quality testing and control
- Non-conformance procedures for inputs, processes, and products
- Control of customer complaints, returns, recalls and rework
- Equipment calibration procedure
- Change management procedure
- Training procedure
- Internal auditing procedure
- Control of externally provided services

Within procedures regarding the manufacturing of rHDPE, critical control points with clear criteria are established with monitoring frequencies identified. Critical control points are based upon recognised risk priority tools of HACCP coupled with FMEA to ensure the rHDPE meets regulatory and customer requirements with a high degree of success.

Performance of the manufacturing process is monitored through internal audits and periodic management reviews. Management reviews monitor customer satisfaction, success rate of meeting quality objectives, process performance, non-conformances and corrective actions, critical control point performance, audit results, and performance of external services. There is also a frequent review of regulatory changes and industry best practices.

To assess the compliance of batches of output materials there is a system of traceability in place. The traceability of the system is able to identify that each batch complies with the criteria established on controlled procedures. Records are kept of movements of batches between customers, the recycling facility and external storage facilities by use of uniquely identifiable units. The types of information that are traceable through this unique identifier are:

- Dates of movements
- Storage locations and/or vessels
- Production dates
- Product testing results
- Process measurement records
- Intermediate products testing results

- Inputs used and testing results

The traceability system is also suitable to identify output products based on monitoring information from the process, so in the case of a process measurement failure identified a significantly long time after an event, related output products have the ability of being identified and either quarantined or recalled.

Table 25 provides a testing schedule for rHDPE, intermediates, processes, and input materials expected to ensure compliance with regulatory requirements along with Table 26 showing the process monitoring records retained.

Table 25: Testing programme for food contact rHDPE

Test	Frequency
Raw materials analysis	Each batch
Purity into granulation by weight	Daily
Purity into granulation by count	Hourly
Wash water caustic strength	Daily
Pellet colour	Every 3 hours
Pellet inclusions	Every 3 hours
Moisture	Every 12 hours
Melt flow rate	Each output batch
Volatiles by GC headspace	Every 6 hours
Accelerated specific migration	Each output batch
Other product stewardship requirements	Annually / As required

Table 26: Process monitoring records for food contact rHDPE

Parameter	Frequency
Input materials used	Timestamp and identification number for each bale entering the process
Bale throughput rate	Hourly
Automatic bottle sorter maintenance	Each shift, including error logs
Manual bottle sorting	Hourly, number of pickers
Washing throughput rate	Hourly, including deviation records
Washing temperature	Continuous, including deviation records
Washing sodium hydroxide concentration	Daily, including deviation records
Conductivity measurement	Continuous, including deviation records
Washing water consumption	Continuous
Flake sorter maintenance	Each shift, including error logs
Vacurema temperature	Hourly, including deviation records
Vacurema vacuum pressure	Hourly, including deviation records
Vacurema fill level	Hourly, including deviation records
Extruder throughput rate	Hourly, including deviation records
Extruder degassing temperature	Hourly, including deviation records
Extruder vacuum pressure	Hourly, including deviation records
Extruder melt pressure	Hourly, including deviation records
Extruder filter changes	As required

Records relating to the compliance of product batches will be retained for at least 3 years. Records retention also applies to physical samples of batches.

The quality control system uses testing information gathered by the Veolia Plastics internal laboratory which conforms with the Eurofins LabTRUST laboratory accreditation scheme. The scheme outlines the requirements for laboratories seeking to conform with ISO 17025, general requirements for the competence of testing and calibration laboratories. The test methods on the scope of compliance for LabTRUST are colour measurements, melt flow, density, volatiles by GC-MS headspace and accelerated migration.

3. Glossary

2,4-DTBP	2,4-Di-tert-butylphenol
bw	Body weight
CM	Carcinogenic or Mutagenic substance
CT	Challenge Test
BEHP	Bis(2-ethylhexyl) phthalate
BHT	Butylated hydroxytoluene
EC	European Community or European Commission
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EREMA	Engineering Recycling Maschinen und Anlagen GmbH
EU	European Union
FCM	Food contact Material
FDA	United States Food and Drugs Administration
FG	Food Grade
FIBC	Flexible Intermediate Bulk Container
FID	Flame Ionisation Detection
FMEA	Failure Mode and Effect Analysis
GC	Gas Chromatography
GMP	Good Manufacturing Practice
HACCP	Hazards Analysis and Critical Control Points
HDPE	High Density Polyethylene
INRA	French National Institute of Agricultural Research
IPA	Isopropanol
ISO 9001	ISO requirements for a quality management system
KT	Crystalisation dryer (first chamber) on Vacurema
MRF	Materials Recovery Facility
MS	Mass Spectrometry
Mw	Molecular weight
NFG	Non-Food Grade or Non-food use
NIAS	Non-Intentionally Added Substances
OM2	Standardised conditions for testing the overall migration, 10 days at 40 °C
PCA	Principal Component Analysis
PET	Polyethylene Terephthalate
PRF	Plastics Recovery Facility
QAS	Quality Assurance System
QMS	Quality Management System
RCL	Reference Contamination Level
rHDPE	Recycled High-Density Polyethylene
SML	Specific Migration Limit
SOP	Standard Operating Procedure
TDI	Tolerable Daily Intake
THF	Tetrahydrofuran
TTC	Threshold of Toxicological Concern
WHO	World Health Organisation
WRAP	Waste and Resources Action Programme

4. List of annexes and references

4.1. List of annexes

Annex 1.   Common ingredients in non-food use post-consumer HDPE packaging

Annex 2.   WRAP Fraunhofer Develop a food grade HDPE recycling process

Annex 3.   Example Veolia Plastics certificate of analysis for rHDPE

Annex 4.   HDPE contamination chemometric study on Veolia Plastics feedstock

Annex 5.   Veolia Plastics challenge test report 2022

Annex 6.   Pira International Generation of challenge test data on the Vacurema at Closed Loop Ltd Dagenham (09A11J1163)

Annex 7.   Pira International Generation of challenge test data on the Vacurema at Closed Loop Ltd Dagenham (10A11J1252)

Annex 8.   Pira International Generation of challenge test data on the Vacurema at Closed Loop Ltd Dagenham – migration data (09A11J1163m)

Annex 9.   Smithers Pira Overall Migration Test Report (13A12J5279)

Annex 10.   Leatherhead Food International Sensory triangular assessment of milk packaging (0902752)

Annex 11.   Leatherhead Food Research Sensory triangular assessment of milk packaging (0906814)

Annex 12.   FDA No objection letter for recycled plastics #108

Annex 13.   Veolia Plastics ISO 9001 certificate

Annex 14.   Veolia Plastics Eurofins LabTRUST certificate

Annex 15.   OFI Ames MPF test report

4.2. List of references

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