Technical dossier of the NEXTLOOPP recycling process to produce recycled polypropylene intended to be used for the manufacture of materials and articles in contact with food

Recycling process name: NEXTLOOPP

NEXTLOOPP
CLOSING THE LOOP ON FOOD GRADE PP

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1. Administrative data

1.1. Applicant information

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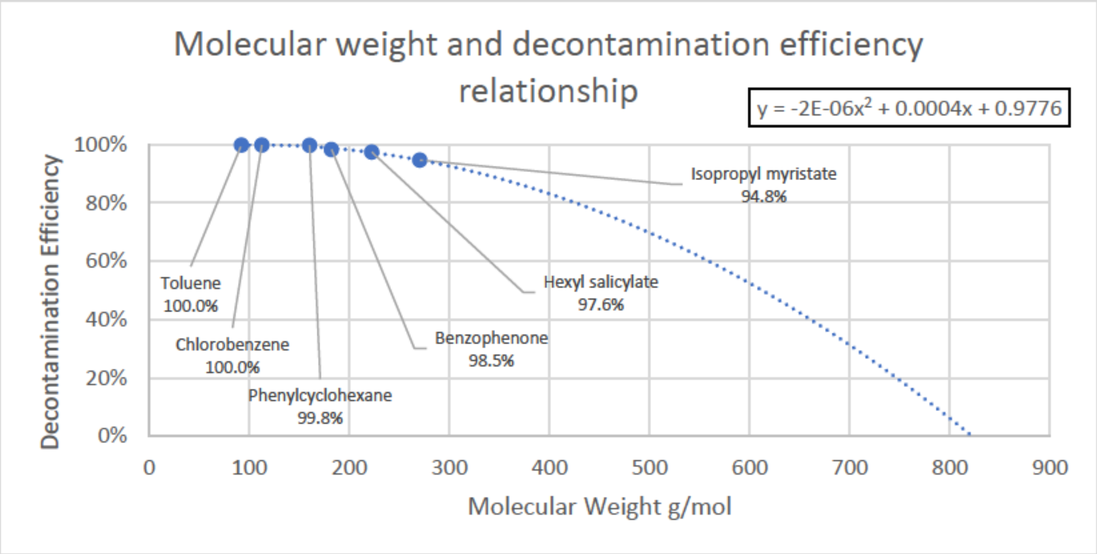
2. Public summary

The NEXTLOOPP recycling process is designed to transform post-consumer PP packaging back into food contact PP, referred to as PPristine, using technologies that remove contaminants that may be incidentally introduced into PP from its previous use or during collection and sorting processes.

The decontamination steps are performed in two phases, initially under a molten state, then a longer duration in the solid-state. The extrusion equipment is specially designed to have a high residence time in the degassing section to allow for the escape of semi-volatile substances. The solid-state treatment involves heating the pelletised extrudate under vacuum to allow for further degassing over several hours.

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.

Table 1: NEXTLOOPP challenge test performance



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 PP bales. PP bales are received at the recycling facility which are then sorted into colour categories using automated sorting technologies and purified further to 95% food-use PP 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 PP washed flake material. The washed flakes are sorted further into either individual or mixed coloured streams 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 and if there are limitations on the intended use of rPP. The harmful contamination observed in washed PP flakes has been calculated to be approximately 0.02 mg/kg, determined by a large GC-MS headspace survey of approximately 17,500 flakes combined with the statistical approach of Principal Component Analysis.

The coupling of the reference contamination rate of 0.02 mg/kg and the decontamination efficiency allows for the concentration estimation of low abundance substances which cannot be identified conventional analytical methods. Migration modelling has been employed to provide a severe over estimation of migration into a wide array of food contact applications, with suitability demonstrated for conditions equivalent or less severe than OM2 (long term storage at room temperature including hot fill or heating up to 100 °C). Considerations have also been made for toddler scenarios where some foods, such as jelly, may be packed into PP containers for room temperature storage for up to a year.

NIAS testing on rPP included both heavy metals testing, organic exhaustive extraction identification and quantification by GC-MS, and the use of Ames testing as a tool for assessing the presence of genotoxic substances which may migrate into foods, where no activity was detected even for PPristine INRT (80% food use containers).

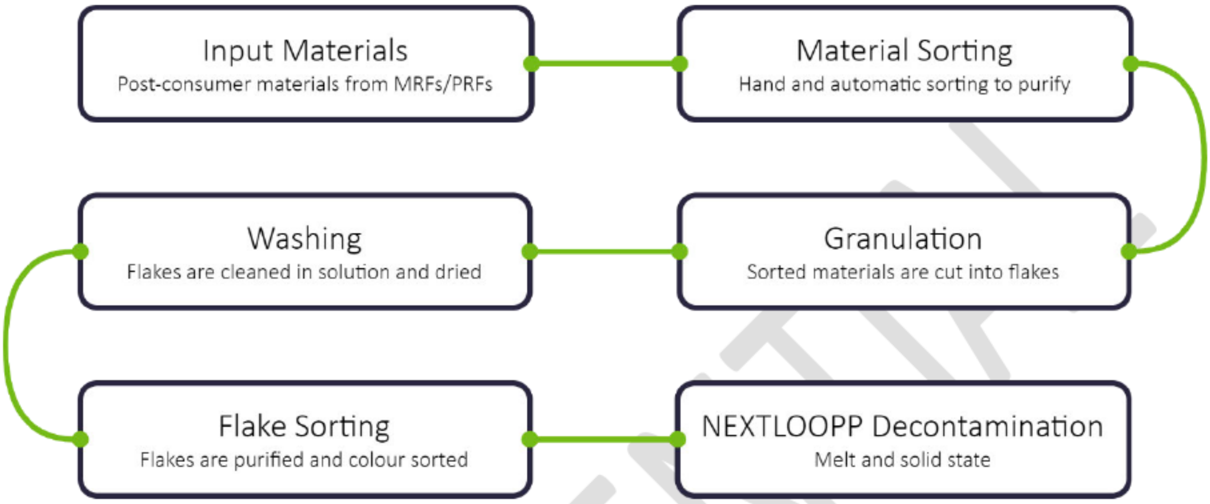
The safety criteria used for the safety evaluation of the NEXTLOOPP process is based on the Threshold of Toxicological Concern (TTC) approach, with the genotoxic exposure threshold of 0.0025 µg/kg bw/day being the critical target to be sure there is negligible risk to both adult and toddler consumers.

3. Technical dossier

3.1. Recycling process

3.1.1. Process flow chart

Figure 1: Flow chart diagram of the NEXTLOOPP recycling process



3.1.2. Short written process description

3.1.2.1. Input materials

Post-consumer materials for the recycling process come from MRFs, PRFs, food packaging business operators or deposit return schemes. These businesses either hand sort or automatically sort recyclate collections into material types, or plastics into polymer types. The recycling process receives input batches of post-consumer PP, either as a mix of colours, or pre-sorted into colour fractions of natural, white or multi-coloured.

3.1.2.2. Material sorting

The recycling facility will use a combination of automatic and manual sorting methods to purify the input PP materials. The objective of the sorting process is to achieve a purity of at least 95% of PP that is of food packaging origin.

3.1.2.3. Granulation

The recycling facility will cut the food packaging into flakes of a suitable size for further processing. Granulation methods may be either wet or dry processes.

3.1.2.4. Washing

PP flakes are washed using a solution of sodium hydroxide, detergents, and possibly antifoaming agents. The washing cycle will have a controlled concentration, throughput, residence time and temperature to provide a consistent washing quality. Following the wash, the flake is separated from solution, with a rinsing stage to wash off residual washing solution. There will be a process step within the washing manufacturing stage where impurities of densities different to PP are separated out by either sink-float tanks or hydro cyclones or both processes. The washed flakes are dried for suitable conveyance to the flake sorting manufacturing stage.

3.1.2.5. Flake sorting

Washed PP flakes will pass through a flake sorting system configured in such a way that it can purify the PP flakes so that more than 98% of the accept material is PP and over 99.9% is polyolefinic. The sorting equipment will use infrared, visible or ultraviolet detectors for discrimination. This will allow the separation of the PP flakes into different colour streams for separate decontamination processing. Metal separation and label removal is incorporated into this manufacturing stage also.

3.1.2.6. Decontamination

The sorted flakes are passed through a specialised extruder coupled with solid-state treatment system at controlled temperatures, throughput rates and residence time. The decontamination equipment is fitted with measuring devices that can be used to control its operation autonomously so that conditions are continuously met.

3.1.3. Detailed process description

3.1.3.1. Input materials

Materials received from suppliers will be inspected visually before accepting the material, to ensure it is of an appropriate polymer type and purity. Each input batch received from a supplier will be uniquely identifiable and further purity assessments performed. At least 10 kg of each input batch should be sampled and categorised to determine the approximate concentration of rigid PP packaging, and how much of the PP packaging was previously used for food purposes. The data collected should be 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 3.2.1.

Figure 2: Input PP bales

3.1.3.2. Material sorting

At the recycling facility, input batches of PP will have a further sorting step. The method of sorting may use a strategy of positively selecting PP, or by removing materials which are not PP. These could be carried out by either or both automatic and hand sorting methods, with the option of a single or multiple pass sorting system. The objective of the material sorting process is to achieve a high purity accept stream for the next manufacturing stage, where at least 95% of the PP is food packaging (95% food grade PP), and that the remaining balance of material is post-consumer material manufactured with food grade PP resins.

Food packaging would include, but not limited to:

- Ice cream containers
- Meat trays
- Fish trays
- Vegetable trays
- Dairy tubs
- Yogurt/cream containers
- Soup pots
- Butter/fat tubs
- Condiment containers/bottles
- Chocolate boxes
- Cake boxes
- Spice containers

Methods of sorting could be hand sorting, conventional automated sorting or advanced sorting technology using markers, digital watermarks, or AI, so long as the sorting accept purity is greater than 95% food grade PP.

For the hand sorting method, prior use of material is identified either by the labels, the definitive package shape (meat tray or fruit tray) or other printed decoration and reference to the PP material identification logo embossed on the base of packaging items. Belt speeds and burden depth is set accordingly to the purity of inputs to the sorting stage, the target purity out of the sorting stage, and the number of personnel available to remove the selected PP packaging into positive outputs, or contamination into negative outputs.

Conventional automated sorting methods involve either or both infrared or visible detectors which can measure the reflective infrared or visible signature of an object and determine its material or polymer type. Depending on the sorting strategy, the automatic sorter can activate air nozzles which will blow the object into an accept stream or reject stream. Where input streams are of high purity, typically only non-target objects are ejected due to air demand. Accepted bottles would continue on into the NEXTLOOPP recycling process, where the rejected fraction would be used in alternative recycling processes.

Advanced sorting technologies have been developed which use automatic sorting machinery coupled with positive identification of food packaging that has been labelled with intelligent markers (optical or digital) which have been shown capable of selecting food packaging at belt speeds of up to 3 m/s at 2 tonnes/hour/meter of belt width.

The sorting system could have up to 4 accept output categories:

- Mixed PP food packaging
- Natural PP food packaging
- White PP food packaging
- Multi-coloured PP food packaging

The sorting system may include further sorting steps for the purification of reject outputs categorised by, or a mixture of:

- Natural PP
- White PP
- Multi-coloured PP

Figure 3: Visual representation of the difference between 1) white, 2) coloured and 3) clear PP packaging, as well as the difference between their a) food contact and b) non-food contact applications

Reject outputs of PP will not be used any further within the NEXTLOOPP food grade recycling process and may be used for alternative recycling processes.

The purity of the accept outputs should be assessed frequently to ensure the purity is meeting the minimum target of 95% food grade PP. The assessment frequency and sample size should be defined, to ensure that the sample is representative with high confidence that the true mean lies above the target 95% food grade PP, and to demonstrate that it is consistently met. There will be at least 1 assessment made which represents 1 output batch, which in general, will be once per 30 tonnes of the accept material from the sorting stage.

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

Other processes such as metal sorting and label removal may be used at any point in this manufacturing stage.

3.1.3.3. Granulation

After sorting, the PP packaging is granulated in either a dry or wet granulation process where the items are cut into flakes of approximately 1 cm^2, which is a suitable size for subsequent manufacturing stages.

Wet granulation provides a small washing step removing the majority of residues, which are present from the contents retained in the packaging or had been introduced during the collection and sorting processes. The use of dry granulation processes are suitable for the decontamination process, so long as the subsequent manufacturing stages can clean the flake material suitably to meet the input requirements of the decontamination process.

Other processes such as drying, metal sorting and label removal may be used at any point between the granulation and washing manufacturing stages.

3.1.3.4. 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. Washing technologies and sequences of treatment stages may differ between recycling facilities, however they will objectively achieve near equivalent outputs, where the flake looks visibly clean, labels are removed, or delaminated for removal in the flake sorting stage, to a sufficient degree, and other polymer types or metals are minimised.

The PP flakes are washed using a solution of sodium hydroxide, detergents, and possibly antifoaming agents. The washing cycle will have a controlled concentration, throughput, residence time and temperature to provide a consistent washing quality. Typical washing conditions would be between 0.5-2% sodium hydroxide (w/v), a washing temperature of 70-80 °C, and a residence time of at least 10 minutes. The washing ingredients may only be of substances or mixtures designed for food industry use. The essential monitoring parameters in line with GMP are:

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

Following the wash, the flake is separated from solution, with a rinsing stage to wash off residual washing solution. There will be a process step within the washing manufacturing stage where impurities of densities different to PP are separated out by either sink-float tanks or hydro cyclones or both processes. The washed flakes are dried for suitable conveyance to the flake sorting manufacturing stage.

The washing process will be fitted with a water treatment process, which may either treat the used process water suitable for another process, or use water treatment equipment to make effluents compliant for disposal, or treat the process water in a closed loop system so that it is reusable in the washing process once again.

3.1.3.5. Flake sorting

Washed PP flakes will pass through a flake sorting system configured in such a way that it can purify the PP flakes so that more than 98% of the accept material is PP and over 99.9% is polyolefinic. The sorting equipment will use infrared, visible or ultraviolet detectors for discrimination. The flake sorting step may also include the separation of the PP flakes into different colour streams for separate decontamination processing. Typical colour fractions, separated from the non-PP plastics reject, could be:

- Natural
- White
- Multi-coloured

Typically, metal separation and label removal are incorporated into this manufacturing stage also.

3.1.3.6. Decontamination

The decontamination of either the clear, white, multi-coloured PP, or a mixture of PP is performed as one manufacturing stage in two phases with the objective of removing substances that have penetrated into the flakes which washing processes could not remove. The first stage involves an advanced extrusion step which under vacuum degasses the polymer melt, before it is melt filtered, and the extrusion cut into pellets. The extrusion equipment is fitted with measuring devices that can be used to control its operation autonomously so that it meets the following controlled parameters:

- Throughput rates
- Vacuum pressures
- Extrusion temperatures

The first phase is fitted with an automated material handling system to divert materials from the next phase of the decontamination process should the conditions being monitored be outside of tolerance levels.

The second phase involves a decontamination step performed on the pellets from the first phase. This step involves an alternative decontamination method which has a long residence time, at a high temperature, under vacuum. The decontamination equipment is fitted with measuring devices that can be used to control its operation autonomously so that it meets the following controlled parameters:

- Vacuum pressures
- Chamber temperatures
- Residence time

The second phase is fitted with an automated material handling system to divert materials from the storage of compliant material should the conditions that are being monitored be outside tolerance levels. An automated sampling system is fitted so that it frequently takes a sample of the material which has completed the recycling process for quality control testing purposes.

3.1.4. Confidential section

3.1.4.1. Phase 1 decontamination

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3.1.4.2. Phase 2 Decontamination

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END OF CONFIDENTIAL SECTION

3.2. Characterisation of input

3.2.1. Material sources

Materials for the recycling process may come from a variety of sources. There are multiple parties which play different roles within the supply chain. The plastic waste originates from municipal waste, deposit return schemes, or from recycling schemes involving food retail, or other food businesses where it was only intended and used for contact with food and does not leave the controlled closed loop of that recycling scheme.

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 of the recycling facility will need to obtain at least 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 it's suppliers provide sorted wastes from unsorted municipal collections, 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 have the ability to 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.

PP 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 PP producers, nearly all PP resins used for packaging applications comply to EU regulations and directives.

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

Scrap materials from manufacturers of PP 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 PP 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 may be made more resource efficient, with a potential to lower the sodium hydroxide strength and washing temperature.

3.2.2. Sorting input materials

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

The recycling facility and its suppliers may have different sorting strategies allowing the use of mixed plastics or pre-sorted plastics therefore it may not be appropriate to have a single specification for input material. There shall be 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, used for an alternative recycling process, or suitably treated to meet the minimum requirement of 95% food grade PP with extra resourcing or precautions.

3.2.3. Sorting input material study

The feedstock for recycled PP assessed in this technical dossier had an in-depth compositional analysis performed to understand the typical packaging purities expected, and the nature of the non-food packaging items.

Food packaging categories identified on this study were:

- ice cream containers
- meat trays
- fish trays
- vegetable trays
- dairy tubs
- yogurt/cream containers
- soup pots
- butter/fat tubs
- condiment containers/bottles
- chocolate boxes
- cake boxes
- spice containers

Figure 10: Food grade material after a hand sort. A) Clear, B) Multi-coloured, C) White

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

Figure 11: Non-food material after a hand sort. A) Clear, B) Multi-coloured, C) White.

Non-food PP packaging largely consists of laundry detergent tubs containing wrapped pods or powder 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 electrical and electronics plastics. Table 3 showing an 'Other' fraction, which was composed of cardboard, glass, film, and food cans, and did not contain industrial plastics, indicating that the established input controls produce high levels of post-consumer purity.

Table 3: Audit results showing the breakdown of PP bales into food grade, non-food grade and other applications and the sequent product types

Category	Quantity (kg)	Percentage
Food	64.17	71%
Bottles	1.055	1%
Lids	8.405	9%
Pots	9.61	11%
Pots & Tubs	13.755	15%
Trays	15.57	17%
Tubs	15.775	17%
Non-Food	16.57	18%
Other	9.465	10%
Grand Total	**90.205**	**100%**

Between February 2009 and April 2010, WRAP had performed a scoping study into food grade PP recycling (Annex 3) where the target food grade material was 56% of the input. The comparison of the information from 2010 and 2021 shows the greater growth in the UK collection of household PP packaging and improvements in sorting systems in reducing the proportion of non-food packaging materials, shifting from approximately 50% to 70% food grade PP.

Table 4: WRAP PP Scoping study (Annex 3 - Table 2) showing compositional analysis of a PP bale sample

Category	Weight (kg)	%	Category subset	Weight (kg)	%
Tubs and pots	24.0	35	Yoghurt pots	1.15	2
			Yellow margarine pots	3.00	4
			Non-yellow margarine tubs	3.81	6
			Clear food product packaging	5.71	8
			Non-clear food product packaging	7.35	11
			Ice-cream tubs	2.90	4
Trays	8.5	12	Blue food trays	0.80	1
			Clear food trays	5.45	8
			Other food trays	2.30	3
Bottles	5.5	8	Beverage bottles	1.65	2
			Sauce bottles	3.81	6
Cleaning products	7.5	11	Household cleaning	2.36	3
			Personal hygiene	2.60	4
			Detergents	2.86	4
Caps	1.5	2	Closures	1.50	2
Black plastics	1.0	1	Black plastics	1.00	1
Non-assignable	21.0	30	Notable non-food objects	5.65	8
			Small fragments	15.10	22
Total	69.0				99%

Ingredients used in post-consumer non-food packaging PP, such as shower gels and detergents, are typically of low toxicity due the on-skin nature of the products. Annex 4 shows some ingredients found within different types of non-food packaging products which could contaminate the plastic material. Assessing the structure of the substances via the Cramer Classification system and Threshold of Toxicological (TTC) approach, the ingredients were a mixture of Cramer Class I, II and III. This shows that the post-consumer PP packaged products are highly unlikely to contain substances such as organophosphates, carbamates, carcinogenic or mutagenic substances, therefore the polypropylene packaging would also be unlikely contain harmful substances.

3.2.4. Washing input material

The input material for the washing process needs to be a minimum of 95% food grade PP. The stage where this is easily identifiable is before the food packaging material is granulated into a flake. Therefore, the purity of the sorting accept should be assessed prior to granulation. The assessment frequency and sample size should be defined, to ensure that the sample is representative with high confidence that the true mean lies above the target 95% food grade PP, and to demonstrate that it is consistently met. There will be at least 1 assessment made which represents 1 output batch, which in general will be once per 30 tonnes of the accept material from the sorting stage.

3.2.5. Washing input material study

Bales of PP were sorted and separated into natural, white and multi-coloured streams by using conventional automated sorting technologies. Each colour type was then hand sorted into food use and non-food use packaging, creating 6 output types. Audits were carried out on the food use streams to determine the proportion of food use packaging, which is also closely representative of the proportions for the washing input.

Table 5: Audit of PP natural bale before washing

Category	Quantity (g)	Percentage
Food	19,520	95.7%
Clear	18,912	92.8%
Multi-coloured	230	1.1%
White	378	1.9%
Non-Food	722	3.5%
Clear	298	1.5%
Multi-coloured	424	2.1%
White	0	0.0%
Other	148	0.7%
Grand Total	**20,390**	**100%**

Table 6: Audit of PP white bale before washing

Category	Quantity (g)	Percentage
Food	18,394	95.3%
Clear	1,412	7.3%
Multi-coloured	132	0.7%
White	16,850	87.3%
Non-Food	762	3.9%
Clear	172	0.9%
Multi-coloured	206	1.1%
White	384	2.0%
Other	152	0.8%
Grand Total	**19,308**	**100.0%**

Table 7: Audit of PP Multi-colour bale before washing

Category	Quantity (g)	Percentage
Food	36,690	91.7%
Clear	6,066	15.2%
Multi-coloured	14,678	36.7%
White	15,946	39.8%
Non-Food	2,958	7.4%
Clear	250	0.6%
Multi-coloured	1,952	4.9%
White	756	1.9%
Other	380	0.9%
Grand Total	**40,028**	**100.0%**

Greater than 95% food use was achieved for natural and white PP fractions. The sorting of multi-coloured PP had achieved a purity of approximately 92% of food use packaging. With further investigation it was noticed that some of the multi-coloured materials were identified incorrectly as non-food, for example lids from powdered infant milk as shown in Figure 12, therefore the actual food use packaging is close to 95%.

Figure 12: Multi-coloured PP classified as non-food use PP during multi-coloured PP feedstock audits

A significant proportion of the non-food packaging are containers holding detergent capsules as shown in Figure 13. The dissolvable packet of detergent liquid is typically made of PVA as the primary packaging which acts as a barrier between the contents and PP container, which is secondary packaging, significantly reducing the amount of detergent chemicals that might be migrating into the plastic packaging.

Figure 13: Example of liquid detergent capsule and packaging

For the purposes of developing prototypes of recycled PP, the study of the safety and performance of the recycled coloured PP continued with a 92% food grade PP feedstock. Continuing the assessment with the lower than 95% food grade PP feedstock will help identify the criticality of the specification. The recycling installation will still be required to meet the 95% food grade PP standard, where the liquid capsule packaging would still fall under the non-food category.

3.2.6. Decontamination input material

The material for the decontamination process is derived from applying the sorting, washing, and flake sorting processes on the input materials. Firstly, the material will have been sorted so that at least 95% of the PP is food packaging. This shall be verified by audits of the accept material from the sorting process, where at least 10 kg of the material is assessed at least once every 30 tonnes of accepted material.

Secondly, the sorted material will have been granulated and washed to controlled parameters, removing surface contamination. The parameters will be monitored continuously wherever practicable or to at least once every 30 tonnes of accepted material processed. The washing process should treat the flake to at least the following conditions:

- Sodium hydroxide concentration should be between 0.5-2% (w/v)
- Washing temperature of at least 70°C
- Residence time of at least 10 minutes

Finally, the washed PP flake materials will be sorted by at least one sink-float separation step where the PP will remain in in the float fraction and other polymers with a density greater than that of water will be in the sink fraction. The float fraction is then subjected to automatic NIR/VIS flake sorters to purify the flake so that at least 99% of the flakes are PP. The flake sorting process may achieve this with the use of metal separation, air classification, polymer sorting or colour sorting. The contamination content in the flake entering the decontamination process should be evaluated at least once every 30 tonnes for the following parameters:

- Colour (e.g. L* a* b*)
- Loose labels
- Adhered labels
- Non-PP polymers (e.g. HDPE, LDPE, LLDPE)

- Metals
- Residual alkalinity
- Volatiles (e.g. limonene content)

3.2.7. Decontamination input material studies

3.2.7.1. Washing parameters

The sorted natural, white and coloured streams of PP were washed using a conventional washing process in August 2021. Materials were washed in a 1% caustic soda solution containing a washing detergent additive. The washing stage involved high agitation for 10 minutes between 70-80 °C.

3.2.7.2. Flake properties

The nominal size of the flakes was observed to be approximately 4 to 8 mm as show in Table 8 and other flake properties are illustrated in Table 9 and Table 10.

Table 8: Particle size distribution of PP flakes

Flake Size (mm)	Natural	White	Multi-coloured
> 11.2	0.0%	0.1%	0.3%
10 - 11.2	0.4%	0.5%	1.0%
8 - 10	2.7%	5.7%	8.4%
4 - 8	39.2%	56.4%	68.5%
3.15 - 4	17.8%	14.9%	9.0%
2 - 3.15	25.7%	17.7%	11.1%
1 - 2	13.4%	4.6%	1.7%
0.6 - 1	0.8%	0.1%	0.0%
< 0.6	0.0%	0.0%	0.0%

Table 9: Properties of PP flakes

Property	Natural	White	Multi-coloured
Bulk density (kg/m^3)	252	261	294
Residual alkalinity (ref pH 7.72)	7.92	7.90	7.94
L*	69.2	79.1	66.7
a*	0.3	1.5	1.3
b*	4.9	5.5	3.9

Table 10: PP flake composition

Flake type	Natural	White	Multi-coloured
Natural flake	91.7%	21.6%	24.0%
White flake	6.6%	73.2%	38.1%
Coloured flake	1.5%	5.0%	37.9%
Other	0.2%	0.3%	0.0%
Flake with labels	6.0%	31.7%	36.8%

3.2.7.3. Chemical contaminants

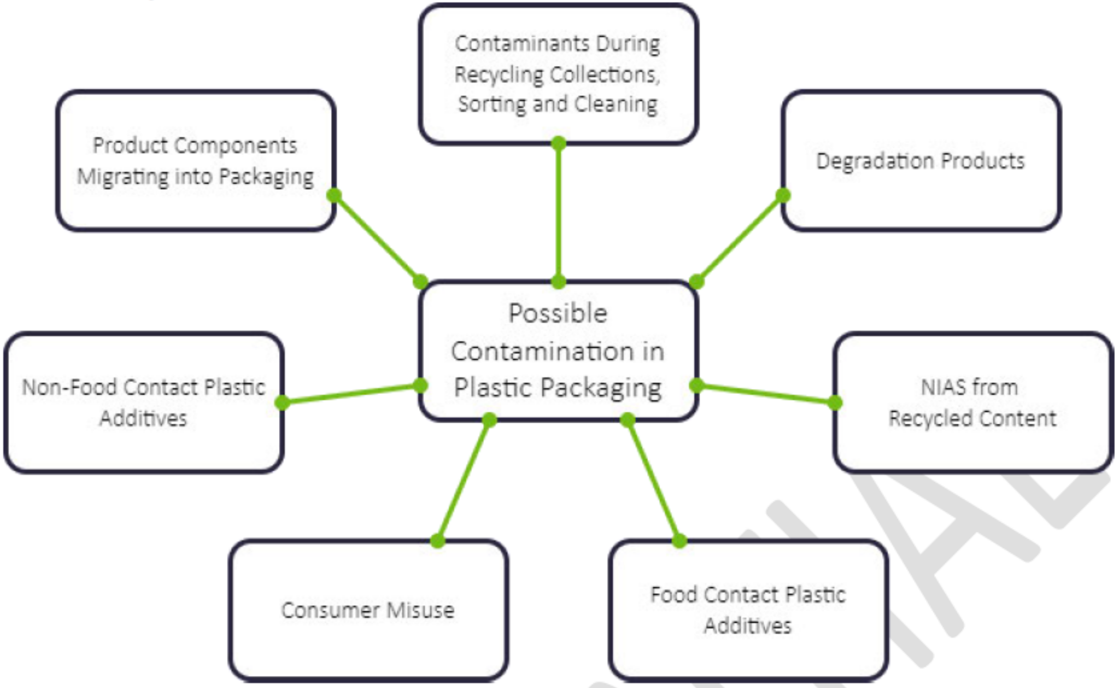
Substances may be introduced into the PP materials at various stages of its lifetime. It will begin with the manufacture of polypropylene packaging resins where additives, designed predominantly for food applications may be added. The manufacture of articles may also introduce substances in the form 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 also 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 come into contact with 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 14: 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 4 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. Most PP packaging found in supermarkets are used for storage of either food or personal care cosmetic 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 only significant homecare (non-food) use for PP is the storage of liquid laundry capsules which has a low probability of contaminating the PP secondary packaging. The majority of homecare products are contained in HDPE or PET bottles, which is also is a preferred choice for plant care products, where no PP containers have been observed.

The ingredients of the non-food products are generally in the TTC classifications of Cramer Class I, II and III. There have been no substances observed fitting the organophosphate and carbamate classes. When surveying non-food product ingredients, butylated hydroxyanisole (BHA) was found in a well-known antiseptic healing cream where some data submitters to ECHA consider the substance as carcinogenic and is currently under investigation for endocrine disrupting properties. However, this substance is regarded as non-genotoxic and is an authorised FCM (FCM No 635) with an SML of 30 mg/kg therefore is unlikely to be of immediate concern. Another substance with a warning was sodium hydroxymethylglycinate found in a shower gel as carcinogenic due to the ability of releasing formaldehyde. Because the ingredient concentration is so low the product does not require labelling as carcinogenic. The decontamination process is effective at removing low molecular weight contaminants therefore formaldehyde is not expected to be an issue for the decontamination process.

3.2.7.4. 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). 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.

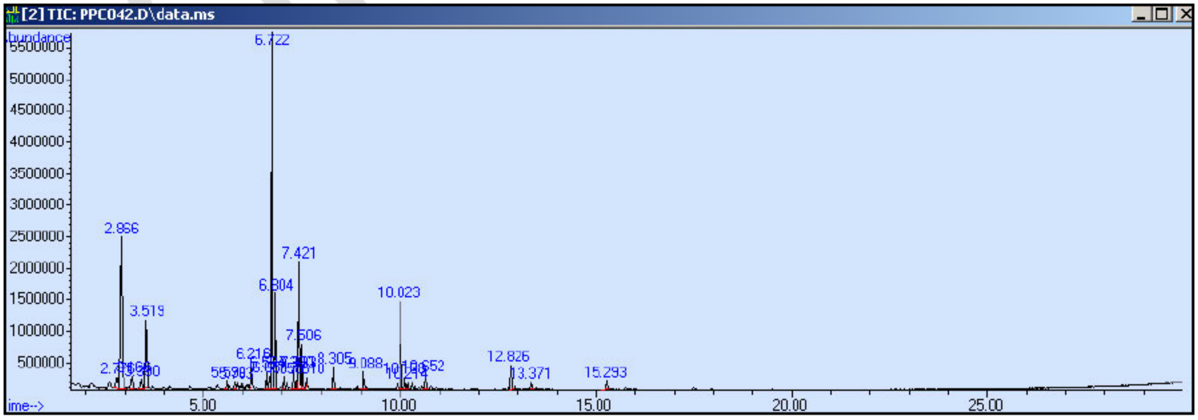
For the HDPE study, Fraunhofer IVV identified a single outlier sample and the investigation concluded that there were 2 unknown substances with approximate concentrations of 130 and 40 mg/kg for the sample containing 50 flakes. It had been inferred that a single flake contributed to the amount observed 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 set 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 safety assessments.

NEXTLOOPP commissioned a similar study for obtaining a reference contamination level for PP packaging to enable comparison to safety criteria. In this study, 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.

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 PP washed flakes. This is believed to add additional information not available in surveys for PET and HDPE, where substances like toluene and xylene, which are Cramer Class I substances, are used to set a carcinogenic reference. The full report into the reference contamination study is found in Annex 6.

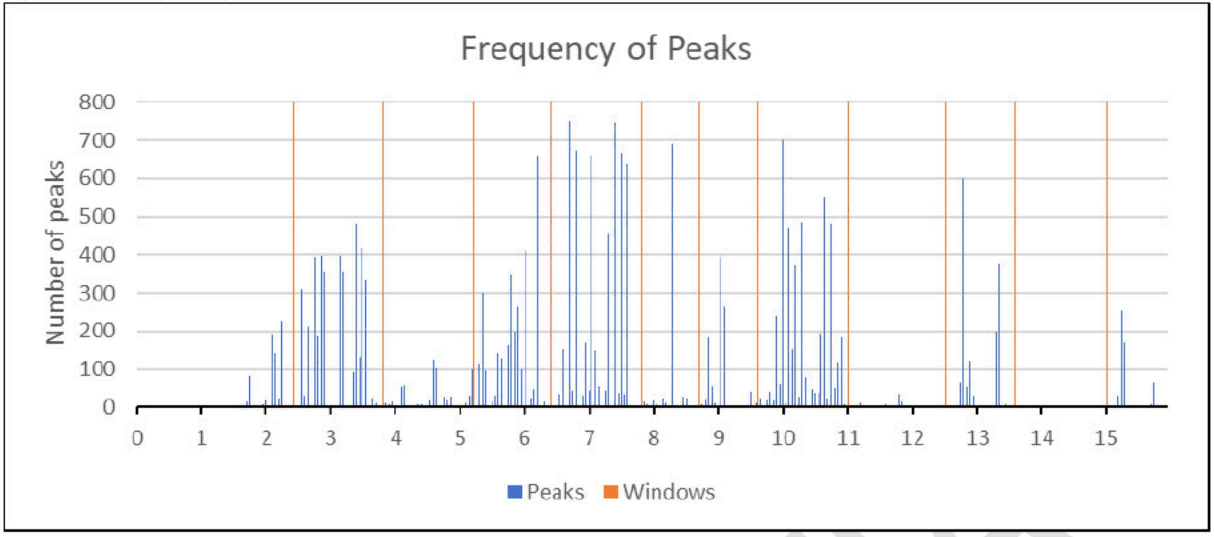
The study was performed on PP washed flakes used for the manufacture of PPristine prototype resins. A 20-tonne batch of PP bales were sorted into different fractions of food use, non-food use and colours. The entire batch represented approximately 260,000 items of packaging based upon an average article weight of 40 g. Approximately 700 samples were analysed by GC-MS, each sample representing 25 flakes, generating a total of 17,500 flakes, or articles, represented in the survey.

Figure 15: Typical GC-MS headspace chromatogram of washed PP flakes



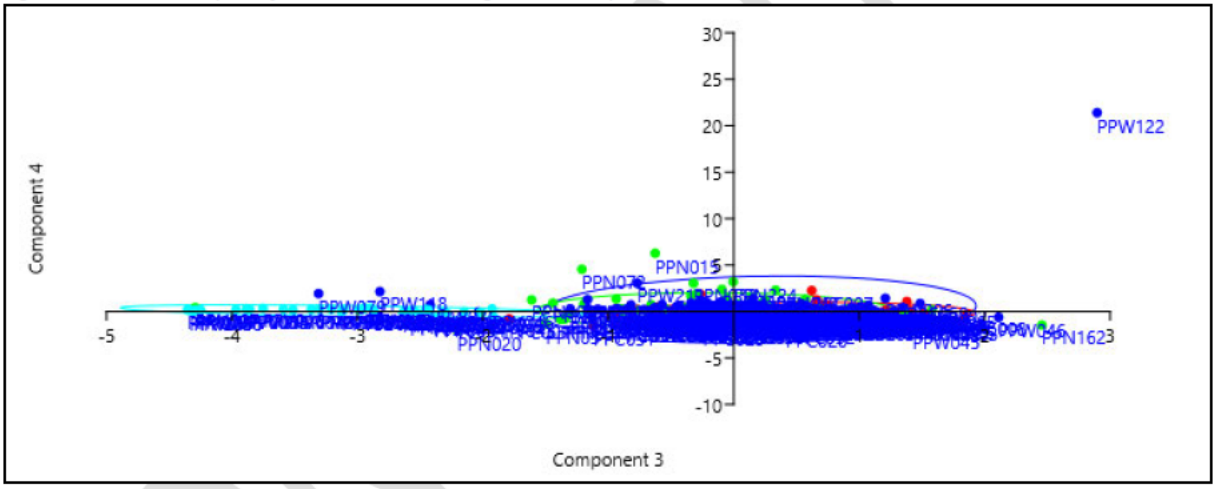
Using the same approach as Fraunhofer IVV, retention time windows were established, and abundances summed for each window.

Figure 16: Histogram of peak frequencies for all samples



The Mahalanobis distances were calculated for each sample from the entire set of observations as the test for outlier samples. One sample was identified as an outlier as shown in Figure 17.

Figure 17: PCA Scores plot of PC3 and PC4 showing outlier sample PPW112



Investigations into PPW112 had identified the presence of cyclopentasiloxane (CAS No 541-02-6), isohexadecane (CAS No 4390-04-9), and cyclohexasiloxane (CAS No 540-97-6). The concentration of the substances across the 1 g sample was estimated to be 550, 245, 465 mg/kg respectively. All 3 substance are common ingredients for cosmetic products such as hand moisturisers and face creams. A product such as L'Oreal Paris Collagen Moisturiser contains all 3 of these substances as listed ingredients, suggesting that the study had not identified an incident of misuse, rather it's a case of mis-sorting where a non-food packaging had not been sorted from the feedstock for the decontamination process.

Since the PCA study had not identified any carcinogenic or mutagenic substances, further investigations were carried out, looking at the top 1% Mahalanobis distance samples. Substances identified are summarised in Table 11. All of the substances identified fall into Cramer Class I, II, or III categories, with none showing hazards for carcinogenic or mutagenic activity.

Table 11: Substances identified in top 1% Mahalobis distance samples

Substance	CAS No	Class	FCM	Conc. mg/kg
Cyclopentasiloxane	541-02-6	III	-	550
Isohexadecane	4390-04-9	I	-	245
Cyclohexasiloxane	540-97-6	III	-	465
Hexane, 2,4-dimethyl-	589-43-5	I	-	30
2,2,4-Trimethyl-1,3-pentanediol diisobutyrate	6846-50-0	I	497	55
Amberonne	54464-57-2	III	-	40
Limonene	5989-27-5	I	-	745
1-Terpinenol	586-82-3	III	-	35
Camphor	76-22-2	III	136	55
Isoborneol	124-76-5	I	-	30
Borneol	10385-78-1	I	-	35
4-Terpineol	562-74-3	III	-	25
Terpineol	98-55-5	III	-	230
τ-Terpineol	586-81-2	III	-	40
1-Ethyl-4-methylcyclohexane	3728-56-1	I	-	15
o-Xylene	95-47-6	I	-	15
Nonane	111-84-2	I	-	70
2,2'-Azobis(2,4-dimethylvaleronitrile)	4419-11-8	III	-	740

The next screening approach in the attempt of identifying a relevant carcinogenic or mutagenic substance, was to use the NIST spectral library to assign it's top 3 assignments for each peak observed on the 700 chromatograms. The list of CAS numbers generated were cross referenced with a list of category 1 and 2 mutagenic and carcinogenic substance CAS numbers within Table 3 of Annex VI CLP Regulation. Two substances were identified as category 2 carcinogens, suspected of being carcinogenic by data submitters to ECHA. During the screening, triethyl phosphate was also observed which would fall into the organophosphate TTC category. Table 12 provides information on the substances observed, number of detections and concentrations.

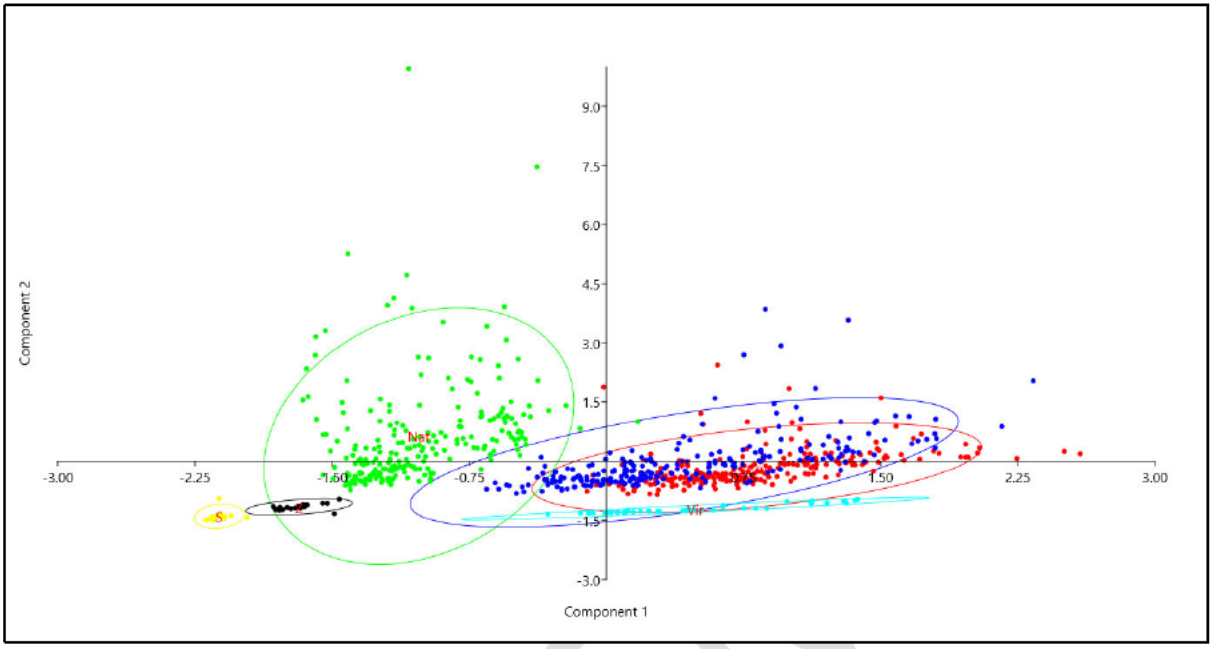
Table 12: Substances identified during screening against positive NIST matches and Annex VI CLP Regulation

Substance	CAS No	Category	# Detections	Concentration mg/kg
Methyl isobutyl ketone	108-10-1	Carc. 2	1	7
Tetrachloroethylene	127-18-4	Carc. 2	1	6
Triethyl phosphate	78-40-0	Organophosphate	1	58

Methyl isobutyl ketone (MIBK) is a common solvent for resins, paints, varnishes, lacquers, and nitrocellulose which may have been introduced via PP paint containers which is not target material for the NEXTLOOPP recycling process. MIBK is not regarded as a genotoxic carcinogen therefore falls within the Cramer Class III threshold. Tetrachloroethylene is found in dry cleaners and stain removers, therefore is likely present from mis-sorting rather than misuse also. Tetrachloroethylene itself is not regarded as genotoxic however a number of its metabolites are considered genotoxic. Triethyl phosphate may have been introduced into the recycling stream as a plasticiser used for non-food plastics.

The PCA study was extended to investigate hand-picked material (HPM) that has been completely hand selected and cleaned by additional washing process. The aim of the study was to determine if there were significant differences between UK recycling stream materials and HPM materials, and if that difference was a concern. The additional data had shown lower variance in the HPM materials compared to UK recycling stream derived materials as shown in Figure 18.

Figure 18: PCA study extension with hand-picked materials (yellow and black) combined with UK source material (green, blue and red) and virgin (teal)



The study had shown that the HPM material has variance similar to virgin in Principal Component 2 (PC2), related to the low activity of substances such as limonene. The low PC1 score is related to smaller low molecular weight oligomeric concentrations in the hand-sorted material, in comparison to both UK recycling stream sourced materials and sampled virgin resins. The study shows that hand sorted materials can be suitable for the NEXTLOOPP recycling process as it is relatively clean and consistent.

Based on these findings, it has been calculated the incidence rate of a carcinogenic or mutagenic substance in the PP washed flake is 2 in 17,500 being 0.01%. The concentration within a single flake is calculated to be 175 mg/kg (7 mg/kg across 25 flakes). Based on an occurrence rate of 0.01% and a contamination concentration of 175 mg/kg, the reference contamination level for a carcinogenic or mutagenic substance would be 0.02 mg/kg for comparison to the 0.15 µg/person/day TTC category. In the case of the organophosphates, the reference contamination level would be 0.08 mg/kg for comparison to the 18 µg/person/day TTC for organophosphates.

3.3. Determination of the decontamination efficiency of the recycling process

A challenge test was performed as a part of a WRAP project developing a food-grade recycling process for post-consumer PP (Annex 1 Trial 4 and Trial 5) in 2011 using the [redacted] extrusion process and [redacted]. The laboratory analytical test report is in Annex 7. The feedstock for the challenge test was prepared by [redacted] and analysed by [redacted]. Two 50 kg drums of virgin PP flakes were contaminated with surrogate chemicals as described in Table 13, with storage at 40 °C for 10 days. The challenge test was performed using a 25 kg portion of the surrogate flake, without dilution of any other uncontaminated flakes.

Table 13: Surrogates used for challenge testing

Surrogate	CAS No.	Mw	Bp °C	Polarity
Toluene	108-88-3	92.14	111	Non-polar
Chlorobenzene	108-90-7	112.56	132	Polar
Phenylcyclohexane	827-52-1	160.26	239	Non-polar
Benzophenone	119-61-9	182.22	305	Polar
n-Hexyl salicylate	6259-76-3	222.28	290	Non-polar
Isopropyl myristate	110-27-0	270.45	193(1)	Non-polar

(1) at 20 mmHg

3.3.1.1. Phase 1 operating parameters

Table 14: Challenge test Phase 1 operating parameters

Parameter	Value
Degassing section temperature	[redacted]
Throughput rate	[redacted]
Vacuum pressure	[redacted]

3.3.1.2. Phase 1 decontamination efficiency

A portion of the output from Phase 1 had the residual concentration of surrogates determined. The concentrations were determined by performing an exhaustive extraction of 5 g rPP pellets in 25 mL tetrahydrofuran, at 60 °C for 3 days, with quantification by GC-MS. Table 15 provides a summary of the decontamination efficiency of Phase 1. Since there was no dilution with uncontaminated flake and the residence time within the extruder is effectively constant for all flakes, the yield of decontamination is simply the relative difference between the initial and residual concentrations.

Table 15: Challenge test Phase 1 decontamination efficiency

Surrogate	Initial concentration[(1)] mg/kg	Residual concentration[(2)] mg/kg	Yield of decontamination
Toluene	1,242	42	96.6%
Chlorobenzene	1,291	59	95.4%
Phenylcyclohexane	930	119	87.2%
Benzophenone	583	143	75.5%
n-Hexyl salicylate	906	212	76.6%
Isopropyl myristate	783	226	71.1%

(1) Sample 9 of Table A-6 of Annex 2 *(2) Sample 10 of Table A-6 of Annex 2*

3.3.1.3. Phase 2 operating parameters

Table 16: Challenge test Phase 2 operating parameters

Parameter	Value
Reactor temperature	[redacted]
Residence time	[redacted]
Vacuum pressure	[redacted]

3.3.1.4. Phase 2 decontamination efficiency

A portion of the output from Phase 2 had the residual concentration of surrogates determined. Table 17 provides a summary of the decontamination efficiency of Phase 2. Since there was no dilution with uncontaminated pellets and the residence time within the reactor was constant for all pellets, the yield of decontamination is simply the relative difference between the initial and residual concentrations.

Table 17: Challenge test Phase 2 decontamination efficiency

Surrogate	Initial concentration[(1)] mg/kg	Residual concentration[(2)] mg/kg	Yield of decontamination
Toluene	42	< 0.5	98.8%
Chlorobenzene	59	< 0.5	99.2%
Phenylcyclohexane	119	1.7	98.6%
Benzophenone	143	9.0	93.7%
n-Hexyl salicylate	212	22	89.6%
Isopropyl myristate	226	41	81.9%

(1) Sample 10 of Table A-6 of Annex 2 *(2) Sample 11 of Table A-6 of Annex 2*

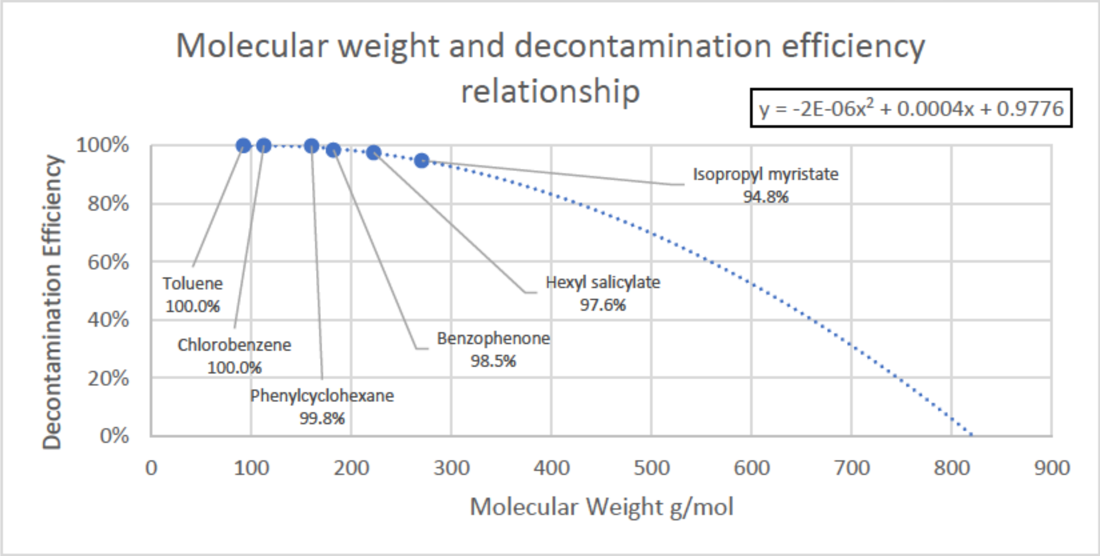
3.3.1.5. Overall decontamination efficiency

Table 18: Challenge test overall decontamination efficiency

Surrogate	Initial concentration[1] mg/kg	Residual concentration[2] mg/kg	Yield of decontamination
Toluene	1,242	< 0.5	>99.9%
Chlorobenzene	1,291	< 0.5	>99.9%
Phenylcyclohexane	930	1.7	99.8%
Benzophenone	583	9.0	98.5%
n-Hexyl salicylate	906	22	97.6%
Isopropyl myristate	783	41	94.8%

(1) Sample 9 of Table A-6 of Annex 2 *(2) Sample 11 of Table A-6 of Annex 2*

Figure 19: Challenge test molecular weight-decontamination efficiency relationship



The decontamination process has a high decontamination power for all the surrogate substances used. Extrapolating the trendline of the decontamination efficiency and molecular weight, it indicates that decontamination rate approaches 0% at 700 to 900 g/mol. For the purposes of evaluation of migration using the reference contamination level in Section 3.7.3, the molecular weight of 700 has been selected for migration modelling as it may have a low rate of decontamination (approaching 0%) and a higher polymer diffusion rate compared to 800 or 900 g/mol. The migration of surrogates following the challenge test has been assessed and summarised in Table 19 using simulation parameters given in Table 20 assuming an article made from 100% rPP at 40 °C for 10 days, using a conservative partition coefficient representing fatty food. [redacted]

Table 19: Challenge test migration evaluation

Surrogate	Mw	Residual concentration mg/kg	Migration mg/kg
Toluene	92	< 0.5	< 0.00593
Chlorobenzene	113	< 0.5	< 0.00593
Phenylcyclohexane	160	1.7	0.0202
Benzophenone	182	9.0	0.107
n-Hexyl salicylate	222	22	0.261
Isopropyl myristate	270	41	0.481

Table 20: Challenge test migration modelling parameters

Parameter	Value
Surface area	100 cm^2
Food volume	150 mL
Layer thickness	0.2 mm
Polymer density	0.9 g/cm^3
Food density	1 g/cm^3
Food/packaging coefficient	1
Temperature	40 °C
Duration	10 days
Diffusion coefficient calculation	Piringer

The combination of the reference contamination level and decontamination performance is addressed in Section 3.7.3, where the food application is also considered when assessing the dietary exposure to consumers.

3.4. Characterisation of the recycled plastic

3.4.1. Physical properties

Several properties have been assessed for the recycled PP materials intended for food contact use. The properties in Table 21 are properties measured during the manufacture of prototype materials. It is important to note that PP is provided in extrusion and injection moulding grades, therefore the properties of the are likely to change depending on the feedstock into the recycling process.

Table 21: Typical properties of recycled PP from the NEXTLOOPP recycling process

Property	Natural	White	Grey
Pellets per 5 g	147	136	174
Tensile stress at yield (MPa)	30.5	28.5	28.0
Tensile strain at yield (%)	9.0	6.3	6.1
Tensile modulus (MPa)	1,183	1,255	1,248
Flexural modulus (MPa)	1,379	1,426	1,376
Izod impact, notched, 23 °C (kJ/m^2)	5.1	5.7	5.4
Izod impact, notched, -20 °C (kJ/m^2)	3.0	3.6	3.5
Melt flow rate (g/10min)	14.1	20.2	27.3

3.4.2. Non-intentionally added substances

Recycled PP materials were screened for NIAS substances to understand the components which may be commonly found in recycled resins. Table 22 shows the samples analysed, including a description of the feedstock used to create the product.

Table 22: Materials screened for inorganic and organic substances

Sample name	Description			
		Annex 8 Sample code	Annex 9 Sample code	Annex 10 Sample code
PPristine Natural	95% food grade natural PP sourced from UK recycling stream	Pristine Nat FG	YE0522045	P22-03160-1
PPristine White	95% food grade white PP sourced from UK recycling stream	Pristine White FG	YE0522047	P22-03160-2
PPristine Grey	95% food grade multi-coloured PP sourced from UK recycling stream	Pristine Colour FG	YE0522043	P22-03160-3
PPristine IM	99% injection moulded food grade natural PP sourced from hand-picked materials	Pristine IM FG	YE0522046	P22-03160-4
PPristine INRT	80% food grade natural and white PP sourced from UK recycling stream	Pristine INRT	YE0522044	P22-03160-5

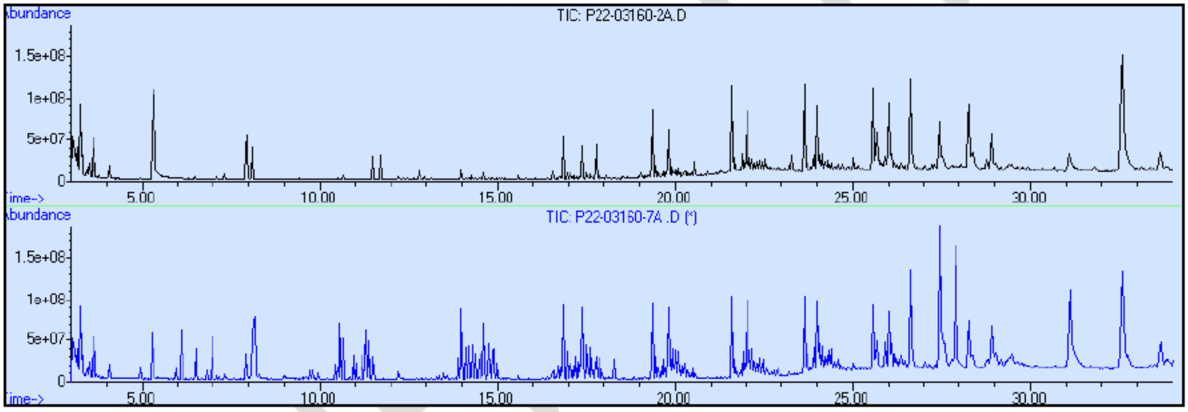
3.4.2.1. Inorganics

A semi-quantitative analysis was performed on 5 recycled PP samples by ICP-MS (Annex 8). The natural, white and coloured rPP resins contain typical levels of metals relating to the use of allowable pigments and fillers. The results also show that the material meets the heavy metal requirements of the packaging and packaging waste directive 94/62/EC. Annex 9 also includes data on heavy metals carried out by another laboratory.

3.4.2.2. Organics

A semi-quantitative analysis was performed on 5 PP samples by GC-MS (Annex 10). The samples analysed were a variety of PP products as described in Table 22. A food grade PP tray was used as a reference point for understanding the key differences between recycled and virgin PP resins. Materials were exposed to tetrahydrofuran at 60 °C for over 3 days with the extract analysed by GC-MS. [redacted] provided a report of proposed identifications of substances for each material. The RSSL analytical work was expanded upon to identify components which were not present in the virgin food grade tray as a focus for the NIAS study (Annex 11).

Figure 20: Solvent extraction GC-MS chromatogram of PPristine White (black) and virgin PP tray (blue)



The materials show very low volatile activity as shown in material analysis by [redacted] (Annex 9). Headspace testing involved incubating recycled pellets at 120 °C for 60 minutes and analysing the gas phase by GC-MS. Figure 21 shows how little volatile content there is in comparison to virgin resins, showing the effectiveness of the decontamination process for semi-volatile, medium molecular weights of 100 to 200.

Figure 21: Headspace GC-MS chromatogram of PPristine Natural (black) and virgin PP pellets (blue)

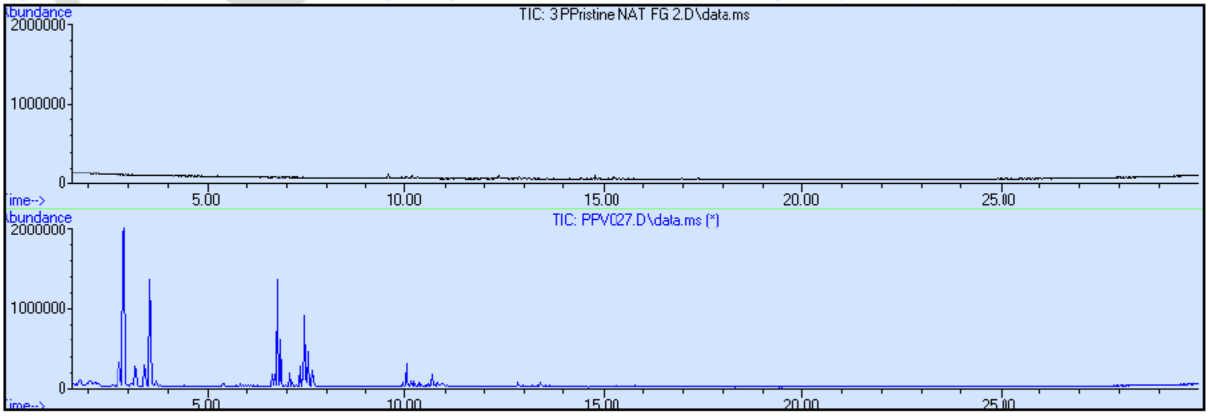


Table 23 shows estimated concentrations and best identity of substances. Ten of the substances are approved FCM in Annex I of EU Regulation 10/2011, seven of which are listed food additives in 21 CFR. None of the substances identified are classified as carcinogenic or mutagenic. The Cramer Classification of the substance or substance type was determined using Toxtree, where all non-FCM NIAS substances were Cramer Class I excluding antioxidant related substances.

Table 23: NIAS found in NEXTLOOPP rPP materials (Table 6 - Annex 11)

RT	CAS No	Name	FCM	Cramer Class	Conc mg/kg
13.133	5779-95-3	Benzaldehyde, 3,5-dimethyl-	-	I	4
13.964	28785-06-0	Benzaldehyde, 4-propyl-	-	I	9
15.812	4536-30-5	Laureth-1	-	I	2
16.581	719-22-2	2,6-Di-t-butylquinone	-	II	26
17.762	-	Benzoic acid ester	-	I	34
19.043	3055-94-5	Lauryltriethoxylate	-	I	5
19.861	5333-42-6	2-Octyldecanol	-	I	5
20.32	110225-00-8	2-Hexyldodecanol	-	I	8
20.562	110-27-0	Isopropyl myristate	-	I	12
20.834	-	Sebacic acid ester	-	I	3
21.614	82304-66-3	Antioxidant by-product	-	III	9
21.91	732-26-3	2,4,6-Tri-t-butylphenol	-	II	38
21.931	57-10-3	Palmitic acid	EU	I	2
22.145	-	Butyric acid ester	-	I	13
22.377	-	Phenyl acetate	-	I	8
22.537	142-91-6	Isopropyl palmitate	-	I	12
23.284	112-80-1	Oleic acid	EU / FDA	I	13
23.502	112-61-8	Methyl stearate	-	I	4
23.882	111-62-6	Ethyl oleate	-	I	32
24.219	-	Benzoic acid ester	-	I	15
24.733	77-90-7	Tributylacetylcitrate	EU / FDA	I	5
24.908	-	Aliphatic alcohol	-	I	10
25.021	29013-28-3	1,2-Propyleneglycol palmitate	EU	I	28
25.153	6316-30-9	Benzoic acid undecyl ester	-	I	13
25.693	301-02-0	Oleamide	EU / FDA	III	67
27.013	1330-80-9	1,2-Propyleneglycol oleate	EU	I	18
28.058	117-81-7	Ethylhexyl phthalate	EU / FDA	I	25
31.133	1323-39-3	1,2-Propyleneglycol stearate	EU / FDA	I	79
31.807	6422-86-2	Dioctylterephthalate	EU / FDA	I	15
32.597	112-84-5	Erucylamide	EU / FDA	III	419

FDA – FDA listed substance in 21 CFR *EU – Listed in Annex I of EU Regulation 10/2011*

3.4.3. Migration performance

3.4.3.1. Overall migration performance

Overall migration testing was performed on 5 different types of PPristine prototypes with the full laboratory report given in Annex 15. The overall migration testing conditions were 40 °C for 10 days (OM2), and the choice of food simulants were 3% acetic acid, 10% ethanol and olive oil. The 5 types of material are the same as those given in Table 22, thermoformed into sheets of 1 mm thickness. A summary of results is given in Table 24.

Table 24: Overall migration results for 5 PPristine prototypes using 3% acetic acid, 10% ethanol and olive oil at 40 °C for 10 days

Sample name	3% Acetic acid overall migration mg/dm^2	10% Ethanol overall migration mg/dm^2	Olive oil overall migration mg/dm^2
PPristine Natural	1.38	1.30	6.54
PPristine White	2.49	1.09	9.66
PPristine Colour	3.47	1.45	8.70
PPristine IM	0.78	1.04	6.58
PPristine INRT	2.67	1.46	6.59

The overall migration for all materials for all simulants at 40 °C conditions for 10 days are below the 10 mg/dm^2 requirement for food contact materials. This means that the resins could be suitable for any food type 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.

The materials tested also include PPristine IM, where the material was produced from hand-picked material from outside of the UK, and PPristine INRT which is derived from UK material consisting of approximately 80% food use packaging, providing evidence that the materials sourced meet EU 10/2011 regulation requirements with respect to overall migration.

3.4.3.2. Multilayer migration performance

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]		
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

3.4.4. Sensory performance

In WRAP's scoping study into food grade rPP (Annex 3), taste and odour testing on rPP articles was commissioned. The results from the testing panel show that some assessors reported relatively strong odours, but the majority experienced slight or no apparent odour. Unlike the odour testing no statistically significant difference was found between the control samples and test samples exposed to the sample of rPP.

3.4.5. 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. [redacted] are project leads into the development of a miniaturised Ames test suitable for identifying mutagenic activity in recycled food contact materials called [redacted] PPristine Natural and INRT resins were selected for evaluation using the method developed in the project, with the results and detail of the method provided in Annex 14.

[redacted] 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.

The results of the Ames testing had shown no genotoxic activity for both the PPristine Natural and INRT resins, as summarised in Table 26.

Table 26: Ames testing results

Strain (Enzyme)	PPristine Natural Result (LOD) µg/L	PPristine INRT Result (LOD) µg/L
TA98 (- S9)	< LOD (23)	< LOD (25)
TA98 (+ S9)	< LOD (0.9)	< LOD (1.0)
TA100 (- S9)	< LOD (1.8)	< LOD (1.9)
TA100 (+ S9)	< LOD (3.7)	< LOD (4.1)

Migration testing at 60 °C for 10 days covers storage conditions over 6 months at room temperature, and is likely to have reached equilibrium, therefore the maximum concentration in the 95% ethanol simulant.

Strain TA98 is used to detect frameshift mutations, and strain TA100 is used to detect point mutations. To deduce the limit of detection for mutations, positive controls have been used which should induce mutations to enable histidine synthesis. The amount of mutation inducing substance added is used to deduce a limit of detection. For the bioassay with the TA98 (frameshift) assay and without liver enzyme, histidine was not detected. This means that there was some inhibition from rPP, preventing the 2-nitrofluorene from inducing a mutation. Therefore, testing was repeated using a diluted migration concentrate, resulting in a higher limit of detection for TA98 (- S9).

Based upon the limits of detection determined in the Ames test, the mutagenic activity of migrants from rPP is very low, shown to be less than 1 µg/L for TA98 (+ S9). Assuming that the concentration of any migrant is nearly equal in the simulant and polymer after 10 days at 60 °C in 95% ethanol, it is possible to calculate the maximum theoretical concentration of a mutagenic substance. The presence of a mutagenic substance may be much lower than 0.9 µg/L in terms of migration, however for the purposes of the calculation, 0.9 µg/L shall be used as the actual concentration of a mutagenic substance. [redacted] would result in a concentration of 0.01 mg/kg, a value with similar magnitude obtained from the Reference Contamination Level study being 0.02 mg/kg.

3.5. Intended application in contact with food

The recycled PP is intended to be used for the majority of food use PP packaging applications already placed onto the market. NEXTLOOPP partners have shared some details of the intended uses of rPP summarised in Annex 5. The applications use a wide variety of food types such as most drink types, dairy, chilled meats and dried foods.

Due to the variety of foods used, the condition and duration of rPP in contact with food has a wide range also. Some notable applications are:

- Trays for chilled meats
- Pots for chilled pasta sauces which may be microwaved
- Pots for porridge and noodle which are dry and cooked with boiling water
- Caps and closures for containers
- Liners to store powdered infant milk
- Pots for yogurts
- Trays for microwavable meals
- Pots for butters
- Tubs for ice cream
- Tubs for wrapped confectionary

Most applications intended to use the materials as a monolayer whilst there are some multilayer uses also. Most intended uses aim to use at least 30% however there are some applications aiming to use 50 to 100% rPP.

In general, the intended use of rPP at 100% is for all food types covering 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, equivalent to OM2 standardised testing condition of 40 °C for 10 days, in Commission Regulation (EU) No 10/2011.

One of the most severe foreseeable contact temperatures of the PP packaging is approximately 85 °C, where dried instant foods are cooked using boiling water. Due to the instant nature of this type of food, it will typically be consumed within 30 minutes. Using the Arrhenius equation Annex V 2.1.4.f of Regulation 10/2011, 40 °C for 10 days is expected to be the equivalent of 5 hours at 85 °C, allowing for significant time at room temperature storage as a dried food.

Table 29 in Section 3.7 shows the typical storage and cooking conditions of a variety of products to form a basis for migration simulations. Packaging contents, servings and servings per day has also been taken into consideration to estimate the quantity of food consumed per person each day.

The rPP material is intended to be used to generate blends of virgin and rPP resins so that the properties can be tailored to specific requirements. The blends are expected to contain approximately 30-50% rPP.

3.6. Compliance with relevant provisions on food contact materials and articles

All the recycled PP materials 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 must be manufactured according to Commission Regulation (EC) No 2023/2006 on good manufacturing practice. This technical dossier provides the framework on GMP for recycling facilities to produce NEXTLOOPP rPP in Section 3.8.

3.7. Process analysis and evaluation

3.7.1. Identification of critical steps

3.7.1.1. Sorting

The evaluation is based upon a feedstock of 95% food-use PP packaging collected from the UK for three of the rPP categories; natural, grey and white. Alongside the UK recycling stream feedstock, a hand-picked material feedstock of injection moulded food-use PP packaging was also prepared for evaluation, referred to as injection moulding (IM) grade, with the aim of producing a suitable food grade rPP for injection moulders.

The sorting process will need to achieve at least 95% food use PP packaging to reduce the risk of non-authorised additives and processing aids used in non-food use PP materials entering the recycling process. Of the 5% non-food use PP materials, most of the articles will be manufactured from PP that use additives which compliment FDA and EU food contact regulations.

The sorting process will actively remove non-household PP materials, such as paint containers and equipment parts, to below 1% to reduce the likelihood of non-authorised additives entering the recycling process.

3.7.1.2. Washing

The decontamination process has been evaluated based upon the use of a 95% food use feedstock which is also influential to the setting of reference contamination level in PP feedstocks. As the reference contamination study was performed on washed 95% food use PP flakes, it is essential that residues on and within the washed flakes remains comparable or better than the study.

With the intention of establishing a washing performance reference point, all flakes entering the decontamination process should be washed in a 1% caustic solution at 70-80 °C for at least 10 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.

3.7.1.3. 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. 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 include into the recycling process. It will also provide an opportunity to remove other plastics and materials not intended for the extrusion process.

3.7.1.4. Melt decontamination

The melt decontamination process is a critical step where the material should be subject to [redacted] °C in the degassing section under a maximum pressure of [redacted] mbar. The design of the degassing section is critical where it must provide a large surface area with sufficient time to remove volatiles. The [redacted] is well suited equipment to provide high degassing efficiency. The size of the degassing section, therefore surface area exchange rate, will dictate the throughput of the decontamination process. The screw speed can be limited to achieve sufficient residence time in the degassing section.

[redacted]

[redacted]

The effect of operating at lower temperatures is expected to be 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. Maintaining a pressure below [redacted] mbar will ensure that boiling points are reduced for optimum degassing of the melt. The screw speed will control the residence time in the degassing section therefore the maximum screw speed should not be exceeded, to ensure the standard residence time has been applied. Screw speeds may be reduced based on upstream or downstream equipment performance, such as melt filtration pressures, and is expected to have similar performance on the decontamination performance even though the surface exchange rate is reduced, the residence time has increased.

3.7.1.5. Solid-state decontamination

The solid-state decontamination step has critical vacuum, temperature and residence time parameters. Like the melt decontamination step, the vacuum and temperature play a role in the excitation and extraction of volatile substances. The vacuum and temperatures used for the challenge test were a maximum of [redacted] mbar at a minimum of [redacted] °C. The residence time spent at these conditions was [redacted] hours. Increasing the residence time beyond [redacted] hours is expected to improve the decontamination rate at cost of the overall throughput rate, with decreasing the residence time having the opposite effect.

3.7.2. Modelled migration performance using NIAS study

Using the estimated NIAS concentrations from the analytical work in Section 3.4.2.2, estimates of the migration into food were determined using migration modelling software. The migration values in Table 27 is based upon modelling parameters in Table 34, where the exposure conditions are 40 °C for 10 days, representing long term room temperature storage. No non-FCM's are expected to migrate above 0.5 mg/kg. All FCM substances found in the NIAS study are not expected to exceed specific migration limits.

Table 27: NIAS found in NEXTLOOPP rPP materials (Table 6 - Annex 11)

RT	CAS No	Name	FCM	Cramer Class	Conc mg/kg	Mw	Migration mg/kg	SML mg/kg
13.133	5779-95-3	Benzaldehyde, 3,5-dimethyl-	-	I	4	134	0.05	-
13.964	28785-06-0	Benzaldehyde, 4-propyl-	-	I	9	148	0.11	-
15.812	4536-30-5	Laureth-1	-	I	2	230	0.02	-
16.581	719-22-2	2,6-Di-t-butylquinone	-	II	26	220	0.31	-
17.762	-	Benzoic acid ester	-	I	34	est 220	0.40	-
19.043	3055-94-5	Lauryltriethoxylate	-	I	5	318	0.06	-
19.861	5333-42-6	2-Octyldecanol	-	I	5	299	0.06	-
20.32	110225-00-8	2-Hexyldodecanol	-	I	8	270	0.09	-
20.562	110-27-0	Isopropyl myristate	-	I	12	270	0.14	-
20.834	-	Sebacic acid ester	-	I	3	est 270	0.04	-
21.614	82304-66-3	Antioxidant by-product	-	III	9	276	0.11	-
21.91	732-26-3	2,4,6-Tri-t-butylphenol	-	II	38	262	0.45	-
21.931	57-10-3	Palmitic acid	105	I	2	256	0.02	60.0
22.145	-	Butyric acid ester	-	I	13	est 256	0.15	-
22.377	-	Phenyl acetate	-	I	8	est 256	0.09	-
22.537	142-91-6	Isopropyl palmitate	-	I	12	299	0.14	-
23.284	112-80-1	Oleic acid	270	I	13	282	0.15	60.0
23.502	112-61-8	Methyl stearate	-	I	4	298	0.05	-
23.882	111-62-6	Ethyl oleate	-	I	32	311	0.36	-
24.219	-	Benzoic acid ester	-	I	15	est 300	0.17	-
24.733	77-90-7	Tributylacetylcitrate	138	I	5	402	0.04	60.0
24.908	-	Aliphatic alcohol	-	I	10	est 300	0.11	-
25.021	29013-28-3	1,2-Propyleneglycol palmitate	665	I	28	315	0.31	60.0
25.153	6316-30-9	Benzoic acid undecyl ester	-	I	13	276	0.15	-
25.693	301-02-0	Oleamide	355	III	67	281	0.78	6.0
27.013	1330-80-9	1,2-Propyleneglycol oleate	408	I	18	341	0.19	60.0
28.058	117-81-7	Ethylhexyl phthalate	283	I	25	391	0.23	1.5
31.133	1323-39-3	1,2-Propyleneglycol stearate	406	I	79	343	0.84	60.0
31.807	6422-86-2	Dioctylterephthalate	798	I	15	391	0.14	60.0
32.597	112-84-5	Erucylamide	271	III	419	338	4.48	60.0

Table 28: Migration simulation parameters

Parameter	Value
Surface area	100 cm^2
Food volume	150 mL
Layer thickness	0.2 mm
Polymer density	0.9 g/cm^3
Food density	1 g/cm^3
Food/packaging coefficient	1
Temperature	40 °C
Duration	10 days
Diffusion coefficient calculation	Piringer

3.7.3. Modelled migration performance using RCL study

Migration simulations using the Piringer diffusion coefficient calculation is known to be a severe estimation of migration in comparison to experimental migrations, however it allows the estimation of the concentration of substances below analytical limits of detection. The computed migration data needs to be coupled with consumption factors to determine if the concentration in food exceeds daily thresholds of toxicological concern. As the intended applications may vary for rPP, migration modelling has been performed based upon various uses, with a mixture of storage and cooking conditions as well as consumption rates as shown in Table 29.

Table 29: Example rPP applications including storage and cooking conditions along with servings information (Table 1 - Annex 12)

#	Packaging	Food type	Typical storage conditions	Typical cooking conditions	SA	F	S	N	D
1	Tray	Chilled meats	5 °C 2 weeks	-	400	300	2	2	300
2	Pot	Dried, add boiling water food	Long term ambient	85 °C to 30 °C over 30 mins	a. 105 b. 250	a. 115 b. 350	1	1	a. 115 b. 350
3	Pot	Yoghurts	5 °C 1 month	-	430	500	5	2	200
4	Tray	Ready meals, mash etc.	5 °C 2 weeks	100 °C for 5 mins	400	300	1	1	300
5	Tub	Spreads	5 °C 3 months	-	350	500	50	3	30
6	Tub	Ice cream	-18 °C 3 months	-	780	900	9	1	100
7	Pot	Pasta sauces	5 °C 2 weeks	100 °C for 5 mins	340	350	2	1	175
8	Bottle	Sauces	Long term ambient	-	420	450	30	2	30
9	Tub	Wrapped confectionary	Long term ambient	-	810	600	20	3	90
10	Pot	Jelly	Long term ambient	-	140	125	1	1	125

SA – Surface area in contact cm²
F – Mass of food per pack in g
S – Servings per pack
N – Number of daily servings
D – Daily intake of food g per person per day
a. – Storage value
b. – Cooking value

Migration modelling was performed on 7 substance types. Three of the substances were Cramer Class I, II and III, which were highest concentration non-FCM substances identified in the NIAS study summarised in Table 27 of Section 3.4.2.2. Since these substances were identified in the PP resin after the decontamination process, no decontamination factor had to be applied before modelling. The remaining four substances modelled were based upon findings from the reference contamination level study as described in Section 3.2.7.4. The carcinogenic reference contamination level had been established as 0.02 mg/kg for the input material for the decontamination process. Since the decontamination efficiency is dependent on the properties of the substance, for example the efficiency has an inverse relationship to molecular weight, the residual concentration expected to be remaining in rPP had been calculated for 3 molecular weights; 92 (low), 270 (medium), 700 (high). It has been assumed that the decontamination rate of Mw 700 substance is approaching zero for the NEXTLOOPP decontamination process as shown in Figure 19 of Section 3.3.1.5. The final substance modelled was triethyl phosphate which was identified during the reference contamination level study and falls into the organophosphate TTC category. Table 30 summarises the residual concentrations used for the migration modelling of various substances.

Table 30: Reference concentration values used for migration modelling (Table 3 - Annex 6)

Substance type	Mw	Initial concentration mg/kg	Decontamination	Residual concentration mg/kg
Cramer Class I	359	-	-	79
Cramer Class II	262	-	-	38
Cramer Class III	276	-	-	9
Substance type	**Mw**	**Initial concentration mg/kg**	**Decontamination**	**Residual concentration µg/kg**
TEP	182	0.08	98.5% (benzophenone)	1.2
CM A	92	0.02	99.9%	0.02
CM B	270	0.02	94.8%	1.04
CM C	700	0.02	0%	20

CM – Carcinogenic and mutagenic *TEP – Triethyl phosphate (organophosphate)*

The migration modelling factored both migration into food during storage and migration into food during cooking. The modelling is based upon 100% rPP with a layer thickness of 0.5 mm.

Typically, the long-term ambient conditions contribute to the highest migration concentrations. There are some applications, such as sauces, where the actual exposure from long term ambient conditions would be low due to the low dietary intake of the food type. It must be noted that the wrapped confectionary example does not factor in the barrier properties of the individual wrapping (assumed unwrapped) therefore expected to be very low with respect to migration into the confectionary realistically.

Table 31 shows the expected daily exposure per person for an array of applications, in descending order of exposure, showing that chilled and very low dietary intake applications use a small proportion of the 0.15 µg/person/day tolerance.

Table 31: Example rPP applications in descending order of carcinogenic or mutagenic exposure (Table 30 - Annex 12)

#	Packaging	Food type	Typical storage conditions	Typical cooking conditions	CM exposure µg/person/day	% of TTC tolerance
2	Pot	Dried, add boiling water food	Long term ambient	85 °C to 30 °C over 30 mins	0.0276	18.4%
10	Pot	Jelly	Long term ambient	-	0.0268	17.9%
9	Tub	Wrapped confectionary	Long term ambient	-	0.0231	15.4%
4	Tray	Ready meals, mash etc.	5 °C 2 weeks	100 °C for 5 mins	0.0152	11.2%
7	Pot	Pasta sauces	5 °C 2 weeks	100 °C for 5 mins	0.0042	4.7%
8	Bottle	Sauces	Long term ambient	-	0.0053	3.5%
1	Tray	Chilled meats	5 °C 2 weeks	-	0.0032	2.1%
3	Pot	Yoghurts	5 °C 1 month	-	0.0021	1.4%
5	Tub	Spreads	5 °C 3 months	-	0.0005	0.3%
6	Tub	Ice cream	-18 °C 3 months	-	0.0001	0.1%

The jelly application is expected to be mainly consumed by children, and less so for infants below the age of 1. Based on a 12 kg toddler scenario, the exposure is calculated to be 0.0022 µg/kg bw/day, below the threshold of 0.0025 µg/kg bw/day.

Using the toddler jelly scenario as a benchmark, the minimum decontamination performance required for any PP recycling process can be determined using the 0.02 mg/kg reference contamination level. Table 32 shows that the minimum decontamination performance of contaminants of varying molecular weights using migration modelling parameters in Table 33, representing the jelly scenario.

The calculated minimum decontamination efficiencies allow for the benchmarking of variations to the PP recycling process, which may use different decontamination equipment. Such variations may be in the solid-state treatment or extrusion equipment which meet the required performance, so long as the feedstock contamination level is equal to or less than that found in the reference contamination study.

Table 32: Minimum decontamination efficiencies required to meet the toddler jelly scenario using a reference contamination level of 0.02 mg/kg

Mw	Initial contamination mg/kg	Minimum decontamination efficiency	Residual contamination µg/kg	Migration µg/kg	Exposure µg	Toddler exposure ug/kg bw
100	0.02	75%	5	0.24	0.0300	0.0025
200	0.02	75%	5	0.24	0.0300	0.0025
300	0.02	74%	5.2	0.24	0.0300	0.0025
400	0.02	65%	7	0.24	0.0300	0.0025
500	0.02	48%	10.5	0.24	0.0300	0.0025
600	0.02	23%	15.5	0.24	0.0300	0.0025
700	0.02	0%	20	0.21	0.0263	0.0022
800	0.02	0%	20	0.15	0.0188	0.0016
900	0.02	0%	20	0.11	0.0138	0.0011
1000	0.02	0%	20	0.08	0.0100	0.0008

Table 33: Migration modelling parameters used to calculate minimum decontamination efficiencies

Parameter	Value
Surface area	140 cm^2
Food volume	125 mL
Layer thickness	0.5 mm
Polymer density	0.9 g/cm^3
Food density	1 g/cm^3
Food/packaging coefficient	1
Temperature	25 °C
Duration	365 days
Diffusion coefficient calculation	Piringer
Dietary intake	125 mL
Toddler body weight	12 kg

3.7.4. Overall evaluation

The input material for the recycling process has been well characterised with detailed information on the types of PP articles found in collected PP. A detailed survey has been carried out on substances found within non-food use packaging showing that the presence of harmful ingredients in consumer products is very low. Chemical screening had been performed on washed flakes to determine the frequency and concentration of potentially harmful substances, which was found to be 0.02 mg/kg, the reference contamination level.

NIAS testing of rPP prototypes did not show substances harmful to health falling into the carcinogenic or mutagenic category. This also includes the prototype PPristine INRT, manufactured using 20% non-food use packaging, and PPristine IM, manufactured using material sources from handpicked material (HPM). Ames testing results were negative on PPristine Natural and INRT grade confirming the absence of carcinogenic or mutagenic activity with a limit of detection approximately 1 µg/L, giving confidence in the actual safety of rPP from any type of feedstock.

Coupling the reference contamination level, decontamination performance, product application and consumer dietary intakes, the exposure to carcinogenic or mutagenic substances is not expected to exceed 0.0025 µg/kg bw/day, including toddler scenarios. The very worst case, infrequent, acute scenario identified was a 100% rPP jelly container which may have been stored for up to a year at room temperature and consumed by a toddler yielding in an exposure of 0.0022 µg/kg bw/day, below the 0.0025 µg/kg bw/day, indicating there is negligible risk.

Based on the information from migration testing, it's likely that the rPP produced using the process conditions indicated is suitable to be used at 100% for all food types under conditions equivalent to 40 °C for 10 days or at lower temperatures, representing intended food contact conditions of any 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.

3.8. Quality Assurance System

Any business operating the NEXTLOOPP recycling process must have a quality management system (QMS) in place. The QMS must be designed such that customers of recycled PPristine can be assured that each batch supplied meets the requirements of Article 3 of Regulation 1935/2003, hence the need to be compliant with GMP Regulation 2023/2006.

The scope of the QMS system shall, as a minimum, cover the manufacture and distribution of recycled plastics intended for food contact use. Within this system there shall be 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 which shall be in place, providing descriptions and objectives of processes along with criteria established which should be met to meet regulatory or customer requirements. Such procedures needed would be:

- Control of documentation
- Control of raw material and suppliers
- Control of processing ingredients and suppliers
- Control of use of raw materials
- Sorting process
- Washing process
- Flake sorting process
- Extrusion decontamination process (Phase 1)
- Solid state vacuum decontamination process (Phase 2)
- Product packaging and storage
- Product quality testing and control
- Non-conformance procedures for inputs, processes, and products
- Control of customer complaints, returns, recalls or rework
- Equipment calibration procedure
- Change management procedure
- Training procedure
- Internal auditing procedure
- Control of externally provided services

Within procedures regarding the manufacturing of recycled plastics, they shall include critical control points with clear criteria established with monitoring frequencies identified. Critical control points will be based upon recognised risk priority tools such as HACCP or FMEA to ensure products meet regulatory and customer requirements with a high degree of success.

Performance of the manufacturing process will be monitored through internal audits and periodic management reviews. Management reviews will 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 shall also be a frequent review of regulatory changes or industry best practices.

To be able to assess the compliance of batches of output materials there will need to be a system of traceability in place. The traceability of the system should be able to identify that each batch or lot of a batch complies with the criteria established on controlled procedures. Records shall be 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 shall be traceable through this unique identifier would be:

- 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 shall also be 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 34 provides a testing schedule for products, intermediates, processes, and input materials expected to ensure compliance with regulatory requirements along with Table 35 indicating the process monitoring records expected.

Table 34: Testing programme for food contact recycled PP

Test	Frequency
Raw materials analysis	Each batch
Purity into granulation	Daily / every 30 tonnes input
Wash water caustic strength	Daily / every 30 tonnes input
Flake purity analysis	Daily / every 30 tonnes input
Residual alkalinity	Daily / every 30 tonnes input
Pellet colour	Hourly / every tonne output
Pellet size	Visual - hourly / every tonne output Measured - daily / every 30 tonnes output
Pellet inclusions	Hourly / every tonne output
Moisture	Daily / every 30 tonnes input
Melt flow rate	Daily / every 30 tonnes input
Volatiles by GC headspace	6-hourly / every 6 tonnes
Accelerated migration	Each output batch
Other product stewardship requirements	Annually / As required

Table 35: Process monitoring records for food contact recycled PP

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	Hourly, including deviation records
Washing sodium hydroxide concentration	Hourly, including deviation records
Conductivity measurement	Hourly, including deviation records
Washing water consumption	Each shift
Rinsing water consumption	Each shift
Residual alkalinity	Each shift
Flake sorter maintenance	Each shift, including error logs
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
Solid-state temperature	Hourly, including deviation records
Solid-state vacuum pressure	Hourly, including deviation records
Solid-state residence time	Timestamps of batch entry, decontamination temperature achieved, batch cooling/evacuation
Solid-state rotation frequency	Hourly, including deviation records

Records relating to the compliance of product batches will be retained for the expected shelf life of the products it contains in the market. Due to the long-term nature of some of the intended applications and taking into account the storage of resins before manufacture, records should be kept for at least 3 years. Records retention also applies to physical samples of batches.

4. Glossary

AI	Artificial Intelligence
BHA	Butylated hydroxyanisole
Bp	Boiling point
bw	Body weight
CM	Carcinogenic or Mutagenic substance
DMSO	Dimethyl sulfoxide
EC	European Community or European Commission
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EU	European Union
FCM	Food contact Material
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
IM	Injection moulding grade
ISO	International Organization for Standardization
ISO 9001	ISO requirements for a quality management system
MIBK	Methyl isobutyl ketone
MRF	Materials Recovery Facility
MRS	Multi Rotational System
MS	Mass Spectrometry
Mw	Molecular weight
OM1	Standardised conditions for testing the overall migration, 10 days at 20 °C
OM2	Standardised conditions for testing the overall migration, 10 days at 40 °C
OM5	Standardised conditions for testing the overall migration, 1 hour at 121 °C
PCA	Principal Component Analysis
PP	Polypropylene
PRF	Plastics Recovery Facility
PVA	Polyvinyl alcohol
QAS	Quality Assurance System
QMS	Quality Management System
RCL	Reference Contamination Level
rPP	Recycled Polypropylene
[redacted]	[redacted]
SML	Specific Migration Limit
WRAP	Waste and Resources Action Programme

5. List of annexes and references

5.1. List of annexes

Annex 1	WRAP (2011) - Development of a Food-Grade Recycling Process for Post-Consumer Polypropylene
Annex 2	WRAP (2011) - Development of a Food-Grade Recycling Process for Post-Consumer Polypropylene - Data from Extraction & Migration Tests
Annex 3	WRAP (2010) - Scoping study into food grade polypropylene recycling
Annex 4	Common ingredients in non-food use post-consumer PP packaged products
Annex 5	List of intended applications for rPP in contact with food
Annex 6	Reference contamination chemometric study
Annex 7	Challenge test 2010 analytical report
Annex 8	[redacted] inorganic NIAS report
Annex 9	[redacted] analysis of rPP materials report
Annex 10	[redacted] organic NIAS report
Annex 11	Interpretation of [redacted] organic NIAS report
Annex 12	Migration simulations
Annex 13	Multilayer migration reports
Annex 14	[redacted] Ames MPF test report
Annex 15	Intertek overall migration test report

5.2. List of references

1. Franz , A. Mauer & F. Welle (2004) European survey on post-consumer poly(ethylene terephthalate) (PET) materials to determine contamination levels and maximum consumer exposure from food packages made from recycled PET, Food Additives & Contaminants, 21:3, 265-286, DOI: 10.1080/02652030310001655489.

2. Welle, Frank. (2005). Develop a food grade HDPE recycling process.

3. ILSI Europe Report Series. 2015;1-70 ILSI Guidance on Best Practices on the Risk Assessment of Non Intentionally Added Substances (NIAS) in Food Contact Materials and Articles.