

# **Executive Summary**

This report details the novel technology for post-consumer mechanical HDPE recycling developed by Veolia ES Plastics UK Limited at the Dagenham facility. The process, based on a recycling system developed by WRAP, focuses on recycling HDPE bottles back into food-grade materials, specifically for milk bottle applications. The technology has demonstrated consistent output quality and high decontamination efficiency, with ongoing monitoring to ensure compliance with EC 2022/1616 regulations.

## **Contents**

- 1. Background
  - a. Purpose of the report
  - b. Description of the Novel Technology
- 2. Sampling strategy
- 3. Monitoring
  - a. Entry Quality
  - b. Pre-sorted Quality
  - c. Input Quality
    - i. Contaminating materials in plastic input
    - ii. Substances Found in Plastic Inputs
  - d. Output Quality
    - i. Substances found in plastic output
    - ii. Migration levels of contaminants
  - e. Decontamination efficiency
- 4. Analytical procedures
  - a. Method
  - b. Method validation and performance
- 5. Summary
  - a. Review
  - b. Comparison with previous report
  - c. Analysis of discrepancies
  - d. Other considerations
  - e. Recommendations
- 6. References
- 7. Amendments log
- 8. Appendices
  - Appendix 1: Quantitative migration of contaminants in recycled HDPE by GC-FID and GC-MS Appendix 2: Quantitative Determination of Limonene Concentration in HDPE by Headspace GC-MS
  - Appendix 3: Analysis of Non-Intentionally Added Substances (NIAS) in Recycled HDPE



## 1. Background

# a. Purpose of the report

The process now owned by Veolia ES Plastics UK Limited for the Dagenham facility is based on a recycling system developed by WRAP (2005) ISBN: 1-84405-225-7.

This was followed by a large-scale trial by Wrap (2007) ISBN: 1-84405-308-3.

"The development of world leading UK recycling technology allows post-consumer milk bottles to be recycled back into food contact milk bottles. Milk bottles with 30% recycled content perform identically as virgin resin bottles, have been extensively tested and have passed all EU, UK and consumer tests and are currently in production within UK dairies. The novel technology represents the first time post-consumer HDPE Milk bottles have been recycled back into Milk Bottles with full food contact status."The process was submitted to the United States Food and Drug Administration for approval. Subsequently a No Objection Letter 108 was issued (2007).

Based on this the Dagenham facility was built (2009). The process contains the following key steps: Sorting of natural HDPE milk bottles, grinding and washing of the bottles then decontamination. Quality management of the feedstock, combined with improvements in pre-processing and decontamination reduce the risk of incidental contamination.

Since 2010 the Dagenham facility has supplied 10,000 tonnes / year to the UK dairy industry with no incidents and each batch of output material is tested for its suitability to come into contact with food.

The process was also submitted to EFSA (RECYC063) with a final safety assessment still pending on further additional data (2015).

The regulation was updated and the process was deemed a Novel Technology requiring self monitoring data and reporting based on EC 2022/1616 Article 13

The controlled version will be available online and previously superseded versions archived offline.

# b. Description of the Novel Technology

Polymer type	Short description of the recycling technology	Specification of plastic input	Specification of output	Subject to the authorisation of individual processes	Recycling scheme applies
HDPE	Mechanical recycling	Only HDPE PCW containing maximum 1% of materials and articles that were used in contact with non-food materials or substances	Decontaminated HDPE, final materials and articles intended use for milk bottle applications	Yes	No

This a Novel Technology and there were no deviations from the requirements set out in Articles 6, 7 and 8. No recycling scheme was used. This data is consistent with the <u>Technical dossier</u> page 21 / 57. Confirmation of input source and traceability through the process has been independently assessed using RecyClass - Certification compliant with EN 15343:2007 Audit Report and Certificate Code: RP261-VEO-07-25-CIR-PC)



Figure 1

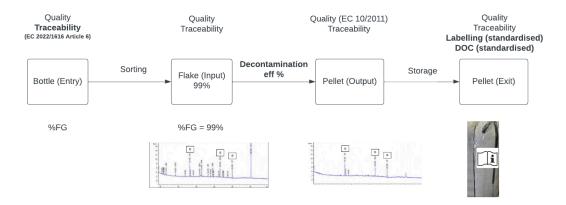
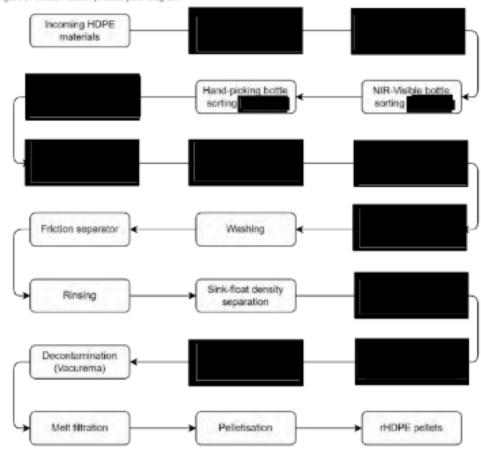


Figure 2: Veolia Plastics process flow diagram





# 2. Sampling strategy

The strategy is designed to ensure consistent quality and safety at each stage of the recycling process. Here's a detailed breakdown of the sampling and testing procedures:

- I. Entry Stage (Every batch):
  - A. Visual inspection of all bales
  - B. Random testing of one bale per load using ISO 15344:2008
  - C. Traceability verification through supplier pre-assessments, declarations, regulated waste transfer notes and supplier audits
  - D. Individual batch identification based on ISO 22095:2020
- II. Post-sorting (after the hand-picking bottle sorting stage) and pre-wash
  - A. Bottle count every 2 hours to confirm previous food use purity
- III. Input Stage (Every batch random spot sample during production of that batch):
  - A. Physical characteristics:
    - 1. Presence of non-HDPE plastics
    - 2. Glue content
  - B. Chemical analysis:
    - 1. Quantitative analysis for volatiles (Limonene) using GC-MS(Headspace)
    - 2. Semi-quantitative analysis using THF extraction (ASTM D7210-21)
    - 3. Migration study using 50% ethanol (EC 10/2011)
- IV. Output Stage (Composite sample, minimum 1 kg/hr at 1t/hr production rate):
  - A. Physical characteristics:
    - 1. Melt Flow Rate at 2.16 kg and 21.6kg, density, shape and colour
  - B. Chemical analysis:
    - 1. Semi-quantitative analysis using THF extraction (ASTM D7210-21)
    - 2. Migration study using 50% ethanol (EC 10/2011)
- V. Exit Stage:
  - A. Declaration of Compliance
  - B. Compliant labelling

Sampling every batch with full traceability for at least a full year is designed to factor in seasonal, suppliers and process variations. This will provide a larger dataset for trending and reduce the overall uncertainty.

# 3. Monitoring

# a. Entry quality

For commercial reasons results for incoming material are not discussed in this report although the records are readily available for the competent authorities to inspect at any time.

REC-001-01 Suppliers Register

REC-002-01 Incoming HDPE Load Inspections - LAB

REC-018-02 Supplier and Storage Audit Log

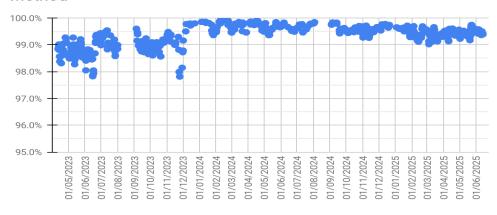
Traceability of the process has been independently assessed using PRE RecyClass - Certification compliant with EN 15343:2007 audit report and certificate code: RP261-VEO-07-25-CIR-PC)

# b. Pre-sorted Quality

Average 99% after the initial sorting but before granulation and further sorting. This data is consistent with the <u>Technical dossier</u> page 26 / 57



Batch Average Food Use Purity After Sorting by Counting Method

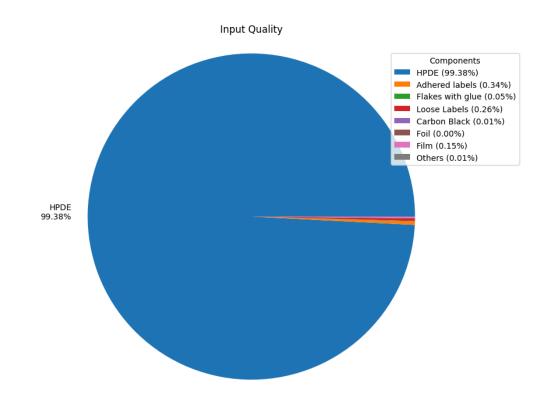


# c. Input Quality

# i. Contaminating Materials in Plastic Input

Average of input quality by mass percentage (raw data:REC-061 HDPE Flakes and Byproducts)

Гионо	06/06/2022	TO	29/5/2025	Number of			
From	06/06/2023	ТО	29/5/2025	samples	511		
HPDE %	Adhered labels %	Flakes with glue %	Loose Labels %	Carbon Black %	Foil %	Film %	Others %
99.38	0.34	0.05	0.26	0.01	0.00	0.15	0.01

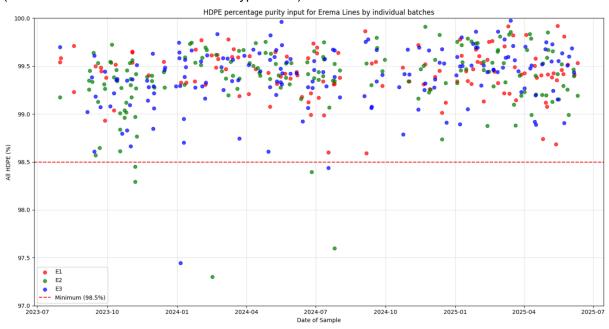




Carbon black is typically from the middle layer in long life milk bottles. Foil is typically from the milk bottle foil seal at the top of the bottle.

99% HDPE input is consistent with the data in the Technical dossier page 27 / 57

(raw data:REC-061 HDPE Flakes and Byproducts)



## Samples below 98.5% HDPE:

All sample outliers below 98.5 were retested and passed based on the average result; this is consistent with the high purity at the initial sorting stage.

# ii. Substances found in plastic inputs

Semi-quantitative analysis using THF extraction (ASTM D7210-21) on the flakes which was analysed on a GC-MS (raw data: REC-062 THF screening on flakes).

All Input samples were checked between 10 June 2023 and 10 June 2024 this covered all the batches produced during that time, screening down to 1.5 ppm

\* Multiply the concentration by 10 to convert the concentration in solution to concentration in the polymer as mg/kg

Library/ID		Washed Flake Mean Conc	Washed Flake Max Conc	Washed Flake RT	CAS#	Qual	Source
1-Docosene	593	6.59	14.18	23.7	001599-67-3	64	Oligomer
1-Hexacosene	592	5.99	15.09	26.63	018835-33-1	64	Oligomer



1-Tetracosene	356	6.94	17.77	25	010192-32-2	64	Oligomer
Cetene	379	5.75	20.16	16.98	000629-73-2	64	Oligomer
5-Eicosene, (E)-	355	5.69	16.41	21.57	074685-30-6	64	Oligomer
Cyclotetracosane	335	7.21	13.86	24.64	000297-03-0	62	Oligomer
1-Octadecene	323	4.81	19.61	18.99	000112-88-9	64	Oligomer
Tris(2,4-di-tert-butylph enyl) phosphate	260	12.66	46.3	32.73	95906-11-9	60	Irgafos 168
Cyclooctacosane	244	4.83	13.21	27.61	000297-24-5	62	Oligomer
3-Eicosene, (E)-	224	5.95	18.23	20.84	074685-33-9	64	Oligomer
Hexadecane	183	4.26	41.87	16.46	000544-76-3	64	Oligomer
E-15-Heptadecenal	166	6.19	19.26	19.52	1000130-97- 9	72	Unknown
Benzenepropanoic acid, 3,5-bis(1,1-dimethylet hyl)-4-hydroxy-, octadecyl ester	162	3.87	33.28	33.15	002082-79-3	60	Irganox 1076
Isopropyl myristate	155	4.59	45.89	18.97	000110-27-0	62	Cosmetics
Tetradecane	130	4.08	41.89	14.23	000629-59-4	64	Oligomer
1-Nonadecene	129	6.05	19.51	24.95	018435-45-5	64	Oligomer
Eicosane	124	2.65	11.39	21.36	000112-95-8	62	Oligomer
9-Eicosene, (E)-	122	5.75	17.25	20.01	074685-29-3	68	Oligomer
n-Hexadecanoic acid	128	2.97	29.65	20.53	1957-10-3	62	Food
Octadecane	112	3.23	9.57	18.91	000593-45-3	70	Oligomer
Isopropyl palmitate	111	2.73	10.69	21.04	000142-91-6	62	Cosmetics
1-Tricosene	92	5.78	16.33	25.75	018835-32-0	70	Oligomer
17-Pentatriacontene	95	4.44	8.76	28.67	006971-40-0	60	Oligomer
D-Limonene	105	6.42	49.8	8.89	005989-27-5	62	Food
5-Octadecene, (E)-	100	7.02	22.25	18.65	007206-21-5	64	Oligomer
Nonacos-1-ene	95	4.68	14.18	27.37	018835-35-3	80	Oligomer

# d. Output Quality

# i. Substances found in plastic output

Semi-quantitative analysis using THF extraction (ASTM D7210-21) analysed on GC-MS Raw data: REC-062 THF screening on pellets

All samples were checked between 10 June 2023 and 10 June 2024 this covered all of the batches produced during that time, screening down to 1.5 ppm.



		1	I			I	I
Library/ID	Sample Count	Pellet Mean Conc	Pellet Max Conc	Pellet RT	CAS#	Qual	Source
1-Docosene	584	4.88	11.64	23.4	001599-67-3	64	Oligomer
1-Hexacosene	476	4.22	12.37	26.41	018835-33-1	64	Oligomer
Cyclotetracosane	371	4.99	10.73	24.65	000297-03-0	62	Oligomer
1-Tetracosene	289	4.87	13.06	24.96	010192-32-2	64	Oligomer
5-Eicosene, (E)-	310	4.71	16.63	21.27	074685-30-6	64	Oligomer
Cyclooctacosane	231	3.48	7.79	27.3	000297-24-5	62	Oligomer
1-Octadecene	231	4.15	14.62	19.23	000112-88-9	78	Oligomer
3-Eicosene, (E)-	205	5.02	14.65	21.16	074685-33-9	68	Oligomer
Tris(2,4-di-tert-butyl phenyl) phosphate	184	7.93	25.52	32.71	95906-11-9	60	Irgafos 168
Cetene	156	4.53	13.21	18.11	000629-73-2	70	Oligomer
9-Eicosene, (E)-	139	5.15	19.69	20.26	074685-29-3	64	Oligomer
E-15-Heptadecenal	127	4.93	16.48	20.22	1000130-97-9	64	Unknown
Isopropyl myristate	130	3.15	5.35	18.89	000110-27-0	62	Cosmetics
Hexadecane	113	4.79	39.78	16.19	000544-76-3	64	Oligomer
1-Nonadecene	107	4.74	14.66	23.53	018435-45-5	64	Oligomer
17-Pentatriaconten e	89	3.38	8.66	27.93	006971-40-0	62	Oligomer
Isopropyl palmitate	82	2.12	3.65	20.98	000142-91-6	60	Cosmetics
Octadecane	80	2.48	6.53	18.64	000593-45-3	72	Oligomer
5-Octadecene, (E)-	78	6.5	19.48	18.9	007206-21-5	72	Oligomer
Nonacos-1-ene	78	3.58	8.03	26.39	018835-35-3	76	Oligomer
1-Tricosene	66	5.36	15.23	24.05	018835-32-0	64	Oligomer
1-Eicosene	57	4.64	13.25	22.22	3452-07-01	64	Oligomer
9-Hexacosene	55	3.52	5.95	26.5	071502-22-2	84	Oligomer
Cycloeicosane	53	4.37	9.19	21.59	000296-56-0	68	Oligomer
Benzenepropanoic acid, 3,5-bis(1,1-dimethy lethyl)-4-hydroxy-, octadecyl ester	54	2.53	5.04	32.96	002082-79-3	60	Irganox 1076

<sup>\*</sup> Multiply the concentration by 10 to convert the concentration in solution to concentration in the polymer as mg/kg

Qual = Minimum match score using NIST spectral search algorithm on GC-MS

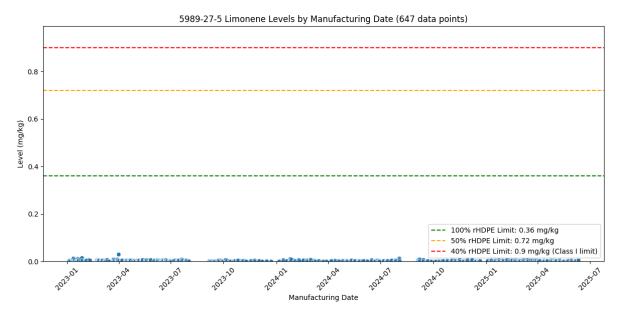
**ii. Migration levels of contaminants (**Article 13(5)(f) a measurement or estimation of the migration levels );

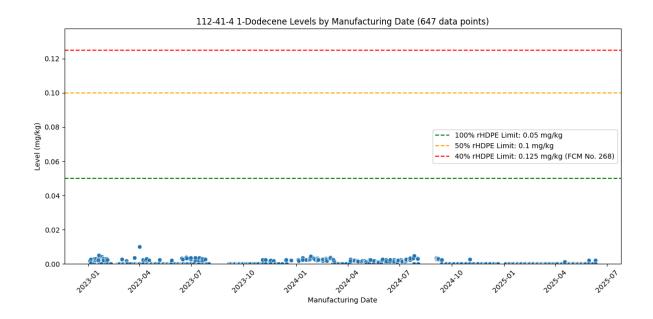


Every batch produced complied with the limits stated on the declaration of compliance when blended with virgin at 40%. This can be found on the website <a href="https://dagenhamplastics.veolia.co.uk/">https://dagenhamplastics.veolia.co.uk/</a>

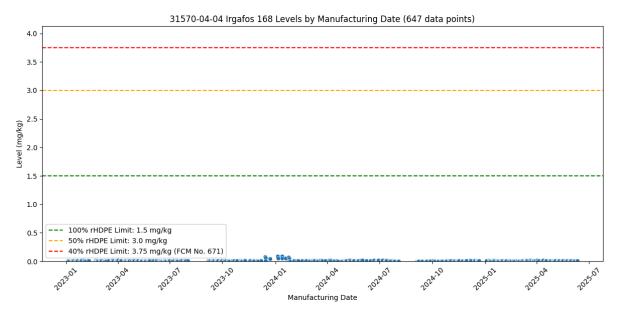
CAS	Name	mg/kg	FCM
5989-27-5	Limonene	< 0.017	(Class I)
112-41-4	1-Dodecene	< 0.008	268
31570-04-04	Irgafos 168	< 0.040	671
2082-79-3	Irganox 1076	< 0.181	433
6259-76-3	n-Hexyl salicylate	< 0.045	(Class II)
5444-75-7	2-Ethylhexyl benzoate	< 0.049	(Class I)
101-86-0	α-Hexyl cinnamaldehyde	< 0.045	(Class II)
110-27-0	Isopropyl myristate	< 0.150	(Class I)
142-91-6	Isopropyl palmitate	< 0.040	(Class I)
109-43-3	Dibutyl sebacate	< 0.181	242
	Unknown	< 0.010	

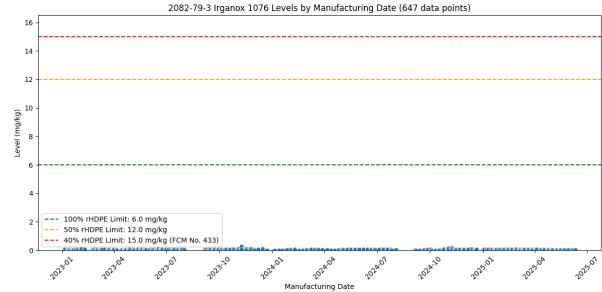




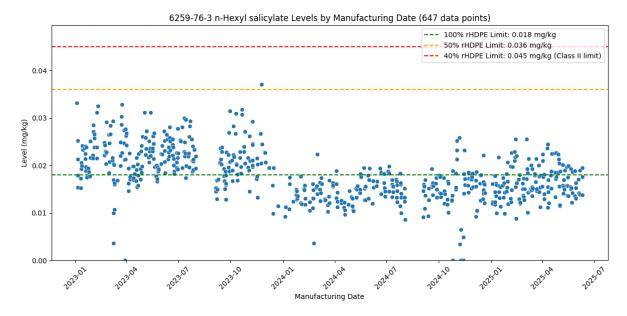


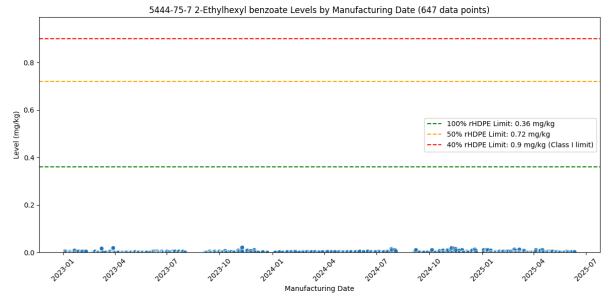




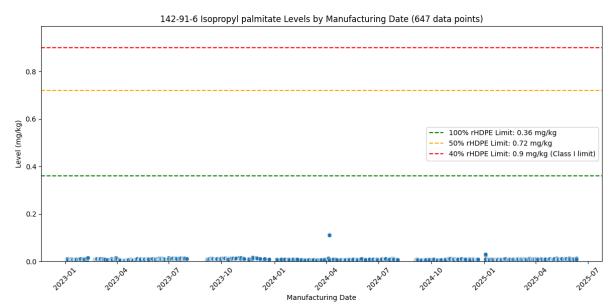


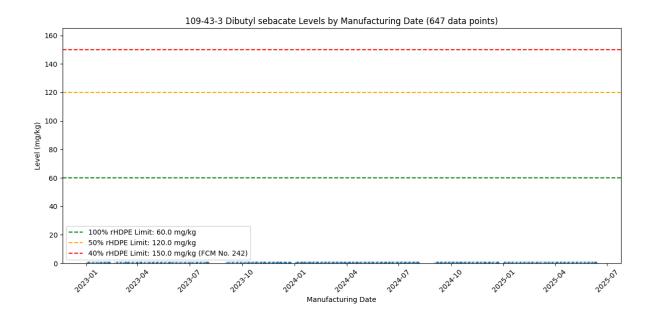




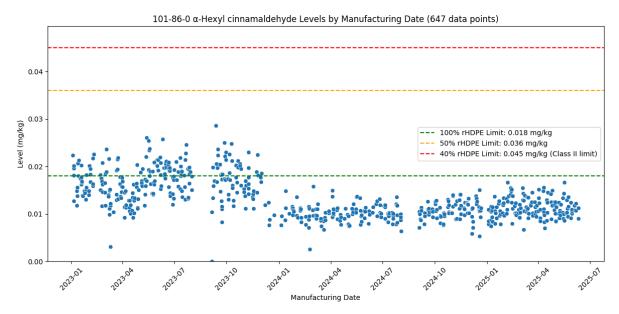




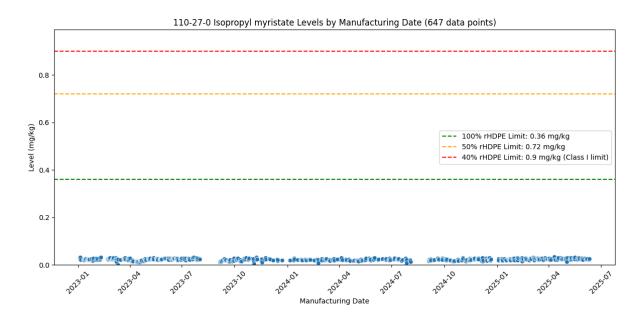




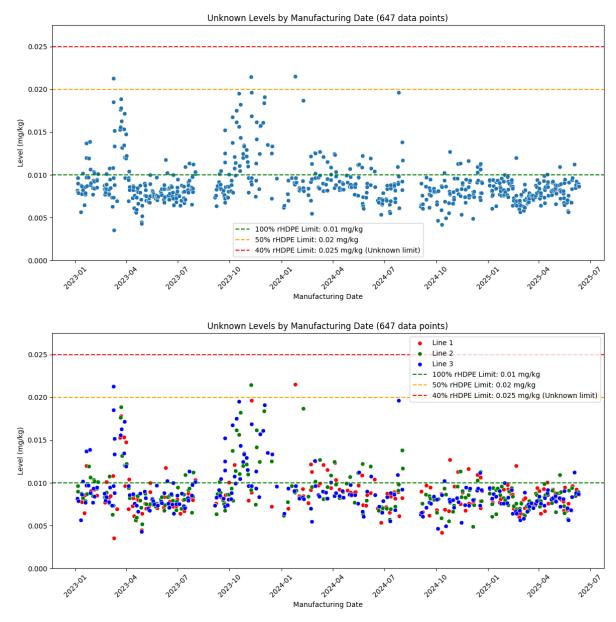




Whilst it is possible to meet the limits of 50% in most cases further work is ongoing to identify unknowns and sources of Class II compounds to maintain a margin of safety.







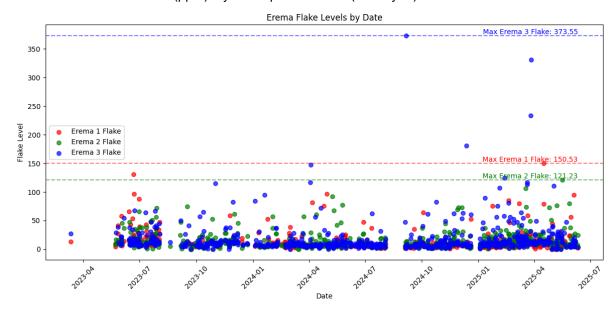
The unknown levels were re-plotted for different production lines to confirm there is no difference between them.

A step change reduction in unknown compounds occurred after October 2023 following the identification of Oleic acid, stearic acid and palmitic acid which were previously classed as unknown compounds. All three fatty acids fall under FCM No. 106, which covers 'Acids, C2-C24, aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and triglycerol esters.' These substances have no specific migration limit (SML) and no restrictions on their use in food contact materials



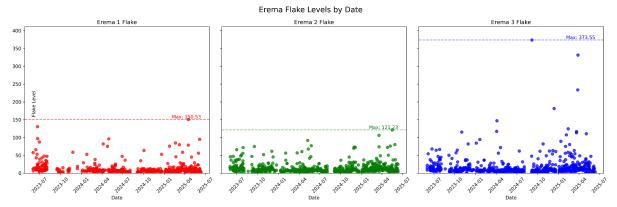
# e. Decontamination efficiency

Input flake limonene concentrations (ppm) by headspace method (overlayed)

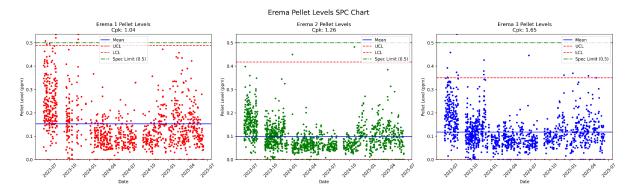


(Raw data: REC-009-01 FG rHDPE Pellet Results)

Input limonene concentrations (ppm) by headspace method (individuals plots)



Output limonene concentrations (ppm) by headspace method (individuals plots)





(Raw data: REC-009-01 FG rHDPE Pellet Results )

June 2023 - June 2024

Erema	Input Date Time	Output Date Time	Input Limonene (ppm)	Output Limonene (ppm)	Decontamination Efficiency (%)
1	21/06/2023 03:00:00	21/06/2023 12:00:00	130.51	0.25	99.81
2	08/05/2024 15:00:00	09/05/2024 00:00:00	91.88	0.05	99.94
3	04/04/2024 00:00:00	04/04/2024 06:00:00	147.06	0.06	99.96

June 2023 - June 2025

Erema	Input Date Time	Output Date Time	Input Limonene (ppm)	Output Limonene (ppm)	Decontamination Efficiency (%)
1	16/04/2025 15:00:00	17/04/2025 06:00:00	150.53	0.14	99.90
2	16/05/2025 15:00:00	16/05/2025 18:00:00	121.23	0.19	99.84
3	05/09/2024 02:00:00	05/09/2024 06:00:00	373.55	0.06	99.98



Decontamination efficiency was also calculated using the THF extraction results between June 2023 and November 2024. THF extractions chosen to be studied represented compounds found in the output migrations

Decontamination efficiencies for Limonene using THF extractions were slightly lower than the headspace extraction.

Compound	Batch	Max Flake Concentration (ppm)	Max Pellet Concentration (ppm)	Decontamination Efficiency %
Limonene	B1	14.28	1.71	88.01
Limonene	B2	35.15	0.37	98.96
Limonene	В3	19.60	0.28	98.55
Isopropyl myristate	B1	16.62	5.35	67.82
Isopropyl myristate	B2	239.47	0.69	99.71
Isopropyl myristate	B3	3.85	1.67	56.66
Isopropyl palmitate	B1	10.69	3.65	65.91
Isopropyl palmitate	B2	5.38	0.76	85.88
Isopropyl palmitate	B3	10.14	1.98	80.46
Benzenepropa noic	B1	6.97	5.04	27.73
Benzenepropa noic	B2	5.71	0.86	84.87
Benzenepropa noic	B3	1.31	1.51	-15.74
Octanal, 2-	B1	5.77	1.89	67.23
Octanal, 2-	B2	8.73	0.36	95.85
Octanal, 2-	B3	3.24	0.68	79.07
n-Hexyl salicylate	B1	8.91	1.35	84.86

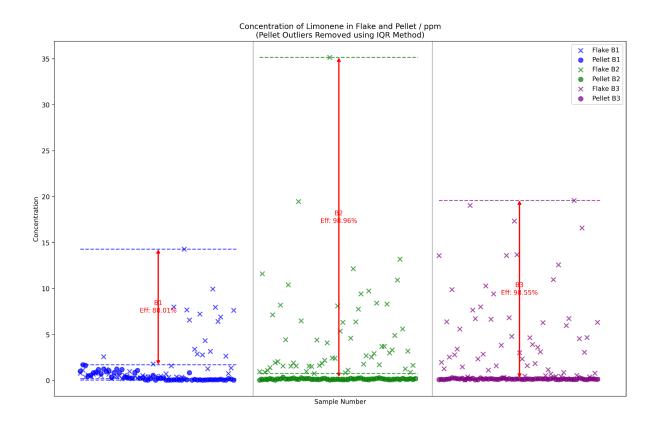


n-Hexyl salicylate	B2	1.27	0.35	72.54
n-Hexyl salicylate	В3	1.54	0.54	65.05
2,4-di-tert-butyl phenyl	B1	41.22	14.14	65.70
2,4-di-tert-butyl phenyl	B2	46.30	25.52	44.88
2,4-di-tert-butyl phenyl	B3	22.33	4.42	80.21

Benzenepropanoic = Benzenepropanoic acid, 3,5-bis(1,1-dimethylethyl)-4-hydroxy-, octadecyl ester

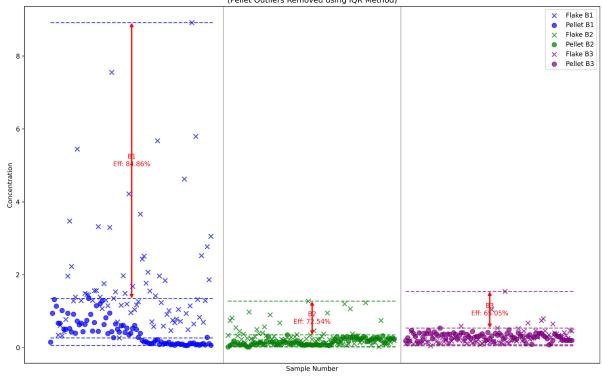
Octanal, 2- = Octanal, 2-(phenylmethylene)- ( $\alpha$ -Hexyl cinnamaldehyde)

2,4-di-tert-butylphenyl = Tris(2,4-di-tert-butylphenyl) phosphate

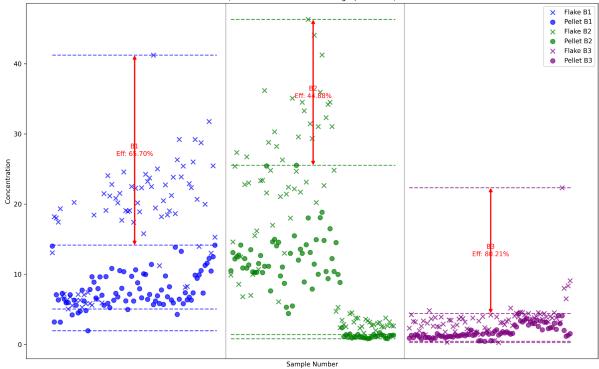




Concentration of n-Hexyl salicylate in Flake and Pellet / ppm (Pellet Outliers Removed using IQR Method)

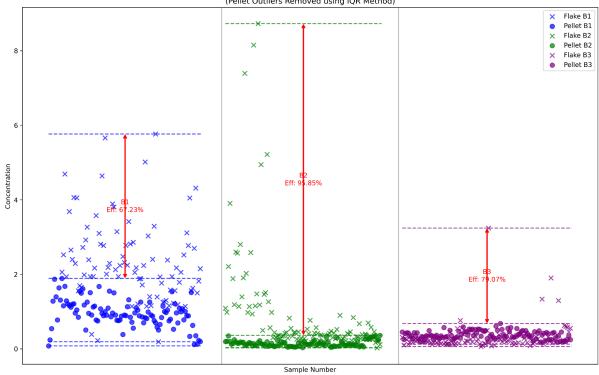


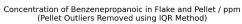


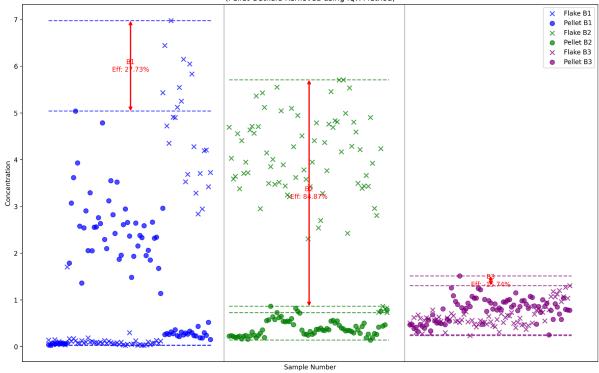




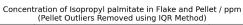


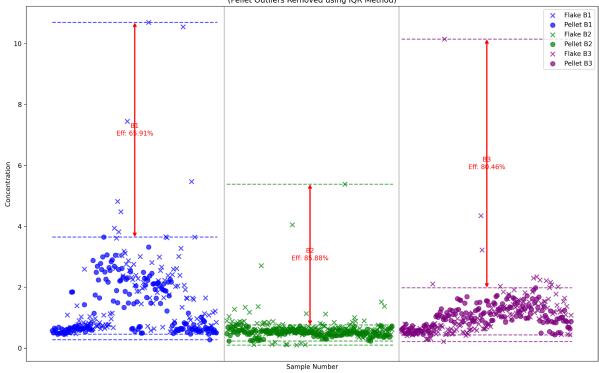








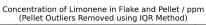


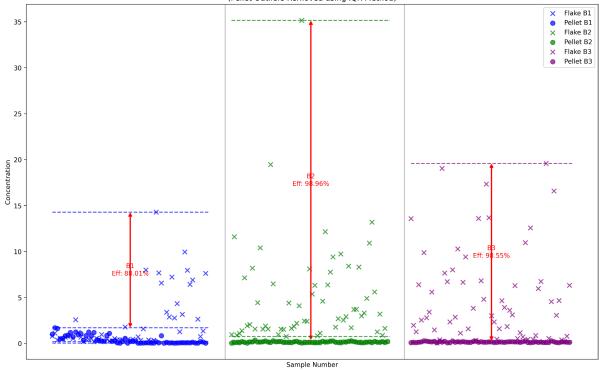


# Concentration of Isopropyl myristate in Flake and Pellet / ppm (Pellet Outliers Removed using IQR Method) X Flake B1 Pellet B2 Flake B3 Pellet B3

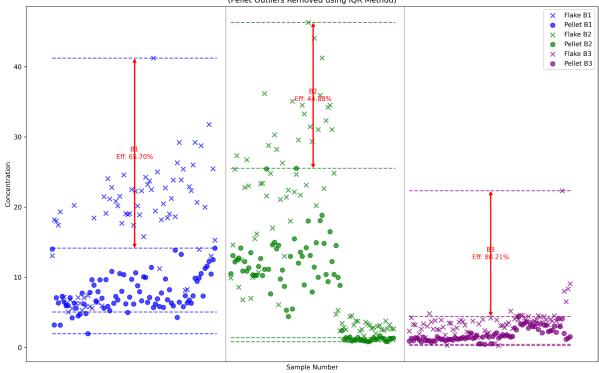
Sample Number





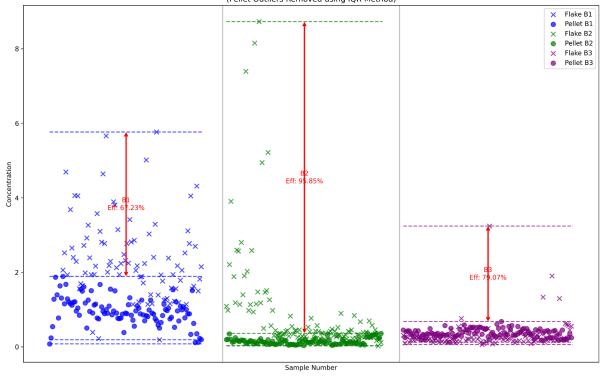


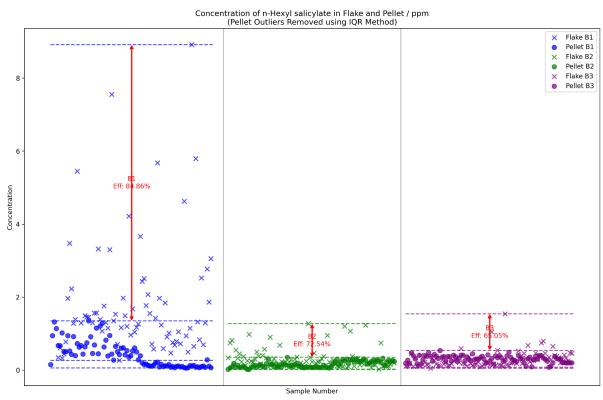
## Concentration of 2,4-di-tert-butylphenyl in Flake and Pellet / ppm (Pellet Outliers Removed using IQR Method)



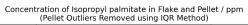


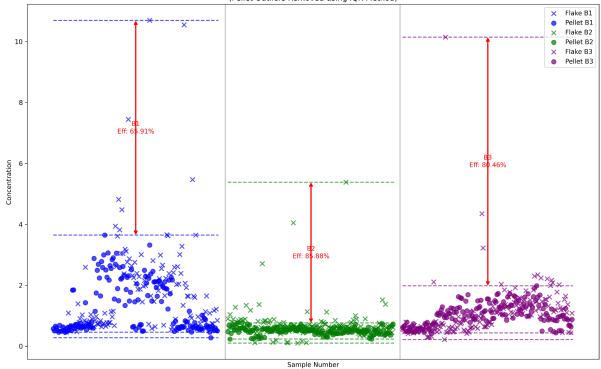
Concentration of Octanal, 2- in Flake and Pellet / ppm (Pellet Outliers Removed using IQR Method)



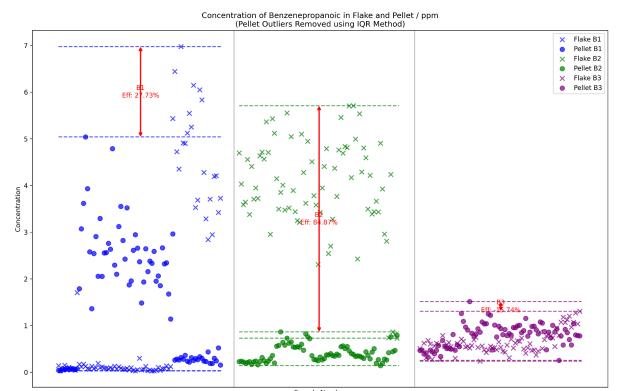


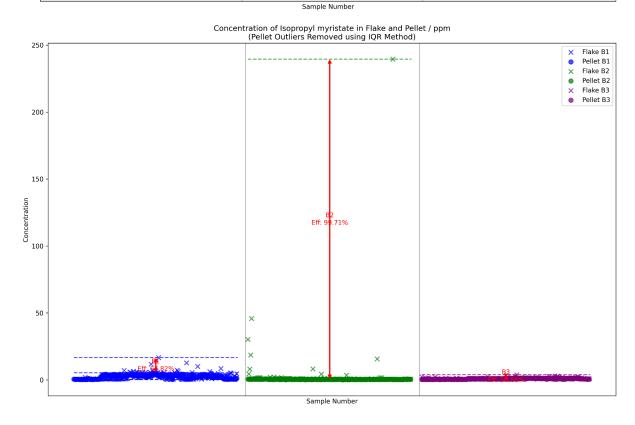




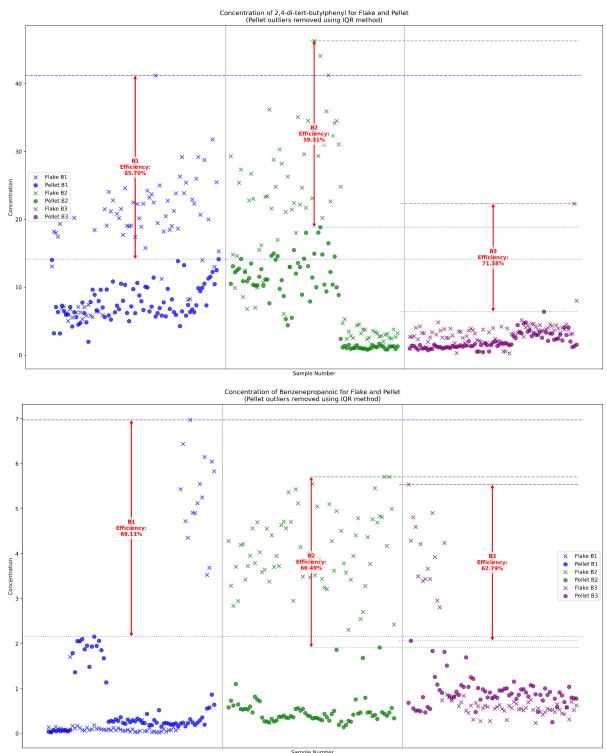




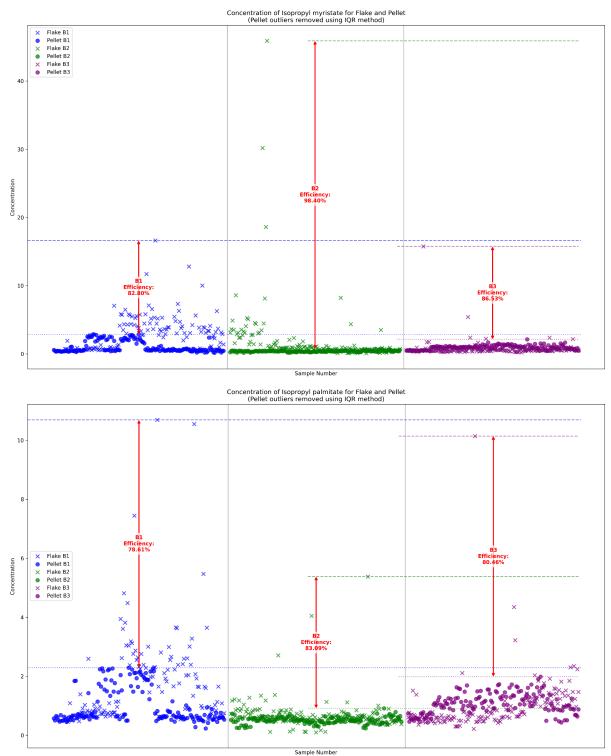




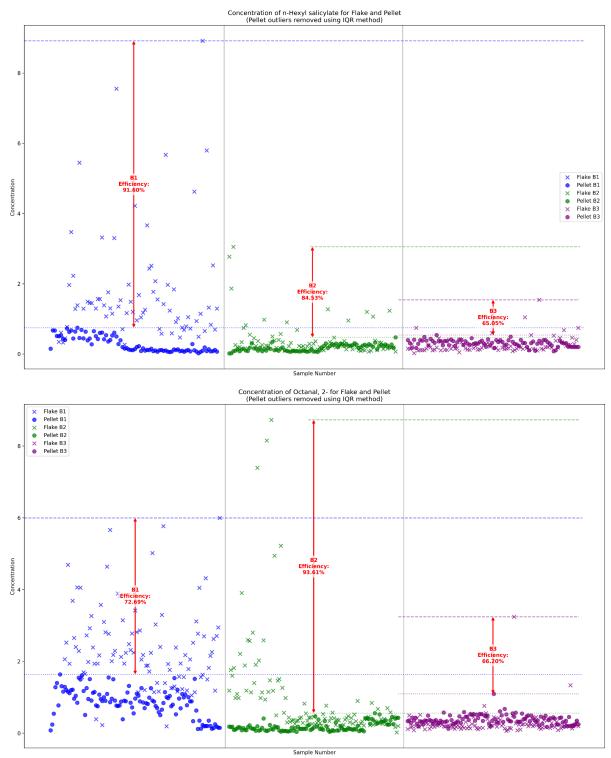














# 4. Analytical Procedures

- a. Appendix 1: Migration: Quantitative Evaluation of Purity of Recycled HDPE by rapid migration test. This method was originally developed by (Pira International Research) reference: 08A11J0703 Development of an accelerated migration test for recycled rHDPE (Pira International Research) September 2008. The method has been updated to include calibrations for known substances commonly occurring.
- b. Appendix 2: Headspace: Quantitative Determination of Limonene Concentration in HDPE by Headspace GC-MS. This method was originally developed by (Pira International Research) reference: 08A11J0703
- Appendix 3: Extraction: Analysis of Non-Intentionally Added Substances (NIAS) in Recycled HDPE. Based on ASTM D7210-21

## 5. Summary

## a. Review

Summary of the reasoning on the capability of the technology to produce safe recycled materials (Article 13.5 b):

The Veolia Plastics rHDPE recycling process demonstrates a robust capability to produce safe recycled materials for food contact applications, particularly milk bottles. This conclusion is supported by several key factors: First, the process consistently achieves a high decontamination efficiency, with worst-case scenarios showing 99.8% removal of surrogate contaminants like limonene. This level of decontamination is comparable to that demonstrated in challenge tests, indicating the process's effectiveness in removing potential contaminants. Secondly, the output quality remains consistently high, regardless of input variability. Migration testing on every batch confirms compliance with EU Regulation 10/2011, with all monitored substances falling below specified limits. The process's ability to maintain this quality, even with varying input contamination levels, demonstrates its reliability in producing safe recycled materials. Additionally, the comprehensive monitoring strategy, which includes analysis of both known contaminants and potential NIAS, provides ongoing assurance of the technology's capability to meet food safety requirements.

Analysis of whether contaminant origins could lead to other undetected substances of concern (Article 13.5 e):

The majority of contaminants identified in the input material can be traced to three primary sources: residual product contents (e.g., milk components), packaging additives, and environmental contamination. While the current analytical methods effectively detect and quantify a wide range of substances, there is a possibility of undetected compounds of concern

For instance, residual milk components could potentially harbor unidentified metabolites or breakdown products. Packaging additives, while generally well-characterized, may include proprietary formulations with undisclosed components. Environmental contaminants present perhaps the most significant unknown, as they can vary widely based on the post-consumer waste's origin and handling. To address these potential unknowns, ongoing research is focused on expanding the range of analyzed compounds and lowering detection limits. The



sorting process, which achieves at least 99% food-use HDPE packaging, significantly reduces the risk of non-authorized additives. Additionally, the process's high decontamination efficiency provides a safety margin against potential undetected substances, assuming they would behave similarly to known contaminants during processing.

# b. Discussion of the difference of previous report

Compared to previous reports, this dataset demonstrates a high degree of consistency in both input quality and process performance. The decontamination efficiency remains stable, with no significant deviations from earlier findings. However, one notable difference is the increased focus on identifying and quantifying frequently occurring compounds. This shift has led to the identification of a new substance E-15-Heptadecenal, which was not prominently featured in previous reports.

The previous technical reports used decontamination efficiencies based on challenge test data. Monitoring day-to-day decontamination efficiencies are only indicative as a large number of tests are needed to find the occasional input with elevated levels.

Even on those rare occasions the input is still approximately 90% lower than the levels used in the challenge test.

# c. Analysis of discrepancies in decontamination efficiency

Three methods could have been used to monitor the decontamination efficiency. Each method has advantages and disadvantages. The headspace method is quantitative and fast. This allows for more measurements throughout the batch for every batch. Limonene can be monitored as an indicator of decontamination efficiency for volatile compounds. The disadvantage of this method is that there is less confidence in detection of semi-volatile compounds. The extraction method is performed on every batch using an aggressive solvent to give more confidence in extracting all chemicals present. This technique is ideal for NIAS and satisfactory for the decontamination efficiency; it should be noted that numbers are semi-quantitative. The migration is much better suited to quantitative measurements of the output. All three methods provide valuable information about decontamination performance and efficiency. This larger dataset covering two years highlights the correlation between bottle purity post-sorting and the output quality in terms of migration for Class II (n-Hexyl salicylate &  $\alpha$ -Hexyl cinnamaldehyde) and unknown compounds.

# d. Other considerations

The monitoring data focuses on decontamination efficiency

## e. Recommendations

- i. Developer
  - 1. Continue to monitor data for trends
- ii. Recycler
  - 1. Continue to identify frequently occurring unknowns and quantify them using calibrated standards
  - 2. Find the source of E-15-Heptadecenal and confirm any migration levels using a calibrated standard
- iii. Reprocessors
  - 1. Feedback on both positive and negative issues
  - 2. Share external test reports



# iv. Competent Authority Assessment

Article 13(5(i)) an analysis and explanation of any <u>discrepancies observed</u> between contaminant levels <u>expected</u> in the input plastic and in the output of the installation and its decontamination efficiency based on the reasoning provided under point (b) and the actual results under point (c).

This dataset remains similar to the initial technical report and shows batch batch consistency irrespective of any variation in the input material quality.

The data showed that routinely both input and output contamination levels were low. The main reason is due to a high quality of input material and also a consistently good decontamination stage. The low level of input contamination made it difficult to compare the maximum decontamination efficiency relative to the previous challenge test. Although the data gave an insight into what real contamination was found in the input material before decontamination and actual decontamination levels achieved. Irrespective of the input contamination levels a baseline decontamination was always achieved.

The following evaluation criteria are proposed for the Authority's future assessment of recycling processes applying this novel technology: (Article 10.3.f)

- 1. Input Material Characterization:
  - a. Detailed analysis of the post-consumer HDPE input, including:
  - b. Polymer composition (minimum 98.5% HDPE), plastics other than HDPE, Glue
  - c. Presence and quantification of potential migrants
  - d. Contamination levels (maximum 1% non-food contact materials for a defined blend rate with virgin material)
  - e. Composition and bulk density of the flake (range average)
  - f. Flake dimensions, such as range and average of thickness, size distribution
- 2. Process Parameters Monitoring:
  - a. Continuous monitoring and recording of critical process parameters: a) Washing temperature and detergent concentration
  - b. Drying temperature and duration
  - c. Extrusion temperature profile
  - d. Vacuum levels in decontamination reactors
  - e. Residence time in each critical step of the process
- 3. Decontamination Efficiency:
  - a. Assessment of decontamination efficiency using challenge tests:
    - i. Challenge tests which are based on a standard methodology or matching previous challenge tests by the developer
    - ii. Requirement for the decontamination efficiency to match or be better than previous results
  - b. Regular assessment of decontamination efficiency by monitoring each batch
    - i. Using compounds consistently identified in the input e.g. limonene
    - ii. Day to day input material may show lower calculated decontamination efficiencies than the challenge test when the input quality is good because the Erema is not challenged. The focus should be on a consistent output level
    - iii. A large dataset approximately 100 results or more are needed to spot outliers



- iv. Accelerated migration results for input and output can be used to calculate decontamination efficiency. This is because most compounds identified in THF extractions are also identified in 50% migration results quantitatively
- 4. Output Quality Control:
  - a. Characterisation of the output HDPE, output including:
    - i. Melt flow index
    - ii. Colour
    - iii. Density
    - iv. Visual appearance
    - v. Form e.g. flakes, pellets, sheets
- 5. Migration Testing:
  - a. Compliance with EU Regulation 10/2011 on plastic materials and articles intended to come into contact with food
  - b. Specific migration limits (SML) for identified substances on each batch initially
  - c. Overall migration limit (OML) testing
- 6. Non-intentionally Added Substances (NIAS) Evaluation:
  - Screening for NIAS using advanced analytical extraction techniques (THF/GC-MS or ethanol 95% LC-MS)
  - b. Risk assessment of identified NIAS and likely sources of contamination
- 7. Instruction and labelling for reprocessors
  - a. Specify safe blend rate with virgin, intended application
- 8. Traceability System:
  - a. Implementation of a robust traceability system compliant with EU Regulation 1935/2004
  - b. Ability to trace each batch of recycled material back to its input source
- 9. Quality Management System:
  - a. Implementation of a comprehensive quality management system
  - b. Regular internal audits and third-party certifications
- 10. Long-term Performance Monitoring:
  - a. Ongoing monitoring of recycled material performance in final applications
  - b. Collection and analysis of data from end-users (e.g., dairy industry)
- 11. Continuous Improvement Plan:
  - Unknown compound retention times or mass fragments and concentrations should be trended to identify frequently occurring unknowns as they can significantly affect the blend rate.
- 12. Completion of a CMSS (ANNEX II) template provided by the developer highlighting critical control points, quality assessment stages and corrective actions.

# 6. References

- a. 08A11J0703 Development of an accelerated migration test for recycled rHDPE (Pira International Research) September 2008
- b. 08A11J0798 Studies on Recycled HDPE used for milk packaging (Pira International Research) November 2008
- c. <a href="https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4016">https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4016</a>

# 7. Amendments log

- a. Section 3: Monitoring data has been updated
- b. Section 5: Review updated

## 8. Appendices

 Appendix 1: Quantitative migration of contaminants in recycled HDPE by GC-FID and GC-MS



- Appendix 2: Quantitative Determination of Limonene Concentration in HDPE by Headspace GC-MS
- c. Appendix 3: Analysis of Non-Intentionally Added Substances (NIAS) in Recycled HDPE

## Abbreviations:

ASTM: American Society for Testing and Materials

AVG: Average

CAS: Chemical Abstracts Service CIR: Circular Economy Certification

CMSS: Compliance Monitoring Summary Sheet

CONC: Concentration EC: European Commission

EFSA: European Food Safety Authority

EN: European Standard EU: European Union

FCM: Food Contact Material

FDA: Food and Drug Administration

FID: Flame Ionization Detector

GC-MS: Gas Chromatography-Mass Spectrometry

HDPE: High-Density Polyethylene

ID: Identification

ISO: International Organization for Standardization

LAB: Laboratory MAX: Maximum MIN: Minimum

NIAS: Non-Intentionally Added Substances

NOL: No Objection Letter OML: Overall Migration Limit PCW: Post-Consumer Waste

ppm: Parts Per Million

PRE: Plastics Recyclers Europe

QUAL: Quality
QC: Quality Control

REC: Record (as in REC-001-01, REC-002-01, etc.)

rHDPE: Recycled High-Density Polyethylene

**RP: Recycled Plastics** 

RT: Retention Time in minutes SML: Specific Migration Limit

TBC: To Be Confirmed THF: Tetrahydrofuran

WRAP: Waste and Resources Action Programme