2nd Six Month Report according to Article 13(4) of the Commission Regulation (EU) 2022/1616

Version 1: 12.11.2024

Recycling of Post-consumer HDPE Closures and Pallets / Crates into new Pallets for Direct Food Contact Application

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Description of Novel Technology

This chapter describes briefly the Novel Technology.

The company Craemer, Herzebrock-Clarholz Germany, introduce post-consumer HDPE into new pallets / creates. The process uses HDPE bottle closures and discarded or damaged multi-use HDPE pallets / crates as input material.

The Craemer recycling process for HDPE flakes comprises the following main process steps:

- Step 1a: Grinding of collected post-consumer HDPE closures into flakes followed by a washing step with surfactants and by surface drying (done by flake suppliers).

- Step 1b: Grinding of HDPE pallets / crates into flakes followed by a washing step and by surface drying (mechanical step).
- Step 2: Extrusion of the flakes from steps 1a and 1b to pellets with vacuum degassing, with melt filtration and underwater pelletizing system, followed by surface drying of the pellets.
- Step 3: Manufacturing of palettes from recycled material from step 2.

The Craemer recycling process pallet to pallet with similar process conditions got an approval from the US Food and Drag Administration FDA (PNC 2679, October 21, 2021)

The intended food contact applications are pallets / crates for agricultural products like dry food, whole food, vegetables, fruits and pre-packed meat. The contact conditions are 7 days in maximum at room temperature.

The recycled HDPE is intended to be used for the production of new pallets / crates with up to 100% of recyclate content.

Compliance with Article 3 of Regulation (EC) No 1935/2004

Craemer provided on 26.09.2023, an initial report on the Novel Technology in accordance with Article 10 of Commission Regulation (EU) No. 2022/1616. This report include extensive reasoning, scientific evidence, and studies that demonstrate that the recycled HDPE complies with Article 3 of Regulation (EC) No. 1935/2004.

List of substances in plastic input and recycled output

Within the last six months five batches of recycled HDPE were produced. According to Regulation 2022/1616 input and output samples were tested according to potential contaminants. The samples were analysed by the Fraunhofer IVV in Freising, Germany.

Fraunhofer Test report PA-1623-24 from 08.11.2024 investigates the following samples:

- Sample 1: HDPE flakes bottle caps, different colors, input, 25.09.24
- Sample 1o: HDPE pellets, black, output, 25.09.24
- Sample 2: HDPE flakes bottle caps, different colors, input, 26.09.2024 early shift
- Sample 2o: HDPE pellets, black, output, 26.09.2024 early shift
- Sample 3: HDPE flakes bottle caps, different colors, input, 26.09.2024 late shift
- Sample 3o: HDPE pellets, black, output, 26.09.2024 late shift
- Sample 4: HDPE flakes bottle caps, different colors, input, 26.09.2024
- Sample 4o: HDPE pellets, black, output, 26.09.2024
- Sample 5: HDPE flakes bottle caps, different colors, input, 30.09.2024
- Sample 5o: HDPE pellets, grey, output, 30.09.2024

The results of the identification and semi-quantification are given in Table 1 to Table 10. Substances which are also determined in virgin HDPE are marked with "*" in Table 1 to Table 10.

Table 1: Results of the identification / characterisation and **semi-quantification** of volatile substances in the investigated recyclate samples

R_t [min]	Identification	Semi-quantification [mg/kg]	
		Sample 1	Sample 1o
1.72	too small for clear identification	<5	7.5
1.82	too small for clear identification	<5	5.5
2.68	glycerine	<5	51.5
4.71	branched alkene	<5	8.3
5.46	branched alkane	5.1	<5
7.80	decene	5.3	<5
7.86	decane*	9.0	8.6
8.13	limonene	122.9	80.0
8.49	terpene	9.1	5.5
9.97	dodecane*	17.9	13.3
11.61	tetradecane*	**	**
13.01	hexadecane*	**	**
14.27	octadecane*	**	**

* substance also detectable in virgin HDPE, ** quantified based on the extracts, see below

Table 2: Results of the identification / characterisation and **semi-quantification** of volatile substances in the investigated recyclate samples

R_t [min]	Identification	Semi-quantification [mg/kg]	
		Sample 2	Sample 2o
1.72	too small for clear identification	<5	16.3
1.82	too small for clear identification	<5	9.3
2.07	too small for clear identification	<5	6.4
2.68	glycerine	<5	65.3
4.71	branched alkene	<5	9.2
6.90	terpene	16.3	<5
7.47	terpene	9.6	<5
7.86	decane*	11.9	10.5
8.13	limonene	196.5	125.2
8.46	terpene	16.7	8.7
9.97	dodecane*	20.2	16.1
11.61	tetradecane*	**	**
13.01	hexadecane*	**	**
14.27	octadecane*	**	**

* substance also detectable in virgin HDPE, ** quantified based on the extracts, see below

Table 3: Results of the identification / characterisation and **semi-quantification** of volatile substances in the investigated recyclate samples

R_t [min]	Identification	Semi-quantification [mg/kg]	
		Sample 3	Sample 3o
1.72	too small for clear identification	<5	12.8
1.82	too small for clear identification	<5	7.9
2.07	too small for clear identification	<5	6.3
2.68	glycerine	<5	51.5
4.71	branched alkene	<5	8.7
6.90	terpene	12.1	5.7
7.63	terpene	8.1	<5
7.86	decane*	11.7	12.3
8.13	limonene	380.0	140.0
8.46	terpene	16.9	9.9
8.79	terpene	5.4	<5
9.97	dodecane*	20.8	16.9
11.61	tetradecane*	**	**
13.01	hexadecane*	**	**
14.27	octadecane*	**	**

* substance also detectable in virgin HDPE, ** quantified based on the extracts, see below

Table 4: Results of the identification / characterisation and **semi-quantification** of volatile substances in the investigated recyclate samples

R_t [min]	Identification	Semi-quantification [mg/kg]	
		Sample 4	Sample 4o
2.07	too small for clear identification	<5	6.5
2.68	glycerine	<5	29.9
3.27	methylcyclohexane	26.1	25.1
4.46	branched alkane	8.4	5.6
4.49	branched alkane	12.0	9.4
7.86	decane*	5.1	5.9
8.13	limonene	40.4	57.9
9.97	dodecane*	9.3	11.3
11.61	tetradecane*	**	**
13.01	hexadecane*	**	**
14.27	octadecane*	**	**

* substance also detectable in virgin HDPE, ** quantified based on the extracts, see below

Table 5: Results of the identification / characterisation and **semi-quantification** of volatile substances in the investigated recyclate samples

R_t [min]	Identification	Semi-quantification [mg/kg]	
		Sample 5	Sample 5o
1.72	too small for clear identification	<5	18.7
1.82	too small for clear identification	<5	13.8
2.07	too small for clear identification	<5	13.5
2.41	too small for clear identification	<5	10.4
2.68	glycerine	<5	15.1
3.27	methylcyclohexane	31.3	30.8
4.25	branched alkane	12.8	7.3
4.46	branched alkane	9.0	7.6
4.49	branched alkane	15.7	13.5
4.62	branched alkane	5.2	<5
4.66	branched alkane	8.9	7.9
4.71	branched alkene	22.7	16.4
5.17	branched alkane	5.1	<5
5.26	branched alkane	12.5	8.9
5.35	branched alkane	6.9	<5
7.86	decane*	11.6	10.3
8.13	limonene	153.0	150.1
8.45	terpene	<5	7.4
9.97	dodecane*	15.6	15.0
11.61	tetradecane*	**	**
13.01	hexadecane*	**	**
14.27	octadecane*	**	**

* substance also detectable in virgin HDPE, ** quantified based on the extracts, see below

Table 6: Results of the identification / characterisation and **semi-quantification** of medium and non-volatile substance substances in the investigated recyclate samples

		Sample 1	Sample 1o
1	Limonen	57 ±6	58 ±6
2	n-Alkane C12*	22 ±10	23 ±2
3	n-Alkane C14*	126 ±17	96 ±2
4	n-Alkane C16*	269 ±33	192 ±3
5	n-Alkane C18*	359 ±39	267 ±6
6	n-Alkane C20*	342 ±4	211 ±7
7	n-Alkane C22*	335 ±45	206 ±5
8	n-Alkane C24*	290 ±46	165 ±4
9	Octadecene nitrile CAS 112-91-4 or similar	17 ±19	352 ±15
10	Octadecane nitrile CAS 95491-05-7 or similar	63 ±23	51 ±5
11	Tinuvin 326 CAS 3896-11-5	17 ±4	24 ±2
12	n-Alkane C28*	228 ±38	112 ±2
13	Glyceride ester (closer identification not possible)	17 ±19	264 ±14
14	Erucamide CAS 112-84-5	560 ±358	437 ±7
15	Behenamide CAS 124-26-	241 ±12	212 ±4
16	n-Alkane C26*	169 ±24	80 ±1
17	n-Alkane C30*	119 ±18	53 ±1
18	n-Alkane C32*	81 ±11	36 ±1
19	Irgafos 168* CAS 31570-04-4	494 ±29	317 ±5
20	oxid. Irgafos 168*	270 ±2	432 ±8

* substance also detectable in virgin HDPE

Table 7: Results of the identification / characterisation and **semi-quantification** of medium and non-volatile substance substances in the investigated recyclate samples

Peak	Identification	Concentration [mg/kg]	
		Sample 2	Sample 2o
1	Limonen	129 ±8	107 ±6
2	n-Alkane C12*	27 ±1	27 ±5
3	n-Alkane C14*	130 ±12	117 ±1
4	n-Alkane C16*	240 ±32	224 ±4
5	n-Alkane C18*	309 ±58	304 ±5
6	n-Alkane C20*	310 ±62	243 ±4
7	n-Alkane C22*	264 ±55	229 ±3
8	n-Alkane C24*	224 ±47	176 ±4
9	Octadecene nitrile CAS 112-91-4 or similar	4 ±4	27 ±5
10	Octadecane nitrile CAS 95491-05-7 or similar	2 ±1	42 ±3
11	Tinuvin 326 CAS 3896-11-5	31 ±16	29 ±3
12	n-Alkane C28*	178 ±40	122 ±2
13	Glyceride ester (closer identification not possible)	2 ±1	50 ±12
14	Erucamide CAS 112-84-5	552 ±27	497 ±4
15	Behenamide CAS 124-26-	375 ±192	279 ±3
16	n-Alkane C26*	130 ±30	86 ±1
17	n-Alkane C30*	93 ±21	54 ±2
18	n-Alkane C32*	65 ±16	38 ±1
19	Irgafos 168* CAS 31570-04-4	395 ±53	323 ±4
20	oxid. Irgafos 168*	273 ±25	465 ±6

* substance also detectable in virgin HDPE

Table 8: Results of the identification / characterisation and **semi-quantification** of medium and non-volatile substance substances in the investigated recyclate samples

Peak	Identification	Concentration [mg/kg]	
		Sample 3	Sample 3o
1	Limonen	165 ±5	121 ±9
2	n-Alkane C12*	33 ±7	30 ±4
3	n-Alkane C14*	174 ±5	125 ±1
4	n-Alkane C16*	332 ±37	239 ±4
5	n-Alkane C18*	454 ±41	327 ±6
6	n-Alkane C20*	418 ±42	238 ±6
7	n-Alkane C22*	392 ±45	247 ±11
8	n-Alkane C24*	336 ±40	187 ±12
9	Octadecene nitrile CAS 112-91-4 or similar	117 ±35	296 ±12
10	Octadecane nitrile CAS 95491-05-7 or similar	32 ±18	42 ±10
11	Tinuvin 326 CAS 3896-11-5	53 ±8	37 ±5
12	n-Alkane C28*	259 ±31	126 ±6
13	Glyceride ester (closer identification not possible)	128 ±36	411 ±14
14	Erucamide CAS 112-84-5	478 ±28	487 ±23
15	Behenamide CAS 124-26-	600 ±82	336 ±16
16	n-Alkane C26*	189 ±22	92 ±4
17	n-Alkane C30*	132 ±16	58 ±4
18	n-Alkane C32*	87 ±11	38 ±2
19	Irgafos 168* CAS 31570-04-4	471 ±35	306 ±13
20	oxid. Irgafos 168*	287 ±4	464 ±19

* substance also detectable in virgin HDPE

Table 9: Results of the identification / characterisation and **semi-quantification** of medium and non-volatile substance substances in the investigated recyclate samples

Peak	Identification	Concentration [mg/kg]	
		Sample 4	Sample 4o
1	Limonen	41 ±13	40 ±4
2	n-Alkane C12*	17 ±5	17 ±1
3	n-Alkane C14*	84 ±18	90 ±2
4	n-Alkane C16*	130 ±34	173 ±1
5	n-Alkane C18*	172 ±57	240 ±4
6	n-Alkane C20*	33 ±10	215 ±5
7	n-Alkane C22*	99 ±50	185 ±3
8	n-Alkane C24*	89 ±46	142 ±4
9	Octadecene nitrile CAS 112-91-4 or similar	82 ±9	744 ±27
10	Octadecane nitrile CAS 95491-05-7 or similar	57 ±6	88 ±19
11	Tinuvin 326 CAS 3896-11-5	7 ±7	30 ±5
12	n-Alkane C28*	57 ±32	98 ±2
13	Glyceride ester (closer identification not possible)	112 ±10	476 ±25
14	Erucamide CAS 112-84-5	680 ±253	325 ±5
15	Behenamide CAS 124-26-	41 ±19	282 ±3
16	n-Alkane C26*	49 ±28	74 ±1
17	n-Alkane C30*	29 ±15	39 ±5
18	n-Alkane C32*	21 ±10	29 ±1
19	Irgafos 168* CAS 31570-04-4	297 ±85	265 ±3
20	oxid. Irgafos 168*	237 ±25	507 ±6

* substance also detectable in virgin HDPE

Table 10: Results of the identification / characterisation and **semi-quantification** of medium and non-volatile substance substances in the investigated recyclate samples

Peak	Identification	Concentration [mg/kg]	
		Sample 5	Sample 5o
1	Limonen	154 ±12	131 ±4
2	n-Alkane C12*	29 ±4	29 ±2
3	n-Alkane C14*	123 ±2	109 ±2
4	n-Alkane C16*	239 ±3	202 ±3
5	n-Alkane C18*	342 ±27	276 ±6
6	n-Alkane C20*	231 ±61	218 ±9
7	n-Alkane C22*	284 ±34	210 ±4
8	n-Alkane C24*	243 ±35	167 ±3
9	Octadecene nitrile CAS 112-91-4 or similar	60 ±10	94 ±11
10	Octadecane nitrile CAS 95491-05-7 or similar	34 ±12	44 ±6
11	Tinuvin 326 CAS 3896-11-5	28 ±5	26 ±2
12	n-Alkane C28*	184 ±27	114 ±2
13	Glycerid ester (closer identification not possible)	92 ±3	150 ±3
14	Erucamid CAS 112-84-5	543 ±46	504 ±16
15	Behenamid CAS 124-26-	303 ±43	250 ±3
16	n-Alkane C26*	133 ±22	83 ±1
17	n-Alkane C30*	89 ±16	53 ±1
18	n-Alkane C32*	59 ±8	35 ±1
19	Irgafos 168* CAS 31570-04-4	382 ±11	297 ±5
20	oxid. Irgafos 168*	292 ±11	543 ±11

* substance also detectable in virgin HDPE

List of contaminating materials regularly present in plastic input

The input materials used for the production of the above-mentioned lots were produced with a extrusion process. Foreign materials as well as impurities were filtered. Foreign polymers or other impurities are therefore not detected in the input materials.

Analysis of the most likely origin of the identified contaminants

The results given in Table 1 to Table 10 show that many of the substances determined in the recyclate samples are also found in virgin HDPE. These substances are generally found at similar concentrations in both virgin and recycled

samples. Other substances (e.g., limonene, terpenes, branched alkanes, …) are oligomers or flavouring substances from the first use of the HDPE input.

Estimate of migration levels of contaminants to food

Within the initial safety report, the exposure to consumers was evaluated based on migration modelling. Following this calculations, the maximum migration into food in 12.5 µg/kg, which is very low. Assuming a toddler (10 kg b.w.) and a consumption of 100 g agricultural products per day, will result in an exposure of 0.125 µg per kg body weight per day.

It should be noted, that typically foodstuffs that are stored on the pallet are in most cases already packed in primary packaging and have no direct contact to the pallets / crates. Therefore, the low amount of migration is considered as critical. Only vegetables or fruits might be stored without primary packing on the pallets / crates. However, these agricultural products are washed and often peeled before they are consumed. This washing and peeling reduces or eliminates the contaminants from the agricultural products.

Description of applied sampling strategy

In accordance with Article 13(1) of Commission Regulation (EU) No. 2022/1616, samples from each batch of input and the corresponding output were drawn. Within the six months period, five lots were produced and therefore five input/output pairs were analysed using the method described below.

Screening for volatile substances

Based on the accredited Fraunhofer IVV Method 1.334:2021-11 (quantification not accredited)

For each test 1.0 g of sample material was weighed into a headspace vial and analysed by headspace GC/FID under normal atmosphere. Gas chromatograph: Column: ZB 1 (length 30 m, inner diameter 0.25 mm, film thickness 0.32 µm), temperature program: 50°C (4 min) to 320°C (15 min) with a heating rate of 20°C/min. Headspace Autosampler: oven temperature: 120 °C, equilibration time: 1 h. Quantification of limonene was achieved by external calibration. Identification was achieved by mass spectrometry.

Screening for medium and low volatile substances

Based on the accredited Fraunhofer IVV method 1.337:2024-02

1.0 g of sample material was extracted with 10 ml of dichloromethane and stored for 3 days at 60 °C. An internal standard of butylated hydroxyanisole (BHA) und Tinuvin 234 was added to an aliquot of the extracts, and analysed by gas chromatography with flame ionisation detection (GC-FID) for semi-volatile compounds. Gas chromatograph: capillary column DB-1 (length 30 m, inner diameter 0.25 mm, film thickness 0.25 µm), temperature programme: 50 °C (2 min up to 340 °C (10 min) with a heating rate of 10 °C/min. Peaks of interest were semi-quantified using the internal standard BHA. This method is valid for organic components with a molecular weight of approximately 150 to 700 g/mol. Identification was achieved by mass spectrometry.

Analysis and explanation of discrepancies

No discrepancies have been observed between the contaminant levels expected in the input and output of the installation and its decontamination efficiency. The data above supports a finding that the decontamination process adequately removes contaminants from the waste stream.

Discussion of differences with previous reports

This is the second 6-month report on this technology, and thus, no differences are observed.