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D4.2 EVALUATION OF BARRIER CONCEPTS

WORK PACKAGE 4

Associated Task(s):
T4.5: Design and validation of functional barrier concepts for the use of PCR in food packaging

T5.2: Functional barrier layer combinations – Assessments with model contaminants

Lead Partner: Fraunhofer IVV
Partners involved: NESTLE, AMCOR-K, AMCOR-G, SIEGWERK
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PUBLISHABLE EXECUTIVE SUMMARY

The main tasks of Work Package (WP) 4 comprise the evaluation of migration barrier concepts in order to assess if contaminations are reduced down to threshold values below which there is a very low probability of adverse health effects toxicological concern.

The design of high performance functional barriers is required to effectively prevent migration of any residual contaminants from the post-consumer recyclates (PCR), and to keep them below the migration limits set out by legislations and European Food Safety Authority (EFSA) in order to qualify the packaging structures for food contact applications.

For this purpose, barrier structures as developed in WP5 containing a virgin PE-layer were intentionally contaminated with selected surrogates and subjected to permeation experiments. The results of permeation experiments serve as a basis to conclude on the effectiveness of the barrier layers (and combination thereof) and will support WP5 in defining the final design of novel flexible packaging.

The permeation tests were performed on functional barrier combinations of inorganic or polymeric coatings. Moreover, barrier lacquer formulations were investigated.

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ABBREVIATIONS

Abbreviation	
AlO_x	Aluminium oxide
Amcor-G	Amcor Flexible in Gent
Amcor-K	Amcor Flexible in Kreuzlingen
BIF	Barrier improvement factor
CMR	Substances classified as carcinogenic, mutagenic, or toxic for reproduction
EFSA	European Food Safety Authority
EU	European Union
EVOH	Ethylene vinyl alcohol
FCM	Food Contact Material
GC-FID	Gas chromatograph - Flame Ionization Detector
IAS	Intentionally added substances
LDPE	Low density polyethylene
metOPP	Metalized oriented polypropylene
NIAS	Non intentionally added substances
PCR	Post-consumer recyclates
PE	Polyethylene
PET	Polyethylene terephthalate
ppb	Parts per billion
ppm	Part per million
TTC	Threshold of Toxicological Concern
SiO_x	Silicon oxide
WP	Work package

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1. INTRODUCTION

The main objective of work package (WP) 4 is to define, evaluate and assess innovative recycling strategies and newly developed packaging structures for the use of recycled polyethylene in flexible packaging for food and personal care applications.

For this purpose, analytical migration and compliance testing will be applied in order to assess and ensure food regulatory compliance of the laminate structures developed within this project.

The packaging structures developed within WP5 target at least 70% of PCR in one single layer. To date, such recycled plastic materials may only be used behind a functional barrier layer, which must ensure that migration of any contaminants will remain below levels of toxicological concern as set out by European legislation for food contact material, primary Regulation (EC) No 1935/2004 and Regulation (EU) 2022/1616. Therefore, the effectiveness of functional barrier structures needs to be evaluated in order to design high performance functional barriers.

For this purpose, Amcor-K and Amcor-G supplied different barrier films including functional barrier combinations of inorganic or polymeric coatings/layers. Moreover, barrier lacquer formulations and top coating possibilities from Siegwerk and Fraunhofer IVV were also used for the investigations. These supplied barrier films or barrier lacquers were laminated to an artificially contaminated virgin PE cast film and permeation experiments were performed as described in this deliverable and the previous deliverable D5.1.

Based on the results obtained from these barrier tests, the structures for the targeted food and non-food applications will be designed with the selected functional barriers, including the developments of WP2 for an improved sorting and respecting the suitability for the recycling process developed in WP3.

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2. EVALUATION OF BARRIER PROPERTIES BY PERMEATION TESTING

2.1 SAMPLE PREPARATION

The production of laminate samples for the permeation measurements has been described in detail in Deliverable 5.1 and 5.2 of WP5. In summary, the sample preparation procedure comprises the following steps:

1. Contamination of virgin PE

The virgin PE-material was contaminated with a defined amount of model contaminants in liquid form. These contaminants represent a set of chemicals, which is already well established for the authorization of recycling processes for the manufacturing of recycled polyethylene terephthalate (PET). The surrogates as given Table 1 are chemical substances covering different molecular weights and polarities and thus are representatives of possible contaminants of concern that were selected to be monitored during plastic recycling[1]. Such contaminants include for example contaminants introduced by misuse of the packaging by the consumer, residual food components, and cross-contamination from other (non-food) packaging in the collection system and components used in the laminate such as printing inks, adhesives and primers.

Moreover, the combination is based on extensive experimental and analytical experience performed at Fraunhofer IVV. The contamination was performed in a lab sized twin-screw extruder at Fraunhofer IVV.

2. Extrusion of contaminated PE-film

The spiked material was processed into a mono-cast film at Fraunhofer IVV.

3. Lamination

The produced, contaminated PE-film was laminated to the chosen barrier films at Fraunhofer IVV (sample overview in Table 2). The laminated film rolls were winded up with a layer of aluminium foil between contaminated and virgin side to avoid set off, packed into aluminium bags, sealed and stored at -18 °C until the starting day of the permeation measurements to avoid the loss of volatile components.

[1] Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food, EFSA Journal 2011;9(7):2184, DOI: https://doi.org/10.2903/j.efsa.2011.2184

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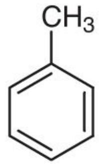
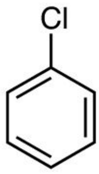
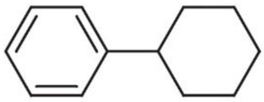
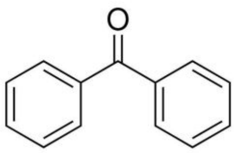
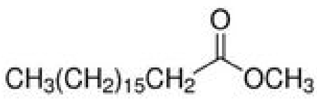
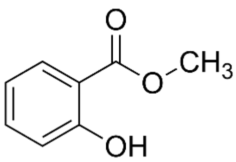
Table 1: Model contaminants (surrogates)

Surrogate	Structure	Physico-chemical properties
Toluene CAS: 108-88-3 M_W: 92.1 g/mol		volatile, non-polar
Chlorobenzene CAS: 108-90-7 M_W: 112.6 g/mol		volatile, medium-polar
Phenyl cyclohexane CAS: 827-52-1 $M_{W:}$ 160.3 g/mol		non-volatile, non-polar
Benzophenone CAS: 119-61-9 M_W: 182.2 g/mol		non-volatile, polar
Methyl stearate CAS: 112-61-8 M_W: 298.5 g/mol		non-volatile, polar
Methyl salicylate CAS: 119-36-8 M_W: 152.2 g/mol		non-volatile, polar

$M_{W:}$ Molecular Weight

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Table 2: Film types investigated by permeation measurements

Set No	Laminate No	Barrier film type
Set I	CFP00101	with EVOH1
	CFP00102	with inorganic coating
	CFP00103	with primer A
	CFP00104	with primer A and inorganic coating
Set II	CFP00120	with primer B and inorganic coating
	CFP00121	with SiO_x and PET
	CFP00122	with metOPP
	CFP00123	with primer A and inorganic coating
Set III	CFP00135	with EVOH2
	CFP00136	with "Lacquer 2" of Amcor
	CFP00137	"new lacquer" of Fraunhofer IVV

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2.2 PERMEATION MEASUREMENTS

Permeation experiments were performed in special permeation cells. Sheets were cut from the laminated reels to prepare samples at the shape of a circle with a diameter of 17cm. These circular samples were then put into the measurement cells, which are depicted in Figure 1 and have a lower and an upper space separated by the laminate. The samples were clamped with screws inside of these tight cells. The measurement cells were then put inside of a climate chamber. For the performed experiments, the temperature of the chamber was set at 60 °C.

The samples were measured at 60 °C for 10 days, which corresponds to the authorized testing conditions for a food/packaging contact of more than 30 days (long-term storage) or below. These specific measurement conditions cover a long-term storage conditions of 6 months at room temperature or below, including hot filling and/or heating up to 70 °C-100 °C[2].

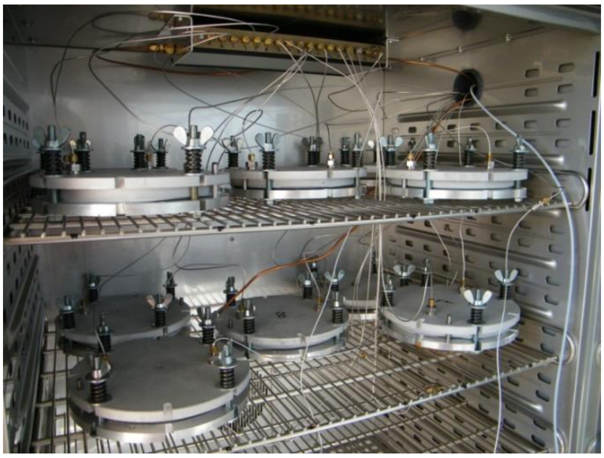

Figure 1: Measurement cells in climate chamber (exemplary layout)

A schematic layout of the setup is shown in Figure 2. The upper space of the cells is connected via small tubes and valves to a nitrogen reservoir on the one side, and a 16-position valve on the other side. The upper side of the cells is rinsed with pure nitrogen which moves permeated substances out of the cells. The cabinet valve is connected to a cryogenic trap and subsequently to a gas chromatograph (GC-FID) for analysis of the gas stream.

Every 40 min, one valve of the 16-way valve opens and the nitrogen stream with the permeated substances form the measurement cells reaches the cryo trap. It is kept there 20 minutes for enrichment of the analytes and then desorbed into the gas chromatograph with flame ionisation detection (GC-FID). The presence of every above-mentioned substance is recorded in µg. For the measurement of a set of four samples, a measurement point is recorded every 160 minutes, which gives a total of 90 measurement points within the 10 days. This is highly sufficient to obtain informative permeation graphs.

[2] Commission Regulation (EU) 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food

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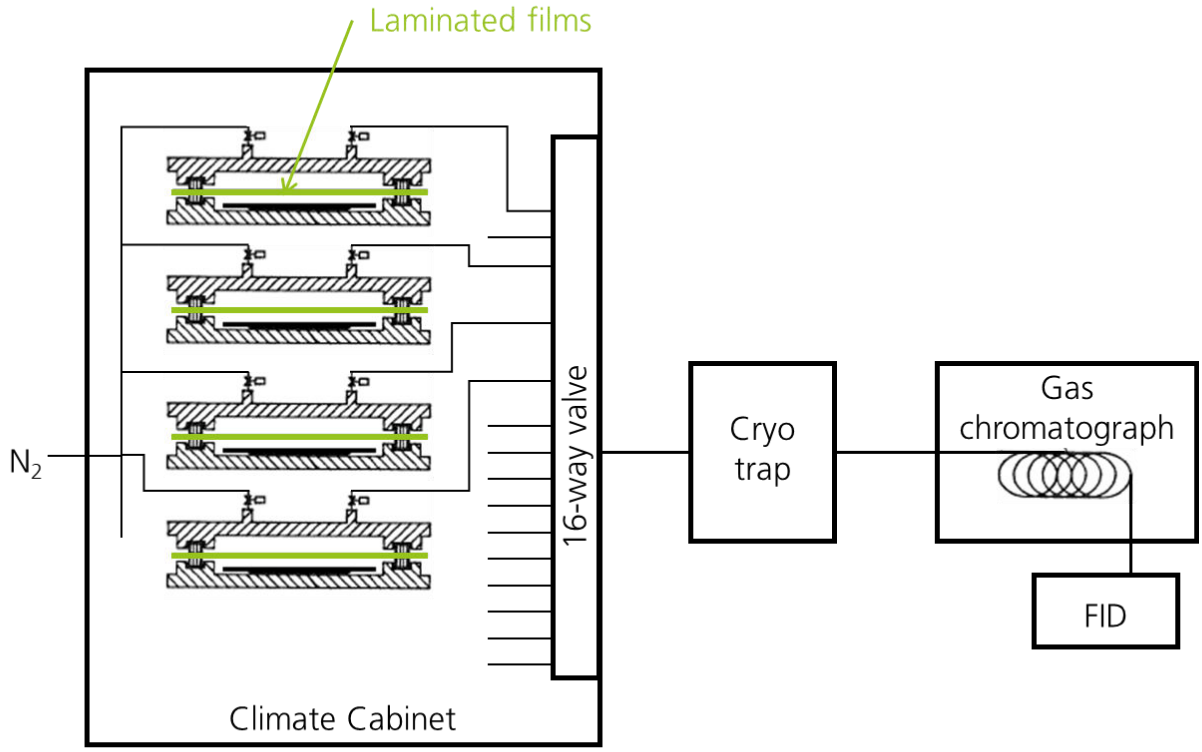

Figure 2: Schematic layout of measurement setup

Determination of permeation values

The obtained values, which are a collected in mass [µg], are converted into permeation values [µg/cm²] using the measurement surface area. To calculate a barrier improvement factor (BIF), the laminates were measured first with the barrier-side facing upwards (permeation value p_b), and subsequently with the contaminated side (initial permeation value p_0) facing upwards in the migration cells. BIF calculates according to the following equation (1):

$$BIF = \frac{p_b}{p_0} \quad (1)$$

p_0 represents the permeation through the spiked PE when there is no barrier layer. However, due to possible differences between the p_0 of the different laminate structures, the BIF is not a valid single method to evaluate the performance of the screened films. Instead, the substance concentrations in the contaminated material were determined (c_0) and the concentration per kg of film was calculated. For the expression of specific migration, the European Regulation (EU) No 10/2011 refers to a cubic packaging containing 1 kg of food, with a side length of 1 dm (EU cube model with surface-to-volume ratio of 6 dm²/kg food). Therefore, the measured migration values are converted into specific migration values. The specific migration is normalized to a defined initial concentration.

The actual contamination levels of the film materials (waste) that will be used in the further project before ("pre-processed") and after applying the decontamination (recycling) cascade are not yet known. Therefore, for the sake of comparison of the barrier performance of the different film structures an initial concentration of 500 and 1000 ppm was set as *theoretical* contamination level of the recyclates to be used in the structure. The normalized values are

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discussed in more detail below, in order to be able to compare the performance of the different laminate structures.

3. RESULTS

The measured permeation values and the derived normalized migration values for all investigated samples (please refer to Table 2) are given in the following overview.

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Table 3: Barrier improvement factors determined, and the derived migration evaluation, normalised to an initial concentration of 1000 mg/kg (based on the EU cube model for food), x in green for suitable as migration barrier, o for not suitable.

		Set I				Set II				Set III		
Normalized migr. [µg/kg] to 1000 ppm		**CFP00101**	**CFP00102**	**CFP00103**	**CFP00104**	**CFP00123**	**CFP00120**	**CFP00121**	**CFP00122**	**CFP00135**	**CFP00136**	**CFP00137**
Toluene	BIF	4284,9	2,1971	703,92	249,04	1081,8	168,13	1812,3659	4,4157	n/a	54,181	n/a
		x	**o**	**x**	**x**	**x**	**o**	**x**	**o**	n/a	**o**	n/a
Chloro benzene	BIF	5770,3	1,8373	606,57	328,41	1260,2	301,21	7720,6875	4,6501	n/a	87,910	n/a
		x	**o**	**o**	**x**	**x**	**o**	**x**	**o**	n/a	**o**	n/a
Methyl salicylate	BIF	4396,4	1,3587	685,55	844,85	1307,5	588,12	17154,03	115,62	35281,6	823,39	38327,53
		x	**o**	**x**	**x**	**x**	**x**	**x**	**o**	**x**	**o**	**x**
phenyl cyclohexane	BIF	6416,3	5,2751	792,10	433,67	372,94	1384,5	528998,0	701,03	296,50	387,38	2915,2
		x	**o**	**x**	**x**	**o**	**x**	**x**	**x**	**o**	**o**	**x**
benzo phenone	BIF	1512,2	1,5864	397,53	379,43	943,29	346,49	864,93	175,48	1717,65	1216,70	359,63
		x	**o**	**x**	**x**	**x**	**x**	**x**	**o**	**x**	**x**	**o**
methyl stearate	BIF	304,7	2,6545	161,66	118,33	96,980	274,0313	33,838	80,466	25,273	2635,00	56,622
		x	**o**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**

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4. DISCUSSION

4.1 COMPARISON OF BARRIER PROPERTIES

Within the performed permeation studies, three sets of laminate structures were investigated for their barrier properties.

Set I comprises a laminate with EVOH (**CFP00101**), a laminate with an inorganic coating (**CFP00102**), a laminate structure with a confidential organic primer (referred to as Primer A, **CFP00103**) and the combination of the organic primer with the inorganic coating (**CFP00104**). Comparing the permeation results and the calculated migration values for Set I, it can be concluded that structure **CFP00101** showed the highest barrier effect towards the tested substances, whereas **CFP00102** showed no effective barrier performance for none of the substances analysed, possibly because of the mechanical damages that might have occurred during material handling processes[3]. Adding a primer to the inorganic coating (**CFP00104**) greatly improved the barrier properties compared to sample **CFP00102**. The barrier performance of the structure with the primer alone (**CFP00103**) was determined to be slightly lower than the organic-inorganic combination (**CFP00104**). The primer A seems to be a fairly efficient barrier itself.

Set II includes one of the best barrier film of Set I with the combination of primer A and inorganic coating (**CFP00123**) for repetition measurements, a barrier film using a confidential primer from Fraunhofer IVV with inorganic coating by Amcor (referred to as Primer B, **CFP00120**), a PET/SiO_x combination (**CFP00121**) and a laminate containing only metallized oriented polypropylene (metOPP, **CFP00122**). The laminate **CFP00122** showed the lowest barrier properties in comparison to the other structures investigated within Set II. The three other samples **CFP00123**, **CFP00120**, and **CFP00121** showed a comparable, good effectiveness towards the tested contaminants. Within the analytical tolerance of the method the values determined in the repetition measurement for structure **CFP00123** were in good accordance with those of **CFP00101** of Set I.

For Set III, laminate structures with different systems of Amcor were investigated (referred to as EVOH2 and lacquer 2, **CFP00135** and **CFP00136**) as well as a structure comprising a "new lacquer" of Fraunhofer IVV (**CFP00137**). All of these structures can be classified as efficient barriers and sample **CFP00137** showed the best barrier properties towards all tested contaminants in comparison to the other two structures.

As an overall conclusion, several of the investigated structures proved to be potential effective barrier options based on the performed experiments. The structures **CFP00101**, **CFP00104**, **CFP00120**, **CFP00121** and **CFP00137** showed the best barrier properties with corresponding migration values below ~10 µg/kg for all analysed substances. It has to be noted that this migration value is based on a theoretical contamination level of 1000 ppm. As stated before, the actual contamination levels of the film materials before ("pre-processed") and after applying the decontamination (recycling) cascade are not yet known.

[3] SiO_x is very susceptible to mechanical stress, which may result in the formation of cracks and pinholes that damage the integrity of the coating layer. We conclude that for the investigated sample the integrity of the SiO_x layer was not given and that the sample was not representative to evaluate the barrier properties of SiO_x.

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4.2 DISCUSSION OF PERMEATION RESULTS AND BARRIER PROPERTIES WITH RESPECT TO THE UPDATED EU LEGISLATION

Commission Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with foods (of 15 September 2022) is replacing the previous Regulation (EC) No 282/2008.

The new Regulation (EU) 2022/1616 aims at ensuring the chemical and microbiological safety of recycled plastic intended to come into contact with food, including food packaging ('recycled plastic FCMs'). It sets out specific rules that become directly applicable to the placing on the market of plastic with recycled content, including the collection and sorting of the plastic input, its decontamination, and conversion, affecting also quality control, documentation and labelling[4]. All kinds of recycled plastic and recycling technologies are in the scope of the Regulation, including mechanical recycling, recycling of products from a closed and controlled product chain, the use of recycled plastic behind a functional barrier, and forms of chemical recycling.

In addition, the Regulation includes a procedure that establishes whether novel recycling technologies are suitable to recycle plastic FCMs. It supports the development of innovative recycling technologies that are likely to allow in the future the recycling of plastics that cannot be recycled today into FCMs, while it maintains a high level of safety of those recycled plastics.

Article 32 of Regulation (EU) 2022/1616 explicitly deals with the use of recycled plastics behind a functional barrier. Here, the functional barriers shall prevent migration to food of contaminants contained in the recycled plastic. As explained in recital clause (33), this technology [i.e. the functional barrier concept] cannot yet be established as a 'suitable recycling technology' from the legislator's point of view. However, unlike other technologies to be considered as novel for the purposes of this Regulation, the main principles of this technology are already understood. This allows to lay down specific adaptations to the rules on novel technologies concerning the use of a functional barrier until a decision is taken on its suitability, and in particular to add a requirement to verify the effectiveness of the barrier principle.

From the legislator's point of view, it does not appear necessary to require the monitoring of all these recycling installations in order to obtain sufficient data on contamination levels, but the ability of the functional barriers to prevent migration of contaminants on the long term must be guaranteed (e.g. by extensive reasoning, and scientific evidence and testing).

In principle, the barrier layers shall ensure that contaminants originating from the PCR layer remain below certain migration limits or levels of toxicological concern.

A limit value of 10 µg/kg is typically applied in the evaluation of *functional barriers* as laid down in the European Plastics Regulation (EU) No 10/2011. According to Art. 13 (2) of Regulation (EU) No 10/2011, non-authorized / non-identified substances may be used in multilayer material beyond the food contact layer, provided that the substances are not classified as mutagenic, carcinogenic or toxic for reproduction (CMR substances) according to the criteria of Regulation

[4] https://food.ec.europa.eu/safety/chemical-safety/food-contact-materials/plastic-recycling_en

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(EC) No 1272/2008 and a transfer (migration) of these non-evaluated components into the food is not detectable at a detection limit of 0.01 mg/kg food simulant (10 ppb).

As a conservative approach, potential contaminants in the recyclate are considered as genotoxic compounds due to the fact that some of the post-consumer substances cannot be identified by instrumental analysis[5]. According to the Threshold of Toxicological Concern (TTC) approach, the threshold value for the oral uptake of genotoxic compounds is set at 0.15 µg/person/day[6] for adults (or 0.0025 µg/kg body weight/day). Under the conventional assumption of a consumption of 1 kg of food per day, this corresponds to a concentration of 0.15 µg/kg (ppb) of the respective substance in food. It must be considered that for some populations such as infants this exposure threshold is lower due to a lower body weight.

In the performed experiments to characterise different materials and structures to be used as a functional barrier, the PE material in the investigated structures was intentionally contaminated. The migration values were then calculated after normalising to a theoretical initial contaminant concentration of 1000 mg/kg as no valid data on the contamination levels of the recyclates is yet available.

Based on permeation properties and BIF obtained for efficient barrier structures, it can be estimated that a CMR substance should not exceed a residual concentration of approx. 10-50 ppm in the PE used behind the functional barrier in order to comply with the limit of 0.15 µg/kg (ppb) of the respective substance in food. In the defined and controlled "Loop 3 material" inherent (known) IAS and NIAS components may be present at ~ 1000 ppm. However, substances with (potential) CRM properties are not expected to be present in such high concentrations.

Regulation (EU) 2022/1616 stresses that both collection and sorting processes as well as the used decontamination technologies will influence the residual concentration of contaminants present in the recycled plastics.

The project's ambition to evaluate the re-use of recycled postconsumer PE in packaging structures that comprise a functional barrier are fully in line with the legal opportunities of the new Recycling Regulation (EU) 2022/1616.

In particular, the analysis of barrier properties via the performed sophisticated permeation analyses of Task 4.5 allows to assess the capability of barrier layers to act as a functional barrier. The performed permeation analyses contribute to the regulatory demands of Article 32 of Regulation (EU) 2022/1616: "results from migration tests, challenge tests, and/or migration modelling, as appropriate and applicable to the notified recycling technology and to the specifics of the process that the recycling installation applies, *unequivocally show that the functional barrier is capable, taking into account the contamination level of the recycled plastic, of acting*

[5] Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food, EFSA Journal 2011;9(7):2184

[6] Scientific Opinion on Exploring options for providing advice about possible human health risks based on the concept of Threshold of Toxicological Concern (TTC). EFSA Journal 2012;10(7):2750, 103 pp

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as a functional barrier in accordance with Regulation (EU) No 10/2011 during the foreseeable shelf-life of the manufactured recycled plastic materials and articles".

Furthermore, WP4 precisely addresses also the additional aspects for such a comprehensive assessment of the capability of a functional barrier. The presence and / or migration of CMR substances in the recycled PE plastics shall be excluded (based on the threshold limits set by Regulation (EU) No 10/2011) within the framework of quality assurance (including the control of potential contamination of the used waste streams) and by employment of analytical testing using bioassays.

The decontamination efficiency of the used technologies developed within the CIRCULAR FoodPack Project (recycling cascades) will be evaluated using the so called challenge tests at pilot industrial level.

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5. CONCLUSION AND OUTLOOK

In summary, several barrier layers (or combinations thereof) with very promising functional barrier properties were identified using sophisticated automated permeation analyses. The functional barrier concepts chosen here are all in line with the current design for recycling guidelines, as also presented in Deliverable D5.1. Therefore, the project team will develop a mono-material laminate including PCRs and functional barrier, which will be in line with the current design for recycling guidelines. Further considerations and discussion on the laminate structure combining the use of recyclate and functional barrier(s) are and will be made in WP5.

Based on this, the most efficient combinations will be proposed to WP5 for further selection within the definition of a final packaging structure (for food packaging and personal care applications).

As described in section 4.1, the final conclusion on the barrier's efficiency and capability to reduce the transfer of undesired contaminants into packed food strongly depends on the level of the residual contaminant levels in the final materials and articles. This is directly linked to level of contamination in the input materials and the applied decontamination technologies. Consequently, these aspects will be addressed, as already foreseen, by conducting challenge tests for the envisaged recycling cascades as well as by analytical characterization and monitoring of the produced recyclates using targeted and not-targeted chemical analytical techniques as well as bioassays.

The selected functional barrier option based on the here shown permeation properties in combination with the produced recyclates (after applying the decontamination cascade) will be used in the final film structure (demonstrator). This film structure will be further evaluated for its safety using migration modelling and/or other mathematical approaches, migration measurements.

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