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Safety assessment of the process Loop Polymers, used to recycle polyethylene and polypropylene printed offcuts and scrap for use as food contact materials

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Abstract

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) assessed the safety of the recycling process Loop Polymers (EU register number RECYC252). The input consists of polyethylene (PE) and polypropylene (PP) offcuts and scrap from the production of food contact packaging that has not been in contact with food, but carry coatings, ink systems and adhesives. Decontaminated material is intended to be used to produce new articles for their original application. The Panel considered critical the management system put in place to provide full traceability from input to the final product, the material review before processing, as well as the removal of coatings, ink systems and adhesives during recycling. The CEP Panel considered that the applicant did not demonstrate that coatings, ink systems and adhesives were adequately removed during the process. Consequently, it concluded that the applicant has not demonstrated that the recycling process is able to reduce the contamination of the PE or PP recyclate to a concentration that does not pose a risk to human health.

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Keywords: Loop Polymers Ltd, food contact materials, plastic, polyethylene (PE), polypropylene (PP), printing ink, recycling process

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Question number: EFSA-Q-2020-00458

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† Deceased.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Recycled plastic materials and articles shall only be placed on the market if they contain recycled plastic obtained from an authorised recycling process. Before a recycling process is authorised, EFSA's opinion on its safety is required. This procedure has been established in Article 5 of Regulation (EC) No 282/2008[1] of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004[2] of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the Member States Competent Authorities, which transmit the applications to the European Food Safety Authority (EFSA) for evaluation.

In this case, EFSA received an application, from the Food Safety Authority of Ireland, for evaluation of the recycling process Loop Polymers, European Union (EU) register No RECYC252. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2020-00458. The dossier was submitted on behalf of Loop Polymers Ltd, United Kingdom (see 'Documentation provided to EFSA').

1.2. Terms of Reference

The Food Safety Authority of Ireland requested the safety evaluation of the recycling process Loop Polymers, in accordance with Regulation (EC) No 282/2008.

1.3. Interpretation of the Terms of Reference

According to Article 5 of Regulation (EC) No 282/2008 on recycled plastic materials intended to come into contact with foods, EFSA is required to carry out risk assessments on the risks originating from the migration of substances from recycled food contact plastic materials and articles into food and deliver a scientific opinion on the recycling process examined.

According to Article 4 of Regulation (EC) No 282/2008, EFSA will evaluate whether it has been demonstrated that the plastic input of the recycling process originates from a product loop which is in a closed and controlled chain ensuring that only materials and articles which have been intended for food contact are used and any contamination can be ruled out.

2. Data and methodologies

2.1. Data

The applicant has submitted a confidential and a non-confidential version of a dossier following the 'EFSA guidelines for the submission of an application for the safety evaluation of a recycling process to produce recycled plastics intended to be used for the manufacture of materials and articles in contact with food, prior to its authorisation' (EFSA, 2008).

Additional information was provided by the applicant during the assessment process in response to requests from EFSA sent on 9 August 2021 and 22 December 2021 (see 'Documentation provided to EFSA').

The following information on the recycling process was provided by the applicant and used for the evaluation:

- General information:
  - general description,
  - existing authorisations.

[1] Regulation (EC) No 282/2008 of the European parliament and of the council of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006. OJ L 86, 28.3.2008, pp. 9–18.

[2] Regulation (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, pp. 4–17.

- Specific information:
  - recycling process,
  - characterisation of the input,
  - determination of the decontamination efficiency of the recycling process,
  - characterisation of the recycled plastic,
  - intended application in contact with food,
  - compliance with the relevant provisions on food contact materials and articles,
  - process analysis and evaluation.

2.2. Methodologies

The risks associated with the use of recycled plastic materials and articles in contact with food come from the possible migration of chemicals into the food in amounts that would endanger human health. The assessment was conducted in line with the principles described in the guidelines on recycling plastics (EFSA, 2008), in the EFSA Guidance on transparency in the scientific aspects of risk assessment (EFSA, 2009) and considering the relevant guidance from the EFSA Scientific Committee.

3. Assessment

3.1. General information[3]

According to the applicant, the recycling process Loop Polymers is intended to recycle offcuts and scrap from the production of food contact polyethylene (PE) and polypropylene PP packaging that have not been in contact with food, but carry print coatings, inks or adhesives. The recyclate is intended to be blended with virgin PE or PP at up to 30% to manufacture new materials and articles for single use in the same product loop and for the original application.

3.2. Description of the process

3.2.1. General description[4]

According to the applicant, the input of the recycling process consists of offcuts and scrap that have not been in contact with food, but carry print coatings, inks or adhesives. Decontaminated flakes will be returned to the original supplier for use in the same application.

The process includes the following steps:

1) Offcuts and scrap are collected, stored and transported from the production site to the recycling facility, where the input material is inspected, tested and stored.
2) The material is visually inspected for hand removal of contaminated material and sorted out before entering the washing stage. It is shredded and broken down to a size allowing efficient removal of ferrous metal and other metal contamination.
3) Input material is subjected to wet or dry grinding into flakes.
4) The flakes are washed in friction vessels for the removal of inks, coatings and adhesives.

The cleaned material is stored and transported to the customer.

3.2.2. Characterisation of the input[5]

According to the applicant, the input material for the recycling process Loop Polymers consists of unused offcuts and scrap carrying print coatings, inks or adhesives. The PE or PP is made in compliance with Regulation (EU) No. 10/2011, but the printing inks and coatings on the non-food contact side may not be approved for food contact.

Before and on receipt at the facility, scrap will have to pass a pre-approval chemistry review before being processed. Only material for which a satisfactory result can be expected will be processed. According to the applicant, scrap will not be processed unless it meets the following criteria:

[3] Technical dossier, Section 3.1.
[4] Technical dossier, Sections 3.1. and 3.2.
[5] Technical dossier, Sections 3.2.1. and 3.2.2.

a) Only from companies manufacturing food contact packaging.
b) Directly printed packaging with inks systems that are food contact approved or completely removable under process conditions. Flexographic inks will be specifically targeted, yellow inks restricted and no yellow polymers will be processed.
c) Passes pre-acceptance chemistry review which checks that the scrap can be safely processed to ensure full compliance with food safety regulations.
d) The output will be returned to the original supplier and application which means the facility can be 'in-house' or on a service basis. This means that Quality Systems will need to be fully integrated with the supplier company to ensure compliance.

According to the applicant, the existing internal quality assurance system (QAS) provides full traceability of the material. Batch numbers are used to trace the material throughout the process and ensure that it is returned to the same application.

3.2.3. Characterisation of the output[6]

Technical specifications on colour, density and melt flow index for the PP or PE flakes have been established by the applicant. Up to 30% recycled flakes are intended to be used to manufacture new recycled PP or PE materials and articles.

3.3. Compliance with the relevant provisions on food contact materials and articles[7]

According to the applicant, the input materials for the recycling process are made of plastics that comply with Commission Regulation (EU) No. 10/2011.

3.4. Experimental data

The applicant provided analytical data for post-consumer high-density polyethylene (HDPE) and PP processed in a pilot plant (at 150 kg/h scale) along with data from experiments with a yellow PP polymer. The samples analysed were:

a) De-inked HDPE printed post-consumer caps, collected in a closed loop system.
b) 'In Mould label (IML)' thermoformed PP.
c) PP yellow printed thermoforming sheet – before (i) and after (ii) de-inking.
d) Yellow post-consumer HDPE bottles, hot washed and extruded on an Erema refresher system.

The data included:

1) Migration of photoinitiators and primary aromatic amines (PAAs) with limits of detection (LOD) below 10 μg/kg.
2) Screening analysis for samples with 200–750 mg/kg of the ink system remaining. A photoinitiator (benzophenone), an ingredient of inks or lacquers (*N*,*N*-dimethyl-1-tetradecaneamine) and a plasticiser breakdown product (tributyl aconitrate) were determined, showing that additives have migrated into the plastic.
3) Overall migration into 95% ethanol and 3% acetic acid for 2 h at reflux temperature and into isooctane for 1.5 h at 60°C. Overall migration was up to 7.9 mg/dm^2.
4) Determination in plastic applying the limits of quantitation of Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[8] which, however, do not apply to the food contact material (FCM) requirements:
   - Volatile organic compounds by dynamic headspace/gas chromatography–mass spectrometry (HS/GC–MS) analysis: benzene < 0.1 mg/kg, D-limonene 0.2 mg/kg.

[6] Technical dossier, Sections 3.2.1. and 3.2.4.
[7] Technical dossier, Section 3.2.6.
[8] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. OJ L 396, 13.12.2006, pp. 1–849.

- Metals by inductively coupled plasma-mass spectrometry (ICP-MS): up to 5.8 mg/kg (Cr), other metals were below 1 mg/kg.
- Listed substances of very high concern (SVHCs) by inductively coupled plasma-optical emission spectroscopy (ICP-OES): < 0.1%.
- Phthalates: < 10 mg/kg.
- Polycyclic aromatic hydrocarbons by GC–MS: < 0.05%.

This data refers to the given samples and cannot be generalised.

For the evaluation of the safety of the process, the applicant considered a migration limit of 0.15 μg/kg food. Applying modelling on a theoretical substance (anthracene), a maximum residual content of ink 165 mg/kg in the process output was derived.

3.5. Process analysis and evaluation by the applicant[9]

According to the applicant, the recycling process will be managed by a QAS with continuous control. Potential risks were identified and the control measures were described.

3.6. Discussion

The data presented by the applicant allow identifying the process, its input, output and the intended uses. The input of offcuts and scrap has not been in contact with food, but carries print coatings, inks or adhesives. It is ground to flakes then processed to remove the coatings, ink system and adhesives. The flakes are returned to the original supplier for use in the same application. According to the applicant, these flakes can be used at up to 30% to manufacture new materials and articles.

The Panel considered the process of removing the ink system and adhesives from the input most critical, but also the management of the whole process is operated under a QAS that includes the use of specific procedures to ensure traceability, i.e. control of the input and return to the customer.

The dossier does not satisfy the requirements of the EFSA guidelines (EFSA, 2008). In particular, despite requests for clarification, fundamental issues were not satisfactorily addressed.

According to Regulation (EC) No 282/2008, the input material should conform with the Plastics Regulation [Regulation (EU) No 10/2011]. Printing inks are not regulated at European level and, therefore, it is likely that not all substances used in the printed input are listed in the Plastics Regulation, but their migration has to comply with the requirements of Article 3 of Regulation No 1935/2004. Taking into account that PE and PP have only weak barrier properties, compounds of low molecular mass are likely to diffuse into the plastic. It was not shown that the recycling process is capable of removing these compounds. Therefore, they can migrate through the plastic into the food, even if the coatings, inks and adhesives are applied on the non-food contact side of the plastic.

It is stated by the applicant that 'all the ink systems processed will have been designed to go onto PP or PE food packaging and the migration of their components (when wet) be understood and be safe for food use'. However, upon clarification request on the composition of inks, coatings, etc. (in order for the applicant to perform specific controls), the applicant responded that the technical and health and safety sheets provided by the scrap supplier can provide the base information for screening analysis, but the exact ink formulations are not provided by the ink suppliers. The Panel considers that if the coatings, ink systems and adhesives are not adequately known, a comprehensive analysis in order to assess the safety of the output is not possible.

Under the high temperatures during extrusion and formation of new articles, degradation products of the remained coatings, inks and adhesives may be formed that cannot be checked using non-targeted analysis at the required detection limits. The applicant's statement on the printing inks' safety for food use is not supported by the available information, since, according to the applicant, full coating, ink and adhesive formulations were not provided by the suppliers.

The estimation of the decontamination efficiency of de-inking is based on a gravimetric method. However, the analytical specificity of the method for components of inks and adhesives was not demonstrated (if ink and adhesive components diffused into the plastic are extracted, then also other substances present in the plastic are extracted). In addition, the method is not adequately described and the analytical tolerance is not known.

[9] Technical dossier, Section 3.2.7.

The applicant proposed an optional additional decontamination step using an EREMA - refresher technology in the case that the Panel considered that the process does not adequately remove the substances from the ink system and the adhesives. It was indeed not shown that the process of washing with friction can remove all possible substances of the ink system and adhesives. However, the EREMA – refresher is ineffective for the removal of high boiling compounds, as shown by the provided challenge test. The applied HS-GC screening test would also not detect such compounds.

Even when applied to the external surface and when set-off is irrelevant, the migration from inks and adhesives applied to plastics without relevant barrier properties, such as polyolefins, must comply with Article 3 of Regulation 1935/2004. In order to enable the applicant to consider the substances diffusing into the plastic and not removed by the proposed cleaning process to be of no safety concern, the applicant should receive adequate information from the ink and adhesive suppliers. Nevertheless, it remains that thermal treatment during the recycling and manufacture of new FCM may form degradation products. The volatiles may be removed by the EREMA process, but it would remain up to the applicant to demonstrate that also degradation products of lower volatility are of no concern.

4. Conclusions

The Panel concluded that, based on the information submitted to EFSA on the process Loop Polymers, the applicant has not demonstrated by appropriate evidence that the recycling process is able to reduce contamination of the input PE or PP offcuts and scrap with printed ink and coating systems to a concentration that does not pose a risk to human health.

5. Documentation provided to EFSA

Dossier 'Loop Polymers'. October 2021. Submitted by Loop Polymers Ltd, United Kingdom.
Additional information, November 2021. Submitted by Loop Polymers Ltd, United Kingdom.
Additional information, March 2022. Submitted by Loop Polymers Ltd, United Kingdom.

References

EFSA (European Food Safety Authority), 2008. Guidelines for the submission of an application for safety evaluation by the EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food, prior to its authorisation. EFSA Journal 2008,6(7):717, 12 pp. https://doi.org/10.2903/j.efsa.2008.717

EFSA (European Food Safety Authority), 2009. Guidance of the Scientific Committee on transparency in the scientific aspects of risk assessments carried out by EFSA. Part2: General principles. EFSA Journal 2009;7 (5):1051, 22 pp. https://doi.org/10.2903/j.efsa.2009.1051

Abbreviations

CEP Panel	Panel on Food Contact Materials, Enzymes and Processing Aids
FCM	Food contact material
GC–MS	gas chromatography–mass spectrometry
HDPE	high-density polyethylene
ICP-MS	inductively coupled plasma-mass spectrometry
ICP-OES	inductively coupled plasma-optical emission spectroscopy
HS/GC–MS	headspace-gas chromatography/mass spectrometry
PE	polyethylene
PP	polypropylene
QAS	Quality Assurance System