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Safety assessment of the process Cajas y Palets en una Economía Circular (CAPEC), used to recycle high-density polyethylene and polypropylene crates 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 Cajas y Palets en una Econom a Circular (CAPEC) (EU register number RECYC242). The input consists of crates made of high-density polyethylene (HDPE) or polypropylene (PP) originating from closed and controlled product loops for the packaging of whole fruits and vegetables. Flakes or pellets are produced that will be used by manufacturers of new crates for food contact. The Panel considered that the management system put in place to ensure compliance of the origin of the input with Commission Regulation (EC) No 282/2008 and to provide full traceability from input to final product is the critical process step. It concluded that the input of the process CAPEC originates from product loops which are in closed and controlled chains designed to ensure that only materials and articles that have been intended for food contact are used and that contamination can be ruled out when run under the conditions described by the applicant. The recycling process CAPEC is therefore suitable to produce recycled HDPE and PP crates intended to be used in contact with fruits and vegetables.

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1. Introduction

1.1. Background

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 282/2008¹ 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 1935/2004² 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 Spanish Agency for Food safety and Nutrition (AESAN), for evaluation of the recycling process Cajas y Palets en una Economía Circular (CAPEC), European Union (EU) register No RECYC242. The request has been registered in EFSA's register of received questions under the number Q-2021-00294. The dossier was submitted on behalf of Cajas y Palets en una Economía Circular (CAPEC), Spain.

1.2. Terms of Reference

The Spanish Agency for Food safety and Nutrition (AESAN) requested the safety evaluation of the recycling process Cajas y Palets en una Economía Circular (CAPEC), in compliance with Article 5 of 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) and the 'Administrative guidance for the preparation of applications on recycling processes to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food' (EFSA, 2021). In accordance with Article 38 of the Commission Regulation (EC) No 178/2002³ and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation and of the Decision of EFSA's Executive Director laying down practical arrangements

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, p. 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, p. 4–17.

³ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

concerning transparency and confidentiality,⁴ the non-confidential version of the dossier was published on Open.EFSA.⁵

According to Article 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations,⁴ EFSA carried out a public consultation on the non-confidential version of the application from 18 March to 8 April 2022. No comments were received.

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

- General information:
 - general description,
 - existing authorisations.
- Specific information:
 - recycling process,
 - characterisation of the input,
 - 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,
 - operating parameters.

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 information⁶

According to the applicant, the recycling process Cajas y Palets en una Economía Circular (CAPEC) is intended to recycle precleaned crates of food-grade high-density polyethylene (HDPE) and polypropylene (PP). CAPEC is an organisation that neither produces crates nor recycles them, but is the manager keeping the recycling loop under control. The recyclate may be blended with virgin HDPE or PP, or be used at up to 100% to manufacture new HDPE and PP crates for repeated use in the same loops, for long-term storage of whole fruits and vegetables for long-term storage at ambient temperature or below.

3.2. Description of the process

3.2.1. General description⁴

According to the applicant, the input of the recycling process consists of precleaned crates and parts of crates that have been used in food contact. Crates are from pooling organisations, where re-used crates are recycled in closed and controlled loops.

The process includes the following steps:

- 1) Crates at the end of the service life (e.g. because of damages), precleaned by the pooling organisations (input), are collected by companies qualified according to the CAPEC Quality Assurance System (QAS) supplier assessment procedure. These collectors check the origin of crates (closed and controlled loops), sort out contaminated crates by visual inspection and

⁴ Decision available at <https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements>

⁵ The non-confidential version of the dossier following EFSA's assessment of the applicant's confidentiality requests is published on Open.EFSA and is available at the following link: <https://open.efsa.europa.eu/dossier/FCM-2021-0583>

⁶ Technical dossier, section 'Recycling process'.

- separate the HDPE and PP streams. The collectors are responsible for confirming that the crates belong to the loop by verifying the presence of the CAPEC logo. The crates are placed on pallets and wrapped into film labelled with the name of the collector, date of collection and type of polymer as well as an orange label identifying the CAPEC circuit. They are stored at covered places signposted to show that the crates belong to the CAPEC circuit.
- 2) Upon reception by the recycler, there is a visual check to ensure that all crates on a pallet are of the same type of polymer, that they comply with the labelling of the pallet and that all the crates belong to the CAPEC loop (embossed PP or HDPE, and CAPEC logo). Cleaning is checked and there is also a colour segregation. The pallets are stored in specifically marked compartments. The further processing depends on whether flakes or pellets are the output:
 - Flakes: the crates are torn, shredded, washed with potable water at room temperature to remove potentially adhering contaminants (paper, fruit and vegetable debris), then dried by a centrifuge, ground and packed in bags.
 - Pellets: The crates are torn, prewashed, shredded, washed with potable water at room temperature, dried by a centrifuge, ground, extruded, filtered and packed.
 - 3) Flakes or pellets are delivered to the producer of new crates. They are used to produce new crates with or without blending with virgin HDPE or PP. Dye is incorporated in the form of a master batch. New crates are formed by injection moulding, stacked on pallets and packed with food-grade plastic film. A production label with an individual code per pallet/batch is added to the film. The pallets are stored at a specified place and under specified conditions, then delivered to the user with a declaration of compliance (DoC) that they comply with the CAPEC requirements.

According to the applicant, the CAPEC loop involves the steps shown in Figure 1.

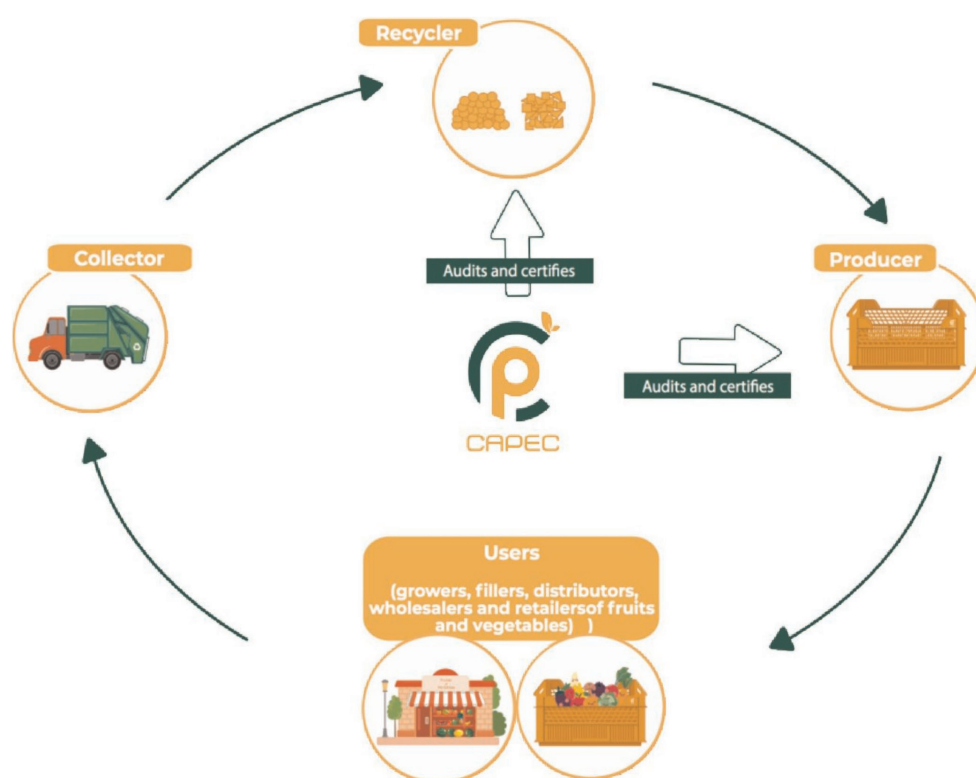


Figure 1: The CAPEC loop according to the applicant

3.2.2. Characterisation of the input⁷

According to the applicant, the input material for the recycling process CAPEC consists of used and cleaned HDPE or PP crates that have been made for and used in contact with food in closed re-use loops for packaging, transport, storage and display of fruits and vegetables. The crates are originally made of HDPE or PP in compliance with Regulation (EU) No 10/2011, using the CAPEC logo to confirm this.

The crates are used in a product loop of a closed and controlled chain by wholesalers and retailers for packaging, transport and storage of whole fruits and vegetables for long-term storage at ambient temperature or below.

According to the applicant, the existing internal QAS ensures that the input originates exclusively from this closed and controlled loop and provides full traceability of the material processed within its premises.

3.2.3. Characterisation of the output⁸

The following technical specifications for the HDPE and PP flakes have been established by the applicant: melt flow rate, colour, regrind particle size and density.

Up to 100% recycled HDPE and PP flakes may be used to manufacture new recycled HDPE or PP crates.

According to the applicant, all crates are embossed with the CAPEC's logo and engraved with the manufacturing date to assure full traceability in the production process and that no other item or material are mixed into the loop.

3.3. Comparative testing of virgin and five-time recycled material⁹

The effect of repeated grinding and injection moulding of HDPE and PP crates on the formation of degradation products was assessed following a protocol proposed by Coulier et al. (2007). Virgin and five times recycled (ground and injection-moulded) material were compared by total immersion (three replicates).

The following parameters were tested:

- Overall migration in 3% acetic acid (10 days at 40°C) and 10% ethanol (10 days at 40°C).
- Specific migrations of several substances (monomers and additives) with a specific migration limit (SML) in the Regulation EU No. 10/2011, used in the manufacturing of the resins or in the original crates. Worst case simulants were selected for each substance and different analytical techniques were used.
 - Specific migration of *N,N*-bis(2-hydroxyethyl)alkyl (C8–C18) amine (FCM 19) in 10% ethanol and 3% acetic acid after 10 days at 60°C, analysed by liquid chromatography/mass spectrometry (LC/MS).
 - Specific migration of 9,9-bis(methoxymethyl) fluorene (FCM 779) in 10% ethanol and 3% acetic acid after 10 days at 60°C, analysed by LC/fluorescence detection.
 - Aluminium in 10% ethanol and 3% acetic acid after 10 days at 60°C, analysed by inductively coupled plasma mass spectrometry (ICP-MS).
- Screening methods have been applied to investigate differences between virgin and 5 times recycled plastic:
 - Release of volatile substances by headspace gas chromatography coupled with mass spectrometry (HS-GC/MS).
 - Migration of semi-volatile substances into 10% ethanol and 3% acetic acid after 10 days at 60°C, screened by GC/MS.
 - Migration of non-volatile substances into 10% ethanol and 3% acetic acid (10 days at 60°C), analysed by LC/MS. There was no significant difference in the overall migrations between virgin and five times recycled material.

⁷ Technical dossier, section 'Characterisation of the input'.

⁸ Technical dossier, section 'Characterisation of the recycled plastic'.

⁹ Technical dossier, section 'Determination of the decontamination efficiency of the recycling process'.

Specific migration of substances with a SML into their worst-case simulants was well below the SML in all cases and in most cases below the limit of quantification. No differences in migration for the substances in the 5 times recycled versus virgin material was observed.

Migration of *N,N*-bis(2-hydroxyethyl)alkyl (C8–C18) amine in 10% ethanol and 3% acetic acid was below the SML (1.2 mg/kg expressed as tertiary amine).

No new volatile compounds were detected in the five times recycled compared to the virgin material. The semi-volatile substances were not increased in the five times recycled material.

3.4. Discussion

The data presented by the applicant allow identifying the process, its input, output and the intended uses of the crates. Based on the description of the process, the Panel considers that this process is within the scope of Art. 4 c(i) of the Regulation (EC) No 282/2008, when the plastic input is supplied by pooling organisations belonging to a product loop in a closed and controlled chain.

Within the loop, the crates are used for long-term storage, transport and displaying of whole fruits and vegetables at ambient temperature or below. At the end of their service life (e.g. because of damages), pre-cleaned crates (input) are recycled. In the recycling process, the crates are processed to flakes or pellets, including washing and drying. These materials can be used at up to 100% by the end customers to manufacture new recycled crates by injection moulding.

Considering the high temperature during processing, the possibility of contamination by microorganisms can be discounted. Therefore, this evaluation focuses on the chemical safety of the final product.

The Panel considered the management of the process as critical, i.e. that the whole process (collection, sorting, recycling, distribution) is operated under a QAS which includes the use of specific identifiers that are intended to ensure traceability and control of the input.

The grinding of the crates, the washing of the recyclate, the extrusion and the injection moulding under the conditions described by the applicant are not of safety concern. By the comparison of the migration from five times recycled with virgin HDPE or PP material it has been demonstrated that recycling has no significant effect on the formation and migration of degradation products, additives, monomers and oligomers.

The Panel noted that the risk calculation was using a worst-case scenario showing very low levels of potential contamination of the crates.

4. Conclusions

The Panel concluded that the process CAPEC ensures that only HDPE and PP crates suitable for food contact are used and that contamination by misuse can be ruled out, since the input originates from this product loop managed in a closed and controlled chain. Therefore, the recycled materials obtained from this process and used within this loop are not of safety concern, when used at up to 100% for the manufacture of crates for contact with whole fruits and vegetables at room temperature or below.

5. Recommendations

The Panel recommends that it should be verified periodically, as part of the good manufacturing practice (GMP) in the meaning of the Regulation (EC) No 2023/2006, that the input originates from materials and articles that have been manufactured in accordance with the EU legislation on food contact materials and articles (Regulation (EC) No 282/2008, Art. 4b). Specifications for input (cleaned crates from closed and controlled loops) and separate processing of the material intended for food contact should be kept under control. Supporting documentation recording the control should be available.

6. Documentation provided to EFSA

Dossier 'Cajas y Palets en una Economía Circular (CAPEC)'. October 2021. Submitted on behalf of Cajas y Palets en una Economía Circular (CAPEC), Spain.

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Abbreviations

CAPEC	Cajas y Palets en una Economía Circular
CEP Panel	Panel on Food Contact Materials, Enzymes and Processing Aids
DoC	declaration of compliance
GC/MS	gas chromatography/mass spectrometry
HDPE	high-density polyethylene
HS-GC/MS	head space-gas chromatography/mass spectrometry
ICP-MS	inductively coupled plasma-mass spectrometry
LC	liquid chromatography
LC/FLD	liquid chromatography/fluorescence detection
LC/MS	liquid chromatography coupled to mass spectrometry
PP	polypropylene
QAS	Quality Assurance System
SML	specific migration limit