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Safety assessment of the process Green Loop System, used to recycle polycyclohexylene dimethylene terephthalate glycol-modified (PCTG) plates 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 Green Loop System (EU register number RECYC174), a closed and controlled product loop. The input consists of washed plates of polycyclohexylene dimethylene terephthalate glycol-modified (PCTG) having been used in, e.g. canteens. The plates are ground, converted to new plates, returned to the users of the loop and used as before recycling. The management system to ensure a closed loop is critical, i.e. compliance of the origin of the input with Commission Regulation (EC) No 282/2008 and full traceability from input to final product should be ensured. The Panel concluded that the input of the process Green Loop System originates from product loops that are in a closed and controlled chain, designed to ensure that only materials and articles that have been intended for food contact are used and that contamination other than by food can be ruled out. The recycling process Green Loop System is, therefore, able to recycle PCTG plates intended for repeated use, for contact with aqueous, acidic and fatty food, at low and high temperatures.

Keywords: Mälarplast AB, Green Loop System, MALKO recirculation plate, food contact materials, plastic, PCTG, recycling process, safety assessment

Requestor: Swedish National Food Agency (NFA)

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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 Swedish National Food Agency (NFA), for evaluation of the recycling process Green Loop System, European Union (EU) register No RECYC174. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2019-00016. The dossier was submitted on behalf of Mälarplast AB, Sweden.

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 the plastic input of the recycling process Green Loop System 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 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). Applications shall be submitted in accordance with Article 5 of the Regulation (EC) No 282/2008.

Additional information was sought from the applicant during the assessment process in response to requests from EFSA sent on 15 October 2019 and 20 October 2020 and was subsequently provided (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.
- 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.

[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.

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

According to the applicant, the process Green Loop System is intended to recycle pre-cleaned plates of canteens. They are made of polycyclohexylene dimethylene terephthalate glycol-modified (PCTG), composed of ethylene glycol, terephthalate, cyclohexane-di-methanol and 1,4:3,6 di-anhydrosorbitol (isosorbide). The recyclate may be blended with virgin PCTG or used at up to 100% to manufacture new plates for repeated use in the same loops, for contact with all types of food and under the conditions of use of the articles before recycling.

3.2. Description of the process

3.2.1. General description

According to the applicant, the input of the recycling process is pre-cleaned plates that have been used in food contact. Plates are, e.g. from canteens, returned for recycling in closed and controlled loop of the recycler and canteens.

The process includes the following steps:

1) At the end of the service life, typically after 3–4 years (controlled by the presence of imprint on the plates), the canteens send the used plates for recycling. Also visual inspections are performed during the service life. If a plate is found not to be imprinted, being discoloured or showing signs of misuse, it is taken out of the loop.
2) Used plates, cleaned at the canteen facility, are received for grinding by the applicant (input). Before grinding, administrative checks on the origin of the plates (closed and controlled product loops) and visual inspections are performed.
3) The regrind is dried with hot air and used to produce new plates by injection moulding at high temperature and pressure, with or without blending with virgin PCTG. The recycled plates are packaged at the applicant's site and returned to the canteens.

The steps of the process are shown in Figure 1.

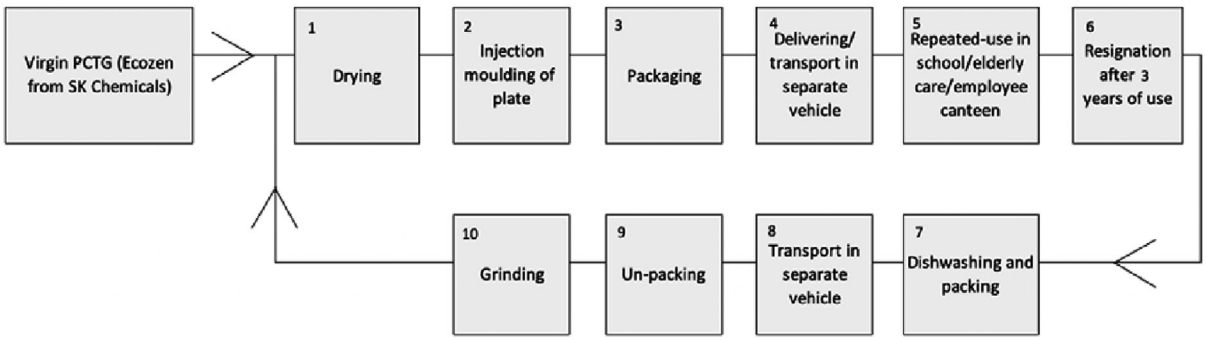

Figure 1: Flow chart for the recycling process (provided by the applicant)

3.2.2. Characterisation of the input

According to the applicant, the input material for the recycling process Green Loop System consists of pre-washed PCTG plates, originally produced in compliance with the Commission Regulation (EU) No 10/2011, that have been used in contact with food, e.g. in canteens, such as at schools, elderly care facilities and lunch restaurants. During service life, typically of 3–4 years, the plates are cleaned

according to the hazard analysis and critical control points (HACCP) system in place, in order to be used again in the closed loop.

According to the applicant, the existing internal quality assurance system ensures that the input of the recycling exclusively originates from this closed and controlled loop and provides full traceability of the material processed, by appropriate imprinting, within its premises. Furthermore, plates which are discoloured or showing signs of misuse are taken out of the loop.

3.2.3. Characterisation of the output

Up to 100% recycled PCTG regrind may be used to manufacture new PCTG plates by injection moulding. According to the applicant, all plates are provided with an imprint with the manufacturer's logo as well as the manufacturing year and month to assure full traceability and that no other items or materials are mixed into the loop.

3.3. Experimental Data

Three, five and seven times recycled plates were manufactured and tested by filling with food simulants to verify compliance with overall and specific migration limits in the Regulation EU 10/2011 under repeated use conditions. Before each reprocessing, the plates were submitted to simulated repeated dishwashing (immersion for 26 hours in warm dishwashing solution).

The following tests were performed:

- overall migration by filling with 3% acetic acid (2 h at 70°C) or substitute food simulant 95% ethanol (0.5 h at 40°C) on plates after the reprocessing cycles (triplicate measurements, three rounds of migration testing for repeated-use articles);
- specific migration of primary aromatic amines (PAAs) and metals in 3% acetic acid (2 h at 70°C) on plates after the 3rd, 5th and 7th reprocessing cycle;
- screening for organic compounds in the migration liquids by liquid chromatography coupled to mass spectrometry (LC/MS), gas chromatography coupled to mass spectrometry (GC/MS) and headspace GC/MS.

After the 7th reprocessing, the overall migration was well below the limit of 10 mg/dm^2 set in the Regulation EU 10/2011 or undetectable (below 2 mg/dm^2). The specific migration of PAAs was below the detection limit (0.002 mg/kg). Specific migration of metals was below the limits of detection (0.02 mg/kg or lower). Semi-quantification by LC/MS and GC/MS did not reveal migrating substances with a detection limit of 0.01 mg/kg as given by the applicant.

3.4. Process analysis and evaluation by the applicant

The applicant presented a process analysis in which the following points are made:

- the recycling process is managed by a quality assurance scheme in which continuous control is performed, ensuring that contamination and the involved risks are avoided;
- traceability tools are used and kept in the loop that rule out the possibility of misuse by the users.

3.5. Discussion

The data presented by the applicant allow identifying the process, its input, output and intended uses of final articles. 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. The recycling process uses input material supplied by canteen services belonging to the product loop of canteens and the recycler company. Within the loop, the plates are used for serving all types except alcoholic foods at room temperature or higher. They are intended for repeated use. At the end of their service life, pre-cleaned plates (input) are recycled. In the recycling process, the plates are ground, dried and can be used at up to 100% to manufacture new plates by injection moulding to be used in the same loop.

Considering the high temperatures used in the processing of the granulates (injection moulding to produce new plates), 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 input material as the critical step, i.e. that the whole process (collection, sorting, recycling, distribution) is operated under a quality assurance system. The traceability system of Green Loop System introduces an adequate number of identifiers to ensure

traceability and control of the input: imprints of the manufacturer's logo as well as the manufacturing year and month.

In addition, the Panel considered that:

- The recycling of the plates is carried out by the same process as their initial manufacture.
- The plates to be recycled are collected only in the canteens and sent to the recycler, where a visual inspection can identify foreign articles without the imprint logo, ensuring a high level of selectivity in the input.
- Post-use contamination of these plates can be ruled out because their intended service life in this product loop does not allow for a misuse.
- The recycled articles are only used by the canteens that belong to this loop. These plates are intended for repeated use and are used many times before recycling is performed at the end of their service life (3–4 years). Therefore, the exposure of users of these articles to potential degradation products, from recycling or aging, is low.

4. Conclusions

The Panel considered that the process Green Loop System only uses materials and articles intended for food contact and ensures that contamination other than by foods can be ruled out since the input is from a product loop in a closed and controlled chain. Therefore, the Panel concluded that 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 plates for contact with all types of foodstuffs under the conditions of use before recycling.

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 (PCTG plates used within this product loop which is in a closed and controlled chain) should be kept under control to ensure that they correspond to the described process. Supporting documentation demonstrating how it is kept under control should be available.

6. Documentation provided to EFSA

1) Dossier 'Green Loop System'. August 2019. Submitted on behalf of Mälarplast AB, Sweden.
2) Additional information, August 2020. Submitted on behalf of Mälarplast AB, Sweden.
3) Additional information, May 2021. Submitted on behalf of Mälarplast AB, Sweden.

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

CEF Panel	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel	Panel on Food Contact Materials, Enzymes and Processing Aids
PCTG	polycyclohexylene dimethylene terephthalate glycol-modified
GC/MS	gas chromatography coupled to mass spectrometry
GMP	good manufacturing practice
HACCP	hazard analysis and critical control points
LC/MS	liquid chromatography coupled to mass spectrometry
PAAs	primary aromatic amines
PET	poly(ethylene terephthalate)