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SCIENTIFIC OPINION

Safety assessment of the process INCOM RESOURCES RECOVERY (TIANJIN), based on the Buhler technology, used to recycle post-consumer PET into 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 INCOM RESOURCES RECOVERY (TIANJIN) (EU register number RECYC312), which uses the Buhler technology. The input material consists of hot washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, e.g. bottles, including no more than 5% PET from non-food consumer applications. Washed and dried flakes are extruded into pellets, which are dried and crystallised in a reactor and then preheated and further treated in a solid-state polymerisation (SSP) reactor. The recycled pellets are intended to be used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs, including drinking water, for long-term storage at room temperature or below, with or without hotfill. The Panel concluded that the information submitted to EFSA is inadequate to demonstrate that this recycling process is able to reduce potential unknown contamination of the input PET flakes to a concentration that does not pose a risk to human health.

KEYWORDS

Buhler, food contact materials, INCOM RESOURCES RECOVERY(TIANJIN) CO.,LTD, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

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1 | INTRODUCTION

1.1 | Background and Terms of Reference

1.1.1 | Background

Recycled plastic materials and articles shall only be placed on the market if the recycled plastic is from an authorised recycling process. Before a recycling process is authorised, the European Food Safety Authority (EFSA)'s opinion on its safety is required. This procedure has been established in Article 5 of Regulation (EC) No 282/2008[1,2] on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004[3] on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the competent authorities of Member States, which transmit the applications to EFSA for evaluation.

In this case, EFSA received, from the Competent Authority of France (Ministère de l'économie des finances et de la relance, Bureau 4B, Qualité des denrées alimentaires), France, an application for evaluation of the recycling process INCOM RESOURCES RECOVERY (TIANJIN), European Union (EU) register No RECYC312. The request has been registered in EFSA's register of received questions under the number EFSA_Q-2022-00028. The dossier was submitted on behalf of INCOM RESOURCES RECOVERY (TIANJIN)CO.,LTD, NO.36 Baofu road, 301800 Tianjin, China.

1.1.2 | Terms of Reference

The Competent Authority of France (Ministère de l'économie des finances et de la relance, Bureau 4B, Qualité des denrées alimentaires), France requested the safety evaluation of the recycling process INCOM RESOURCES RECOVERY (TIANJIN), in accordance with Regulation (EC) No 282/2008 and Articles 9 and 10 of the Regulation (EC) 1935/2004.

1.2 | 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 in a challenge test, or by other appropriate scientific evidence, that the recycling process INCOM RESOURCES RECOVERY(TIANJIN) is able to reduce the contamination of the plastic input to a concentration that does not pose a risk to human health. The poly(ethylene terephthalate) (PET) materials and articles used as input of the process as well as the conditions of use of the recycled PET make part of this evaluation.

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).

Following the request for additional data sent by EFSA on 16 November 2023 (see 'Documentation provided to EFSA'), the applicant requested a clarification teleconference, which was held on 25 April 2023.

[1]Commission Regulation (EC) No 282/2008 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]Commission Regulation (EC) No 282/2008 was repealed by Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008 (OJ L 243 20.9.2022, p. 3) which entered into force on 10 October 2022. Applications submitted to EU Member State competent authorities before the date of entry into force of Commission Regulation (EU) 2022/1616 are evaluated by EFSA in accordance with Commission Regulation (EC) No 282/2008.

[3]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.

In accordance with Art. 38 of the Regulation (EC) No 178/2002[4] and taking into account the protection of confidential information and the personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of the EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[5] the non-confidential version of the dossier has been published on Open.EFSA.[6]

According to Art. 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, EFSA carried out a public consultation on the non-confidential version of the application from 12 June to 3 July 2023 for which 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,
  - 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,
  - 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 quality of the input, the efficiency of the recycling process to remove contaminants as well as the intended use of the recycled plastic are crucial points for the risk assessment (EFSA, 2008).

The criteria for the safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for the manufacture of materials and articles in contact with food are described in the scientific opinion developed by the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (EFSA CEF Panel, 2011). The principle of the evaluation is to apply the decontamination efficiency of a recycling technology or process, obtained from a challenge test with surrogate contaminants, to a reference contamination level for post-consumer PET, conservatively set at 3 mg/kg PET for contaminants resulting from possible misuse. The resulting residual concentration of each surrogate contaminant in recycled PET (C_{res}) is compared with a modelled concentration of the surrogate contaminants in PET (C_{mod}). This C_{mod} is calculated using generally recognised conservative migration models so that the related migration does not give rise to a dietary exposure exceeding 0.0025 µg/kg body weight (bw) per day (i.e. the human exposure threshold value for chemicals with structural alerts for genotoxicity), below which the risk to human health would be negligible. If the C_{res} is not higher than the C_{mod}, the recycled PET manufactured by such recycling process is not considered to be of safety concern for the defined conditions of use (EFSA CEF Panel, 2011).

The assessment was conducted in line with the principles described 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[7]

According to the applicant, the recycling process INCOM RESOURCES RECOVERY (TIANJIN) is intended to recycle food grade PET containers using the Buhler technology. The recycled PET is intended to be used at up to 100% by converters for the manufacture of materials and articles for direct contact with all kinds of foodstuffs for long-term storage at room temperature, with or without hotfill, including bottles for drinking water. The final articles are not intended to be used in microwave or conventional ovens.

[4]Commission 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.

[5]Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements

[6]The non-confidential version of the dossier has been published on Open.EFSA and is available at the following link: https://open.efsa.europa.eu/dossier/FCM-2021-2172

[7]Technical dossier, sections 'Recycling process' and 'Intended application in contact with food'.

3.2 | Description of the process

3.2.1 | General description[8]

The recycling process INCOM RESOURCES RECOVERY (TIANJIN) produces recycled PET pellets from PET containers from post-consumer collection systems (kerbside and deposit systems).

The recycling process comprises the four essential steps below.

Input

- Step 1: Post-consumer PET containers are processed into washed and dried flakes, which are used as input of the process. This step is performed by the applicant.

Decontamination and production of recycled PET material

- Step 2: The flakes are dried, melted and degassed in an extruder at high temperature and under vacuum to produce pellets.
- Step 3: The pellets are heated, dried and crystallised in a continuous fluidised bed reactor at high temperature.
- Step 4: The crystallised pellets are preheated and then treated in a continuous solid-state polycondensation (SSP) reactor at high temperature under vacuum and inert gas flow.

The operating conditions of the process have been provided to EFSA.

3.2.2 | Characterisation of the input[9]

According to the applicant, the input material for the recycling process INCOM RESOURCES RECOVERY (TIANJIN) consists of hot washed and dried flakes obtained from PET containers, e.g. bottles, previously used for food packaging, from post-consumer collection systems (kerbside and deposit systems). A small fraction may originate from non-food applications. According to the applicant, this proportion will be no more than 5%.

Technical data for the hot washed and dried flakes are provided, such as on physical properties and residual contents of moisture, PVC, adhesive, metals, rubber inorganic impurity, other materials than PET (caps, labels and handle material) and heterochromatic sheet (see Appendix A).

3.3 | Buhler technology

3.3.1 | Description of the main steps[10]

The general scheme of the Buhler technology, as provided by the applicant, is reported in Figure 1. The essential steps are:

- Step 2, extrusion: the flakes are introduced into an extruder in which they are dried at solid state before being melted and degassed.
- Step 3, drying and crystallisation: in a continuous process, using a fluidised bed reactor and hot air, the pellets are heated to a [redacted] to be dried and crystallised.
- Step 4, SSP reactor: The pellets are continuously fed into the preheating section of a continuous SSP reactor and heated up to the required solid state temperature. Then they are continuously introduced into the main reactor, running under [redacted] flow at a predefined pressure and residence time.

[8]Technical dossier, sections 'Recycling process', 'Characterisation of the input' and 'Characterisation of the recycled plastic'.
[9]Technical dossier, section 'Characterisation of the input'.
[10]Technical dossier, sections 'Recycling process' and 'Determination of the decontamination efficiency of the recycling process'.

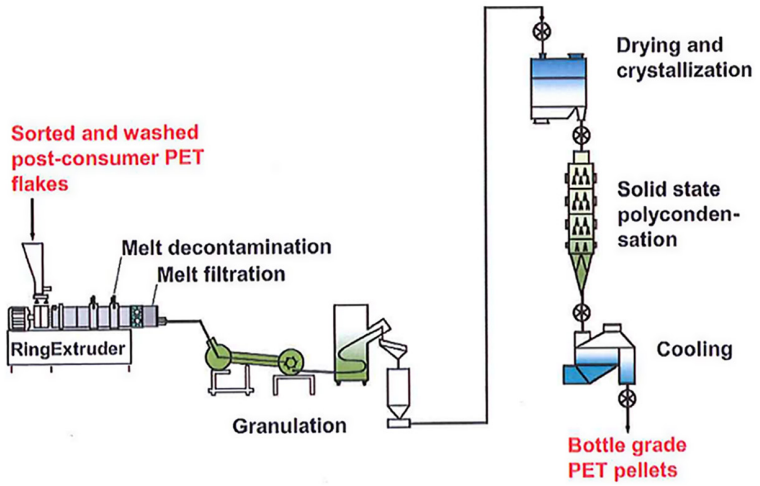

FIGURE 1 General scheme of the Buhler technology (provided by the applicant).

3.3.2 | Decontamination efficiency of the recycling process[11]

To demonstrate the decontamination efficiency of the recycling process INCOM RESOURCES RECOVERY (TIANJIN), challenge tests at three contamination levels were performed at industrial scale.

PET flakes were contaminated with toluene, chlorobenzene, trichloroethane, phenylcyclohexane, benzophenone and methyl stearate, selected as surrogate contaminants in agreement with the EFSA guidelines (EFSA CEF Panel, 2011) and in accordance with the recommendations of the US Food and Drug Administration (FDA, 2006). The surrogates include different molecular masses and polarities to cover possible chemical classes of contaminants of concern and were demonstrated to be suitable to monitor the behaviour of PET during recycling (EFSA, 2008).

For the preparation of the contaminated PET flakes, a mixture of solid surrogates (benzophenone and methyl stearate) and liquid surrogates (toluene, chlorobenzene, trichloroethane and phenylcyclohexane) was added to recycled post-consumer PET flakes in three amounts, namely [redacted] mg/kg flakes (low level), [redacted] mg/kg (medium level) and [redacted] mg/kg (high level). Nine barrels (three per addition level) containing [redacted] kg flakes were prepared and stored for [redacted] days at [redacted] °C with periodical agitation. These flakes were extruded, resulting in a homogenous contamination of the pellets and cut to longer pellets than in the process.

The process was challenged in continuous mode in the installation used for production, applying temperatures, pressures, residence times and nitrogen flow rate as for the process. Due to the large size of the installation, the contaminated pellets were introduced into the stream of non-contaminated pellets. After SSP, the contaminated pellets were isolated by sieving from the smaller non-contaminated pellets. The concentrations of the surrogates were determined in the washed and dried flakes before entering the extruder and in the isolated contaminated pellets after the SSP decontamination step.

3.4 | Discussion

Considering the high temperatures used during the process, the possibility of contamination by microorganisms can be discounted. Therefore this evaluation focuses on the chemical safety of the recycled PET.

Technical data, such as on physical properties and residual contents of PVC, glues, plastics other than PET, wood, paper and metals, were provided for the input materials (i.e. washed and dried flakes, step 1). These flakes are mainly produced from PET containers, e.g. bottles, previously used for food packaging, collected through post-consumer collection systems. However, a small fraction may originate from non-food applications, such as bottles for soap, mouth wash or kitchen hygiene agents. According to the applicant, the collection system and the process are managed in such a way that this fraction will be no more than 5% in the input stream, as recommended by the EFSA CEF Panel in its '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 CEF Panel, 2011).

As the CEP Panel identified gaps, inconsistencies and discrepancies in the information provided by the applicant even after requests for clarification, the evaluation of the INCOM RESOURCES RECOVERY (TIANJIN) process was performed on the basis of the information provided. Based on this information, the Panel could not conclude on the safety of the process due to the following points:

[11]Technical dossier, section 'Determination of the decontamination efficiency of the recycling process'.

1. The technical document does not provide a sufficient description of the challenge test. From an answer to questions, the Panel understood that longer contaminated pellets were mixed with a far higher amount of non-contaminated pellets and sorted out after SSP by sieving. The ratio of contaminated to non-contaminated pellets is unclear, and it is not described how the contaminated pellets were introduced.
2. The residual contamination was tested in the contaminated pellets only. Cross-contamination between contaminated and non-contaminated pellets was not considered for the evaluation of the decontamination efficiency. Even a low concentration of surrogates in the large amount of initially non-contaminated pellets would have a strong effect on the residual amount of surrogates in the output and result in an overestimation of the decontamination efficiency.
3. The results and the presentation of the analytical results indicated an incomplete, unclear and contradictory analytical work. The data provided on the decontamination efficiency are inconsistent, as some concentrations after extrusion were up to many times higher than before extrusion.
4. No data on the gas velocity (e.g. in m/s) in the SSP reactor were provided.

The Panel noted that the information provided in the dossier and the clarifications provided by the applicant do not satisfy the requirements of the EFSA guidelines (EFSA, 2008) and 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 intended to come in contact with food (EFSA CEF Panel, 2011).

4 | CONCLUSIONS

The Panel concluded that the information submitted to EFSA is inadequate to demonstrate that the process INCOM RESOURCES RECOVERY(TIANJIN) is able to reduce potential unknown contamination of the input PET flakes to a concentration that does not pose a risk to human health.

5 | DOCUMENTATION PROVIDED TO EFSA

Dossier. July 2022. Submitted on behalf of INCOM RESOURCES RECOVERY (TIANJIN) CO.,LTD, China.

Additional information, May 2023. Submitted on behalf of INCOM RESOURCES RECOVERY (TIANJIN) CO.,LTD, China.

ABBREVIATIONS

bw	body weight
CEF Panel	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel	Panel on Food Contact Materials, Enzymes and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentrations in PET
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)
rPET	recycled poly(ethylene terephthalate)
SSP	solid-state polycondensation

CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

Competent Authority of France (Ministère de l'économie des finances et de la relance, Bureau 4B, Qualité des denrées alimentaires), France

QUESTION NUMBER

EFSA-Q-2022-00028

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APPENDIX A

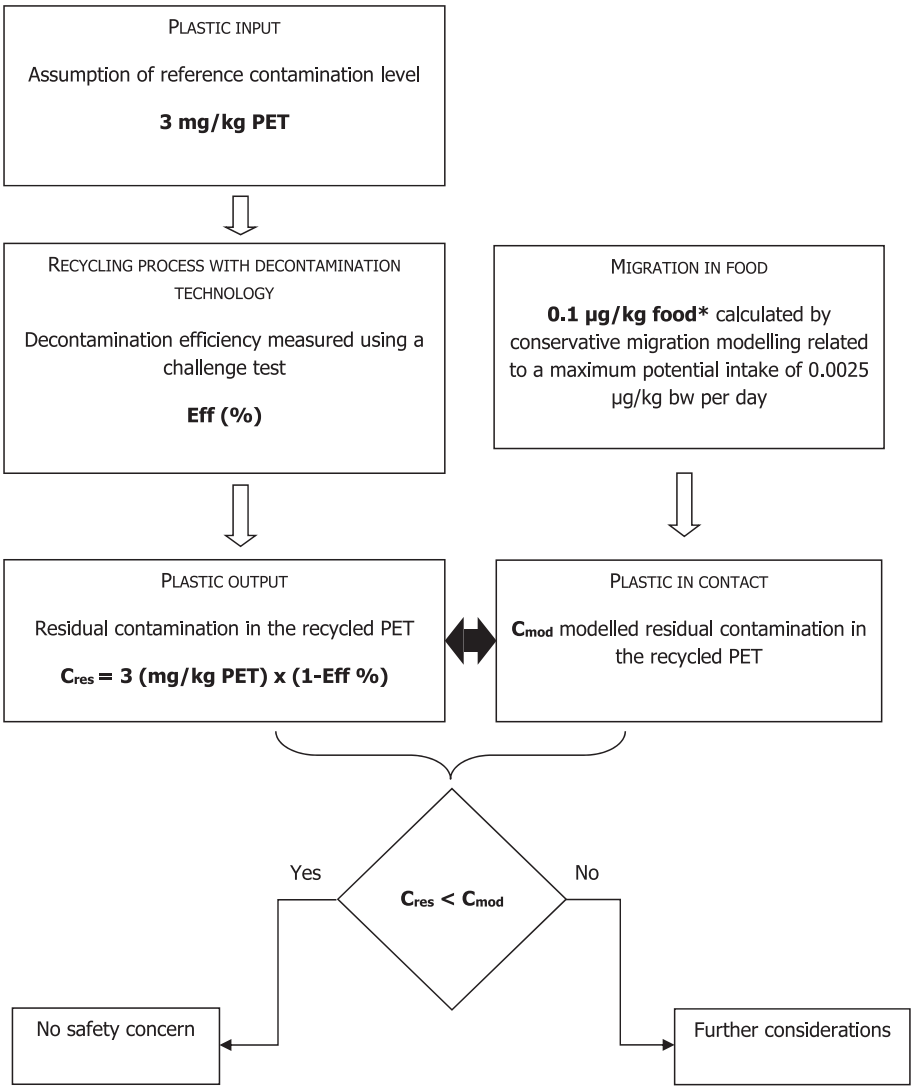
Technical data of the washed flakes as provided by the applicant[9]

Parameter	Value
Moisture max.	0.7%
Bulk density	250–500 kg/m^3
pH value max.	7.5
Metals max.	10
Adhesive max.	5
PVC max.	50 mg/kg
Adhesive max.	5 mg/kg
Caps, labels and handle material max.	100 mg/kg
Rubber max.	5 mg/kg
Heterochromatic sheet max.	300 mg/kg
Inorganic impurity max.	10 mg/kg

Abbreviation: PVC, poly(vinyl chloride).

APPENDIX B

Relationship between the key parameters for the evaluation scheme (EFSA CEF Panel, 2011)



*Default scenario (infant). For adults and toddlers, the migration criterion will be 0.75 and 0.15 µg/kg food, respectively. The figures are derived from the application of the human exposure threshold value of 0.0025 µg/kg body weight (bw) per day applying a factor of 5 related to the overestimation of modelling.