



Údarás Sábháilteachta Bia na hÉireann  
Food Safety Authority of Ireland

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# Application for the Authorisation of Mechanical PET Recycling Processes



# **Application for Authorisation of Mechanical PET Recycling Processes**

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## Scope

This document applies to applications for authorisation of individual mechanical polyethylene terephthalate (PET) recycling processes (technologies) under Commission Regulation (EU) 2022/1616 for the mechanical recycling of PET plastic for use in food contact materials (FCMs).

## Introduction and legal background

Mechanically recycled PET plastic may only be used in FCMs if that PET plastic complies with the following legislation:

- [Regulation \(EC\) 1935/2004 on materials and articles intended to come into contact with food](#)
- [Regulation \(EC\) 2023/2006](#) on good manufacturing practice for materials and articles intended to come into contact with food
- [Regulation \(EU\) 10/2011](#) on plastic materials and articles intended to come into contact with food
- [Regulation \(EU\) 2022/1616](#) on recycled plastic materials and articles intended to come into contact with foods.

At a general level, all FCMs must comply with [Regulation \(EC\) No 1935/2004](#), and be manufactured in accordance with Regulation (EC) No 2023/2006 to ensure a high level of food safety. Additionally, all FCMs must comply, with any specific Union legislation on certain materials. The Plastics Regulation (EU) 10/2011 ensures that substances present in newly manufactured plastic cannot be transferred to food in amounts that can harm human health. Currently only PET plastics which comply with the legislation outlined above can be recycled.

When PET plastic FCMs are recycled, the input plastic can contain microbiological and chemical contaminants. Generally, the microbiological contamination is not a problem for recycling as the high temperatures used in the recycling process will destroy any microbiological contaminants which are present. However, that is not always the case for chemical contaminants which can be present from several sources including the original manufacture of the plastic, the use or misuse of that plastic after manufacture and possible cross contamination during waste collection. It is also not possible to know the nature (type) and quantity of chemical contaminants present in PET plastic FCM to be used for recycling purposes.

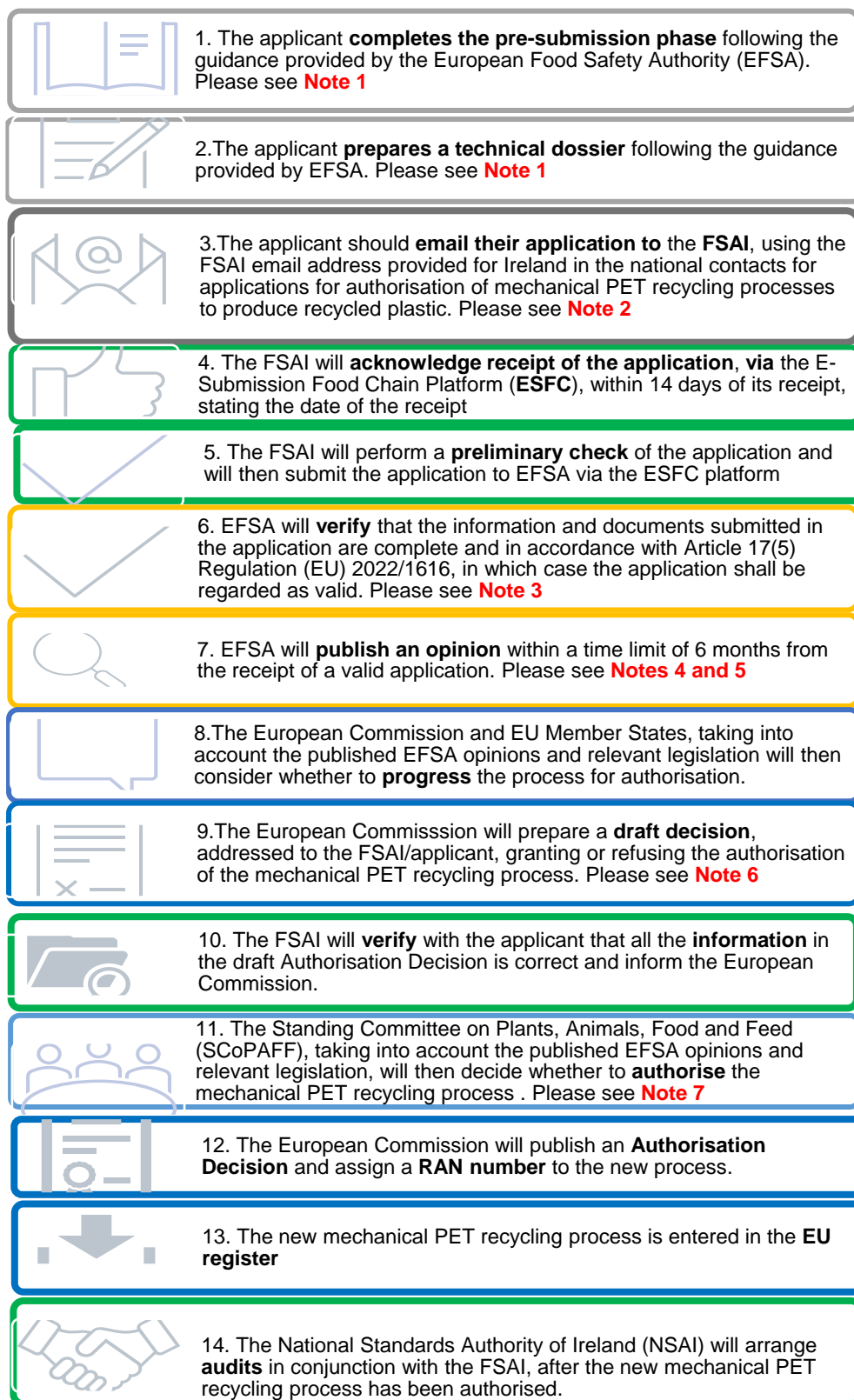
Therefore, during the recycling of PET plastic for FCM use, it must be decontaminated by a recycling process capable of reducing the level of contaminant to a safe level. As such the European Food Safety Authority (EFSA) carries out a risk assessment of each individual mechanical PET recycling process (technology) to ensure that the recycling process decontaminates the input plastic, to a level which does not present a risk to consumers. EFSA refers to this capability as the decontamination efficiency of the recycling process. EFSA also, as part of this process, characterises the maximum level at which specific contaminants can be present in the input PET plastic to be recycled. Finally, EFSA will publish a scientific opinion of its safety assessment of the recycling process. **The EFSA opinion will state whether the mechanical PET recycling process can safely produce plastic materials and articles which are safe for use in FCMs.**

[Regulation \(EU\) 2022/1616](#) on recycled plastic materials and articles sets out a legal framework to implement the above approach and as part of that approach all mechanical PET recycling processes are subject to an individual authorisation decision.

This document outlines that process of authorisation.

# Application for Authorisation of Mechanical PET Recycling Processes

## Process Flow: Application for the authorisation of mechanical PET recycling processes



Actioned by



# Application for the authorisation of mechanical PET recycling process

1. Pre-submission phase: A business (i.e. applicant) who wants to apply for the authorisation of a mechanical PET recycling process should first ensure that they complete the pre-submission phase outlined in page 11-13 of [\*EFSA Administrative guidance for the preparation of applications for the authorisation of individual recycling processes to produce recycled plastics materials and articles intended to come into contact with food\*](#).

2. A business who wants to apply for the authorisation of a mechanical PET recycling process should prepare a technical dossier following the [\*EFSA Administrative guidance for the preparation of applications for the authorisation of individual recycling processes to produce recycled plastics materials and articles intended to come into contact with food\*](#).

**Note 1:** Further information can be obtained from EFSA's [applications helpdesk](#). Applicants should also refer to the requirements of Article 17 of [Regulation \(EU\) 2022/1616](#).

3. The applicant should next email their application to the FSAI, using the FSAI email address provided for Ireland in the [national contacts for applications](#) for authorisation of mechanical PET recycling processes to produce recycled plastic.

**Note 2:** The application to the FSAI must include:

- The name and address of the applicant
- A technical dossier containing the information specified in Article 17(5) of Regulation (EU) 2022/1616 and
- A summary of the technical dossier.

4. The FSAI will acknowledge receipt of the application, via the E-Submission Food Chain Platform (ESFC), within 14 days of its receipt, stating the date of the receipt.

5. The FSAI will perform a preliminary check of the application and will then submit the application to EFSA via ESFC platform.

6. EFSA will verify that the information and documents submitted are in accordance with Article 17(5) Regulation (EU) 2022/1616, in which case the application shall be regarded as valid.

**Note 3:** EFSA will inform the applicant, the European Commission and the FSAI if the application is not valid.

7. EFSA will publish an opinion within a time limit of 6 months from the receipt of a valid application.

**Note 4:** The EFSA opinion will state whether or not the mechanical PET recycling process can safely produce plastic materials and articles which meets the requirements of Article 3 of Regulation (EC) No 1935/2004 and are microbiologically safe. EFSA may extend the time limit of 6 months by a maximum period of a further 6 months. In such a case, EFSA shall provide an explanation for the extension to the applicant, the European Commission and the FSAI.

**Note 5:** EFSA may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specified time, whether in writing or by oral explanation. Where EFSA requests supplementary information, the initial time limit of 6 months is suspended until that information has been provided.

8. The European Commission and EU Member States, taking into account the published EFSA opinions and relevant legislation will then consider whether to progress the process for authorisation.

9. The European Commission will prepare a draft authorisation decision, addressed to the FSAI/ applicant, granting or refusing the authorisation of the mechanical PET recycling process and share it with the FSAI.

**Note 6:** Where the draft decision is not in accordance with the opinion of EFSA, the European Commission shall explain the reasons for its decision.

10. The FSAI will verify with the applicant that all the information in the draft Authorisation Decision is correct and inform the European Commission.

11. The Standing Committee on Plants, Animals, Food and Feed, SCoPAFF, taking into account the published EFSA opinions and relevant legislation, will then decide whether to authorise the mechanical PET recycling process.

**Note 7:** The applicant or any business operator using the newly authorised mechanical PET recycling process must immediately inform the European Commission of any new scientific or



technical information, which might affect the safety assessment of the authorised recycling process in relation to human health (an e-mail suffices).

12. The European Commission will publish an Authorisation Decision and assign a Recycling Authorisation Number (RAN) to the new process.

13. The new mechanical PET recycling process is entered by the European Commission into the Food Contact Materials Union Register of recycling installations, facilities, companies, schemes, authorisations and novel recycling technologies.

14. The NSAI will arrange audits in conjunction with the FSAI after the new mechanical PET recycling process has been authorised.

## Further information

[European Commission Plastic Recycling](#)

[FCM Authorisations](#)

[EFSA: FCM Applications/Regulations and Guidance](#)

[EFSA: Application Procedure for FCM](#)

[EFSA: Webinar on Application Procedure for FCM](#)

## Glossary

Term	Text
<b>EFSA</b>	European Food Safety Authority
<b>ESFC</b>	E-Submission Food Chain Platform
<b>FCM</b>	Food contact materials
<b>FSAI</b>	Food Safety Authority of Ireland
<b>NSAI</b>	National Standards Authority of Ireland
<b>PET</b>	Polyethylene terephthalate plastic
<b>RAN</b>	Authorised recycling processes are assigned a recycling authorisation number
<b>SCoPAFF</b>	The Standing Committee on Plants, Animals, Food and Feed



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