



EUROPEAN  
COMMISSION

Brussels, XXX  
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## COMMISSION IMPLEMENTING DECISION

of XXX

**authorising the mechanical PET recycling process ‘Formas y Envases’ in accordance with Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with foods**

(Only the English text is authentic)

# COMMISSION IMPLEMENTING DECISION

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**authorising the mechanical PET recycling process ‘Formas y Envases’ in accordance with Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with foods**

(Only the English text is authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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<sup>1</sup>, and in particular Article 19(1) thereof,

Whereas:

- (1) Regulation (EU) 2022/1616 provides that recycled plastic materials and articles can only be placed on the market if the recycled plastic therein is obtained using a manufacturing process that applies a suitable recycling technology. Post-consumer mechanical PET recycling is such a suitable technology. Recycling processes applying this technology as set out as technology no. 1 in the list of suitable technologies contained in Table 1 of Annex I to that Regulation, require an authorisation by the Commission based on an application to be submitted to the European Food Safety Authority (‘the Authority’). In accordance with Article 31(1) of Regulation (EU) 2022/1616, an application for authorisation submitted under Commission Regulation (EC) No 282/2008<sup>2</sup> is to be considered equivalent to an application received in accordance with Article 17(1) of Regulation (EU) 2022/1616.
- (2) The Authority received an application for the post-consumer mechanical PET recycling process ‘Formas y Envases’ (‘the recycling process’) in accordance with Article 5 of Regulation (EC) No 282/2008, which received the number EFSA-Q-2014-00443 (‘the application’). In its opinion on the use of the recycling process to recycle post-consumer PET into food contact materials (‘the opinion’)<sup>3</sup>, the Authority concluded that the applicant had demonstrated in a challenge test that the recycling process can reduce contamination of the plastic input to a concentration that does not give rise to a concern for a risk to human health provided that the process it is operated

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<sup>1</sup> Commission Regulation (EU) No 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, [3 pp.]) <http://data.europa.eu/eli/reg/2022/1616/oj>

<sup>2</sup> 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, [9 pp.]) <http://data.europa.eu/eli/reg/2008/282/oj>.

<sup>3</sup> EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2015. Scientific Opinion on the safety evaluation of the following processes based on Starlinger Decon technology used to recycle post-consumer PET into food contact materials: “Baltija Eco PET”, “Eurocast”, “Fernholz”, “Formas y Envases” and “Klößner Pentaplast”. EFSA Journal 2015;13(1):3963, [17 pp.] doi:10.2903/j.efsa.2015.3963

under conditions at least as severe as in the challenge test referred to in the conclusion and in Annex C of the opinion, when the quality of the input, the recycling process itself, and the use of the recycled plastic meet the restrictions described in the conclusion of the opinion. In addition, the Authority considered that the recycling process prevents contamination of the recycled plastic by microorganisms.

- (3) In light of the conclusion of the Authority, it should be considered that the recycling process can manufacture recycled PET that meets the general requirements provided for in Article 3 of Regulation (EC) No 1935/2004 of the European Parliament and of the Council<sup>4</sup>, and that is microbiologically safe, provided that the conditions and restrictions described in the opinion are met.
- (4) Certain restrictions are relevant to all post-consumer mechanical PET recycling processes that the Authority has already evaluated and have been laid down in Regulation (EU) 2022/1616, in particular in its Articles 6, 7 and 8, as well as in columns 3 to 6 of row 1 of Table 1 of Annex I thereto. Taking into account the assurances resulting from those restrictions, which entered into force after the submission of the application, it is appropriate to allow the pre-processing operations and the post-processing to depart from the description made in the application. However, other restrictions described in the opinion have not been laid down in Regulation (EU) 2022/1616, such as the restriction that the operating conditions applied in the installations using the recycling process must be replicated to a degree at least as severe as the conditions achieved in the challenge test that the Authority considered for its evaluation, as well as some further restrictions concerning the use of the manufactured recycled plastic which are based on the extent of the decontamination that the Authority considered necessary for that use. As it has only been shown that the recycling process is capable of manufacturing recycled plastic that does not pose a risk to human health where those restrictions are met, it is appropriate to provide for such restrictions. In addition, in order to ensure that converters and users are informed of the restrictions on the use of the recycled plastic manufactured with the recycling process, it is necessary to require that those restrictions are communicated to them.
- (5) Therefore, it is appropriate to grant the authorisation of the recycling process subject to certain restrictions and specifications.
- (6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

*Article 1*  
*Recycling process*

The recycling process is assigned the recycling authorisation number ('RAN') ES1-2T5-1A8.

The name of the recycling process shall be 'Formas y Envases'.

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<sup>4</sup> 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, [4 pp.]) <http://data.europa.eu/eli/reg/2004/1935/oj>

*Article 2*  
*Authorisation of the recycling process*

1. The recycling process ‘Formas y Envases’ is authorised for the manufacturing of recycled plastic using the ‘post-consumer mechanical PET recycling’ technology listed in point 1 of Table 1 of Annex I to Regulation (EU) 2022/1616 in accordance with the conditions set out in this Decision.
2. The authorisation holder of the recycling process ‘Formas y Envases shall be ‘Formas y Envases, S.A., Pol. Ind. Besaya, Calle E - Parcela 83, 39538 Reocín, Cantabria, Spain’.
3. The authorisation holder shall provide a copy of this Decision to all recyclers applying this process under its license.

*Article 3*  
*Requirements for the use of the authorised recycling process*

1. The pre-processing operations shall ensure that the plastic input is collected and sorted in accordance with Article 6 of Regulation (EU) 2022/1616 and complies with the specification set out in column 5 of row 1 of Table 1 of Annex I thereto.
2. The decontamination operations shall be configured and operated in such a way that they correspond to the process described in the subsection ‘Decontamination and production of recycled PET material’ of Chapter 3 of the opinion<sup>3</sup>, and the equipment used to construct an installation based on the process shall correspond to the detailed description provided in the application.
3. The post-processing may be configured or applied differently from the description in the application provided that the obligations set out Article 8 of Regulation (EU) 2022/1616 are complied with.

*Article 4*  
*Operating conditions applicable to the authorised recycling process*

The decontamination operations shall be controlled to ensure that each critical step described in the opinion operates under conditions at least as severe as the conditions defined for the challenge test as described in Annex C to the opinion.

*Article 5*  
*Authorised use of recycled plastic manufactured with the authorised recycling process*

Recycled plastic manufactured with the recycling process shall meet the specification set out in column 6 of row 1 of Annex I to Regulation (EU) 2022/1616. It may be used at up to 100% to manufacture recycled plastic materials and articles.

Plastic materials and articles containing recycled plastic manufactured with the recycling process may be used for contact with all types of foodstuffs for long term storage at room temperature, with or without hot-fill.

*Article 6*  
*Declaration of compliance and labelling*

The declaration of compliance shall be drawn up in accordance with Annex III to Regulation (EU) 2022/1616 and shall include at least the following instructions for converters and users of recycled plastic materials and articles:

- (a) the relevant instructions necessary for complying with Article 5;
- (b) the instruction that a label with the statement ‘*not for oven or microwave use*’ shall be attached to plastic articles containing recycled plastic manufactured with the process if a user may foreseeably place those in an oven or microwave due to the nature of the packed food.

*Article 7*  
*Addressee*

This Decision is addressed to Formas y Envases, S.A., Pol. Ind. Besaya, Calle E - Parcela 83, 39538 Reocín, Cantabria, Spain.

Done at Brussels,

*For the Commission*  
*Stella KYRIAKIDES*  
*Member of the Commission*