**File No: STD/SC/A-40**

**Food Safety and Standards Authority of India**

(A Statutory authority under the Ministry of Health and Family Welfare)

Science & Standards Division

FDA Bhawan, Kotla Road, New Delhi-110002

Dated, the 18th January, 2022

**Subject: Direction under Section 16 (5) of Food Safety and Standards Act, 2006 regarding operationalization of Draft Food Safety and Standards (Packaging) Amendment Regulations, 2022 regarding use of recycled plastics.**

In exercise of the power conferred under section 92 of the Food Safety and Standards Act-2006, FSSAI had framed the Draft Food Safety and Standards (Packaging) Amendment Regulations, 2022 permitting the use of recycled plastics as food contact materials based on the Plastic Waste Management (Amendment) Rules, 2021 notified on 17.09.2021 and the recommendations of Scientific panel/ committee.

2. The above mentioned draft amendment regulations are in the process of approval by Food Authority, draft publication and its final notification are likely to take more time. Meanwhile, to allow the FBOs to make use of recycled plastics as food contact materials, it has been decided to operationalize the provision of Food Safety and Standards (Packaging) Amendment Regulations, 2022, with immediate effect, as below -

   *"In regulation 4 of Food Safety and Standards (Packaging) Regulations, 2018, sub-regulation (4)(e) shall be substituted, as –*

   *(e) Products made of recycled plastics including carry bags may be used for packaging, storing, carrying or dispensing of food products as and when standards and guidelines are framed by the Food Authority. Such packaging materials shall also comply with any other national standards/regulations as applicable."*

3. Accordingly, the approved guidelines for recycling of post-conusmer PET for food contact applications & acceptance criteria for recycled PET resin for food contact applications (**Annexure-1**) is also made effective for implementation.

4. This issues with approval of the competent authority, in exercise of the power vested under the Section 18(2)(d) read with 16(5) of the Food Safety and Standards Act, 2006.

18/1/22

(Bhaskar N)
Advisor (Science & Standards Division)
FSSAI, New Delhi.

To

1. Food Safety Commissioners (FSCs) of all States/UTs.
2. All Central Licensing Authorities, FSSAI
3. CITO, FSSAI with a request to upload this direction on FSSAI website.

Copy for information to:

1. PPS to Chairperson, FSSAI
2. PS to CEO, FSSAI
3. ED (CS) - with a request to communicate this order to FSCs of all States/UTs

# Guidelines for recycling of post-consumer PET for food contact applications
# &
# Acceptance criteria for recycled PET resin for food contact applications

## 1. SCOPE

This guideline

- pertains to the recycling process/operation of transforming post-consumer PET bottles used for food packaging into food-grade recycled PET resins suitable for making bottles & packaging materials for bottling or packaging and its testing.
- covers the acceptance criteria for using food grade recycled PET resin material in bottling or packaging operations.
- does not apply to industrial rejected PET bottles.
- does not apply to production of resins for non-food grade consumer applications.

## 2. DEFINITIONS

### 2.1 Materials

**PET** –poly (ethylene terephthalate), a plastic resin formed by poly-condensation reaction of ethylene glycol with either terephthalic acid or dimethyl terephthalate.

**Virgin PET (vPET)** – Formed by poly-condensation reaction of ethylene glycol derived from ethylene and terephthalic acid derived from para-xylene as the starting monomers

**Post-Consumer PET** -Material generated by households or by commercial, industrial and institutional facilities in their role as end-users of the product. This includes returns of material from the distribution chain.

**PET Flakes** - an aggregate of fragments from grinding and washing of post-consumer PET/pre consumer industrial PET intended to be used for food applications

**Recycled PET (rPET)** – Made from recycled PET that has already been used for food packaging, such as the PET bottles. This PET is sorted, cleaned, decontaminated and transformed so that it can be reused. This rPET may include reworked content derived from pre-consumer sources (as per us, this is post-industrial recycling and should not be considered under Post Consumer PET).

**Food-Grade Recycled PET (FG rPET)** – resin that has undergone a validated decontamination process (as per US/EU or equivalent standard) to achieve suitable purity for directly holding food or beverages.

### 2.2 Recycling Processes

**Conventional Recycling Process** – a mechanical recycling operation where PET Flakes are washed, melted, extruded, and pelletized without a process step to remove contaminants. A conventional recycling process should not be used for manufacturing food contact materials as it does not have the decontamination process step.

Example processes capable of producing FG rPET:

- **Super-Clean Recycling Process** – a Conventional Recycling Process enhanced with an integrated decontamination step [as per EU/US approved recycling process] to remove absorbed contaminants through a combination of surface treatment, high heat, and/or high

vacuum in a controlled environment such that the output can be used for direct food contact

- **Melt-in Recycling Process**- a virgin PET (v PET) production operation enhanced with the ability of incorporating PET Flakes in the molten form which is decontaminated through a combination of high heat and high vacuum.
- **Paste-in Recycling Process** – a virgin PET (v PET) production operation enhanced with the ability of incorporating PET Flakes in the paste form via partial glycolysis and equipped with an integrated system of removing absorbed contaminants via chemical distillation, vacuum degassing, etc.
- **Enhanced Chemical Recycling Process** – a chemical reaction operation of pyrolysis or fully depolymerizing PET Flakes into purified ethylene glycol and terephthalic acid (or dimethyl terephthalate), or bis(2-hydroxyethylterephthalate)

### 2.3 Testing

**Challenge Test** – a validation test in which virgin PET exposed to a mixture of surrogate chemicals of different molecular weight and polarity at exaggerated levels, processed through the entire recycling process, and analyzed quantitatively for the residual concentrations. Challenge test needs to be repeated in case of changes in process, process parameters or input feed

**Extraction Test** – a quantitative analysis on the substances present in the PET (virgin, rPET, or FG rPET) in any form (flakes or pellets).

**Migration Test** - a quantitative analysis on the substances migrating from the PET containers into the beverage (or food simulants). Refer to Food Safety and Standards (Packaging) Regulations 2018, for details on overall and specific migration limits.

### 2.4 Supply Chain Documentation & Supply Chain Operators

**Declaration of Compliance** – a statement issued by the business operator declaring how the product offered for sale is compliant with an established and/or applicable food contact regulatory standard.

**Regulatory Opinion** - an opinion letter issued by a recognized, competent authority (EU/USFDA) addressing the capability of a given process or operation to recycle PET Flakes into Food-Grade rPET based on an accepted regulatory threshold protective of public health.

## 3. REQUIREMENTS

The following requirements pertain to the operation of a Super-Clean Mechanical Recycling Process:

### 3.1 Process Input

The process input shall be sourced in accordance with an established set of specifications. Such specifications shall include the minimum quality standard on food-grade PET Flakes. Input materials shall be controlled based on process validation criteria as identified by performance of the challenge test.

### 3.2 Process Validation

The recycling process shall have at least one decontamination step capable of removing contaminants to a level of purity suitable for food contact. The decontamination capability shall be validated with a challenge test. Experimental data of the challenge test shall be reviewed by a recognized competent authority. Only recycling processes that have been affirmed to be effective shall be regarded as Super-Clean. The level of decontamination shall be below the 220 µg/kg limit in the resin for each surrogate contaminant by an extraction test (in a USFDA challenge test – Refer Appendix), or below the 10 µg/kg limit in the beverage or food simulant for each surrogate contaminant by a migration test (in an EU challenge test – Refer Appendix). This needs to be validated with local raw material (PET feedstock).

### 3.3 Process Output

The process output shall be subject to a monitoring program that ensures the continuity of FG rPET quality over time. The program shall include a chemical analysis by the process operator. The chemical analysis shall include either an extraction test on the FG rPET output or a migration test on the beverage bottles or food containers made with the FG rPET. The FG rPET shall conform with the food safety regulatory requirements for virgin PET. The sensory analysis shall be conducted in accordance with ISO 13302 or equivalent.

### 3.4 Process Operation

The recycling process shall operate under the principles of Good Manufacturing Practices, including the application of a quality assurance program. Critical quality parameters must be defined and used for the release of each batch to demonstrate the effectiveness of the decontamination process. Supply chain records and quality assurance data shall be maintained to support product traceability and safety compliance.

***The following requirements are of the resin output from recycling process:***

### 3.5 Conventional Recycling Process

PET flakes processed through the Conventional Recycling Process shall NOT be accepted as FG rPET.

### 3.6 Super clean recycling process and Melt in recycling process –

For all the Food grade rPET made from the processes (i.e. Super clean recycling process and Melt in recycling process) below are the requirements –

The level of decontamination shall be below the 220 µg/kg limit in the resin for each surrogate contaminant by an extraction test (per USFDA), or below the 10 µg/kg limit in the beverage or food simulant for each surrogate contaminant by a migration test (as per EU).

### 3.7 Paste-in Recycling Process

PET flakes processed through a Paste-in Recycling Process shall be accepted as FG rPET. The requirements for Paste-in recycled Food Grade rPETshall be as per requirements of virgin PET as defined under Food Safety & Standards (Packaging) Regulations, 2018.

### 3.8 Enhanced Chemical Recycling Process

PET flakes processed through an Enhanced Recycling Process shall be considered as virgin PET. The requirements for enhanced recycled Food Grade rPET shall be as per requirements of virgin PET as defined under Food Safety & Standards (Packaging) Regulations, 2018.

## 4. DOCUMENTATION

Each Recycling operations FBO shall provide their downstream customer with relevant documentation upon request and maintain documents as follows:

### 4.1 Supply Chain Communication

Operator of a Super-Clean Recycling Process shall provide converters, beverage bottlers, and/or food packers

a) a Declaration of Compliance on the FG rPET product, and

b) a Regulatory Opinion on the process of making the FG rPET product.

### 4.2 Supporting Documents

Operator of a Super-Clean Recycling Process shall provide supply chain records on product traceability (plus one and minus one level done by each operator in food chain) and quality assurance data on safety compliance to the inspecting authority.

## 5. REGISTRATION & AUTHORIZATION

The operator of a recycling process/manufacturers of FG rPET shall apply and register with the Food Authority by submitting necessary information as per the 'Performa' (*Annexure*).

The Food Authority shall on the basis of the documents submitted; decide upon the recognition of the applicant. The food Authority shall notify the registered and authorized operator of a recycling process/manufacturers of FG rPET from time to time as per the format annexed. This Authority shall reserve the right to call for any information from the recognized operator of a recycling process/manufacturers of FG rPET.

## 6. REEFERENCES USED

USFDA, Canada, Japan, EU FCM/ RECYLING, MEROCSUR, MEXICO, KSA, Bureau of Indian Standards (BIS), ISO (14021:2016 & 13302:2003)

## 7. APPENDIX

**Challenge test requirements for US-FDA:**

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-use-recycled-plastics-food-packaging-chemistry-considerations

Guidance for Industry: Use of Recycled Plastics in Food Packaging (Chemistry Considerations) - July 2021 (fda.gov)

**Challenge test requirements for EU:**

https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R0282

https://www.efsa.europa.eu/en/efsajournal/pub/717

*Annexure*

**Performa for recycled PET (rPET) manufacturer**

**[to be submitted as a one-way notifying approach]**

| | | |
|---|---|---|
| 1. | Particulars of rPET manufacturer | Details of name and address |
| 2. | Recycler's licenses copy | Details of all licenses - factory, labour, pollution, GST etc. |
| 3. | Name of technology used | Details of plant/machinery, make, material of construction and capacity, complete process flow chart and testing equipment's |
| 4. | Approval of EU or US FDA | Attach the same letter , NOC, approval |
| 5. | Validation done in India | Yes /No |
| 6. | Validation done with Indian post-consumer PET containers | Yes /No |
| 7. | Validation report<br>(Report shall be from a NABL accredited lab) | Attach report |
| 8. | Finished rPET compliance to Indian standards, FSS(Packaging) regulations 2018 including the guidelines | Yes/No |
| 9. | Attach report of rPET as per point 7 above | Attach report |
| 10. | Self-declaration by the authorized personnel | To declare that only post-consumer food packaging materials are used to manufacture recycled PET resin and to maintain records/details* of the source and nature of feedstock (batch/lot) along with the intended application /FBO<br>[*Shall be maintained by the rPET manufacturer] |

Note: In case of any queries, the Food Authority will reach out to the recycler within 30 days else would treat it as a deemed approval subject to notification. Further, the Food Authority reserves the right to call for any information/further queries from the recycler at any point in time.