

## WEBINAR: GUIDANCE ON MECHANICAL PET RECYCLING

## **20 FEBRUARY 2024**



## **INTRODUCTION AND OUTLINE OF WEBINAR**

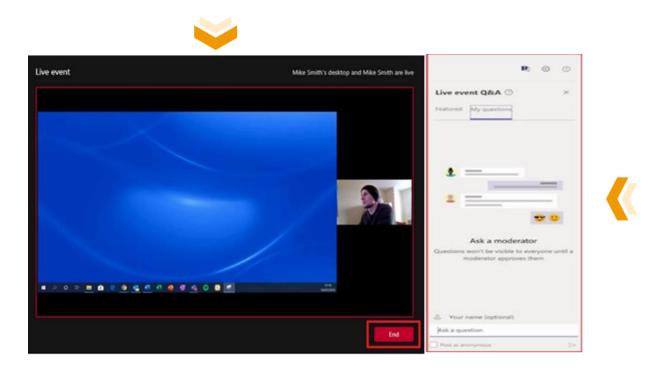
#### Objectives

- To present the draft guidance document on post-consumer mechanical PET recycling processes, focusing mainly on
  - the criteria for the evaluation of such recycling processes, and
  - the requirements for the content of the technical dossier to be submitted by an applicant in the context of an application for authorization
- To provide context for the public consultation on this draft scientific guidance document
  - endorsed by the EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP Panel) on 31 January 2024
  - made available for public consultation from 7 February until 20 March 2024.



### HOUSE KEEPING RULES

- You are automatically connected to the audio broadcast. One-way audio (listen only mode).
- The event is in English. Questions should be submitted in English via tha Q&A chat;
- This event is **being recorded** and recordings will be published on EFSA's website; log of questions and answers will not be published;
- After the event, attendees will receive a link to a survey to evaluate the EFSA's event & services
   Presentation window



<u>Q&A box</u>: For any questions related to the topic or unexpected IT issues



## **OUT OF SCOPE - WEBINAR AND Q&A**

- Interpretation of Regulation (EU) 2022/1616. For instance:
  - Authorisation process;
  - Declaration of compliance for single batch;
  - Role of Member State Competent Authorities (e.g. audit, controls);
  - Role of converters/recyclers
  - Levels of contaminants in input materials
- Limit to the content of recycled PET (rPET)
- Novel technologies and other polymers than PET
- Functional barriers
- Questions related to specific case for submission of applications (Ask a Question or General pre-submission advice, GPSA)
- Any other risk management topic/questions not in the EFSA's remit (European Commission)
- Comments that should be submitted during the public consultation. *Examples*:
  - Proposals/comments on how to rinse the contaminated flakes to remove surface contamination
  - Infant/drinking water scenario applied to tray-to-tray recycling





<b>Time</b>		Speaker	
10:00-10:05	Opening of the event: introduction and outline of webinar	Sandra Rainieri	
10:05-10:15	Introduction to the mandate and scope of the draft guidance	Katharina Volk	
10:15-10:35	Evaluation criteria	Evgenia Lampi	
10:35-10:45	Q&A session 1	Evgenia Lampi Alexis Lioupis Katharina Volk	
10:45-11:05	Content of the technical dossier	Alexis Lioupis	
11:05-11:10	Public consultation	Katharina Volk	
11:10-11:25	Q&A session 2	Evgenia Lampi Alexis Lioupis Katharina Volk	
11:25-11:30	Closing of the event: wrap-up and farewell	Sandra Rainieri	

- Who are we
  - <u>Presenters</u>

Katharina Volk, Evgenia Lampi, Alexandros Lioupis

- <u>Moderator</u>
   Sandra Rainieri
- <u>Contributors</u>

Costanza Casiraghi, Gianluca Colombo, Remigio Marano, Emmanouil Tsochatzis



# INTRODUCTION TO THE MANDATE AND SCOPE OF THE DRAFT GUIDANCE



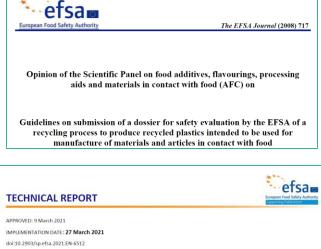
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#### BACKGROUND

- Core documents related to EFSA's work on the safety evaluation of recycling processes:
  - Scientific guidance:
    - Criteria for safety evaluation of PET recycling processes (2011): https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2011.2184
    - Guidelines on recycling plastics (2008; administrative update in 2021 for alignment with the Transparency Regulation ): <u>https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2008.717</u>

 Administrative guidance (2021): <u>https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.ef</u> <u>sa.2021.EN-6512</u>





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



#### BACKGROUND

- October 2022: entry into force of <u>Regulation (EU) 2022/1616</u> on recycled plastics for food contact, and repealing Regulation (EC) No 282/2008
- 20.9.2022
   EN
   Official Journal of the European Union
   L 243/3

   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

- New concepts and terminologies
- New procedures (suitable vs novel technologies)
- New requirements for the technical dossier to be submitted by an applicant

**Need for updating EFSA's guidance documents** for the area of recycling plastics



#### **SCOPE OF THE GUIDANCE: DEFINITIONS**

#### **Recycling technology**

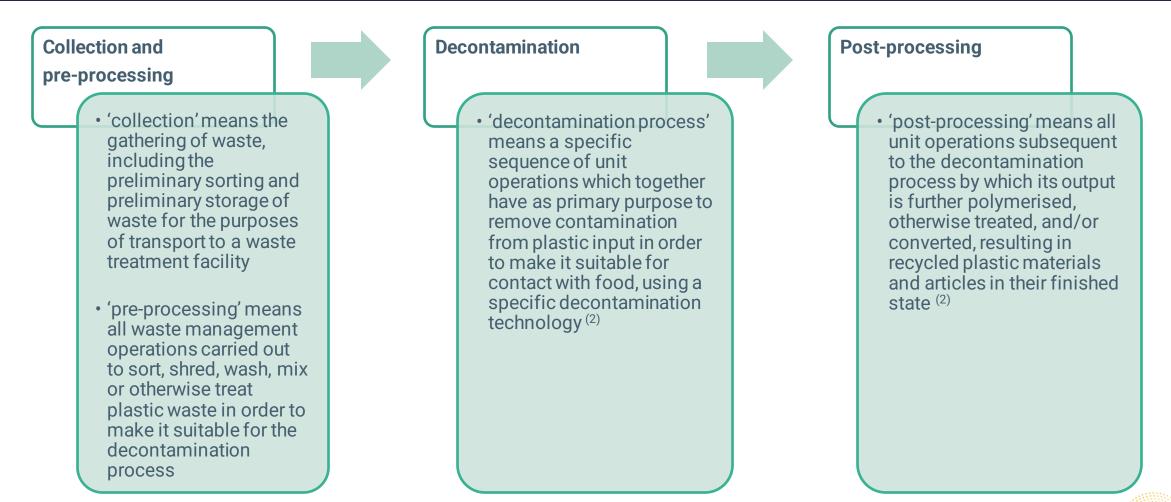
specific combination of **physical or chemical concepts**, **principles and practices** to recycle a **waste stream of a certain type and collected in a certain way** into recycled plastic materials and articles of a specific type and with a specific intended use, and includes a decontamination technology

#### **Recycling process**

sequence of **unit operations** that is intended to manufacture recycled plastic materials and articles through **pre-processing**, a **decontamination process**, and **postprocessing**, and which is **based on a specific recycling technology** 



#### **SCOPE OF THE GUIDANCE: DEFINITIONS**







 Request for EFSA to prepare guidance documents laid down in Article 20 of Regulation (EU) 2022/1616

Article 20

#### Guidance published by the Authority

1. The Authority shall publish detailed guidance, following the agreement with the Commission, concerning the preparation and the submission of the application, taking into account standard data formats, where they exist in accordance with Article 39f of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*.

2. For each suitable recycling technology for which the authorisation of individual recycling processes is required, the Authority shall publish scientific guidance describing the evaluation criteria and the scientific evaluation approach it will use to evaluate the decontamination capability of those recycling processes. The guidance shall specify the information required to be included in an application dossier for the authorisation of a recycling process applying that specific technology.





• → <u>EFSA internal mandate</u> for the preparation of a **scientific guidance** on **postconsumer mechanical PET recycling** processes intended to be used for manufacture of materials and articles in contact with food

(1)	(2)	(3)	(4)	(5)	(6)	(7)
Recycling technology number	Technology name	Polymer type (detailed specification in Table 2)	Short description of the recycling technology (detailed specification in Table 3)	Specification of plastic input	Specification of output	Subject to the authorisation of individual processes
1	Post-consumer mechanical PET recycling	PET (2.1)	Mechanical recycling (3.1)	maximum 5 % of materials	Decontaminated PET, final materials and articles not to be used in microwave and conventional ovens; additional specifications may apply to output from individual processes	

 The development of guidance for other technologies and/or plastics may be considered in the future, in line with the procedures set out for novel technologies in Regulation (EU) 2022/1616



#### **TERMS OF REFERENCE**

- Prepare a scientific guidance on post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food.
- Starting point: the previously published scientific outputs providing the context for the evaluation of recycling processes (i.e. guidelines on recycling plastics (EFSA, 2008) and criteria for safety evaluation of PET recycling processes (EFSA CEF Panel, 2011)) should be

1) updated, taking into account the <u>new legislative context</u> of Regulation (EU) 2022/1616 as well as <u>new scientific evidence</u>, if available, and 2) integrated into one scientific guidance, presenting

 the <u>evaluation criteria and the</u> <u>scientific evaluation approach</u> that will be used to evaluate the decontamination capability of such recycling processes, and

- the <u>requirements for the content of</u> <u>the technical dossier</u>.

• The task should be completed by **30 June 2024**.



#### **ADMINISTRATIVE GUIDANCE**



- Update in consideration of
- the new legislative requirements of Regulation (EU) 2022/1616
- the requirements laid down in the draft scientific guidance
- Updated version will be published alongside the scientific guidance in summer 2024



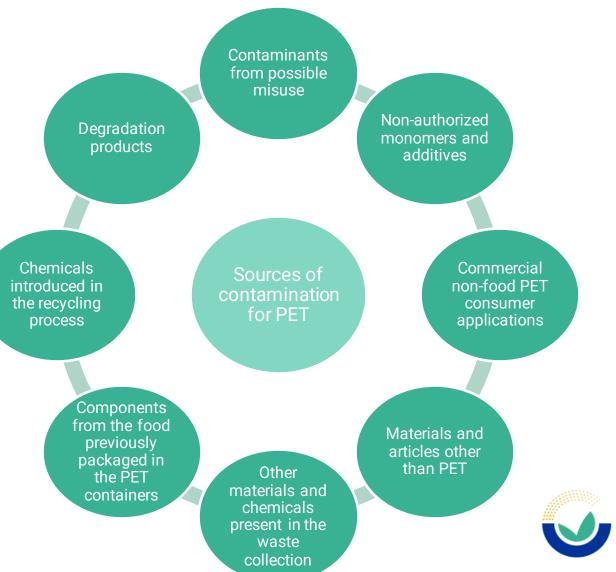
# EVALUATION CRITERIA





#### GENERAL PRINCIPLES FOR SAFETY ASSESSMENT OF RECYCLED PLASTICS FOR FOOD CONTACT

- Health risks associated with use of recycled plastic FCMs due to possible migration into the packaged food of contaminants present in the recycled plastic.
- The recycling process must be capable of applying the suitable technology for PET so that plastic materials and articles manufactured with it meet Article 3 of Regulation (EC) No 1935/2004, e.g. they do not transfer their constituents to food in quantities which could endanger human health, and are also microbiologically safe



#### GENERAL PRINCIPLES FOR SAFETY ASSESSMENT OF RECYCLED PLASTICS FOR FOOD CONTACT

## Input

- Considering the potential sources of contaminants: high importance of quality of input
- Need for pre-established specifications

Recycling process

 Decontamination efficiency to be determined experimentally by challenge test

Safety assessment  Decontamination efficiency to be assessed against a reference input contamination and potential migration of residual contaminants from the recycled articles



## **REFERENCE CONTAMINATION LEVEL**

Main source of data/information: EU project FAIR-CT98-4318 'Recyclability'

- washed and dried post-consumer PET flakes obtained from thousands (7,000-10,000) of soft drink bottles collected in 12 European countries
- most typical post-consumer contaminant: limonene at an average concentration of 2.9 mg/kg and at a maximum of about 20 mg/kg
- **Misuse** contamination in **three cases** of washed and dried PET flakes:
  - Xylene: 2,000-3,000 mg/kg, Toluene: 2,000-3,000 mg/kg and 4,500-6,750 mg/kg
- Incidence of misuse: 0.03-0.04% → highest concentration of toluene: 1.4 to 2.7 mg/kg PET

Reference contamination level: 3 mg/kg PET



Guidance and Criteria for **Safe Recycling** of Post Consumer Polyethylene Terephthalate (PET) into New Food Packaging Applications

EUR 21155

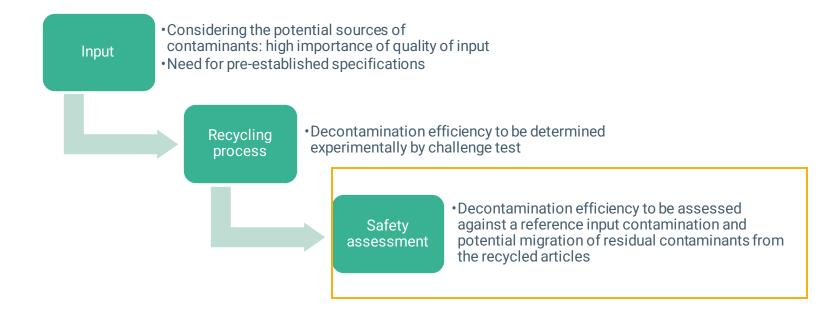
## **NON-FOOD CONTACT APPLICATIONS**

achieved level of decontamination.

 Possible presence of containers for non-food applications in the input stream, e.g. mouthwash, detergents, shampoos, household cleaning products → contained chemicals can be absorbed into the PET → introduction of non-food substances

1.	Requirements regarding collection and input (Regulation (EU) 2022/1616): Waste management operators that participate in the supply chain of plastic input shall ensure that the collected stic waste meets the following requirements:		Specification of plastic input
(a)	the plastic waste originates only from municipal waste, or from food retail or other food businesses if it was only intended and used for contact with food, including waste discarded from a recycling scheme in accordance with Article 9(6);	ļ	Only PET PCW containing maximum 5 % of materials and articles that were used
<b>(</b> b)	the plastic waste originates only from plastic materials and articles manufactured in accordance with Regulation (EU) No 10/2011 or recycled plastic materials and articles manufactured in accordance with this Regulation;		in contact with non-food materials or substances.
(c)	the plastic waste is subject to separate collection;		
(d)	the presence of plastic materials and articles that are different from the plastic for which the decontamination process is intended, including caps, labels and adhesives, other materials and substances, and remaining food is reduced to a level specified in the requirements for the plastic input provided by the recycler and which shall not compromise the		

## **MIGRATION CRITERION**



- Dietary exposure via migration into food of a potential unknown contaminant shall not exceed a level of dietary exposure below which the risk to human health would be negligible.
- It is impossible to predict the identity of contaminants potentially present in post-consumer PET used as input of a recycling process and to ensure that they are not genotoxic.
- Therefore, a level of dietary exposure that can be considered of negligible risk to human health must take this possibility into account.



#### DIETARY EXPOSURE – NEGLIGIBLE RISK TO HUMAN HEALTH

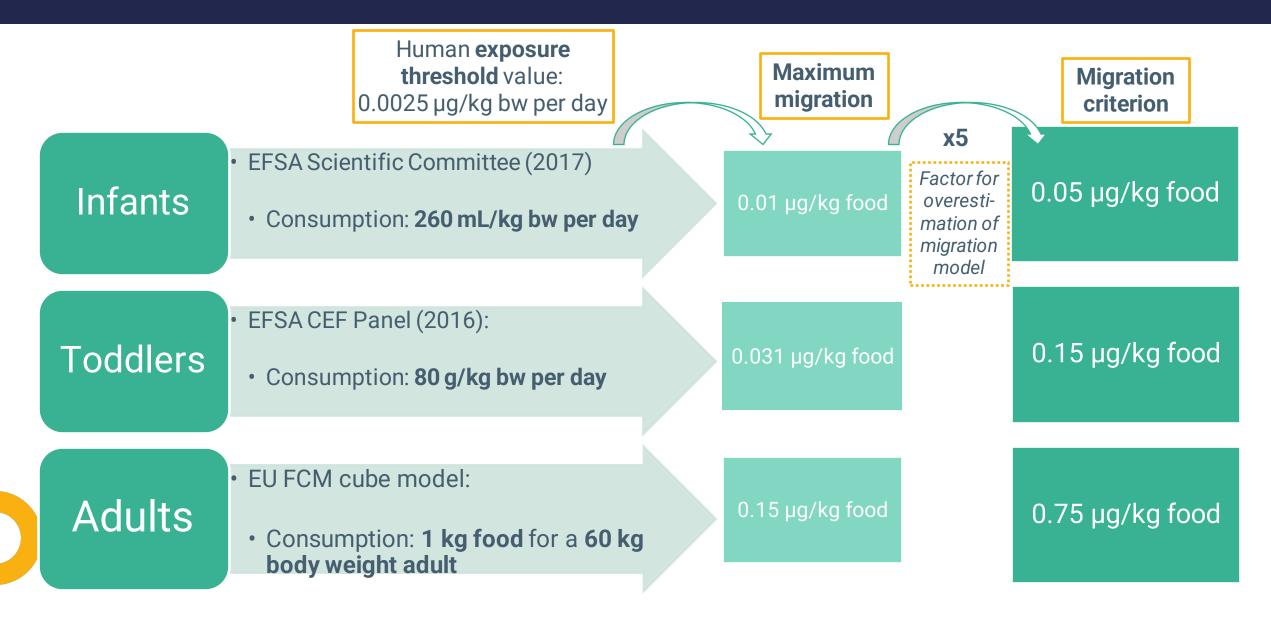
 Exposure level for chemicals with structural alerts that raise concern for potential genotoxicity based on human exposure threshold value below which the probability for adverse effect for human health is negligible

**0.15 μg/person/day** for a person of 60 kg body weight (bw), corresponding to **0.0025 μg/kg bw per day** 

- → Generally considered low enough to address concern over all toxicological effects
- Low probability of contamination of post-consumer PET by misuse with substances classified as genotoxic
- →Reactivity of functional groups associated with genotoxicity → reaction during recycling process at high temperatures → decrease of concentration/migration

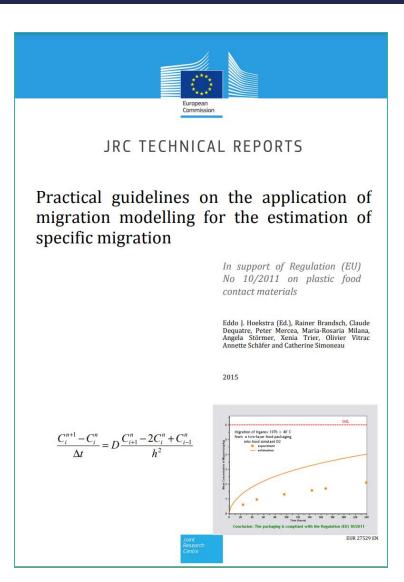


#### **EXPOSURE SCENARIOS AND MIGRATION CRITERIA**



## **CMOD - MIGRATION MODELLING**

- Use of generally recognised migration models in order to estimate the concentration in PET (Cmod), which corresponds to the migration criterion
- Modelling parameters:
  - Migration criterion (infants): 0.05  $\mu$ g/kg food
  - Long term ambient storage, a shelf life of 1 year at 25°C
  - Good solubility of the migrant in food simulant is assumed, (KP/F =1)
  - FCM made entirely with 100% recycled PET
  - Surface/volume ratio: 6 dm<sup>2</sup> PET to 1 kg food/drink
  - Material thickness: 300 µm
  - PET density: 1.375 g/cm<sup>3</sup>
  - Modelling parameters Ap' = 3.1 and  $\tau$  = 1577 (used to estimate the diffusion coefficient in PET)



#### **COMPARISON CRES VS CMOD**

•

Cmod:	Surrogate	MW (Da)	Cmod (mg/kg PET) for infant scenario	Cmod (mg/kg PET) for toddler scenario
	Toluene	92	0.04	0.12
	Chlorobenzene	113	0.05	0.14
	Chloroform	119	0.05	0.15
	Methyl salicylate	152	0.06	0.19
	Phenylcyclohexane	160	0.07	0.20
	Benzophenone	182	0.08	0.23
	Lindane	291	0.15	0.44
	Methyl stearate	298	0.15	0.46

- Cres: by applying the decontamination efficiency to the reference contamination (3 mg/kg)
- Example: Phenylcyclohexane (molecular mass 160 Da)
  - Decontamination efficiency: 98.5%
  - Cres = 3 mg/kg x (1-0.985) = 0.05 mg/kg PET

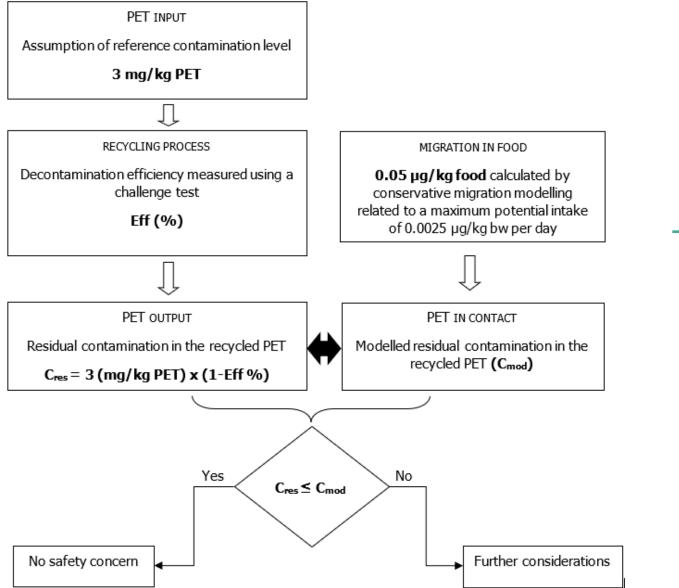
• Cres: 0.05 mg/kg

• Cmod infant scenario: 0.07 mg/kg

#### $\rightarrow$ Cres < Cmod

Decontamination efficiency for phenylcyclohexane is sufficient for infant scenario

#### **EVALUATION SCHEME**



#### $Cres \leq Cmod$

→potential migration of contaminants does not give rise to a dietary exposure exceeding the threshold of toxicological concern for substances with a structural alert for genotoxicity (0.0025 µg/kg bw per day)



#### **ASSUMPTIONS AND UNCERTAINTIES IN THE APPROACH**

No recent surveys on the frequency and severity of the contamination of post-consumer PET waste streams (other than the EU FAIR project)

Overestimation of migration from PET by the migration model due to the inbuilt conservative parameters

Migration calculations based on the assumption that all food consumed each day is in contact with 100% rPET and has been in contact for 12 months at 25°C before consumption

Sporadic, if any, presence of unknown and possibly genotoxic contaminants in recycled PET (taking into account the collection systems)





C



### **QUESTIONS - REGISTRATION FORM**

Questions	Number
Mechanical rPET	19
Novel technologies	8
Risk management	20
Content of technical dossier for mechanical rPET	6
Other	2

Questions regarding mechanical recycling of PET and about the content of an application to be submitted to EFSA have been addressed throughout the presentation.



## **QUESTIONS - REGISTRATION FORM**

#### Risk management questions:

- interpretation of Reg. (EU) 2022/1616
- DoC for single batch
- limit to the content of rPET
- role of MS competent authorities
- novel technologies, other polymers and functional barriers

 $\rightarrow$ 

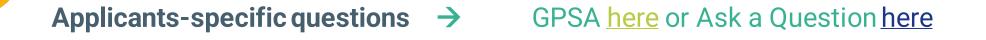
• procedure for changing the operating parameters



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#### **Comments to the guidance** $\rightarrow$ Public consultation <u>here</u>

- Proposals/comments on how to rinse the contaminated flakes to remove surface contamination
- Infant/drinking water scenario applied to tray-to-tray recycling





## **QUESTIONS - REGISTRATION FORM**

- 1. Has any data been developed as to the number of times material can be rerun through a recycling process before it becomes nonviable? Have controlled studies been carried out on the behavior of rPET (and the development of NIAS) as a function of the number of recycling cycles?
- 2. Why does EFSA approve decontamination process available only considering that the input material must be at least 95% from food contact packaging materials? Why Regulation 2022/1616 consider also the input that must come from selective sorting (Yellow bin) or from deposit system? For trays collection will there be different position about the input?
- 3. BPA in recycled PET







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# CONTENT OF THE TECHNICAL DOSSIER



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#### PREMISE

#### Regulation (EU) 2022/1616:

(25) Since this Regulation requires the individual authorisation of recycling processes in certain cases, a procedure should be laid down to this end. This procedure should be similar to the procedure for authorisation of a new substance laid down in Regulation (EC) No 1935/2004, adapted as necessary for the individual authorisation of recycling processes. In particular, since preparing an application for authorisation requires of the applicant an intricate knowledge of the recycling process concerned, and in order to avoid that several applications for the same recycling process, and not any recycler using it, may apply for authorisation. Furthermore, as authorised recycling processes may be subject to minor and major technical and administrative changes over their life-cycle, this Regulation should ensure clarity over the procedures applicable to changes to authorised recycling processes.

Article 17

#### Application for the authorisation of individual recycling processes

1. To obtain authorisation of an individual recycling process, the natural person or legal entity that developed the decontamination process of the recycling process, either exclusively for its own purposes as a recycler or for the sale or licensing of recycling or decontamination installations to recyclers, 'the applicant', shall submit an application in accordance with paragraph 2.

Intricate knowledge as the basis for the preparation of an application → only the developer of the decontamination process of a recycling process can apply for authorisation

## **REGULATORY REQUIREMENTS**

- 5. The technical dossier shall contain the following information:
- (a) any information required in the detailed guidance published by the Authority in accordance with Article 20(2);
- (b) a description of the pre-processing carried out to produce plastic input suitable for being entered into the decontamination process and of the specific quality control procedures applied during collection and pre-processing, including a detailed specification of the pre-processed plastic input;
- (c) a description of any required **post-processing** of the recycled plastic and of the **intended use** of the resulting plastic materials and articles and of uses for which it would not be suitable, including relevant **instructions and labelling** to be provided to convertors and to end-users of the recycled plastic materials and articles;
- (d) a simple block diagram of all unit operations used in the decontamination process, that provides a reference to the input, output and quality control procedures applied by each operation;
- (e) a piping and instrumentation diagram of the decontamination process in accordance with section 4.4 of ISO 10628-1:2014, showing only the instrumentation relevant for decontamination;
- (f) a description of the quality control procedures applied at each unit operation of the decontamination process, including:
  - (i) the values of monitored parameters such as operating temperatures, pressures, flowrates and concentrations, and acceptable ranges thereof;
  - (ii) laboratory analysis and its frequency; if any,
  - (iii) correction and record keeping procedures; and
  - (iv) any other information the applicant deems relevant to fully describe its quality control procedures.

Article 17.5 of Regulation (EU) 2022/1616 defines the information to be provided by the applicant in the technical dossier

## **COLLECTION AND PRE-PROCESSING**

Why are these steps important?

- $\rightarrow$  suitability of input material for decontamination  $\rightarrow$  final output quality
- 1. Collection requirements → Art. 6 of Regulation (EU) 2022/1616
- a. Input:
  - Originates from municipal, food retail/businesses waste
  - Intended to be in contact with food → manufactured in accordance with Regulation (EU) No 10/2011
  - Subjected to separate collection
  - Specifications on: plastic materials & articles other than PET, other materials and substances, remaining food
- b. Quality assurance system

Statement confirming compliance with Art. 6 of Regulation (EU) 2022/1616

Points for which quality control is required



### **COLLECTION AND PRE-PROCESSING**

#### 2. Pre-processing requirements:

- a. Description of the pre-processing
  - > Sorting, shredding, washing, drying, mixing etc
  - More specific information in case of other pre-treatment performed in a different facility

No detailed description of the equipment needed

- b. Statement of compliance with Art. 6 of Regulation (EU) 2022/1616
- c. Quality assurance systemPoints for which quality control is required

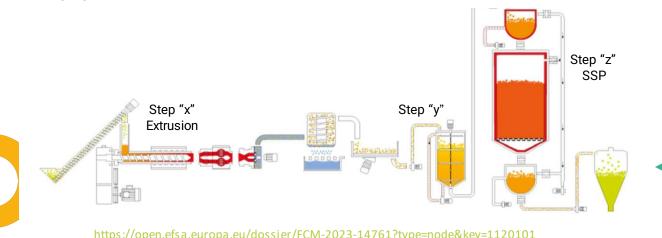
- d. Specifications on the pre-processed plastic input:
  - Compliance with requirement on maximum content of non-food contact PET in the input (5%)
  - Flake dimensions (average thickness, size distribution)
  - Bulk density (range and average)
  - Plastics other than PET (e.g. polyvinyl chloride, polystyrene, polyamide, polyolefins, polycarbonate)
  - ➢ Glues

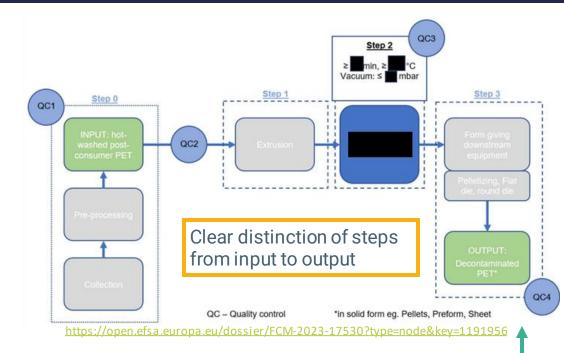


## **DECONTAMINATION PROCESS**

Description of decontamination unit operations and equipment, with information on design details and technical drawings. Critical steps.

- Principal function (e.g. extruder) and type of equipment parts (e.g. stirring tank)
- Heating and cooling systems
- Vacuum and flowing gas incl. design and position of ports
- Stirring tools
- Size of equipment (dimensions and capacity)
- Version and date of installation, details on the producer of equipment



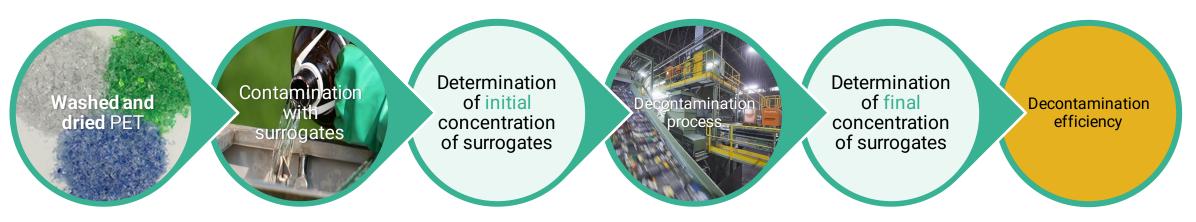


#### Required schemes for the decontamination process:

- Simple block diagram with unit operations and quality control points
- Process flow diagram with distinct unit operations and
   their schematic set-up
- Piping and instrumentation diagram (ISO 10628-1:2014, section 4.4)

## **DETERMINATION OF DECONTAMINATION EFFICIENCY**

#### How? $\rightarrow$ «Challenge test»



#### Surrogates

- Substances whose <u>polarity</u> and <u>molecular weight</u> are representative of possible contaminants of concern
  - e.g.: toluene, chlorobenzene, chloroform, methyl salicylate, phenyl-cyclohexane, benzophenone, methyl stearate

Ctable during desentamination process	
<ul> <li>Stable during decontamination process</li> </ul>	2.2. Notification of studies
Obligation for <b>notification of studies</b> applies for the <b>challenge test</b>	In accordance with Article 32b of the GFL Regulation, potential applicants commissioning or carrying out studies as of 27 March 2021 to support an application concerning recycling processes (new authorisation, modification of an existing authorisation) have the obligation to notify EFSA without delay of the following information <sup>19</sup> related to those studies:
	- title and scope of the study;
For details see administrative guidance:	<ul> <li>laboratory or testing facility carrying out the study;</li> </ul>
https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2021.EN-6512	<ul> <li>starting and planned completion dates of the study.</li> </ul>

## **CONTAMINATION PROCEDURE**

#### Description of contamination procedure:

- <u>Material</u> to be contaminated: origin, type, dimensions, size distribution, bulk density, amount
- Chemicals used as <u>surrogates</u> and amounts added
- Mode of addition of surrogates to the material
- <u>Soaking and storage</u>: time and temperature conditions
- <u>Handling conditions</u> to promote homogenisation
- <u>Washing</u>: Type of liquid used, volume, time and temperature

#### **Contamination conditions**

- 250-1000 mg surrogate/kg PET
- Time and temperature equivalent to 1 year at 25°C
- Mixing  $\rightarrow$  homogeneous distribution of surrogates
- Washing
  - Detergents or organic solvents only (no water)
  - □ Adequate removal of surface contamination to avoid overestimation of the DE
  - □ May not be needed if contamination happens in extruder!

PET can be contaminated directly or with a masterbatch approach

Surrogates should penetrate PET as deeply as contaminants would in a worst-case scenario (misuse)



## **CHALLENGE TEST**

✓ Same level of detail regarding equipment and operation as for the industrial process (ref. slide n.37)

The industrial process must run under conditions at least as severe as those of the challenge test.

If one or more industrial process steps run at less severe conditions compared to challenge test  $\rightarrow$  consider possible effects on decontamination efficiency

✓ Scale of the installation (industrial, small industrial, pilot plant, laboratory scale)

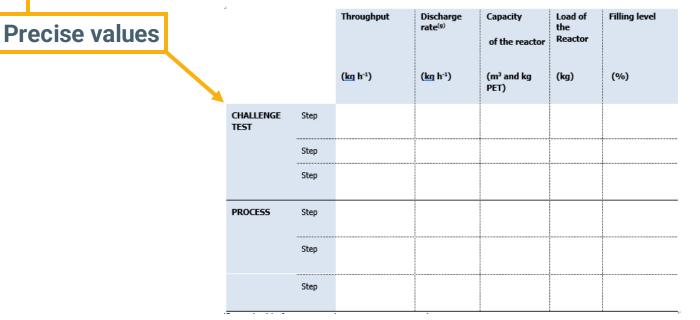
 $\checkmark$  Scale-up evaluation  $\rightarrow$  representativeness of industrial scale line



## **DECONTAMINATION PROCESS - OPERATION**

- Table of operating parameters
  - ✓ Operating parameter values
  - ✓ Mode of operation (batch/continuous)
  - ✓ Reactor capacity, actual load and filling level
  - ✓ Throughput/discharge rate
- Other relevant information
  - ✓ Temperature gradients
  - ✓ Rotational parameters
  - ✓ Melt surface area
  - ✓ Degree of mixing
  - ✓ Length and thickness of formed pellets

						Na	ame of th	ne process	;						
		Nam	Step <sup>(a)</sup> ne of the st	tep			Na	Step <sup>(a)</sup> me of the	step				Step <sup>(a)</sup> e of the st	ер	
Operating Darameters	t (b,e)	Р	Gas flow (d)	T (e)	Other, if applicabl e	t (b,e)	Р	Gas flow (d)	T (e)	Other, if applicab e		Ρ	Gas flow (d)	T (e)	Other, if applica ble
	(unit)	(mbar)	(unit)	(°C)	(unit)	(unit)	(mbar)	(unit)	(°C)	(unit)	(unit)	(mbar)	(unit)	(°C)	(unit)
Challenge test (Report No)	(c)					(c)					(c)				
Process	(c)					(c)				-	(c)				





## **DETERMINATION OF DECONTAMINATION EFFICIENCY**

#### **Determination of surrogate levels**

- Exhaustive extraction
- Consider possible losses during transportation
- Representativeness and homogeneity of samples
  - Before decontamination: at least **10** samples (+ **3** samples in case of temporary storage or transportation to different location)
  - During/after decontamination: at least 3 samples in each step
  - Quantity: At least 1 g per sample
- > Considerations on possible cross-contamination phenomena
  - Surrogate transfer between contaminated and non-contaminated flakes  $\rightarrow$  overestimation of DE
- Provide spreadsheet with calculations

Performance characteristics of analytical method (Note for Guidance for Food Contact Materials)

➢ Considerations on the suitability of the analytical method → should be supported by raw data and chromatograms



## **CONCLUSIONS ON THE CHALLENGE TEST**

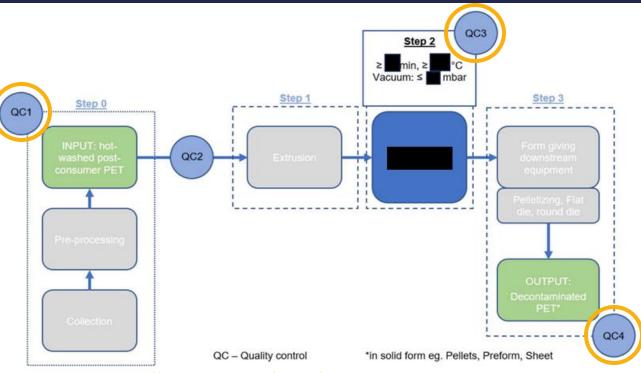
- Self evaluation
- Critical analysis of Cres and Cmod
- > Maximum percentage of rPET in the final article degree of mixing with virgin PET



#### **QUALITY CONTROL SYSTEM AND CHARACTERISATION OF OUTPUT**

#### **Quality control:**

- Critical steps to be covered by quality control
- Possible consequences of "failure"
- Corrective actions
- Laboratory procedures



https://open.efsa.europa.eu/dossier/FCM-2023-17530?type=node&key=1191956

#### **Characterisation of output:**

- Type of output (flakes, pellets, sheets, other)
- Intrinsic viscosity of the output



## **POST-PROCESSING AND INTENDED USE**

#### **Information flow**

Developers > Recyclers

Converters > End users

- Description of any required post-processing (e.g. pre-form injection, bottle blowing, lamination, thermoforming)
- Type of final material/article
- Surface to volume ratio

- Final materials/articles not be used in microwave/ovens (Table 1, Annex I, Reg. EU 2022/1616)
- Intended food application and exposure scenario (infant, toddler, adult)
- Time and temperatures allowed for final use
- Instructions for converters/end users, e.g. degree of mixing needed with virgin PET, other restrictions of use



# PUBLIC CONSULTATION



**#OpenEFSA** 

### **PUBLIC CONSULTATION**



## Please participate to the public consultation (PC-0797) and share your comments with us:

#### https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0ITk0000005wZd/pc07

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## THANK YOU FOR ATTENDING OUR EVENT

- In case we did not manage to answer all your questions, we invite to resubmit them via Ask a Question <u>here</u>
- The recording of today's event will be available on the EFSA website in few days
- Please take few minutes to fill out the <u>evaluation survey</u> that you will receive after the event. Your feedback is essential to improve our future events



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