EFSA GUIDANCE ON MECHANICAL PET RECYCLING PROCESSES

EFSA-Q-2023-00351

FIP FCM Network, 17-19 October 2023

EUROPEAN FOOD SAFETY AUTHORITY

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): https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2008.717
  - **Administrative** guidance (2021): https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2021.EN-6512


efsa
European Food Safety Authority
EFSA Journal 2011;9(7):2184
SCIENTIFIC OPINION
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[1]
EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF)[2,3]
European Food Safety Authority (EFSA), Parma, Italy


efsa
European Food Safety Authority
The EFSA Journal (2008) 717
Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on
Guidelines on submission of a dossier for safety evaluation by the EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food


TECHNICAL REPORT
efsa
European Food Safety Authority
APPROVED: 9 March 2021
IMPLEMENTATION DATE: **27 March 2021**
doi:10.2903/sp.efsa.2021.EN-6512
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
European Food Safety Authority (EFSA)

BACKGROUND

- October 2022: entry into force of Regulation (EU) 2022/1616 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

MANDATE

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

→ EFSA internal mandate

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.

- Focus will be on **post-consumer mechanical PET recycling**:

(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)	Only PET PCW containing maximum 5 % of materials and articles that were used in contact with non-food materials or substances.	Decontaminated PET, final materials and articles not to be used in microwave and conventional ovens; additional specifications may apply to output from individual processes	Yes

UPDATE OF ADMINISTRATIVE GUIDANCE

- Update in consideration of the new legislative requirements (Regulation 2022/1616) currently ongoing
- Incorporation of concepts of the 'old' scientific guidance document (2008) → 'old' scientific guidance document (2008) will become obsolete in order to avoid misalignment

- In parallel: development of new scientific guidance

NEW SCIENTIFIC GUIDANCE

- The aim of the scientific guidance document is to set out

  - the **evaluation criteria and the scientific evaluation approach** for post-consumer mechanical PET recycling processes
    - Formerly 'criteria for safety evaluation of PET recycling processes' (2011): https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2011.2184

  and

  - the **requirements for the content of the technical dossier** for post-consumer mechanical PET recycling processes that applicants have to submit as part of their application
    - Formerly 'guidelines on recycling plastics' (2008): https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2008.717

In consideration of new legislative requirements (Regulation 2022/1616) and recent scientific developments, where applicable

NEW LEGISLATIVE REQUIREMENTS (2022/1616)

Article 17

Application for the authorisation of individual recycling processes

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.

REQUIREMENTS FOR THE CONTENT OF THE TECHNICAL DOSSIER

- In addition to the requirements laid down in Article 17(5), the WG elaborated data requirements for the following topics:
  - Description of the **decontamination process** (equipment and operation)
  - **Challenge test** (contamination procedure, challenge test equipment and operation, determination of surrogate levels, derivation of decontamination efficiency)

RECENT SCIENTIFIC DEVELOPMENTS

- **Literature searches on topics of interest**
  - Update on aspects addressed in ‘criteria for safety evaluation of PET recycling processes’ (2011)
  - Consideration of aspects emerging after publication of ‘old’ scientific guidance documents

  - **Study selection process**, following pre-defined inclusion and exclusion criteria
    - Step 1: title and abstract screening
    - Step 2: full-text screening

    →Information from relevant studies will be taken into account for the new scientific guidance document

  - **Data extraction** (for selected searches)

- Considerations based on the **experience gained during the years of risk assessment of recycling processes**

RESULTS OF THE SEARCHES *CONFIDENTIAL*

	PubMed	Scopus	Web of Science CC	Total	Total after de-duplication
Search 1 Incidental contamination of post-consumer PET materials and articles/Contamination by misuse/Surrogates for challenge test	358	1,246	864	2,468	1,437
Search 2 Sorption of chemicals into PET	260	1,613	1,112	1,985	1,930
Search 3 Migration modelling	241	612	536	1,389	798
Search 4 Aging	368	1,478	1,703	3,549	2,116
				Total	6,281

RESULTS OF THE SEARCHES *CONFIDENTIAL*

- **Search 1** (Incidental contamination of post-consumer PET materials and articles/Contamination by misuse/Surrogates for challenge test)
  - 59 articles passed the full-text screening → further examination by the WG experts
- **Search 2** (Sorption of chemicals into PET)
  - 4 articles passed the full-text screening → further examination by the WG experts
- **Search 3** (Migration modelling)
  - 34 articles passed the full-text screening → further examination by the WG experts
- **Search 4** (Aging)
  - Full-text screening still ongoing

DRAFT STRUCTURE OF THE NEW SCIENTIFIC GUIDANCE

CONFIDENTIAL

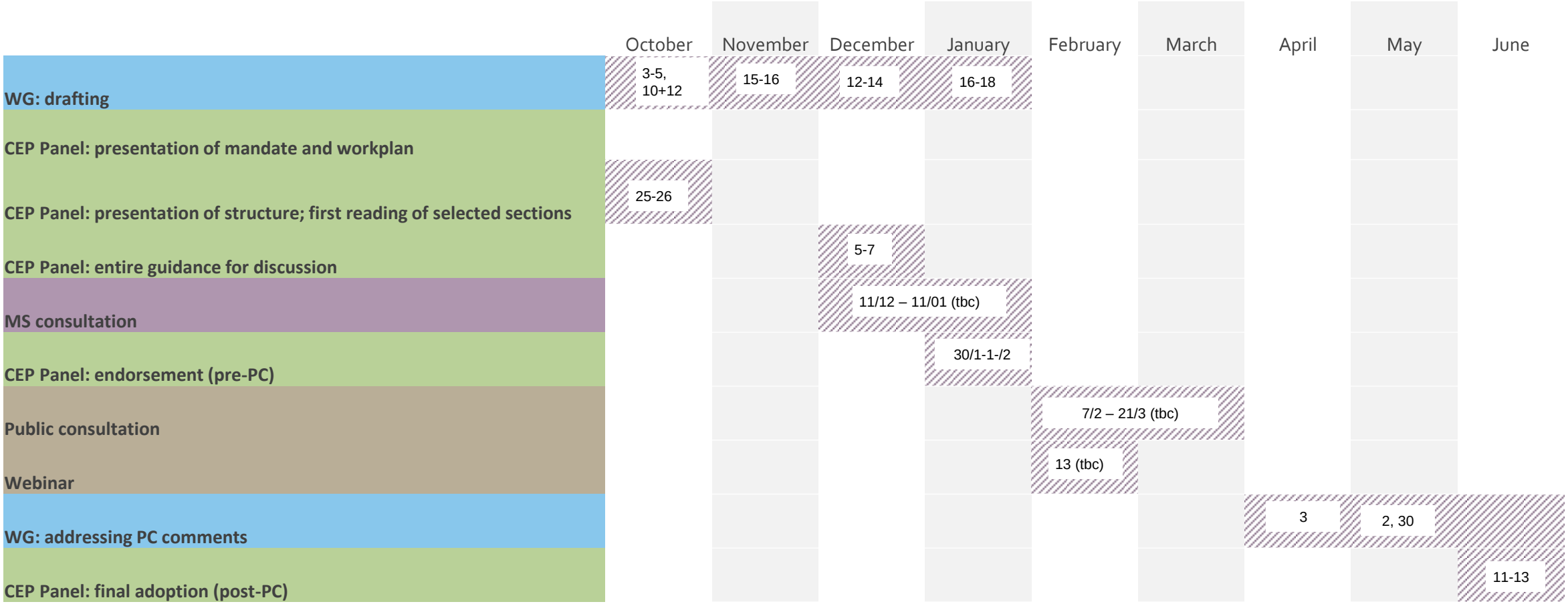
Section		Subsection	
1	**Introduction**	1.1	Background and Terms of Reference as provided by the requestor
2	**Scope of the Guidance**	n/a	
3	**Criteria for the evaluation of post-consumer mechanical PET recycling processes**		
3.1	General principles of the safety assessment of recycled plastics intended to be used for manufacture of materials and articles in contact with food	n/a	
3.2	Principles of the evaluation scheme	n/a	
3.3	Reference contamination level of the input	3.3.1	Overview of contamination, data on post-consumer PET bottles
		3.3.2	Incidence data on contamination cases by misuse
		3.3.3	Data on sorption of chemicals into PET
		3.3.4	Derivation of a reference contamination level from misuse of food contact PET applications
		3.3.5	Considerations for the presence of PET containers from non-food contact applications in the collected PET
3.4	Criterion of migration of potential contaminants	3.4.1	Dietary exposure related to a negligible risk to human health
		3.4.2	Calculation of migration critera
		3.4.3	Considerations on the assumptions used, any uncertainties, and their likely impact
3.5	Application of the key parameters for the evaluation scheme	n/a	

DRAFT STRUCTURE OF THE NEW SCIENTIFIC GUIDANCE

CONFIDENTIAL

Section		Subsection	
4 Content of the technical dossier for post-consumer mechanical PET recycling processes			
4.1	Recycling process	4.1.1	Collection and pre-processing
		4.1.2	Decontamination process
		4.1.3	Post-processing and intended use
4.2	Determination of the decontamination efficiency of the recycling process	4.2.1	Contamination procedure
		4.2.2	Challenging of steps of relevance for the decontamination
		4.2.3	Determination of surrogate levels
		4.2.4	Derivation of the decontamination efficiency
4.3	Self-evaluation of the recycling process	n/a	

WORKPLAN - TIMELINES *CONFIDENTIAL*



→ **Final adoption** of the guidance document needs to take place **by mid June 2024**

MEMBER STATE CONSULTATION *CONFIDENTIAL*

- Targeted consultation on draft guidance: 11 December – 11 January (tbc)
- Feedback will be gathered via Salesforce (EFSA tool for consultations)
- National institutions will be invited to comment
  - MS contact points for mandate intake
  - **FIP FCM Network members**

Your participation to the consultation will be much appreciated!