



# Background on the Authorisation of mechanical PET recycling

Information session on mechanical PET recycling

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# EU legislation on Food Contact Materials (FCMs)

- Applicable to **all FCMs**
  - already in contact with food (e.g. food packaging)
  - intended to be brought into contact (kitchenware, food processing equipment)
  - that can reasonably be expected to be brought into contact with food or transfer constituents to food under normal or foreseeable conditions of use



- Size of the industry is considerable = €100 billion



# Legislation on FCMs

- Basic act applicable to all FCMs: **Regulation (EC) No 1935/2004**
  - it is to ensure
    - **a high level of protection of human health**
    - the effective functioning of the internal market
  - it provides for General rules and procedures
    - **Defines the role of EFSA**, definitions, labelling, traceability, inspection and control
- Specific measures, particularly for plastic FCMs:
  - Regulation (EU) No 10/2011 on plastic FCM authorising substances with restrictions e.g. SMLs
  - **Regulation (EU) 2022/1616 on recycling of plastic**
- Regulation on Good Manufacturing practices ‘GMP’
  - all FCMs to be produced applying GMP



# FCM legislation on plastic materials

- Regulation (EU) No 10/2011:
  - sets rules on the composition of primary/virgin plastic materials
  - requires (in principle) full knowledge on all substances present in plastics
    - substances that are intentionally used, e.g. monomers and additives
    - substance that are also present, e.g. impurities and decomposition products
- Regulation (EU) 2022/1616:
  - sets rules on the recycling of plastic food contact materials (compliant with R 10/2011)
  - concerns the decontamination of used plastic to make is suitable again for food contact
  - production of pure monomers is subject to Regulation (EU) 10/2011)

*Composition*

*Decontamination*

# Regulation (EU) 2022/1616



- Is to ensure that recycled plastics are safe for food contact
  - assumption on contamination level of input, decontamination efficiency, use of output
  - recycling = pre-processing (collection, sorting, washing) + **decontamination** + post-processing
  - recycling technology for FCM = decontamination technology
- Requires that all recycled (FCM) plastic is manufactured:
  - applying a suitable recycling **technology**
  - using an authorised recycling **process** (if the technology so requires)
  - in a registered and audited recycling **installation**
- Requires compliance documentation at batch level

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# Suitable Recycling technologies

- The Regulation requires that **suitable technology** is used
- The Regulation is in principle not specific to any recycling technology
  - it provides a generic framework
- Main suitable technology today: mechanical PET recycling
  - which is presently the only suitable technology for producing PET beverage bottles
  - other technology: recycling from a closed and controlled chain (e.g. retail crates)

# Novel Recycling Technologies

- Novel technologies provide basis to establish suitable technologies
  - examples:
    - use of a functional barrier (so-called ABA material)
    - multi-layer PET (>200 installations) and styrene trays
    - use of chemical decomposition, e.g. producing BEHT as an intermediate
- Novel technologies may therefore only be used for development purposes
  - they are **allowed to gather data** on the real safety of the recycled plastic
- The Commission is after at least two years to ask EFSA to consider suitability
  - If considered suitable, the technology will be established as a suitable technology in Annex I
  - The EFSA evaluation should describe the technology, and may set restrictions on its use
  - If not found suitable, the technology may no longer be used
- EFSA may conclude that individual processes using the technology should be authorised
  - If so, EFSA is to provide guidance on the evaluation of individual processes
  - Mechanical rPET recycling processes require authorisation and therefore guidance

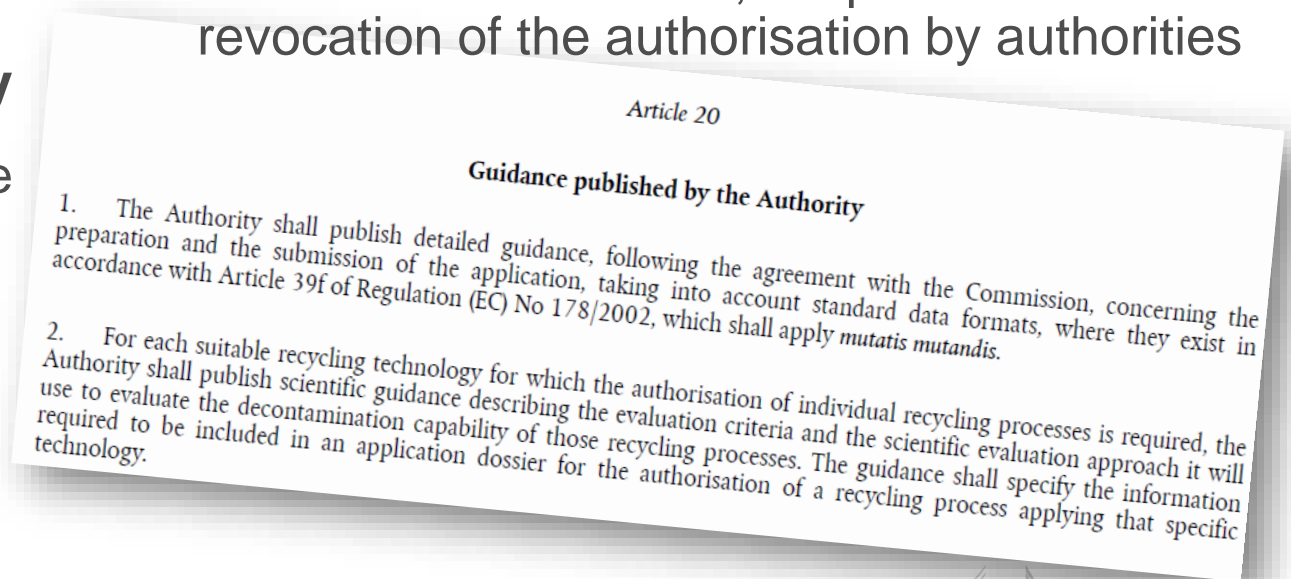
# Authorisation of recycling processes

## (Chapter V of Regulation (EU) 2022/1616)

- Article 17: application for authorisation
- Article 18: opinion of the authority
- Article 19: authorisation of an individual recycling process
- Article 20:  
**guidance published by the Authority**

- on the preparation and submission of the application
- for each suitable technology, the scientific guidance describing the evaluation criteria and the scientific evaluation approach

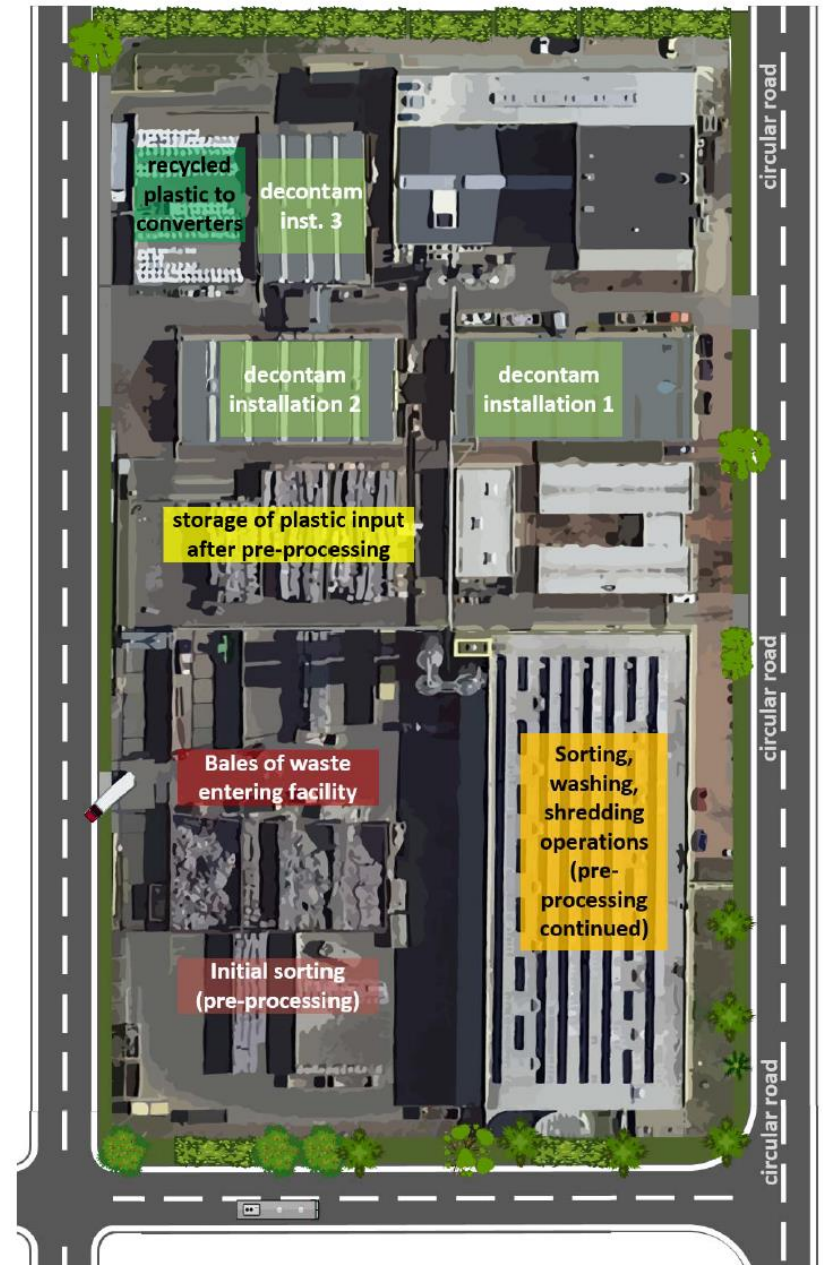
- Article 21: general obligations placed on authorisation holders
- Article 22: modification of the authorisation by the authorisation holder
- Article 23: modification, suspension and revocation of the authorisation by authorities





# Recycling Installations

- A recycling installation is the hardware that is used to recycle plastic
  - it is based on a certain technology, located at a recycling facility
- It is to be built and operated based on a process authorisation
- Three elements describe an authorised process
  - the Authorisation decision (mostly a reference to the opinion)
  - the EFSA opinion (more detail)
  - the dossier (based on the EFSA guidance, full detail)
- The focus of the authorisation is the decontamination installation
  - Also the subject of the EFSA opinion
- Recycling installations require registration and an audit by competent Authorities
  - to apply good manufacturing practices and keep records on their production
  - to describe operation practices in CMSS: compliance monitoring summary sheet



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# Questions received ahead of this meeting

- Is it possible to only submit a specific ‘recycling process’ without a registration of a recycling installation?
  - yes – it is rather the other way around that is unlikely
- Guidance document which shows step by step ... The recycling machinery/recycling installation registration procedure (RIN, RON, etc.)
  - Low priority at present → the Regulation describes the procedure quite clearly already
- What are the developments concerning the status of third countries recyclers whose national authorities are not providing the support required by the EU?
  - if no agreement with authority in the territory where the installation is located, eventual suspension
- How to prove compliance with legislation of the PET content within the packaging (layers of other polymers)?
  - via compliance documentation → DoC under Recycling Regulation to be use

# Questions received ahead of this meeting

- How to speed up processes to allow novel technologies and food grade for polymers other than PET?
  - *we follow procedure, but we will communicate later this year on state of play and future*
- Uncertainty around validation of novel technology; how is the technical data sent for evaluation being screened; is there going to be an interactive communication on the data interpretation?
  - *Answer: the data will form (part) of the dossier, which will be evaluated by EFSA*
- Much is invested in creating data but more details are needed with respect to how good this representation of this data is
  - *it was decided to do it this way because there was very little experience with novel technologies; mechanical rPET recycling will provide the example*
- Any changes in the list of specific NIAS? Any updates on standards to measure NIAS?
  - *there is no list of non-intentionally added substances; and they do not exist under R 2022/1616*
  - *recycling is about removing incidental contamination to a safe level; not about individual substances*
  - *work on monitoring of contaminants is on-going in industry*

# Thank you

Happy to receive questions...

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