



EU Regulatory updates

PETCORE – "Thermoforming: a path to circularity"

14th June

Bologna

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Food Contact Materials



- Plastics Regulation (EU) 10/2011 amendments:
 - 16th amendment adopted
 - 17th ? amendment still pending ←
 - 18-19th ? amendments in preparation (styrene, new substances,...)
- Regulation (EU) No 2022/1616 deadlines
 - 10th July 2023
 - 10th October 2023
- Revision of the FCM Framework Regulation (EC) No 1935/2004 ←

Plastics Regulation (EU) 10/2011: 17th amendment



Background:

- Main motivation is alignment with recycling regulation R 2022/1616:
 - Manufacture of substances from waste outside the scope of R 2022/1616 – purity requirements
 - Reprocessing of plastic (off-cuts and scraps when considered as by-products)
 - GMP requirements (amendment of the Annex to Regulation (EC) 2023/2006)
 - Declaration of compliance – introduction of recycled content
- Natural materials:
 - Purity of substances + clarification on the use of authorised natural materials
- Biocidal substances – possibly:
 - Removal of provisional list + derogation for substances authorised under BPR

Plastics Regulation (EU) 10/2011: 17th amendment



Manufacture of substances from waste outside the scope of R 2022/1616
– purity requirements:

Current Art 8 in (EU) 10/2011

Article 8

General requirement on substances

Substances used in the manufacture of plastic layers in plastic materials and articles shall be of a technical quality and a purity suitable for the intended and foreseeable use of the materials or articles. The composition shall be known to the manufacturer of the substance and made available to the competent authorities on request.



DG SANTE: Art 8 requires strengthening in 17th amendment:

- Recyclers need legal certainty on whether they fall under (EU) 10/2011 or (EU) 2022/1616 (with novel technology).
- Art 1(3) of (EU) 2022/1616 “This Regulation shall not apply to the use of waste to manufacture substances included in the Union list of authorised substances in accordance with Article 5 of Regulation (EU) No 10/2011, [...], **when intended for subsequent use in accordance with that Regulation**”



Main issue is level of contaminants – when is the ‘purity suitable’?

Plastics Regulation (EU) 10/2011: 17th amendment



Article 8

1. Any substance used in the manufacture of plastic materials and articles in accordance with Article 5 shall correspond to the identification and specification of that substance in Table 1 of Annex I by means of its name and where applicable its CAS number, and any additional specifications.
2. The following shall apply to the purity of substances originating from a natural origin:
 - (i) if the substance is identified by a chemical name, it shall be of a high degree of purity, or,
 - (ii) if the substance name refers to the name of a natural multi constituent material, that material may be used as obtained from nature, provided it has been separated in its entirety from other natural matter and parts of the plant or other natural source from which it was obtained that are not identified by the substance name.

Any additional specifications or requirements applicable to a substance or material from a natural origin set out in Table 1 of Annex I, applicable to the substance or material, shall apply.

3. Substances used in the manufacture of plastic materials and articles in accordance with Article 5 or 6 shall be of a technical quality and suitable for the intended and foreseeable use of the materials or articles, and shall be of a high degree of purity.
4. Substances recovered from waste in accordance with Directive 2008/98/EC² may only be used in the manufacture of plastic materials and articles in accordance with Article 1(3) of Regulation (EU) No 2022/1616. These substances shall be of high degree of purity.

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Plastics Regulation (EU) 10/2011: 17th amendment



Article 8(5)

- A = 50 ppb or 90 ppb (or 100 ppb)
 - To be discussed with EFSA
 - (0.05 or 0.09 mg/kg) (or 0.1 mg/kg)
- B to be 0.15 ppb
 - (TTC, 0.00015 mg/kg)
 - No clear argument to justify a higher value
- But 0.15 ppb is an issue:
 - detected substances not identifiable
 - NIAS not available for tox testing
 - other practicable difficulties
- Solution is being analysed

5. For the purpose of paragraph 2, 3 and 4 a high degree of purity shall mean that any substance used in the manufacture of plastic materials and articles in accordance with Article 5 or 6 contains only non-intentionally added substances that individually either:

- (i) are in accordance with specifications or restrictions specified in the authorisation of the substance in table 1 of Annex I, if any; or,
- (ii) have been subject to an individual risk assessment in accordance with Article 19; or,
- (iii) have been subject to a limited toxicological assessment that at least rules out genotoxicity, and are present at a level that cannot give rise to an individual migration from the final plastic material or Article exceeding **A** mg/kg food, assuming their full migration into the food; or,
- (iv) are unknown or unassessed, but are present at a level that cannot give rise to an individual migration from the final plastic material or Article exceeding **B** mg/kg food, assuming their full migration into to the food.

by derogation from point (iii) and (iv), where the plastic is used to pack:

- dry unpeeled fruit or vegetables that must be peeled or washed,
- other dry non-fatty foods when the packaging is in contact with less than 10% of the food surface and is open to the atmosphere,
- fully wrapped in a material without absolute barrier properties, provided this material is not in contact with the plastic for a time exceeding 4 hours or when the contact exceeds 10% of its surface, and the plastic packaging is open to the atmosphere, or,
- as secondary packaging foods packed in sealed metal or glass packaging.

10% migration instead of full migration into the food may be assumed.

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Plastics Regulation (EU) 10/2011: 17th amendment



Reprocessing of plastic (off-cuts and scraps considered as by-products):

- Definition of 'reprocessing of plastics' to be added as Art 3(20)
- Art 10 to be amended: 'General restrictions and requirements on the composition of plastic M&A:

1. Plastic materials and articles may contain reprocessed plastic, if the reprocessed plastic meets the following conditions:
 - (a) it is collected in accordance with point C of the Annex to Regulation (EC) No 2023/2006;
 - (b) it originates only from off-cuts and scraps from plastic materials and articles referred to in Article 2(1)(a) that meet the compositional requirements set out in chapter II of this Regulation, and which are considered to be a by-product in accordance with Article 5 of Directive 2008/98/EC;

- (c) it does not contain substances in an amount which could:
 - (i) exceed migration limits applicable to the plastic materials and articles to which the reprocessed plastic is added; or,
 - (ii) cause any other non-compliance of those plastic materials and articles with Article 3 of Regulation (EC) No 1935/2004;

- (d) it does not contain residues of:
 - (i) food;
 - (ii) printing, coating, or adhesives;
 - (iii) substances used for processing the plastic from which the offcuts and scraps originate, such as lubricants or cutting fluids;

unless those residues together contain only a limited number of well identified substances, of which the compliance with the conditions referred to in point (c) is demonstrated on the basis of an assessment in accordance with Article 19 and has been documented in supporting documentation;

Revision of the FCM Framework Reg. (EC) No 1935/2004



Shifting focus onto the final material



Prioritisation of substances



Supporting safer and more sustainable solutions



Improving supply chain information



System for verifying compliance



Analytical methods

Revision of the FCM Framework Reg. (EC) No 1935/2004



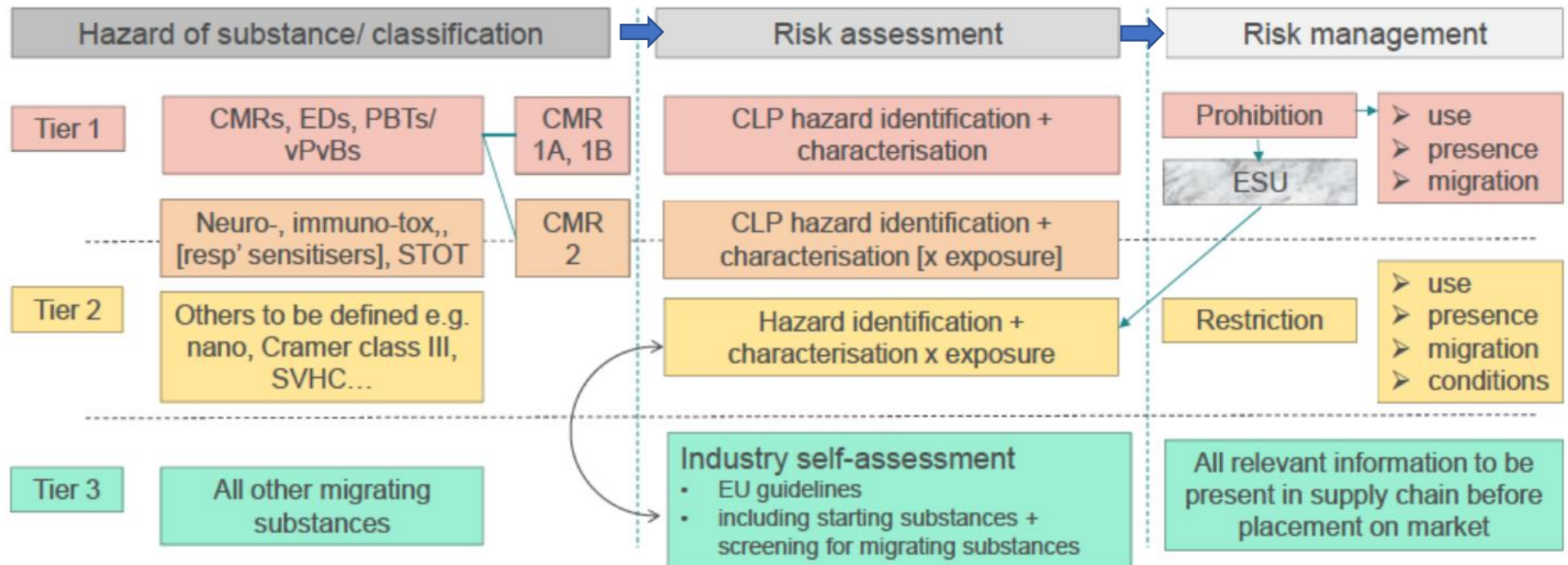
Prioritisation of substances: rules for the risk assessment of all (migratable) substances – tiered approach:



Hazard-based rules

Risk assessment by public authorities

Self-assessment by operators



Packaging and Packaging Waste Reg.- EC proposal



- It is a Regulation (facilitates harmonisation). Repeals PPWDirective 94/62/EC

- Sustainability requirements

All packaging to be fully recyclable

Minimum plastic recycled content* (2030 and 2040) - Claims

Re-use and refill targets

Packaging minimisation

- Labelling, marking and information requirements

Label with material composition. Label if subject to DRS. Label on packaging reusability and digital data carrier.

Harmonised labelling for waste receptacles

- Management of packaging and of packaging waste

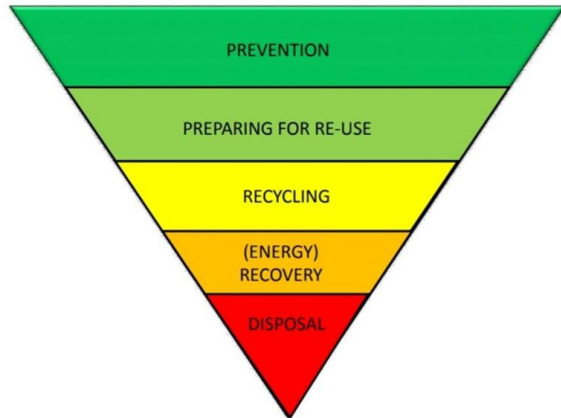
Reduction of packaging waste generated per capita**

DRS for SUP beverage bottles and metal beverage containers

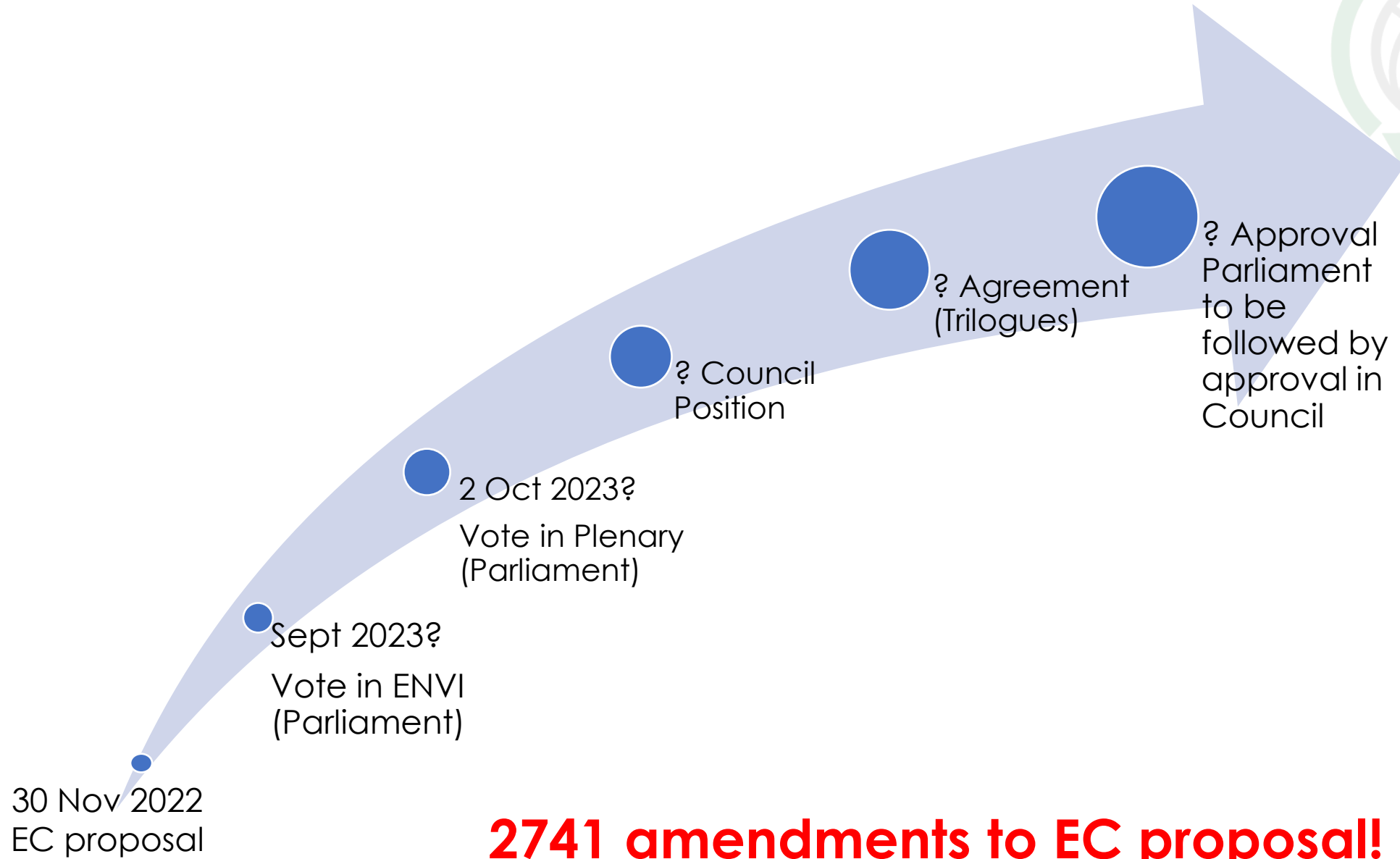
- Large number of implementing and delegated acts

**From post-consumer*

***5% by 2030, 10% by 2035, 15% by 2040 (compared to 2018)*



Packaging and Packaging Waste Reg.- Time line

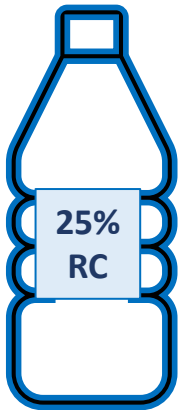


2741 amendments to EC proposal!
337 visits to MEP

Single Use Plastics Directive (EU) 2019/904

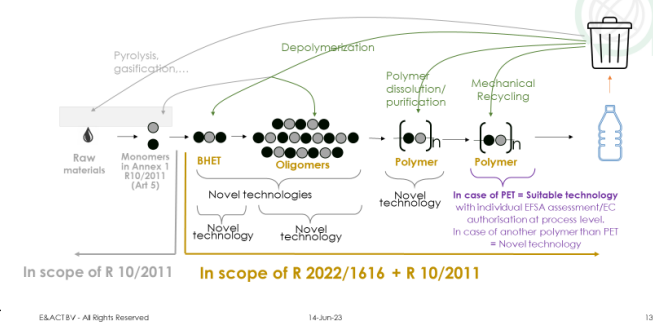


Implementing act on recycled content calculation and verification was due 1 Jan 2022 – EC draft proposal:



- was open for public consultation until 30 May 2023.
- takes only recycled plastic into account that is in the scope of Recycled Plastics Regulation (EU) 2022/1616
- can only include material that has been post-consumer plastic waste before being recycled.
- includes labels and sleeves in the definition of beverage bottle in addition to caps and lids.

Recast recycled plastics regulation R 2022/1616 - SCOPE



This implementing act is to be amended at a later stage to include chemical recycling, appropriate chain of custody, traceability and verification criteria.

Microplastics



Intentionally added microplastics:

- Bans the use of microplastics but exempts certain uses
- Under this restriction, manufacturers and industrial downstream users of synthetic polymer microparticles will have information, labelling and reporting requirements.
- Amendment to the Annex XVII (Restriction) of REACH regulation (EC) No 1907/2006 as regards synthetic polymer microparticles voted on 27 April 2023, now in scrutiny by Parliament and Council (3 months)*.

Non-intentionally added microplastics:

- 22/02/2022-17/05/2022 Consultation. Measures aiming to reduce the presence in the environment of unintentionally released microplastics from tyres, textiles and plastic pellets.
- EC expected to issue (legislative) proposal(s) in 2023.
- **EC indicated a measure on release of “microplastic pellets**” will be proposed before summer break**

** Parliament and Council do not have the power to amend the EC proposal – the most they can do is veto it. If no objection from Parliament or Council, then it will be published on the Official Journal and enter into force (20th day)*

*** in its broad sense*

BPA



TDI of 0.2 ng/kg body weight

Identification of a number of effects in addition to those on the immune system, reproductive and development effects as well as metabolic effects.



Risk management considerations
Scope of restrictions
Transitional period(s)
Effect on supply chain and food safety
Alternatives
Intentional use/unintentional use
(including contamination and BPA in food)

More regulatory activity



✓ ETS – Directive (EU) 2023/959

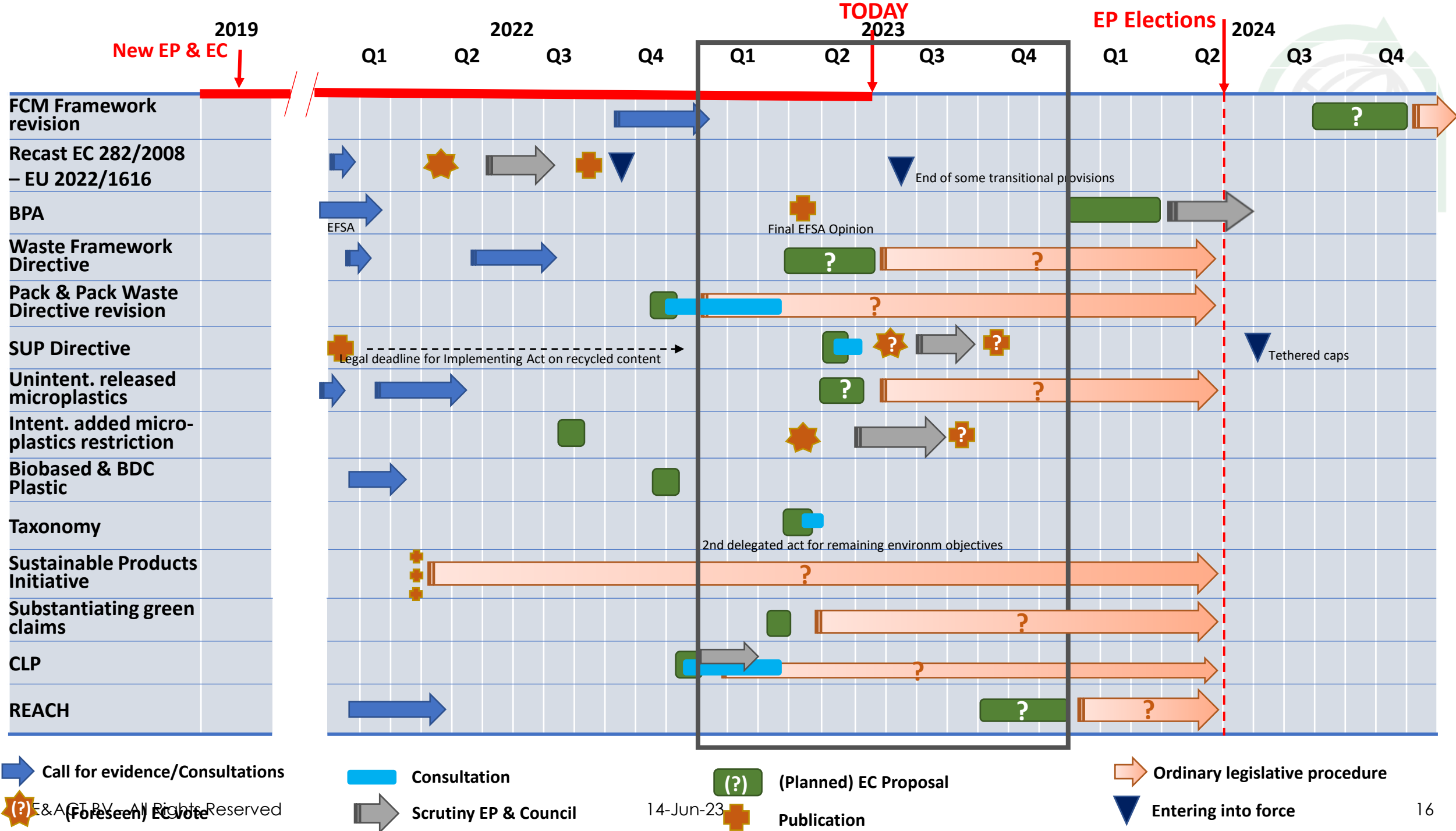
✓ CBAM – Regulation (EU) 2023/956

Taxonomy Environmental Delegated Act Proposal

Waste Shipment proposal: voted in Parliament in Jan 23

Ecodesign Requirements for Sustainable Products

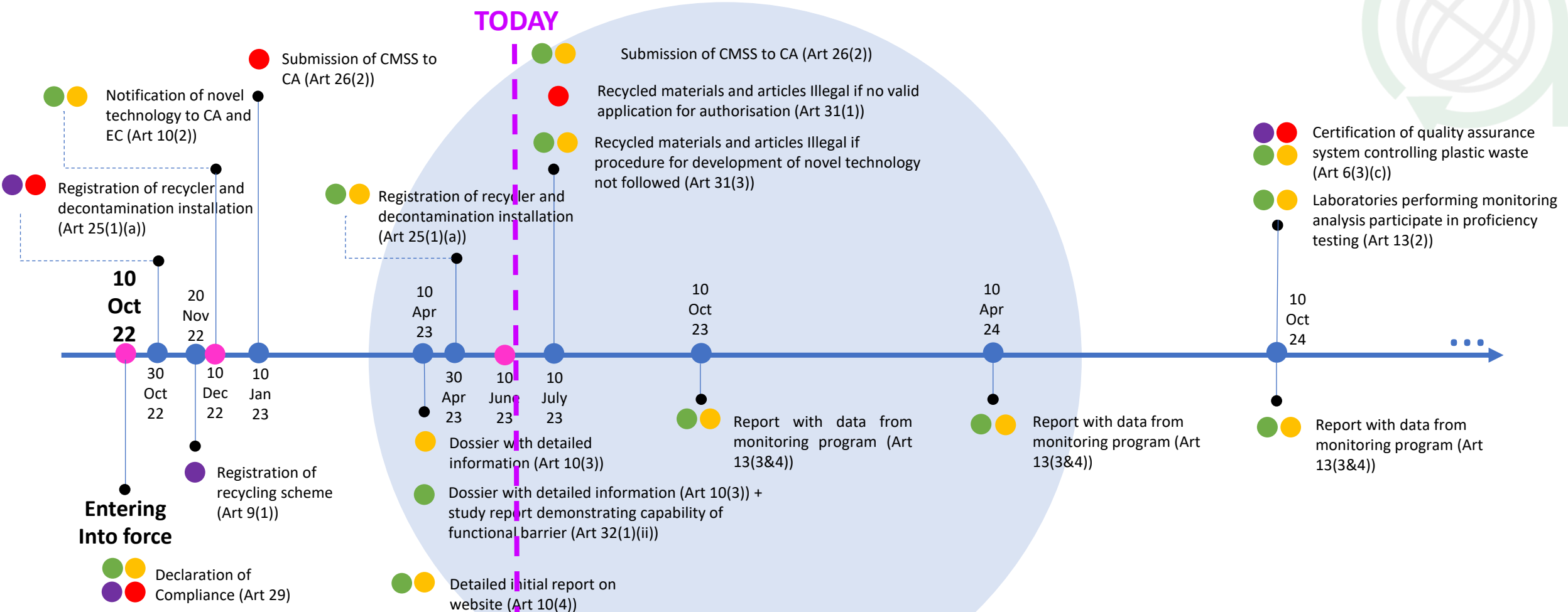
✓ Update of Annex XVII (Restrictions) of REACH





Back up slides

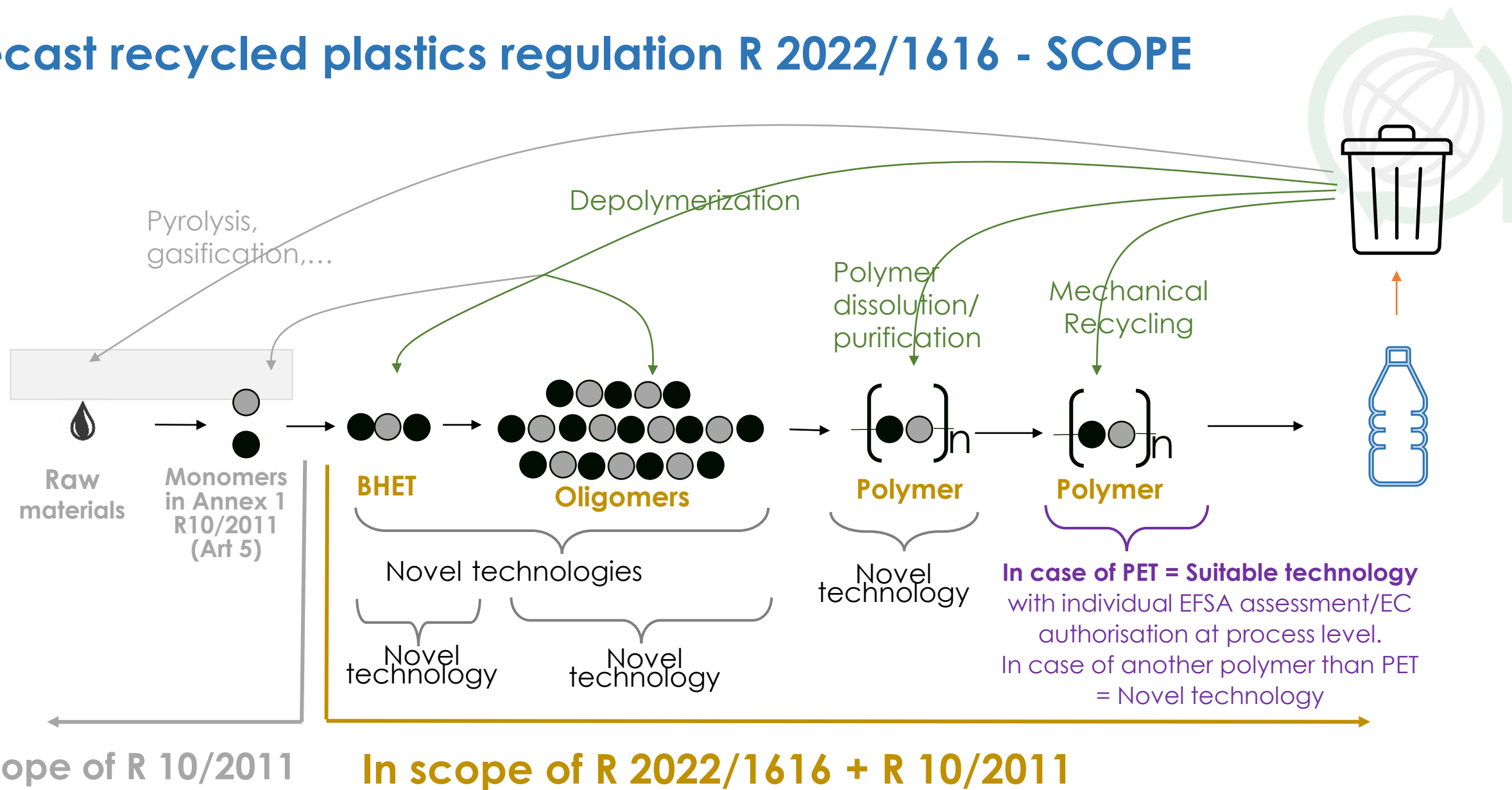
Operation of recycling installations that already manufactured recycled plastic M&A before 10 October 2022 according to regulation (EU) No 2022/1616



- Suitable technologies that require authorisation, already on the market prior to entering into force
- Other suitable technologies already on the market prior to entering into force

- Novel technologies already on the market prior to entering into force
- Novel technologies already on the market prior to entering into force, that use the principle of functional barrier

Recast recycled plastics regulation R 2022/1616 - SCOPE



Revision of the FCM Framework Reg. (EC) No 1935/2004



FCM revision: Main policy themes and pillars

Safety and sustainability

A. Shifting focus onto final material

- Better define level of safety addressing the full characteristics of all final FCM articles including NIAS
- Cluster into broader material types (synthetic, inorganic, natural; recycled, composite, active)

B. Prioritisation of substances

- Define rules for the risk assessment of all (migratable) substances
- Tiered approach:
 - Tier 1: hazard based rules (CMRs, EDs, PBTs and vPvBs)
 - Tier 2: risk assessment by public authorities
 - Tier 3: Self-assessment by operators of more benign substances

C. Supporting safer and more sustainable alternatives

- Ensure fewer hazardous chemicals
- Prioritise more sustainable use of FCM
- Coherence and support to other EU rules on sustainability

Information exchange, compliance and enforcement

D. Improving quality and accessibility of supply chain information

- Clear and consistent rules on data requirements and information transfer throughout the supply chain, including a DoC for all FCMs
- Digitalisation to help businesses, including SMEs to ensure compliance and for Member States to enforce

E. System for verifying compliance

- Delegated bodies under Official Control Regulation 2017/625
- Notified Bodies tasked with conformity assessment

F. Analytical methods

- Migration testing rules
- Analytical Methods (i.e. OCR methods)
- Further development of test methods and technical standards as required
















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Packaging Packaging Waste Regulation



Committee responsible	Rapporteur
 Environment, Public Health and Food Safety	 RIES Frédérique – Shadow rapporteur  SALINI Massimiliano  BURKHARDT Delara  O'SULLIVAN Grace  SARDONE Silvia  FIOCCHI Pietro  PIMENTA LOPES João
Committee for opinion	Rapporteur for opinion
 Agriculture and Rural Development	 DE MEO Salvatore
 Internal Market and Consumer Protection	 JORON Virginie
 Legal Affairs	The committee decided not to give an opinion.
 Industry, Research and Energy	 TOIA Patrizia

More waste-related



L 130/134

EN

Official Journal of the European Union

16.5.2023

DIRECTIVE (EU) 2023/959 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 10 May 2023

amending Directive 2003/87/EC establishing a system for greenhouse gas emission allowance trading within the Union and Decision (EU) 2015/1814 concerning the establishment and operation of a market stability reserve for the Union greenhouse gas emission trading system

ETS

L 130/52

EN

Official Journal of the European Union

16.5.2023

REGULATION (EU) 2023/956 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 10 May 2023

establishing a carbon border adjustment mechanism

(Text with EEA relevance)

CBAM



Taxonomy



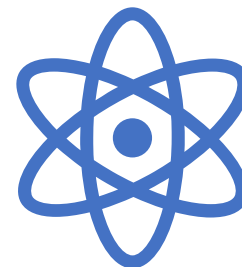
- Delegated Act 'Taxonomy Environmental Delegated Act' – draft published on 5.04.2023
- Delegated Act amending the Taxonomy Climate Delegated Act EU 2021/2129 – draft published 5.04.2023
- Consultation closed on **3 May 2023**
- Next steps:
 - EC to decide (based on feedback from the consultation) whether to make any changes to the two drafts and to adopt the two Delegated Acts.
 - Adopted Delegated Acts to be scrutinized by Parliament and Council (4 months + 2)*.
 - If no objection from Parliament or Council, then the Delegated Acts will be published on the OJ and apply from 1 January 2024.

**Parliament and Council do not have the power to amend the Delegated Acts – the most they can do is veto it.*

Substances added to Annex XVII of REACH



Adopted by EC on 8 June 2023, will be submitted to scrutiny by Parliament and Council*.



Several substances added amongst them:

Cumene,

Benzophenone,

Dibutyltin bis(2-ethylhexanoate),

Dibutyltin di(acetate),

2,4,6-tri-tert-butylphenol,

Tributyltin compounds, except those specified elsewhere in Annex VI to Regulation (EC) No 1272/2008

** Parliament and Council do not have the power to amend the EC proposal – the most they can do is veto it. If no objection from Parliament or Council, then it will be published on the Official Journal and enter into force (20th day)*