

#### Objective of this event

- This event:
  - Concerns changes to existing legislation under Regulation (EC) No 1935/2004
  - It is intended to provide stakeholders with information
    - to ensure general understand and avoid confusion
    - · to anticipate on what the future may bring
    - · to inform on what you can expect the next few months
    - · to prepare your possible positions
  - It will allow participants to ask questions
- This event does not:
  - Discuss the upcoming revision of Regulation (EC) No 1935/2004
  - · Give an authoritative interpretation of EU law, or a definite view on new legislation
  - Provide you with a venue to express your opinions

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#### The Revision of Regulation (EC) No 1935/2004

- The Revision will lead to a possible re-think of how we Regulate FCM
- It may introduce a new system
  - · focus to shift to final manufactures of material and articles
  - · prioritisation of risk assessment, only hazardous substances assessed by authorities
  - better approach to transfer of information, higher level of transparency
  - more prominent role for good manufacturing practices
  - · regrouping (and simplification) of materials
  - · rethinking of verification of compliance, laboratory methods
- Potential additional objective: sustainable FCM (next to safety + market)
- . BUT: not todays objective

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## General Disclaimer This event does not...

- · Provide you with the official position of the European Commission
  - It takes place at a technical level to facilitate understanding and discussion
  - it does not commit the European Commission
- Provide you with an authoritative interpretation of EU law
  - It is the responsibility of the Member States to enforce EU legislation
  - Only the Court of Justice of the EU is competent to authoritatively interpret Union Law
- Provide you with a definite view on the legislation being discussed
  - · The legislative texts that are being discussed may be subject to change
  - For instance, the outcome of this event may lead to changes
  - Any discussed provisions should not at any time be used to determine compliance of present FCMs
  - · However, note the acts being discussed are at a different stage;
    - the BPA text is endorsed by the Member States, the QA text is being developed, on recycling we are at different stages

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## General Disclaimer It also does not...

- Provide you with definite timelines or approaches from the Commission services
  - · Resources are scarce, problems, priorities and positions may change
- Constitute an official step in any procedure towards the adoption of new legislation
  - It provides the Commission services with an additional but informal consultation with stakeholders
  - It is held because of several changes occurring in parallel, noting possible confusion over the state of play – therefore it is for your and our information
- Commit the Commission services to take note of positions expressed by participants
  - but we will of course listen very well to ensure we avoid burden where measures would not be needed to support a high level of food safety

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#### Agenda

09h20: This introduction

09h30: Session I: Discussion new Regulation on BPA

10h45: Session II: Discussion on Quality Amendment Regulation (EU) No 10/2011 ('QA')

12h00: Session III: Discussion on State of play recycling

- · authorisations, register, amendments
- Each session consists of 30 min. presentation, 30 min. Q&A, 15 min. break
  - priority will be given to participants in the room, on-line participants ask questions in the chat. Simple
    questions will be answered directly, for complex questions we may give you the floor.
- · The event is NOT being recorded, and please do not record it
- · This presentation will be made available directly after the event

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#### Lastly

- As said, expressing only your position distracts from the objectives of the event
- However, constructive criticism is very welcome:
  - · describe the context of the problem you may experience
  - · describe the impact to your operations
  - describe potential other solutions that afford the same level of health protection
- We give priority to questions in the room mostly for practical purposes
  - Introduce yourselves be brief, be clear limit yourselves to one question
  - · One intervention per session per participant, unless time allows for more
  - · raise your hand on-line to ask a question (we will not use the chat)
- e-mail follow up will be handled but it will be limited by our resources
  - use sante-fcm@ec.europa.eu

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## 09h30: Session I: Discussion new Regulation on BPA

EU ban on the use of bisphenol A (BPA) in food contact materials



#### Background: EFSA opinion on BPA

- Published 19 April 2023
- Based on all new scientific evidence assessed, EFSA established a TDI of 0.2 nanograms/kg of body weight (previous temporary TDI → 4 μg/kg bw)
- EFSA concluded that consumers with both average and high exposure to BPA in all age groups exceeded the new TDI, indicating health concerns
  - ➤ TDI → estimate of level of substance which can be consumed over a lifetime without presenting an appreciable risk to health
  - > Above this does not necessarily equate to an immediate risk but indicates a need to act to ensure consumer protection
- EFSA noted that a similar dose range also caused adverse effects for reproductive and developmental toxicity and for metabolic effects, which are therefore also relevant for human health

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#### Background: consultation on follow-up

- Intention to ban BPA announced May 2023
- Stakeholder webinar July 2023 + Q&A
- Discussions with Member States end 2023 June 2024
- · Dialogue with stakeholders throughout
- Four-week public feedback period February March 2024

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#### New EU measure: Article 3 and 4; Article 10

 Bans use of BPA and its salts [as a monomer or other starting substance] in the manufacture of FCM

>plastic >rubbers

➤varnishes and coatings
➤ion-exchange resins

➢inks
➢ silicones

▶adhesives

- Removes authorisation of BPA in FCM plastic from Commission Regulation (EU) No 10/2011
- FCMs manufactured using other bisphenols or derivatives e.g. BADGE must not contain residual BPA from the manufacturing process

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#### Derogations: Article 3, 7 and annex II

- Two derogations for the use of BPA as a monomer or other starting substance:
  - > Epoxy resins for large tanks and vats above 1000 litres
  - ➤ Polysulfone plastic for filtration devices
- Articles should be cleaned and flushed prior to use
- No detectable migration permitted
  - To be verified with an analytical method with a level of detection (LOD) of 1 μg/kg
- Subject to a review to determine if derogations are still needed every 5 years

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#### Ban on other bisphenols: Article 5; Article 10

- Bans use of other bisphenols and derivatives subject to harmonised classification as CMR category 1A or 1B in the manufacture of FCM
  - ➤ bisphenol S (BPS)
  - ≥ 2,2-bis(4'-hydroxyphenyl)-4-methylpentane
  - ➤ bisphenol F (BPAF)
- Unless for a specific FCM application that does not present a risk
- Possible applications foreseen after EFSA, in consultation with ECHA, has informed on the information necessary for assessing the risk (max 2 years after the Regulation takes effect)

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#### Application for use of other bisphenols: Article 5 and 6

- As of the date EFSA updates its guidelines or otherwise informs on the information necessary, applications for FCM articles already on the market at that point should be made within 9 months
- Use of other bisphenols that are also subject to the relevant harmonised classification in the future will also need to be assessed
- Business operators will need to provide information to EFSA on current uses of bisphenols and derivatives to support EFSA's work on developing risk assessment guidelines

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#### Compliance: Articles 8 and 9 + annex III

- DoC sets out information necessary for all businesses in the supply chain, except at point of sale
- Supporting Documentation to Competent Authorities on demand
- Testing methods when used in accordance with rules in Regulation (EU) 2017/625 on official controls
- EURL to assist in development of suitable methods, including extraction methods
- Where relevant rules for expression of results and migration testing in accordance with Regulation (EU) No 10/2011

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#### Transitional periods for packaging: Article 11

- A fixed transition period of 18 months is foreseen for the placing on the market of affected single use final food contact articles from the date of entry into force of the measure
- · Exceptionally 36-month transitional period
  - > Canned fish and fruit and vegetables
  - > Exterior of cans
- In practice, this means mainly the finished production of empty cans
- A further 12-months is allowed for filling with food
- Thereafter, no withdrawal of packaged food already placed on the market

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#### Transitional periods for repeat use FCM: Article 12

- A fixed transition period of 18 months is foreseen for the first placing on the market of affected repeat use final food contact articles from the date of entry into force of the measure
- Exceptionally 36-month transitional period
   Professional food production equipment
- A further 12-months is allowed for remaining on the market in order for manufacturers to sell to food businesses or for retail to sell to consumers
- Thereafter, no withdrawal of the articles used by food businesses

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#### Estimated remaining timeline

- Transmission to EP and Council for 3-month scrutiny
- Adoption by the Commission November this year
- Entry into force by the end of the year

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Questions start at 11:15, with priority on questions from participants in the room



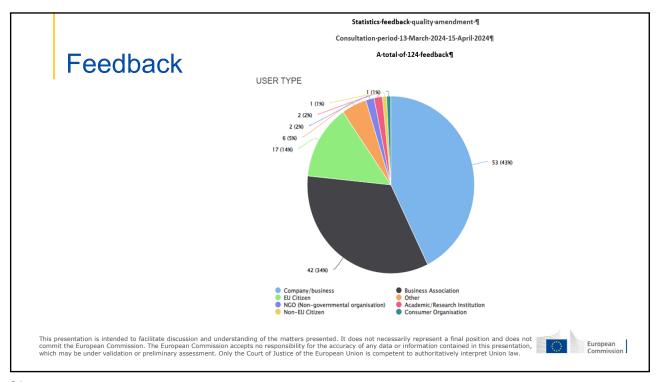
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#### Time-line

- Have your say: deadline 15 April 2024
- SPS deadline 24 May 2024; TBT deadline 8 June 2024
- Information event 14 June 2024
- PAFF 20 September 2024
- Scrutiny EP and Council

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#### Main points raised in feedback

- High purity requirement for substances
   + need to transmit information on substances in the supply chain
- 2. Substances of natural origin
- 3. Lifespan
- 4. Migration testing for multi-material multi-layer materials
- 5. Surface to volume ratio small containers

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#### High degree of purity Article 3a

- Article 3a: Amending the points iii) and iv): substance present in final plastic material, considering the impact of the
  - characteristics of the substance
  - manufacturing process and the (iii) they have been subject to an toxicological assessment in accordance with the relevant guidance adopted by the Authority, which concludes that genotoxicity is ruled out, and which concludes on the basis of documented analysis concerning their foreseeable use, characteristics and fate during subsequent manufacturing stages, that it can be reasonably assumed that they are present at a level in the final plastic material that cannot give rise to a migration resulting in their individual presence in food exceeding 0.05 mg/kg;
    - (iv) they have not been subject to an assessment specified in points (ii) or (iii), but to a risk assessment which concludes on the basis of documented analysis concerning their foreseeable use, characteristics and fate during subsequent manufacturing stages, that it can be reasonably assumed that they cannot be present at a level in the final plastic material that can give rise to a migration into food resulting in their individual presence in food exceeding 0.00015 mg/kg.

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#### High degree of purity Article 3a

- Article 8(1): revised text referring to 'final plastic material'
- Article 8(3): supporting documentation shall show compliance with high purity requirement

Current text in Plastics Regulation

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.

'Article-8← General requirements on substances ¶

 Substances used in the manufacture of plastic materials and articles that may be present in the final plastic material, including those manufactured from waste, shall be of a high degree of purity and shall be of a technical quality 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, together with any documentation regarding their degree of purity.¶

3. → Manufacturers of plastic materials and articles, and of products from intermediate stages of their manufacturing, shall ensure that documentation showing compliance with paragraphs 1 to 2 is part of the documentation referred to in Article 16.¶

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#### High degree of purity Article 3a

Link to Declaration of compliance in Article 15 and Annex IV

Current text in Plastics Regulation

- (5) confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet the relevant requirements laid down in this Regulation and in Article 3, 11(5), 15 and 17 of Regulation (EC) No 1935/2004;
- (6) adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annex I and II to the Regulation to allow the downstream business operators to ensure compliance with the Regulation.

At intermediate stages, this information shall include the identification and amount of substances in the intermediate material,

- that are subject to restrictions in Annex II, or
- for which genotoxicity has not been ruled out, and which originate from an intentional use during a manufacturing stage of that intermediate material and which could be present in an amount that foreseeably gives rise to a migration from the final material exceeding 0,00015 mg/kg food or food simulant:

Annex-IV-is-amended-as-follows: ¶

(a)  $\rightarrow$  point 6 is replaced by the following:¶

6. → adequate information relative to the substances used including nonintentionally added substances that are present for which restrictions and/or specifications are set out in Annexes I and II to allow the downstream business operators to ensure compliance with the Regulation, including adequate information on the presence of nonintentionally added substances if present in an amount that could cause non-compliance of a final material with Article 3 of Regulation (EC) No. 1935/2004. ¶

At intermediate stages, this information shall include the identification and amount of the substances in the intermediate material,¶

- → that are subject to restrictions and/or specifications Annex II, or ¶
- > for which genotoxicity has not been ruled out, and which originate from an intentional use during a manufacturing stage of that intermediate <u>material</u> and which could be present in an amount that foreseeably gives rise to an individual migration into food from the final plastic material or article exceeding 0,00015 mg/kg food or food simulant, ","

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#### High degree of purity Article 3a

 Amendment of Recycling Regulation: the purity requirement in Article 8(1) does not apply to input and output of decontamination process

Article-2¶

Amendment-to-Regulation-(EC)-No-2022/1616¶

٩

Article 4, paragraph 2 of Regulation (EC) No 2022/1616 is replaced by the following: ¶

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'2. The requirements set out in Chapters II and III and Chapter V of Regulation (EU) No 10/2011 shall apply to recycled plastic materials and articles. By derogation from Article 8(1) thereof, the quality and purity of plastic input and the output of a decontamination processes shall be in accordance with this Regulation.'

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#### Substances of natural origin

 Article 8(2): addressing purity requirement for substances where the source is biological or mineral

#### *`Article-8↔* General requirements on substances¶

2. → By derogation from paragraph 1, as regards purity, for UVCB substances that are identified by a name in this Regulation that refers to a natural multiconstituent material where the source is biological or mineral, that substance may be used as obtained from its natural origin, provided it does not contain substances or materials that do not correspond to its identity as designated by that name. Any additional specifications or requirements applicable to a substance or material of natural origin set out in Table 1 of Annex I, applicable to the substance or material, shall apply.

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#### Lifespan

- References to lifespan are removed in Article 10(3), Article 14a(1) and point 8 of Annex IV (DoC)
- Article 10(3) has been simplified and now reads as follows:
- 3. Where intended for repeated use in contact with food, the composition of and the design of final food contact articles shall be such, so as to guarantee that no increase in the migration of constituents of the material or article to the food would occur when subjected to subsequent use cycles of the materials and articles in accordance with the instructions for intended use as described in documentation or labelling.

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#### Migration testing and multi-material multilayer materials

 SMLs and OML apply only if a plastic layer in direct contact with food; Article 11

Specific migration limits

1. Plastic materials and articles shall not transfer their constituents to foods in quantities exceeding the specific migration limits (SML) set out in Annex I. Those specific migration limits (SML) are expressed in mg of substance per kg of food (mg/kg).

- Note this includes coated plastics
- (16) In Article 14, paragraph 4 is replaced by the following:
- '4. Articles 11 and 12 apply to multi-material multi-layer materials and articles when the surface layer that is in contact with food is made of a material falling within the scope of this Regulation.'

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#### Fixed surface to volume ratio

- It was proposed to amend 17(2)(a) on containers and other articles with less than 500 millilitres or grams or more than 10 litres
  - Reason there is a lot of smaller packaging (including if used also for children) for which 500 ml cut-off in 17(2) is considered not sufficiently protective
- Following feedback the derogations in Article 17(2) revised: 12 dm<sup>2</sup> new norm
  - · Some simplification in the wording, and 'may' instead of 'shall'
- Further revisions are possible in future
  - · (scientific) justification of 17(2) is missing
  - · likely to be considered under the revision, taking account of all materials

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#### Fixed surface to volume ratio

#### Article 17

#### Expression of migration test results

 To check the compliance, the specific migration values shall be expressed in mg/kg applying the real surface to volume ratio in actual or foreseen use.

2. By derogation from paragraph 1 for:

Article 17(2) is replaced with the following:

- (a) containers and other articles, containing or intended to contain, less than 500 millilitres or grams or more than 10 litres.
- '2. By derogation from paragraph 1 for:
- (b) materials and articles for which, due to their form it is impracticable to estimate the relationship between the surface area of such
- (a) containers and other articles of a volume of less than 100 ml, a surface to volume ratio of 12 dm² per kg of food may be applied,
- materials or articles and the quantity of food in contact therewith,
- (b) a material or article for which, due to their form it is impracticable to estimate the relationship between the surface area of such materials or articles and the quantity of food in contact therewith, a surface to volume ratio of 12 dm² per kg of food may be applied,
- (c) sheets and films that are not yet in contact with food,
- (c) sheets and films that are not yet in contact with food, a surface to volume ratio of 12dm² per kg of food may be applied.
- (d) sheets and films containing less than 500 millilitres or grams or more than 10 litres.

This paragraph does not apply to plastic materials and articles intended to be brought into contact with or already in contact with food for infants and young children, as defined by Directives 2006/141/EC and 2006/125/EC.'

the value of migration shall be expressed in mg/kg applying a surface to volume ratio of  $6 \text{ dm}^2$  per kg of food.

12 dm² is S/V of a can of 100 ml of which height=diameter

Please don't take

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# 12h00: Session III: Discussion on State of play recycling

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Questions start at 12:30, with priority on questions from participants in the room



#### **Subjects**

- Authorisation of the mechanical PET recycling process Authorisation Decisions
- 2. FCM Webpage: Recycling of plastic intended for contact with food <u>Plastic Recycling European Commission (europa.eu)</u>
- 3. Union register of novel technologies, recyclers, recycling processes, recycling schemes and decontamination installations (Article 24)
- 4. Amendments to Regulation (EU) No 2022/1616

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## Recycling

 Authorisation of the mechanical PET recycling process – Authorisation Decisions

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#### 1: Authorisation of the mechanical PET recycling process

Authorisation Decisions

**Year 2024** 

- Objective: Authorisation of approx. 350 mechanical PET processes
- Preparatory work: the Commission and the Member States, Applicants
  - the Commission consulted the applicants in order to renew their data
    - Batch 1 RECYC001 to RECYC260 under production
    - Batch 2 RECYC260 to RECYC...(to follow)
  - · the Commission prepares the draft Decisions
  - · the Member States check the draft Decisions
- · Final Step:
  - Commission finalised the Decisions and placing for vote (summer 2024)
  - · Authorisation Decisions to be adopted and shared with the applicants
  - RAN numbers to be displayed in the Register

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- 1: Authorisation of the mechanical PET recycling process
- Authorisation Decisions

Next step

- Objective: Authorisation of approx. 350 mechanical PET processes
- Preparatory work: the Commission and the Member States, Applicants
  - · the Commission will consult the applicants in order to renew their data
    - Batch 1 RECYC001 to RECYC260 under production + the ones not included under Batch 1
    - Batch 2 RECYC260 to RECYC...(to follow)
- Next Step:
  - the Commission prepares the draft Decisions Year 2024 2025
  - the Member States check the draft Decisions Year 2024 2025

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## Recycling

2. FCM Webpage: Recycling of plastic intended for contact with food <u>Plastic Recycling - European Commission</u> (europa.eu)

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## 2: FCM Webpage: Recycling of plastic intended for contact with food

- Plastic Recycling European Commission (europa.eu)
- Structure
  - · Recycling of plastic intended for contact with food
    - · Legislation
    - Terminology
  - Union register of novel technologies, recyclers, recycling processes, recycling schemes and decontamination installations
    - · Food and Feed Information Portal.
    - · RIN, RON & RFN available codes
    - · RAN, RSN & NTN pending
  - Competent authorities
  - Useful information, related links & questions & answers for applicants

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#### Register: Entities and unique numbers

Art 24 describes of 2022/1616 the general rules to be included in the Register:

- √3. The Register shall assign the following entities with unique numbers:
- recyclers are assigned a recycler operator number ('RON');
- decontamination installations are assigned a recycling installation number ('RIN');
- recycling facilities are assigned a recycling facility number ('RFN');
- recycling schemes are assigned a recycling scheme number ('RSN');
- authorised recycling processes are assigned a recycling authorisation number ('RAN');
- novel recycling technologies are assigned a novel technology number ('NTN').

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## 2: FCM Webpage: Recycling Schemes and Novel technology

#### 1. Recycling Schemes

- E-mail concerning the data verification sent to the scheme managers (Monday 11th June);
- ➤ Recycling Scheme should always be linked with a recycling installation, recycling facility and a company (Form 1-4);
- ➤ **Person in charge:** There should only be one scheme manager (Reg 2022/1616 (20) & Art. 9.1. only one entity should be responsible for managing its overall functioning and it should be responsible to provide all participating operators with binding directions);

#### 2. Novel Technology

- Verification and evaluation to follow between the COM and competent authorities (during the summer);
- Novel technology should always be linked with a recycling installation, recycling facility and a company (Form 1-4);
- ➤ **Person in charge:** The technology developer that notified the novel technology used by the process which the installation applies, in accordance with Article 10(2);

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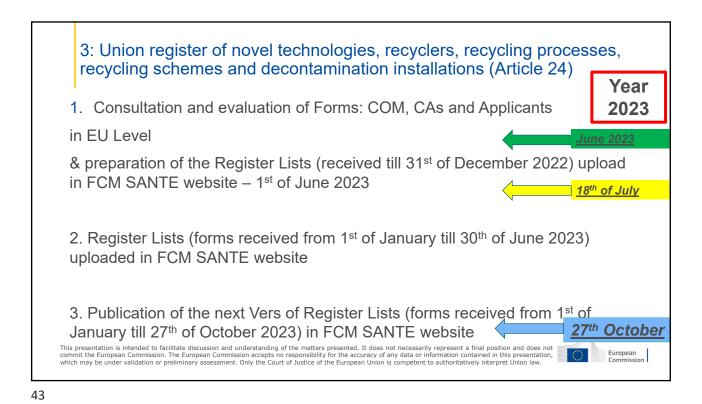
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## Recycling

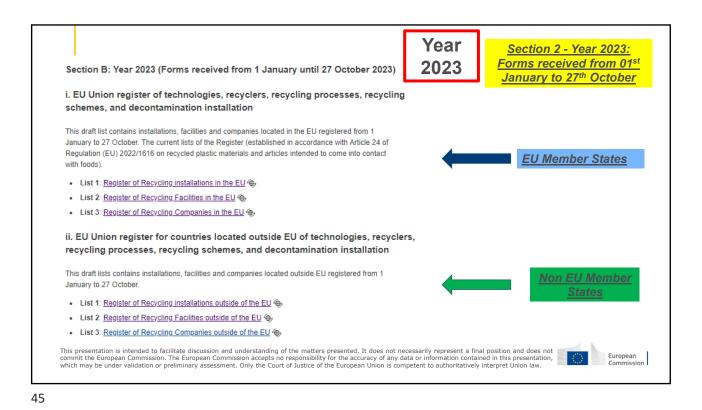
3. Union register of novel technologies, recyclers, recycling processes, recycling schemes and decontamination installations (Article 24)

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Year Last vers: 2023 27th of October 2. The Union Register Section A: Year 2022 (Forms received until 31 December 2022) Section 1 - Year 2022: i. EU Union register of technologies, recyclers, recycling processes, recycling Forms received by 31st schemes, and decontamination installation **December** This draft list contains installations, facilities and companies located in the EU registered before 31 December 2022. The current lists of the Register (established in accordance with Article 24 of Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with foods) will be updated in regular basis. List 1: Register of Recycling installations in the EU [EN | ••• **EU Member States** . List 2: Register of Recycling Facilities in the EU (EN | ... List 3: Register of Recycling Companies in the EU (EN | ●●● ii. EU Union register for countries located outside EU of technologies, recyclers, recycling processes, recycling schemes, and decontamination installation This draft lists contains installations, facilities and companies located outside EU registered before 31 December 2022. The current lists will be updated in regular basis List 1: Register of Recycling installations outside of the EU [EN] | ... European Commission List 2: Register of Recycling Facilities outside of the EU (EN | ••• List 3: Register of Recycling Companies outside of the EU





Year 2024

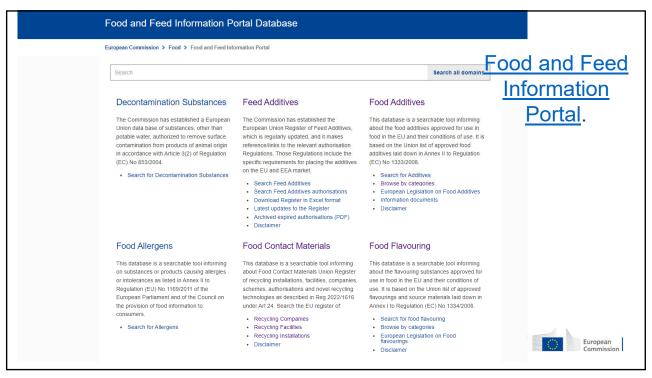
FFSPM- Food and Feed Information Portal Database

Main assets of the online database:

- 1. Access to all the parties involved (COM & CAs, Companies & Public) -Year 2024
- 2. Register Lists online
- 3. Documents in the portal
  - 1. Forms
  - 2. Guidance documents
  - 3. Legislation
- 4. Ability to revise the data in real time
  - 1. COM
  - 2. COM & CAs
  - 3. Applicants

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## Recycling

4. Possible Amendments to Regulation (EU) 2022/1616

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## Possible Amendments to Regulation (EU) 2022/1616

- Since 2022 we gained experience with the implementation of the Regulation
- · To take into account
  - drafting mistakes particularly certain references in Chapter IV are incorrect (example below)
  - · matters that are not entirely functioning as intended
  - · deadlines that cannot be met
  - · new matters that came up, e.g. large-scale use of 100% recycled material possibly from imports
- The work has been postponed due to present lack of resources
  - a decision will be taken over summer when and how to move ahead

Article 10(8):

8. A competent authority that was notified in accordance with paragraph 2 shall verify within 5 months from the notification whether the requirements set out in paragraphs 1 to 7 are met, and verify the requirements forthcoming from paragraph regularly thereafter.

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#### Suspension of recycling installations

- The Regulation results in automatic suspension of recycling installations when competent authorities did not audit and agree compliance of a new installation within a year
- Competent authorities (including in 3<sup>rd</sup> countries) cannot make this deadline
  - · Status of recycling installations not yet implemented in the register
  - · implementation happen following a consultation with the competent authorities
  - estimate: Q4/Q1
- Conversely, some operators want a suspension of their recycling installation in times when it is not possible to operate them economically.
  - a procedure is being considered and may be laid down in the Regulation

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#### Declaration of compliance

- Article 5(2)
  - · 'Recycled plastic placed on the market shall be accompanied by a declaration of compliance in accordance with Article 29'.
  - · This should not only refer to recycled plastic, but also to recycled plastic materials and articles - which are the final products.
  - · Inconsistent with Article 29(3) which states that converters (who manufacture the final material) shall provide the DoC
  - · It undermines the objective to achieve full traceability.
- It questions to what stage in the supply chain the DoC needs to be provided
- present thinking:
  - · operators packing food should receive it, retailers not
  - · when no further mixing occurs, batch-based declarations are not necessary simple version
- In addition: supporting documentation to be made available to competent authorities

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#### Improving certainty over input quality



#### Poor input quality = poor output quality

Establish third party certification of quality assurance systems

- collaborate with stakeholders on what is needed, including in the Regulation
- laying down essential elements of a standard that would need to be used for certification in the Regulation

Consider certification of collected and pre-processed plastic waste

- possible amendment to Regulation (EU) 2022/1616
- certificate may include the origin (EU/non-EU), and mode of collection (DRS, PCW, ...)
- adding a certification / DoC requirement to the Regulation

#### Establish TARIC codes

- increase visibility of specific imported plastic waste
- · collaboration with DG Environment

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## Thank you

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