



# Expert Working Group of the PAFF Food Contact Materials

22 March 2024

SANTE.E.2

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## Agenda

- Exchange on a draft text banning the use of Bisphenol A in FCMs
- Exchange on a draft text amending Regulations (EU) No 10/2011 and (EC) No 2023/2006
- Explanation authorisation Decisions under Article 19 of Regulation (EU) 2022/1616
- AoB?

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# Bisphenol A (BPA) in FCM

Draft Commission Regulation

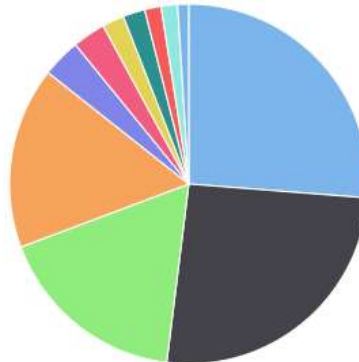
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## Four-week public feedback

- From 9 February until 8 March 2024
- Valid feedback received → 202 (6 Member States)



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## Issues raised by Member States

- BPA as a pre-cursor substance and control of BPA used to make BADGE
- How to enforce compliance including the LoD
- “Use” v “intentional use”
- Derogations concerning BADGE and PSU
- Submission of applications for other bisphenols
- Many questions and need for clarification on monitoring
- Status of food contact articles used in food processing once installed
- [Extended] transitional periods

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## Similar issues raised by stakeholders

- Epoxy derivatives are based on different bisphenols and bisphenol derivatives and technologies – what are BADGE derivatives?
  - BADGE based coatings, vinyl ester resins, adhesives (e.g. glass filaments to polymer in glass fibre, between plastic layers in flexible packaging), inks
- Analytical detection limit
- “Use” v “intentional use”
- Many questions and need for clarification on monitoring
- Status of food contact articles used in food processing once installed

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## Other main issues raised by stakeholders

- Impossible to eliminate all potential traces of BPA in all products
- Scope of derogation
  - other low migrating food processing equipment (PC)
  - drums < 250l
- Use of BPA to manufacture PSU
- Use of BPA behind a functional barrier
- Longer transitional periods for other FCM articles
- Scope of bisphenol derivatives

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## Use of BPA as a precursor chemical

- Intention: to ban BPA in the use of the manufacture of FCM except in cases where it is first converted to 'BADGE' for use in heavy-duty applications with a low SA/V ration and niche use in PSU filters with short contact time
- BADGE may contain oligomers, which should be part of the risk assessment
- Otherwise all BPA molecule should be reacted and not remain in the epoxy resin
- Wording to be clarified – BPA only to be used for these purposes in FCM
- Linked to need for an analytical LoD to confirm compliance

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## Checking for compliance

- DoC and moreover supporting documentation should demonstrate
  - Migration or QM results
  - Mathematical modelling
  - Other reasoning
- For physical sampling and analysis:
  1. QM value in the PSU or liquid BADGE
  2. Third migration test
    - test sample for BADGE, corrected for surface area/ volume ratio
    - based on the actual residence time for PSU filters
  3. BPA content following rinsing steps (third rinse)
- Achievable LoD appears to be 0.001mg/ kg (1ppb)

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## “Intentional use”

- Use is intentional by definition – “unintentional use”?
- No such distinction exists in current EU FCM legislation
- May be used intentionally at a manufacturing stage but it is not intentionally present in the final FCM → this can therefore be prevented
- Other sources of BPA need to be investigated (input waste stream for recycling, third country food manufacturing equipment, environmental contamination)

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## Monitoring

- Questions and need for clarification:
  - Test methods to use
  - Lack of clarity on who is responsible for what – also imported FCMs
  - Action level and what action to take
  - Monitoring already undertaken in accordance with BfR Recommendation XXXVI
  - Other bisphenols
  - Types of food – also dry, non-fatty food
  - Also recycled plastic
  - Question of monitoring of food and request for Recommendation or further guidance

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## Derogations

- MS – some concerns expressed on derogations
- Industry – want derogations extended for certain FCM articles
- Derogations are very limited and have been considered on the basis of
  - Information provided by stakeholders including reasoning on migration of BPA
  - Role that the FCM plays in the food supply chain
  - Availability of alternatives
  - Costs and impacts that may be disproportionate
- General consideration on low migration/ negligible contribution articles that are significantly problematic to replace, otherwise a ban = a ban
- Other requirements e.g. reporting obligations on alternatives

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## Use of BPA in polysulfone resins

- Condensation reaction of the disodium salt of bisphenol A (BPA) with 4,4-dichlorodiphenyl sulfone (EC No 201-247-9, CAS No 80-07-9)
- However, salts of BPA are only intermediate and BPA is still needed
- Possible solution to regulate bisphenols under one Regulation only
  - Derogate bisphenols from Regulation 10/2011, BPA no longer authorised for use
  - New Regulation that bans BPA and other bisphenols except for certain uses for which restrictions apply
  - Would also include BPS and BPAF
- Application process as per Articles 8 – 12 with EFSA note for guidance. To see if adaptation needed but current scope very narrow (BPS in coatings?)

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## FCMs once on market/ transitional periods

- Balance between need to remove FCM from which BPA migrates and practicality for wide-range of difference FCM (packaging, repeat use kitchenware, professional food production equipment [fixed and non-fixed, small-scale and large-scale])
- “Placing on the market” is defined in Article 2(1)(b) of Reg. 1935/2004:
  - “the holding of materials and articles for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves”
  - “first placed on the market” concept for “exhaustion of stock” i.e. can remain on the market
  - Concerns intermediate food contact materials as well as final articles insofar as they are subject to EU rules
  - Necessary to define which FCM for transitional provisions → final food contact articles

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## Transitional provisions

- Clear and justified transitional periods for [mostly metal coated] packaging
  - Must be filled within 12 months
  - Thereafter use-by of BBE dates apply regardless of whether for sale or sold to consumers
- Clarification needed for other types of FCM (repeat-use)
- Kitchenware and tableware (e.g. flasks, re-usable drink bottles, containers)
  - Not appropriate that these remain on the market indefinitely (until exhaustion of stocks)
- repeat-use final articles used in professional food production equipment
  - Fixed equipment such as valves, closures, flanges, seals, gauges and sight glasses)
  - Non-fixed equipment including moulding trays

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## Next steps

- Draft measure to be updated to reflect today's discussions and other pertinent comments from feedback
- Distribution of updated text to MSs in advance of PAFF
- Notification to WTO (TBT)
- Vote foreseen PAFF 24 April 2024
- Transmission to EP and Council from 10 July

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# Amendments to Regulation (EU) No 10/2011 on plastic FCM and Regulation (EC) No 2023/2006 on GMP

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## Time-line

- Have your say: deadline 15 April 2024
- PAFF 12 June 2024
- European election recess until 10 July 2024
- Scrutiny EP and Council
- Adoption 2024

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**Article 2**  
**Scope**

*Article 1<sup>4</sup>*  
*Amendments to Regulation (EU) No 10/2011<sup>¶</sup>*

(1) → Article 2, paragraph 3 is replaced by the following:<sup>¶</sup>


‘3 → This Regulation shall be without prejudice to the Union or national provisions applicable to printing inks, adhesives or coating on substances that may be used in the manufacture of adhesives, coatings and printing inks and applied on or incorporated in plastic materials and articles, if that use complies with Article 3 of Regulation (EC) No 1935/2004.’<sup>¶</sup>

Clarification of the article that it concerns the compositional requirements (in previous version included in Article 6(6), migration rules apply for surface layer in contact with food (point 15, Article 14(4))

The previous version is below

402	6. → By way of derogation from Article 5, any substance may be used in the
403	manufacture of adhesives, coatings and printing inks and applied on or
404	incorporated in plastic materials and articles, if that use complies with
405	Article 3 of Regulation (EC) No 1935/2004 and, where applicable, with
406	specific measures and national law applicable to adhesives, coatings and
407	printing inks.’ <sup>¶</sup>

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**Article 3**  
**Definitions**

(1) → Point (7) is replaced by the following:<sup>¶</sup>

‘(7) → ‘additive’ means a substance or material which is intentionally added to the plastic to achieve a physical or chemical effect during processing of the plastic or in the final material or article and it is intended to be present in the final material or article, including substances or materials in a solid state that become bonded to the polymer that constitute the plastic.’<sup>¶</sup>

This provision has not changed in its essence

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330 (1) → Article 3 is amended as follows: ¶

(2) → The following point is added: ¶

‘(20) ‘reprocessing of plastic’ means remelting, mixing, reacting or otherwise combining plastic materials resulting as a by-product from an intermediate or final manufacturing stage to use them again in the manufacture of plastic materials and articles alone or combined with material originating from earlier manufacturing stages.’ ¶

Change in drafting, the provision has not changed in its essence

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344 (2) → A new Article 3a is added: ¶

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*Article 3a*  
**High degree of purity** ¶

*Article 3a*  
**High degree of purity** ¶

A substance used in the manufacture of plastic materials and articles shall be considered as having a high degree of purity where all of its constituents form part of its identity, and it otherwise contains only a minor amount of contaminants and non-intentionally added substances that fulfil one of the following conditions: ¶


(i) → they comply with the specifications or restrictions specified in the authorisation of the substance in table 1 of Annex I, if any: ¶

(ii) → they have been subject to a risk assessment in accordance with Article 19 and considered compliant: ¶

(iii) → they have been subject to an individual toxicological assessment which concludes that genotoxicity is ruled out, in accordance with the relevant guidance adopted by the Authority, and they are present at a level in the plastic material or article that, assuming their full migration into food, cannot give rise to an individual migration of any of them resulting in their presence in food exceeding 0.05 mg/kg: ¶

(iv) → they are unknown or have not been subject to an assessment specified in points (ii) or (iii), but are present at a level in the plastic material or article that, assuming their full migration into food, cannot give rise to individual migration into food of any of them resulting in their presence in food exceeding 0.00015 mg/kg: ¶

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### Article 5

#### Union list of authorised substances

(6) → In Article 5, the following paragraph is added:¶

‘4. → In case of doubt over the resulting designated identity of a substance, a Member State or the Commission may consult the Authority.¶’

In former version included under Article 8, the identity part is moved to Article 3a (‘where all of its constituents from part of its identity’)

412 1. → A substance used in the manufacture of plastic materials and articles in  
413 accordance with Article 5 shall correspond to the identity of the substance  
414 listed in Table 1 of Annex I which is specified in the opinion of the Authority.  
415 In case of doubt over the resulting designated identity of a substance a  
416 Member State or the Commission may consult the Authority.¶

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### Article 6

#### Derogations for substances not included in the Union list

390 (5) → Article 6 is amended as follows:¶

(3) → paragraph 5 is replaced by the following:¶

‘5. → By way of derogation from Article 5, substances with a biocidal function used in biocidal products authorised to be made available on the Union market in accordance with Regulation (EU) No 528/2012\*\* for product-type 4 for use that covers incorporation into plastic materials and articles which may enter into contact with food, may be used as additives in the manufacturing of plastic materials and articles.¶’

The previous version is below; this provision has not changed in its essence

394 ‘5. → By way of derogation from Article 5, biocidal products allowed to be  
395 placed or made available on the Union market in accordance with  
396 Regulation (EU) No 528/2012<sup>34</sup> for product-type 4 for use that covers  
397 incorporation into plastic materials and articles which may enter into  
398 contact with food, may be used as additives in the manufacturing of  
399 plastic materials and articles. The biocidal product shall be used in  
400 compliance with the applicable terms and conditions, restrictions and  
401 specifications set out in this Regulation.¶’

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## Article 7

## Establishment and management of the provisional list

(8) → Article 7 is deleted.¶

A biocidal product may be incorporated into FCMs provided that both the substance and the product containing the substance are approved and authorised under Regulation (EU) No 528/2012.

The substances included in the provisional list cannot be made available in accordance with Regulation (EU) No 528/2012. So, Article 7 can be deleted.

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## Article 8

## General requirement on substances

409 (7) → Article 8 is replaced by the following:¶

410 *Article 8*¶

411 **General requirements on substances**¶

1. → Substances used in the manufacture of plastic materials and articles, **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.¶

Manufacturers of plastic materials and articles and of products from intermediate stages of their manufacturing shall know the composition of the substance and make it available to the competent authorities on request.¶

The high purity requirement for substances manufactured from waste is included in paragraph 1 (in previous version included in paragraph 4 of Article 8)

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**Article 8**  
**General requirement on substances**

409 (7) → Article 8 is replaced by the following:<sup>¶</sup>

410 *Article 8*<sup>¶</sup>

411 **General requirements on substances**<sup>¶</sup>

2. → **By derogation from paragraph 1, as regards purity**, the following requirements shall apply to substances of natural origin:<sup>¶</sup>


(i) → if the substance is identified by a name in this Regulation that refers to a natural multi-constituent material where the source is biological, that substance may be used as obtained from its natural origin, provided it has been entirely separated from other natural materials from which the substance was obtained and that are not forming part of its identity, or,<sup>¶</sup>

(ii) → if the substance is identified by a name in this Regulation that refers to a natural multi-constituent material where the source is mineral, that substance may be used as obtained from its natural origin, provided it has been entirely separated from the other natural matter that is not forming part of its identity of the substance.<sup>¶</sup>

The previous version is below; the drafting specifies this provision is a derogation to paragraph 1, and refining the text what is considered purity for substances where the source is biological or mineral

423 3. → The following requirements shall apply to the purity of substances of a natural  
424 origin.<sup>¶</sup>  
425 (i) → if the substance is identified by a chemical name in this Regulation, it  
426 shall have a high degree of purity, or,<sup>¶</sup>  
427 (ii) → if the substance is identified by a name in this Regulation that refers to a  
428 natural multi-constituent material, that substance may be used as obtained  
429 from its natural origin, provided it has been entirely separated from the  
430 other natural matter, or parts of the plant or other natural sources from  
431 which was obtained that are not forming part of the identity of the  
432 substance.<sup>¶</sup>  
433 Any additional specifications or requirements applicable to a substance or  
434 material of a natural origin set out in Table 1 of Annex I, applicable to the  
435 substance or material, shall apply.<sup>¶</sup>

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(12) → The title of Chapter IV is replaced by the following:<sup>¶</sup>

**‘LABELLING, DECLARATION OF COMPLIANCE AND DOCUMENTATION’<sup>¶</sup>**

(13) → A new Article 14a is added:<sup>¶</sup>


*Article 14a*<sup>¶</sup>  
**Labelling**<sup>¶</sup>

1. → The manufacturer or other operator responsible for placing on the market a material or article intended for repeated use shall provide information about its the maximum life span to its users by means of labelling or instructions, including appropriate instructions designed to slow down deterioration of the material or article, as well as a description of observable changes of the article or material that may indicate the deterioration of the article or material and that it has reached its maximum life span.<sup>¶</sup>

A new Article 14a, paragraph 1 is proposed (in previous version included in Article 10(3)); this provision has not changed in its essence

475 3. → Where intended for repeated use in contact with food, the composition of  
476 plastic materials and articles shall be such, so as to guarantee that no increase  
477 in the migration of constituents of the material or article to the food would  
478 occur during their maximum life span when subjected to subsequent use cycles.<sup>¶</sup>  
479 The manufacturer or seller responsible for placing on the market shall provide  
480 information about the maximum life span of the material and article to its users  
481 by means of labelling or instructions, including appropriate instructions  
482 designed to slow down deterioration of the material or article, as well as a  
483 description of observable changes of the article or material that may indicate  
484 the deterioration of the article or material and that it has reached its maximum  
485 life span.<sup>¶</sup>

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(13) → A new Article 14a is added: ¶

*Article 14a*  
**Labelling** ¶

2. → Plastic materials and articles intended to be brought into contact with food but are not yet in contact with food shall be labelled with instructions of use directed at the final user of that material or article at the moment of their sale or supply to consumers, where they are manufactured with substances included in the Union list of authorised substances, for which column 10 of table 1 of Annex I sets out restrictions related to one or more of the following elements: ¶

– → specific foods or groups of foods, ¶

– → contact time and/or temperature, and/or, ¶

– → to heating conditions such as oven and microwave use, ¶

The instructions of use shall mention the restrictions and provide the user with adequate information to prevent using the material or article under conditions not complying with them. ¶

If such a material or article is intended for repeated use, such labelling shall be indelibly affixed to the material or article, unless that is not possible for technical reasons. A minimum font size of 3 mm (9 pt.) shall apply. ¶

A new Article 14a, paragraph 2 is proposed (in previous version included in Article 10(4)); this provision has not changed in its essence

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# Recycling

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## State of Play

- Amending text
  - delayed – we missed DL – split too late
  - We are currently assessing the content that can be maintained
  - Main issue with quality control of input material → feedback period required
  - Split of text very likely
- Register
  - IT solution quickly developing
  - nearing final acceptance stage
  - on-line list expected late April

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## Recycling

- Policy matters – possible amendments to Regulation (EU) 2022/2016
  - recyclers allowed to de-activate their installations in the register for economic reasons
  - improved definition of up to which stage compliance documentation is required
  - strengthening of quality assurance of input materials
  - some corrections of references in the Regulation
- Amendments internally being analysed
  - Feedback (if needed) and vote still expected before summer
- Authorisation Decisions nearing completion
  - consultation of individual decisions with future authorisation holder and member states
  - adoption before the summer

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## Improving certainty over input 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

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, ...)

Establish TARIC codes

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

PPWR relevance!

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## Authorisation of Recycling processes

- EFSA Opinions → first batch of authorisation Decisions (about 180/250+)
- Draft text prepared by Commission Services
- Text to be shared for verification
  - with Member States
  - with future Authorisations holders
- Objective:
  - to verify general correctness of text → based on template, so mostly the same
  - to specifically verify authorisation holder and restrictions
  - to prepare for vote (written procedure) in standing committee
- Deadline: 17 April **but please do not start before Tuesday 26 March**

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## Timeline and process: Recycling authorisation decisions

1. The following working and Authorisation Decision documents are being shared with MSs through **CIRCA BC** [FCM - Library \(europa.eu\)](https://ec.europa.eu/fcm/):
  - A. General docs - Cat Decisions
    - MSs Authorisation Decision distribution
    - MSs Authorisation Decision distribution + RECYC Number per MSs
    - Evaluation Categories
  - B. Individual Authorisation Decisions
    - Recycling Efsa Opinion RECYC001
    - Recycling Authorisation Decisions for RECYC001

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## On-Line Demo

- Let's see whether I can demonstrate using CircaBC 😊

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# Essentially two types of Decisions (Article 5)

## Simple

Article 5

*Authorised use of recycled plastic manufactured with the authorised recycling process*

Recycled plastic manufactured with the process shall meet the specification set out in column 6 of row 1 of Annex I, and may be used up to 100% of the plastic content for the manufacturing of the following materials and articles:

all types of foodstuffs for long term storage at room temperature, with or without hot fill



## Several lines (up to 3)

Article 5

*Authorised use of recycled plastic manufactured with the authorised recycling process*

Recycled plastic manufactured with the process shall meet the specification set out in column 6 of row 1 of Annex I, and may be used for the manufacturing of the following materials and articles:

bottles manufactured with up to 70% recycled plastic originating from the process

thermoformed trays and containers manufactured with up to 100% recycled plastic originating from the process and that are not to be used for packaging water

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# Distribution per Member State

Austria	15	1, 2, 3 & 5	RECYC011, RECYC013, RECYC045, RECYC048, RECYC050, RECYC053, RECYC059, RECYC060, RECYC068, RECYC134, RECYC163, RECYC180, RECYC203, RECYC204, RECYC205
Belgium	1	1	RECYC030
Bulgaria	2	1	RECYC122, RECYC165
Croatia	1	1	RECYC217
Czech Republic	1	1	RECYC231
Denmark	1	1	RECYC005
Estonia	1	1	RECYC150
Finland	1	1	RECYC131
France	11	1 & 2	RECYC017, RECYC039, RECYC061, RECYC072, RECYC073, RECYC074, RECYC195, RECYC201, RECYC233, RECYC239, RECYC240
Germany	24	1, 2, 3 & 4	RECYC010, RECYC014, RECYC015, RECYC021, RECYC022, RECYC032, RECYC067, RECYC071, RECYC079, RECYC113, RECYC121, RECYC126, RECYC135, RECYC137, RECYC140, RECYC143, RECYC144, RECYC148, RECYC149, RECYC152, RECYC158, RECYC160, RECYC170, RECYC178, RECYC179, RECYC194, RECYC202, RECYC210, RECYC212
Greece	3	1, 3 & 4	RECYC128, RECYC130, RECYC164
Hungary	2	1	RECYC106, RECYC157

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## Distribution per Member State

Ireland	3	1 & 2	RECYC076, RECYC172 & RECYC245
Italy	23	1,2,4 & 5	RECYC026, RECYC027, RECYC040, RECYC041, RECYC043, RECYC044, RECYC046, RECYC099, RECYC105, RECYC114, RECYC136, RECYC141, RECYC159, RECYC169, RECYC188, RECYC192, RECYC214, RECYC218, RECYC219, RECYC226, RECYC227, RECYC237, RECYC257
Latvia	2	1	RECYC102 & RECYC118
Luxembourg	2	1	RECYC008, RECYC209
Netherlands	10	1, 2, 3 & 5	RECYC001, RECYC038, RECYC047, RECYC064, RECYC075, RECYC085, RECYC103, RECYC139, RECYC211, RECYC251
Poland	8	1 & 4	RECYC078, RECYC111, RECYC162, RECYC187, RECYC213, RECYC252, RECYC253, RECYC255
Portugal	4	1 & 2	RECYC052, RECYC123, RECYC133, RECYC234
Romania	4	1 & 2	RECYC108, RECYC112, RECYC145, RECYC200
Slovakia	1	1	RECYC153
Spain	17	1,2 & 5	RECYC002, RECYC082, RECYC115, RECYC120, RECYC138, RECYC147, RECYC167, RECYC168, RECYC182, RECYC190, RECYC199, RECYC208, RECYC215, RECYC216, RECYC247, RECYC250, RECYC260
Sweden	3	1 & 05	RECYC174, RECYC254, RECYC256

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## Concluding: need to verify

- Are the restrictions correct, in view of your reading of the EFSA opinion
- Is the Authorisation holder referenced correctly
- We are not asking you to suggest detailed changes to recitals and wording common to all decisions
  - if you consider change is needed, flag it by e-mail
- You can make other changes – if necessary – directly in the document
  - CircaBC guideline is following
  - Do you all have access?

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## Checking of decisions for processes outside EU

- 46 processes (in this batch)
- about 2 processes per MS
- you will receive the assignments next week
- it will be more difficult to verify the operators

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## Final remarks

- Please wait until Tuesday
  - Final check of the texts by us
  - Assignments of international processes
- Any Questions

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# EY workshop

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## Organisation of the work on the Revision

- Most of the work done in house
  - Policy paper (delayed due to present implementation workload)
  - Specific working groups → define policy + provisions (delayed due to missing paper)
    - each group independent chairing expert + stakeholders
  - Refined policy paper which serves as basis for impact assessment and proposal
- Studies by contractors
  - Consumer perception (finished)
  - **Study on information exchange, compliance and enforcement**
  - Study on sustainability (starting)
  - Overall impact assessment

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## Background of the study on information exchange, compliance and enforcement

- Study to develop options and to assess impact thereof:
  - to support IT infrastructure for information exchange
  - to verify compliance, controls, and the roles of different actors
    - develop options for under pillars D + E of the evaluation
- IT infrastructure for information exchange needed to facilitate
  - self-assessment of the risk of 'tier 3' substances
  - full knowledge on the identity and amount of all substances present in final FCMs
  - enforcement authorities to quickly understand the safety of FCMs

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## Main objectives of the study – Terms of Reference

- Three options to be developed for an IT infrastructure, including how verification of compliance and controls can be carried out and the roles of the relevant actors
- Options to include are the following (modifications + sub-options possible)
  1. a centralised system – EU body principally responsible
  2. de-centralised system – MS responsible
  3. de-centralised system – businesses responsible
    - sub-options to investigate the use of supporting bodies (EU agency, MS CAs, notified bodies)
- Study to develop and describe the overall architecture
- Additional elements
  - consider feasibility, funding, and implementation pathways
  - compare feasibility and impacts
  - consider practical and efficient use (including security, intellectual properties, enforcement)
  - describe process of verification of compliance + roles and responsibilities
  - assess impact of information requirements on FCM operators, particularly SMEs

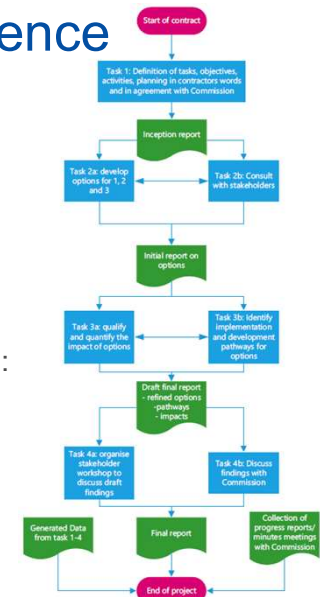
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## Tasks and reports – Terms of Reference

- Inception report, based on:
  - Task 1: definitions of tasks, objectives, activities and planning
- Initial report on options based on:
  - Task 2a: develop options
  - Task 2b: consult with stakeholders
- Draft final report (refined options, pathways, impacts), based on:
  - Task 3a: qualify and quantify the impact
  - Task 3b: Identify implementation and development pathways
- Final report, based on:
  - **Task 4a: stakeholder workshop to discuss draft findings**
  - Task 4b: discuss findings with Commission



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## Recap on policy options

### Policy Option 1: Centralised EU-level IT system

- ▶ Single database at the EU level which is used by all actors of the supply chain and NCAs.
- ▶ An EU-body sets up the system and manages it within the guidelines of the EU Commission.
- ▶ Actors within the EU interact with the EU-level database, including NCAs

### Policy Option 2: Decentralised MS-level IT systems

- ▶ Multiple national databases
- ▶ Communication among databases is ensured by an EU data hub or by interoperability between databases
- ▶ Each MS has to bear responsibility for setting up their own database and manage it according to EC's guidelines
- ▶ Actors within each MS interact with their national database, including NCAs who have access to information across MS

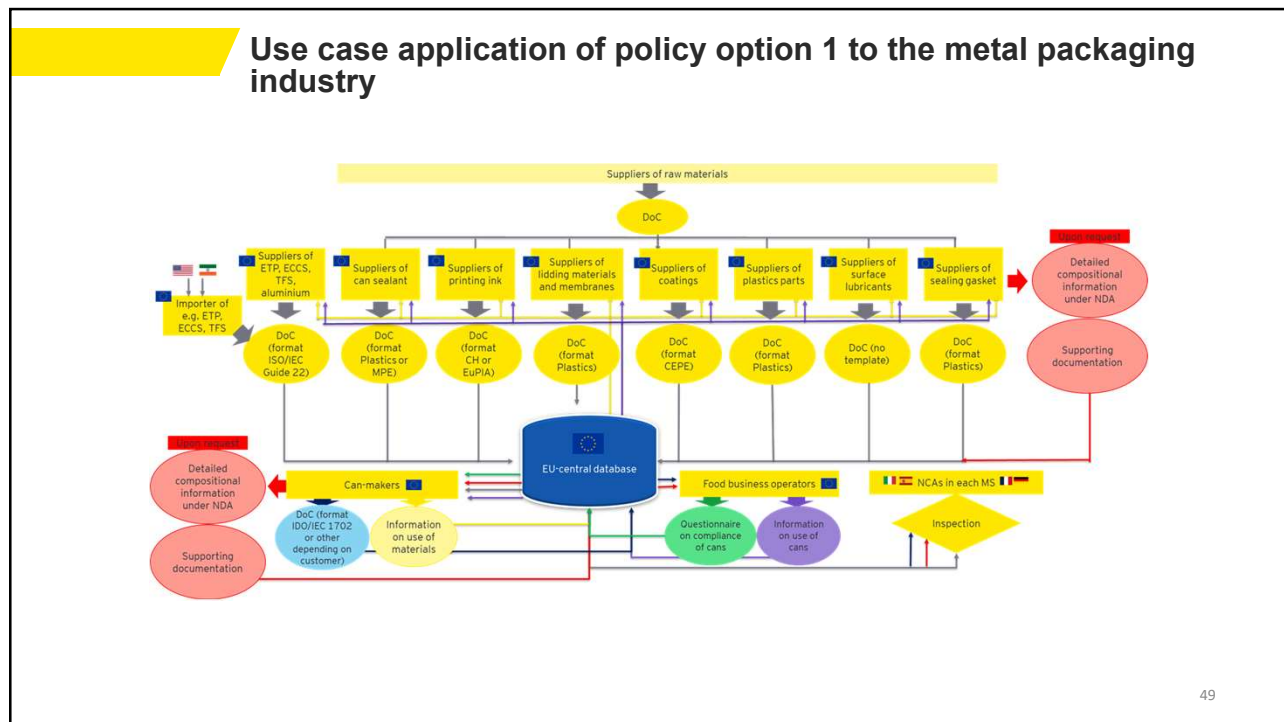
### Policy Option 3: Decentralised industry-level IT systems

- ▶ Multiple industry-specific databases
- ▶ Industry associations or consortia of industries set up their own database which does not communicate with other industry-led databases
- ▶ Actors doing business with specific industries interact with the relative industry-level databases
- ▶ NCAs access all single industry-led databases

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## Conclusions

- **Conclusions**
  - Policy option 1 voted first: the industry asks the Commission to keep their data
  - We do now better understand the criteria by which to look at IT systems
  - However, we do not yet have concrete elements for a system
    - the 'system' is still very abstract
  - We do not really understand the impacts of the policy options
  - We do not really understand the role of enforcement
  - However, the 'system' is not necessarily considered 'science fiction'
- **Limitations**
  - Full future policy context not fully known columns A, B, C and F
  - Impact assessment cannot be fully achieved at this phase

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# Thank you

Happy to receive questions...

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