WORKING GROUP ON FOOD CONTACT MATERIALS

9-10 February 2022

DG SANTE
European Commission

Agenda

10:00 – 12:30 hrs

1. Opening, determination of AoB
2. Revision
   from challenges to options for solutions
3. Revision – progress reports
   a. Pillar A – shift to final products
   b. Pillar B – risk management of chemicals
   c. Pillar C – sustainable FCMs
   d. Pillar D+E – information exchange and enforcement
   e. Pillar F – Analytical methods

14:00 – 17:00 hrs

4. Regulation (EU) No 284/2004
5. 17th amendment to Regulation (EU) No 10/2011
6. Other amendments to Regulation (EU) No 10/2011
   a. 18th amendment
   b. Authorisation of DEHCH
   c. future

10:00 – 12:30 hrs

7. General matters Regulation (EU) 2022/1616
   a. State of play (overview)
   b. Correcting act Article 5(2) – DoC
8. Detailed discussions concerning Regulation (EU) 2022/1616
   a. **EU register**
   b. **Authorisations**

14:00 – 17:00 hrs

9. Presentation of phase 2 of the general BTSF FCM training
10. Compliance Monitoring Summary Sheet
    a. Discussion of present guidance
    b. Feedback from Member States
    c. Q&A Member States
11. AoB
    a. Organoleptic properties of wood (DE)

Revision of FCM Legislation

FCM revision approach

1. Define main policy themes and broad initial solutions	2022
2. Refine solutions and define more detailed policy options	2023
3. Assess feasibility and impact of policy options	
4. Conclude on preferred policy options	2024
5. Work towards legislative proposal	2024 and beyond

Today more in-depth presentation – ***from challenges to options for solutions***

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FCM revision: Main policy themes and pillars

Safety and sustainability

A. Shifting focus onto final material

- Rules to better define level of safety required, also addressing the risk (e.g. synthetic, inorganic, natural fibres etc); include composite FCMs

B. Prioritisation of substances

- All substances to which consumers may be exposed via food contact materials, groups
- Tiered approach, with precedent given to certain hazard classes (CMRs, EDs, PBTs and vPvBs)
- Self-assessment of more benign substances and/or those migrating in low amounts

- A + B together to become the core of the future risk management approach
- + new material categories to apply that approach

C. Supporting safer and more sustainable alternatives

- Ensure safety, less hazardous chemicals → sustainability
- Expand rules to prioritise and support sustainability
- Rules on sustainability e.g. packaging use

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
- ~~Further development of test methods and technical standards as required~~

F. Analytical methods

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

Detailed approach of the Revision process

- We will discuss challenges as we perceive them
- We will discuss objectives / goals of the FCM revision
  - considered a potential ideal outcome, but not necessarily attainable

  → 'aspirational targets'
- We will not yet discuss options to achieve these goals
- Options will be developed along three scenarios
  - base-line scenario – no change
  - intermediate scenario – change versus present legislation, objective not fully achieved
  - full scenario – objectives will be fully implemented

Challenges (reworded from evaluation)

- **Safety** is **insufficiently** defined at EU level for most FCMs (lack of harmonisation)
- **Safety** of migrating substances is **not transparent** – is an FCM actually safe?
- Public authorities have **insufficient capacity** to
  - **risk assess** all **substances**
  - **harmonise** and manage **specific FCM** rules under the present system
  - comprehensively **enforce compliance** and safety

  (this is not a criticism, but an observation, we expect the evaluation of policy options to confirm)
- Specific detailed **rules** with **ever increasing complexity** – problems may be left in fog
- The **use of** certain **chemicals** is **no longer** automatically accepted
- **Environmental challenges** call for more sustainable production and use
- **New products** are entering the market that **challenge present categories**

Objectives of the Revision ('aspirations')

- Strengthen Article 3 – **FCMs are to be inert** – migration to be the exception
  - and as migration is unavoidable, it shall not adversely affect food safety/quality
  - rules to encourage **inherently safer FCMs** – 'limits' no longer driving force
  - rules to drive innovation towards safer materials
- Ensure we can effortlessly know **that a final material is safe**
- Keep **new rules** simple, practicable, enforceable and **achievable**
- Ensure there is **full harmonisation**, level playing field, including imports
- Ensure **high level of transparency** over composition and sustainability

(***inherent safety:*** *materials have been produced fewer toxic substances, so less controls such as limits are needed)*

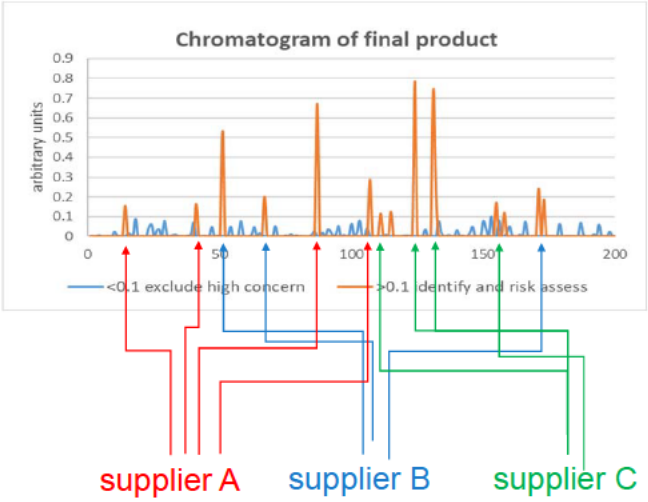
A: shifting focus on final materials

What does this mean?

- Producers of final FCM to have full knowledge on '*migratables*'
  - They become fully accountable
- All '*migratables*' to be risk assessed
  'migratables':
  substances that can foreseeably migrate into food under foreseeable conditions of use
- Difference between NIAS and IAS to dissapear
  NIAS/IAS:
  '(non) intentionally added substances'
  (term originates from R 10/2011)

A: In practice

- **<u>If</u>** the **final** producer were to make a 'forest of peaks' style chromatogram:
- They would need to be able to explain all peaks give rise to safe migration level
- Information can't come from (present) analytical techniques **(→F)**
- Information to come from suppliers as shown on right→



A: Legislation would consider

What information to provide?

- All substances in product with migration potential above cut-off
- Exclude presence of certain categories (tier 1 substances)
- risk assessment **(→B)**

How to provide it

- supporting documentation
- via IT system **(→D)**
- keeping information up to date
  (it is to be provided 'continually')

Data management

- definition of IT system
- data
  - ownership
  - formats
  - storage
- **rules for handling proprietary data**

A: shifting focus on final materials

Accountable for final material

- all substances that may migrate are known by the producer of the final material or article
  - the maximum migratable quantity is known (GMP required)
  - substances have been risk assessed
  - no difference between NIAS and IAS
- the information is provided by the supply chain

Drivers

- Inherent safety:
  Producers have reason to keep materials clean and simple
- Simplification:
  No detailed rules on starting-substances and supply chain needed
- Transparency:
  It is immediately clear what migrates from a specific FCM, and in what amount

Barriers

- Information flow
  final producer depends on supply chain
- confidential information
  commercial practices prevent transfer of certain information on composition

B: Prioritisation of assessment of substances

What does this mean?

- Substances are no longer prioritised for risk assessment and risk management purely on the basis of the need to authorise their use in the manufacture of FCMs
- Rather, 'migratables' should be assessed according to a number of criteria including identified hazardous properties, use, migration, exposure, grouping and combination effects, vulnerable populations, essentiality
- Different levels of risk assessment and possible risk management depending on these criteria

B: Prioritisation of assessment of substances

A basic tiered system…

- Tier 1: Prohibition of use/presence
- Tier 2: Risk assessment by authorities
- Tier 3: Risk assessment by operators

..based on generic risk / hazard:

- Tier 1: e.g. CMRs, EDs, PBTs and vPvBs.
- Tier 2: Other substances of concern, e.g. neurotoxins, immunotoxins, substances in nano-form or that migrate in high amounts
- Tier 3: More benign substances

Drivers

- Prioritisation / resources
  - Harmonisation (more materials)
  - Focus on final material (more substances)
- Commission policy on substances of concern/ most hazardous substances
- One Substance One Assessment
- Inherent safety
- Need to include updated scientific knowledge

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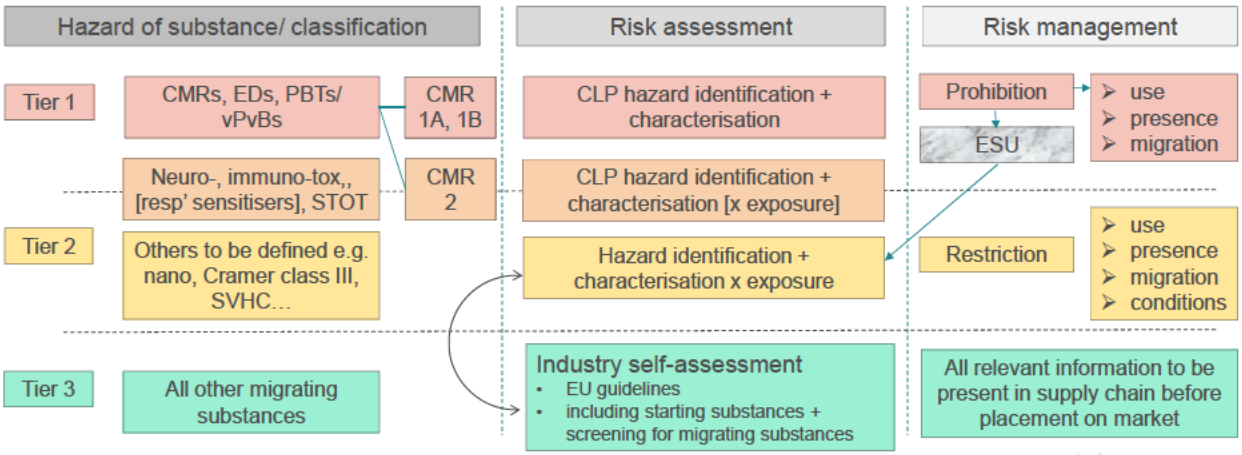
B: Prioritisation of assessment of substances



B: Prioritisation of assessment of substances

How should the tiers be determined and who is responsible for the risk assessment?

- **Tier 1** substances: determined by CLP and possibly REACH. Proposals under CLP by MSs, industry and (soon) Commission. Identification of properties of concern may also come from ECHA in the context of the REACH Regulation
- **Tier 2** substances: criteria to be determined, role for EFSA. Risk assessment by EFSA and/ or MSs
  - dependent on capacity in Member States and EFSA
  - taking into account the requirements of the Transparency Regulation
- **Tier 3** substances: EU Guidance is likely to be required to set out information requirements and approach to be done by BO (or representative)

B: Prioritisation of assessment of substances

Where should the information come from?

- Supply chain/ business operators
  - Information on starting substances and other migrating substances via screening
  - Toxicological information, migration data, risk assessments
- EFSA (existing data and risk assessments)
- ECHA
  - Information on substances registered under REACH, risk assessments including those on drinking water materials, SVHC identification etc
- Member States
  - National lists and existing risk assessments
- One Substance One Assessment principle should apply
  - transparency and access to data

B: Prioritisation of assessment of substances

Risk management tools

- Prohibition for tier 1 substances
  - Ban on their use or in the manufacture of FCMs or presence or migration
- Restrictions for tier 2 substances
  - Use in manufacturing, presence in final FCM, migration, conditions of use, labelling
- EU risk assessment and positive/ authorised listing
  - Substances that are ‘essential’, for specific uses, potentially subject to a transition time
  - Materials which should be prioritised for safety assessment and market access e.g. based on sustainability and innovation

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B: Prioritisation of assessment of substances

Essential use of FCM substance

- In principle for tier 1 substances for which a hazard-based approach would be taken
- A specific risk assessment of the substances in question (taking into account migration, exposure etc) would be required
- An evaluation of alternatives would be required
- Criteria need to be laid out in accordance with the principles agreed across chemicals legislation (awaiting Commission output as part of CSS)
- Decision making body: Commission and/ or Member States?

applying A+B to specific material groups

Simplification of material groups

- Main Materials
  1. Synthetic organic type materials (plastics, rubbers, coatings, inks, adhesives, …)
  2. Natural organic type materials (wood, fibres, plant-based)
  3. Inorganic based materials including metals
- Special materials (made from 1, 2 and 3)
  4. Active and Intelligent materials
  5. Recycled materials
  6. Composites (paper, multi-material)

grouping is done on the basis of a high similarity in applicable rules
i.e. if substances can be regulated in the same way, they will be in the same group

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1: synthetic organic type materials

- Plastic and rubbers (including silicones, etc.), coatings, adhesives, inks
- Also to include:
  - additives of the same composition to be added to other groups (e.g. additives to paper)
  - liquid materials used to manufacture or maintain FCMs (lubricants, detergents)
  - refined materials from a natural origin (17th amendment discussion)
- To be risk assessed and used in accordance with the tiered system **(→B)**
- To be subject to
  - information transfer requirements in the supply chain **(→A)**
  - a single set of rules on verification of compliance **(→F)**

2: Natural organic type materials

- **Unrefined material** gotten from nature
  - e.g. wood (pulp), cotton, and processed sugarcane, that hasn't been purified
  - still a question: really only organic or also inorganic? presently the first
- Each material may contain **hundreds of substances**
  - cannot be subject to the approach set out in A+B; substances cannot be identified

  → they need to be regulated differently
- Approach: positive list following EFSA assessment?
  - e.g. list of species / parts of species assessed under EU responsibility
  - authorised uses, harvesting + processing techniques, …
- EFSA is presently discussing their approach towards this material group

3: Inorganic based materials

- Metals, ceramic, glass, (natural?) stoneware
- Rules to be as simple as possible - list of migration limits
  - rules to apply to the elements, e.g. regulated on the basis of a list of migration limits
  - tier 1 to apply **(→B)**
  - CoE guidance / table 1 of Annex II to Regulation (EU) 10/2011
- How to deal with certain species with a particular hazard?
  - e.g CrIII/CrVI, TiO_2 vs Ti, …
  - non-dissociating species, nano-form
- Regulate those species with additional limits / positive or negative list?

4: Active (and intelligent) materials

- All material of which the composition intentionally changes after production
  - but not substances intentionally released to the food to have technical function in the food

  → food legislation
- Materials to comply with group 1-3 to which they belong, however
  - Substances that are formed/present in the FCM subject to A+B **(→A)(→B)**
  - these substances are to be known
  - active nature to be fully taken into account, including reaction products
- Wider scope than at present
  - not only about shelf-life of packaged foods
  - also for instance anti-oxydants in plastic
- Rules also to control specific aspects of use
  - applications
  - contact with the food (pouch, capacity)
  - type and quality of container
- Possible approach
  - passive component group 1-3
  - generic list of materials commonly used (e.g. main absorbers, anti-oxidants), and,
  - decisions addressed to individual operators
  - tiered system to apply
  - functional barrier will not explicitly apply **(→A)**

5: recycled materials

Recycled plastics

- Regulation (EU) 2022/1616 to apply

Recycled paper and board

- Rules to be similar to plastic approach
  - assumptions on presence of contaminants
  - decontamination efficiency

  + rules for dealing with printing inks / MOH ?
- possible use of standards
- general prohibition of substances beyond FCM? (e.g. certain inks, MOAH)

6: Composites

Multi-layer multi material materials

- layers are flat
- in principle A+B could apply to each layer, based on material group 1-3
- However less migratable substances if barrier layers used
- Reliance on migration modelling + testing

Other composites

- typically particles/fibres in matrix
- in principle A+B could apply to both particles and matrix, group 1-3
- special rules for major composite material groups, e.g.
  - paper and board
  - plastic / natural material composites

Positive lists

- Positive lists are at present the central element – are they to remain?
  - both EU positive lists, National positive lists
- Authorisation of tier 2 substances likely to be very specific to use
  - no positive lists according to the present model
  - positive lists may have role in transition to new model
- Tier 3 substance used on basis of risk assessment by business operators
  - no positive lists according to the present model
  - present positive lists may have role in starting point for risk assessment + transition
- Potentially a limited use of positive lists in material groups
  - List of suitable natural materials
  - List of certain inorganic compounds (mostly as a derogation to migration limits)

Summary pillar A+B

- A: putting the focus on the final materials
  - migratable substances need to be known and risk assessed
  - below a certain (to be defined) level only presence of Tier 1 substance needs excluding
  - information on composition to be delivered by supply chain
- B: prioritising the assessment of substances
  - tier 1: generic rules to apply to the use of most hazardous substances
  - tier 2: risk assessment by public Authorities – width of tier depends on capacity
  - tier 3: more benign substances assessed by business operators
  - OSOA applies – risk assessment to be available
- Rules on specific materials define how A+B are applied in practice

Pillar C+D+E – limited discussion today

- C to be discussed under next agenda point
- D + E in summary
  - to facilitate information exchange on composition ('migratable substances')
  - to facilitate access to information on risk assessment
  - to facilitate enforcement

F: Analytical methods

- Present: focus on enforcement of migration limits under OCR
  - in practice, only a very limited number of substances is routinely subject to verification of compliance by competent authorities on the basis of analytical methods
  - in many cases methods do not exists, or accreditation does not exist
- Future:
  - lower importance of migration testing **(→A)**
  - rules to be made specific to the tiered approach **(→B)**
    - **Tier 1: confirm absence**
    - **Tier 2: the present approach?**
    - **Tier 3: screening**
  - consider novel approaches (e.g. screening / finger printing approaches)
  - rework migration testing (Annex III + V to R 10/2011) to become generally applicable

Important Disclaimer

- The previous slides describe the 'aspirations' of the revision
- These do not necessarily reflect the reality of what will be final legislation
- Some of these aspirations may not be achieved, or be differently achieved
- Discussions with Member States and Stakeholders will be very important

- The next slides explain how we intend to work

How will we work? Studies

- Commission to focus on the main regulatory issues
  - materials, tiered system, analytical methods, verification of compliance
  - specific study on analytical methods
- Other studies
  - Study on IT architecture and enforcement – contractor – EY – kicked-off last week
  - Study on consumer perceptions – final phase
  - Study on sustainable FCM – to be defined – planned middle 2023

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How will we work? Discussion paper

- Step 1: discussion paper to be disseminated to MS and stakeholders
  → based on view of Commission Services
- Step 2: definitions of Expert WGs for main pillars (A, B, and F)
  - pillar C + D and E subject to separate studies
- Step 3: Expert WGs to refine and steer the discussion paper
  →add their view
- Step 4: consolidate views in new discussion paper
- Step 5: Commission to continue impact assessment on basis of that paper
- Step 6: Discussion on policy options
- Step 7: Final report → basis for Commission proposal

How will we work? Discussions

- We will encourage discussions on alternative solutions
- The objective of the revision will be leading
  - High level of safey, Transparency, Prioritisation, Harmonisation
- Solutions need to be implementable in practice
  - e.g. if solution requires resources that are not available, it is not a solution
  - if it takes time to implement a solution that is not necessarily an issue
- Experts will be welcome to disagree
  - but will be asked for alternative approaches if they do so ;-)

How will we work? Options

- It will explain and discuss the detailed elements of revised FCM leglislation
- It will explain and discuss the options for implementing these elements
- Options will be based on implementation level
  - limited implementation → what happens if the element is not implemented
  - intermediate implementation → the element is only to a certain extent implemented
  - full implementation → the element is implemented
- Impact will then be assessed on the basis of scenarios of options
  - options to be combined so that they actually can function

How will we work? Working Groups

- the agenda of future working groups will keep the same agenda points
  - general discussion
  - progress per pillar will be reported
- participation at individual level in expert WG per pillar + studies
- final discussion paper to be presented for feedback in WG (step 4)
- discussion on finalised options (step 6)

How will we work? Time-line

- We try to organise the expert WGs in Q2, continue Q3
- That means our discussion paper needs to exist soon
- Step 4-6 in Q4
- Several potential sources of delay
  - reform ambition itself – open questions
  - present implementation work

Messages

- We are considering and working on major reform of FCM domain
- The work is organised in 6 pillars
  - final materials, risk assessment/prioritisation, sustainability
  - Information infrastructure, enforcement, analytical methods
- At the end of 2023 we strive to have agreed working paper
  - main concepts, options, implementation scenarios
- In 2024 further work particularly on finalising impacts
- In 2025 work towards legislative text

Pillar C:
Making FCM sustainable

Consequences of EU Green Deal initiatives and possible ways to improve the sustainability of FCM

FCM revision: Main policy themes and pillars

Safety and sustainability

A. Shifting focus onto final material

- Rules to better define level of safety required aimed at addressing the full characteristics of all final FCM articles
- Refocus on broader material types (e.g. synthetic, inorganic, natural fibres etc); include composite FCMs

B. Prioritisation of substances

- All substances to which consumers may be exposed regardless of origin, substance groups
- Tiered approach, with precedent given to certain hazard classes (CMRs, EDs, PBTs and vPvBs)
- EU regula ion of other substances
- Self-assessment of more benign substances and/or those migrating in low amounts

C. Supporting safer and more sustainable alternatives

- Ensure safety, less hazardous chemicals → sustainability
- Expand rules to prioritise and support sustainability
- Rules on sustainability e.g. packaging use

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
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E. System for verifying compliance

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How do FCMs fit into the wider EU sustainability picture?

Green Deal 'Striving to be the first climate-neutral continent'

Regulation on packaging and packaging waste

Recommendation on bioplastics

Regulation on eco-design for sustainable products

Green claims and empowering consumers

FCM revision is part of Farm to Fork strategy

Food waste reduction targets

Framework for sustainable food systems

Food labelling (FoP, nutrition)

Essential use

Safe and sustainable by design

OSOA and Generic risk assessment

C. Supporting safer and more sustainable alternatives

- Ensure coherence and support objectives under environmental legislation, e.g. packaging waste reduction, reuse and recycling targets, eco-design for consumer products, zero pollution and reduce the most hazardous substances, food waste and sustainable food system.

- Current legislation only deals with the (chemical) safety of FCM

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C. Supporting safer and more sustainable alternatives

- Rules to ensure the **safety of reusable FCM** and their safe (hygiene) reuse, e.g. food delivery systems, supermarkets, HoReCA.
- Rules to **enable** the **recycling** of food contact waste back into food contact
  →From only plastics to all materials
- Rules to **facilitate the safety of innovative and sustainable materials**
  - e.g. plant-based and bio-based
- **Incentivize** the development and use of **more sustainable**
  - production **methods** e.g. best available practices, transparent resource use
  - **materials** EU assessment of "green" materials
- Information to **enable consumers to make informed choices**,
  - e.g. footprint of packaging versus food, reusability of articles, making the sustainable choice the safe and convenient one.

C. Supporting safer and more sustainable alternatives – Next steps

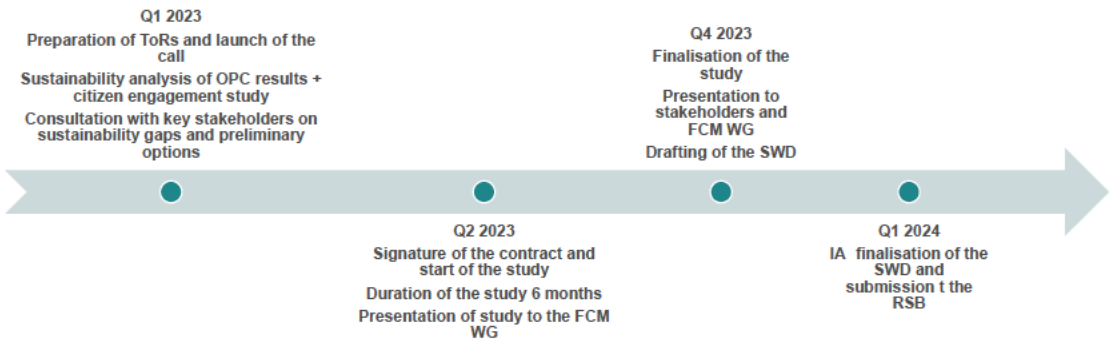
- New objective
- Adds to work to ensure safety of sustainable materials
  - Study to assess impacts and options in 2023
- Measures to support environmental objectives set by PPWR and possibly Eco-design and Sustainable Food Systems
  - Material consequences and response – e.g. recycling of paper and board
  - Food supply chain consequences and response – e.g. hygiene rules (GMP)
- Going beyond → intervention logic, objectives and measures/policy options towards safe and sustainable production and use of FCM

C. Supporting safer and more sustainable alternatives – Study

Scope of the study:

- Assess the different options to address the issues identified in the intervention logic (under preparation) regarding recycling, reuse (hygiene) and information to consumers.
- Assess whether and to what extent other consumer and environmental initiatives (slide 3) address identified issues and what are the gaps
- Assess whether the proposed options address the identified gaps including possible recommendations.

C. Supporting safer and more sustainable alternatives – Study



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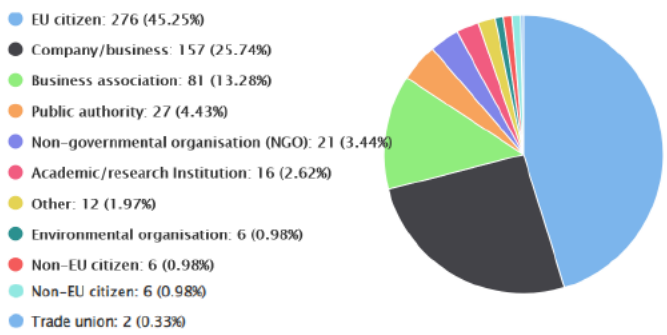
Progress

Public consultation

- 5 October 2022 - 11 January 2023
- Valid feedback received:
  - 610 + many position papers; results being analysed
  - Responses from 8 EU national administrations, 11 regional/ local authorities

By category of respondent



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Ongoing study work for revision of EU FCM rules

- **Citizen focus groups study. Objectives:**
  1. Gain understanding of the habits and behaviours of consumers with regards to FCM, particularly on the topics of safety, hygiene and sustainability;
  2. Obtain in depth understanding of the needs and preferences of consumers with regards to FCM; particularly on the topics of safety, hygiene and sustainability;
  3. Understand the information needs with regards to FCM: the type of information that is needed, the way it should be communicated
  - Practical exercises completed in 8 Member States
  - Final report due this month; presentation of results foreseen next WG

study on Pillar D + E

- contractor is working – delivered inception report – discussion on-going
- some of you have already been contacted
- no substantial feedback

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Afternoon Programme

Regulation (EU) 284/2004

Observed issues

- We are aware of several issues
  - Limits and testing partly out of sync with Regulation (EU) 10/2011
  - Outdated scope – wider geographical range + melamine could improve effect
  - Tableware in or out of the scope – clarified via note, some apparent doubts
    - tableware considered in the scope
  - Several more minor issues related to other provisions
  - Discussion on reporting systems
- The first 4 points can only be solved by means of an amendment
  - outdated legal basis (old official control Regulation)
  - not a priority

17th Amendment to Regulation (EU) No 10/2011 on plastic FCM

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not necessarily represent a final position and does not commit the European Commission. The European Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary assessment. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.

European Commission

Time-line

- Presently foreseen time-line
  - 2022: initial consultation over **certain specific provisions** (inputs received)
  - Late February: Internal consultation in the Commission
  - Feedback consultation with stakeholders (earliest mid March)
  - Discussion next WG (20 April)
  - Vote in April unlikely
- To note: priority on revision and recycling
- Delay by about 5 weeks versus December Discussion

Background 17th amendment

- Main motivation alignment with recycling regulation
  - Manufacture of substances from waste (Article 1(3) R 2022/1616, 'chemical recycling')
  - (revision of 'layer approach') + SML for plastic inner layers under Article 14
  - reprocessing of plastic (off-cuts and scraps)
  - GMP requirements (amendment of Annex to Regulation No (EU) 2023/2006)
  - DoC – introduction of recycled content
- Natural materials
  - purity of substances + use of authorised natural materials
- Biocidal substances – possibly
  - removal provisional list + derogation for substances authorised under BPR

Reprocessing – related to recycling

(1) The following point 20 is added to the end of Article 3:

'reprocessing of plastic means the return of plastic materials after their production at an intermediate or final manufacturing stage either to that stage or to an earlier stage in the manufacturing chain to use it again in the manufacture of plastic materials and articles.'

'Article 10

general restrictions and requirements on the composition of plastic materials and articles

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 reprocesses 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;

Reprocessing – GMP – Regulation 2023/2006

'C. Reprocessing of plastics in the scope of Regulation (EU) No 10/2011

1. Plastic offcuts, scraps, and similar by-products of plastic manufacturing processes and intended to be reprocessed in accordance with Article 10(1) of Regulation (EU) No 10/2011 ('materials intended for reprocessing') shall be collected as close to their point of first production as technically achievable, i.e. the point at which they are cut, scrapped or originate from a similar operation.

2. Materials intended for reprocessing shall be collected either using a closed piping or belt system only intended for that purpose, or in clean bins, bags, or other containers designated to this purpose and which can easily be recognised as being intended only for this purpose. Those containers shall be closed as soon as they are fully filled with a lid or closure that prevents mixing with plastic of another composition, other materials, or with waste materials until they are inserted for reprocessing back into the plastic production process.

3. Such bins, bags or containers may be transferred to reprocessing individually or be grouped in secondary packaging. The resulting unit shall be considered as a batch of material intended for reprocessing. The definition of 'batch' as defined in Article 2(20) of Regulation (EU) 2022/1616 shall apply.

4. At any stage of production or reprocessing operations until the actual return to the plastic production process, operators shall ensure that the quality assurance system prevents that materials intended for reprocessing are mixed with batches of plastic of another composition, other materials, or with waste materials.'

Article 4 - Recycling

- Ensure that plastics in scope fo Regulation (EU) 2022/1616 are used in accordance with that:

(2) Point (e) of Article 4 is replaced with the following:

'(e) comply with the compositional and declaration requirements set out in Chapters II, III and IV of this Regulation; and

(f) comply with Regulation (EU) 2022/1616 on recycled plastic materials and articles if they are in the scope of that Regulation'

- Note, remark from a Member State:
  shouldn't there be a link in Article 4 to Article 17, 18, Annex III and Annex V?
  - there is no reference to Chapter V in point (e)

Layer issue

- main alignment may cause problem with 'layer' approach under R 10/2011
  - at present we consider this likely not problematic for alignment with recycling, should we still change it?
- E.g. Article 5 says:
  - *Only the substances included in the Union list of authorised substances […] set out in Annex I may be intentionally used in the manufacture* ***of plastic layers in plastic materials and articles****.*
  - Also Article 6 and 8 refer to layers in this way
  - the Regulation doesn't say that layers need to be flat
- Why? Because R 10/2011 includes plastics that are printed or coated
  - to apply the OML and SML to printed or coated plastics, but not the other compositional requirements
- Alternative approach is to remove references to 'plastic layers' in Article 5, 6, 8
  - and include a derogation for substances in printing inks and coatings in Article 6
  - *'substances other than those included in the Union list may be used in the manufacture of coatings and printing inks applied on plastic materials and articles subject to other applicable specific measures and national law,*

removing reference to layers

(3) Paragraph 1 of Article 5 is replaced with the following:

'1. Only the substances included in the Union list of authorised substances (hereinafter referred to as the Union list) set out in Annex I may be intentionally used in the manufacture of plastic materials and articles.'

(4) In paragraph 1 and 2 of Article 6 the phrase 'plastic layers in' is deleted;

(5) In paragraph 4 of Article 6 the phrase 'plastic layers of' is deleted;

(6) Paragraph 5 of Article 6 is replaced with the following:

6. By way of derogation from Article 5, any substance may be used in the manufacture of adhesives, coatings and printing inks applied on plastic materials and articles, if that use is in accordance with Article 3 of Regulation (EC) No 1935/2004, and with specific measures and national law applicable to adhesives, coatings and printing inks.'

Biocides in FCM: Current situation

Regulation 10/2011 concerning authorisation of biocidal substances in plastic FCM

- Currently on an EU provisional list for which a derogation applies for the need to authorise these substances (Article 7). These substances are subject to national legislation
- Triclosan + 10 silver-based substances, for which EFSA has published positive opinions
- Otherwise subject to Article 5 i.e. need to be assessed by EFSA and authorised in Annex I

Regulation 528/2012 concerning approval of biocidal substances and authorisation of biocidal products (the 'BPR')

- Includes treated articles
- Approval required for substances used in products used to impregnate materials which may enter into contact with food (and subsequently authorisation of the biocidal product)

Biocides in FCM: Recent risk assessments

- Applications for silver substances evaluated under BPR:
  - silver zeolite, silver zinc zeolite, silver copper zeolite and silver sodium hydrogen zirconium phosphate
  - evaluated based on two representative uses including FCM i.e. the incorporation of silver compounds into food contact materials to avoid cross contamination with pathogens
  - Based on the evaluation reports by the competent authority of Sweden, ECHA issued opinions recommending **non-approval** due to lack of efficacy and due to the identification of unacceptable risks for human health
- ECHA and EFSA have issued a joint document
- EFSA has recently (2021) given a positive opinion on silver nanoparticles to be used in FCM, using the revised ADI for silver determined by ECHA

Biocides in FCM: Conclusions

- Once non-approval of the silver substances for PT4 may be adopted for the BPR, it is no longer legal to place FCM on the market containing those active substances
- Other substances on the provisional list and silver nanoparticles are not supported by a valid application or approval for PT4 under the BPR
- BPR supports:
  - a risk assessment and approval process for biocidal substances to be used in FCM and
  - subsequent authorisation of the biocidal product to be incorporated into the FCM and
  - possibility to set restrictions (SML) if required

Biocides in FCM: Way forwards

- Since substances on the provisional list are not supported by an approval or valid application under the BPR, the provisional list will be withdrawn and Article 7 deleted
- FCM substances providing a biocidal function as an additive in plastic FCM will be subject to Article 6 (i.e. a derogation subject to the BPR)
- Follow-up to EFSA opinion on silver nanoparticles via Article 11

Biocidal substances in plastics

- Derogation is introduced in Article 6

> '5. By way of derogation from Article 5, substances approved in accordance with Regulation (EU) No 528/2012 for use in biocidal products intended to impregnate plastic materials which may enter into contact with food, may be used as additives in the manufacturing of plastic materials and articles. Any applicable restrictions and specifications set out in that approval shall be met.

  - If appropriately authorised under the BPR, the substance can be used in plastics
  - may require the definition of a migration limit
  - biocidal processing aids, etc., do not have function in final material → NIAS
- Article 7 is deleted – including the provisional list therefore!

Article 8 - purity

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.

- We consider the purity requirement requires strengthening
- Article 1(3) of R 2022/1616 states:
  - 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**
- Recyclers need legal certainty: 'novel technology' or Article 1(3)?
  - main issue is level of contaminants – when is the 'purity suitable'?

Update of Article 8; high degree ofpurity

Reasons

- **'chemical recycling'** (quantifiable maximum contaminant level)
- natural substances
- NIAS (when to apply Article 19?)

- New structure of Article 8
  1. substance to correspond to its identification and specification in table 1 of Annex I
  2. 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**
  3. Substances recovered from waste in accordance with Directive 2008/98/EC may only be used in the manufacture of plastic materials and articles in accordance with Article 1(3) of Regulation (EU) No 2022/1616, **and shall be of high degree of purity**.
- So, what is a high degree of purity?

Clarification of Natural substances also in Art. 8

- Article 8(1) to include the following:
  - substance to correspond to its identification and specification in table 1 of Annex I
  - In case the substance originates from a material that has been obtained from natural sources, including from food sources, and it is identified by a chemical name, the substance identified by that name shall be of a high degree of purity.
    → lignocellulose ≠ random plant material that happens to have a high lignocellulose content
  - However, where the substance name includes the name of the natural material, that material may be used as obtained from nature provided it has been separated from other natural matter not identified by the substance name. In this case, it may contain all substances that are naturally present in the natural matter identified by the name of the substance.
    → cotton fibres (FCM 24) do not need to be purified to contain only one substance, but cannot contain other parts of the cotton plant

Ensuring the safety of plastic FCMs - **impurities**

- <u>Only</u> authorised substances may be used to manufacture plastics
  - EFSA assesses all starting substances (monomers) and additives (+ related impurities)
  - they are authorised subject to restrictions (e.g. permitted use, limits,…)
  - impurities are permitted without authorisation ('NIAS'), but subject to risk assessment

- What about those 'permitted' impurities?
  - originating from the manufacturing process
  - <u>individual</u> impurities must be risk assessed
    → they **must be identifiable**
  - contaminants (from waste) ≠ impurities (from manufacture)!

Article 19

Assessment of substances not included in the Union list

Compliance with Article 3 of Regulation (EC) No 1935/2004 of substances referred to in Articles 6(1), 6(2), 6(4), 6(5) and 14(2) of this Regulation which are not covered by an inclusion in Annex I to this Regulation shall be assessed in accordance with internationally recognised scientific principles on risk assessment.

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/EC[2] 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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Updated purity requirement; core provision

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.

4. For the purpose of paragraph 2 and 3 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 impurities 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 migrating into the food; or,
   (iv) such as contaminants from waste 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.

- the **draft wording** of the core provision is to help you to start your thinking
- What are your views?
- What should A and B be?
- What is reasonable?
- this approach is also relevant for the revision

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Article 8(5)

- not a lot of feedback
- A = 10 ppb (0.01 mg/kg)
- B could be
  - 0.15 ppb (TTC, 0.00015 mg/kg)
  - 1 ppb
- However
  - detected substances not identifiable
  - NIAS not available for tox testing
  - other practicable difficulties
- Solution
  - a) reason that most substances are unlikely to be toxic, B to be higher, and/or
  - b) provide derogation if supply chain excluded presence of genotoxic substances, or
  - c) long transition time…?

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.

Additional provision Article 8, Article 9

6. Documentation showing compliance with paragraph 1-4 shall be part of the documentation referred to in Article 16.

7. Manufacturers of plastic materials and articles, and of products from intermediate stages of their manufacturing shall ensure that it is possible for competent authorities to verify the degree of purity and composition of substances by taking samples at the manufacturing stage where the substance is first used.'

(9) The following paragraph 3 is added to Article 9:

'3. Substances meeting the definition of 'additive' which are in the form of solid particles or fibres of which only the surface is covalently bound to the polymers contained in the plastic shall be considered additives.'

Can particles be starting substances?

- Certain filler materials are covalently bound to the polymer chains
  - Glass fibres using Glymo, organic materials may be bound in a similar way
  - does that chemical link make them starting substances?
  - No, they remain additives, bulk (most of the polymers contained in them) do not react

- We will consider to add to Article 9 the following:

'3. Substances meeting the definition of 'additive' which are in the form of solid particles or fibres of which only the surface is covalently bound to the polymers contained in the plastic shall be considered additives.'

Repeat use

- Stability rule
  - to be discussed next
  - stability rule is not a requirement on composition
  - it a testing requirement
- New provision on aging
  - Article 10(3)
  - would this make sense?
  - provision needs clarification; present wording just illustrative

3. Where intended for repeat use in contact with food, the composition of plastic materials and articles shall be such that plastic materials and articles do not deteriorate during their foreseeable lifespan. An increase in the migration of constituents of the material or article when subjected to subsequent use cycles shall be considered as deterioration. In addition, observable changes to the surface of plastic materials and articles, including surface cracks (crazes), blisters, delamination, shrinkage or other deformation, and yellowing or other permanent discoloration or loss of gloss or transparency, shall also be considered to indicate an unacceptable deterioration, unless the operator prior to placing the material or article on the market has documented scientific evidence in accordance with Article 16 demonstrating that a particular kind of deterioration does not contravene Article 3 of Regulation (EC) No 1935/2004. Usage related changes such as tainting from colorants from foods, including from lycopene and curcumin, or mechanical damage such as scratches or breakage shall not be considered a deterioration of the material or article, unless so extensive that it may result in higher migration of the constituents of the material.

The maximum expected life span of the material and article shall be provided to its users by means of labelling or instructions, including instructions designed to slow down deterioration, as well as a description of observable changes that indicate end of life of the article or material.

The documentation required in accordance with Article 16 shall include a report on the assessment of the maximum foreseeable lifespan of the material or article.

Clarification of stability rule

- Introduction of performance criteria for analytical methods
- Made it possible to specify range for specific substances
- Many thanks to the EURL-FCM!

COMPLIANCE TESTING

For testing compliance of migration from plastic food contact materials and articles, an analytical method in accordance with the requirements of Article 34 of Regulation (EU) 2017/625 shall be selected, applying the following specific performance criteria:

– For the purpose of enforcement the calibration range of analytical methods shall be at least R_L * LL to R_U * LL, using a minimum of 5 calibration points equally distributed in this range. The legal limit (LL) shall be :
  – LL=SML for verification of compliance with a SML,
  – LL=5*SML for verification of compliance with a SML with food simulant D1 or D2 in case the fat reduction factor applies,
  – LL=OML for verification of compliance with the OML.

  Unless otherwise specified in table 1 or 2 of Annex I for the substance of which the LL is being verified, R_L (relative lower calibration range threshold) shall be 0.2, and R_U (relative upper calibration range threshold) shall be 2;

– The relative standard measurement uncertainty is calculated as the reproducibility coefficient of variation (CV_R) using the following formula's:

  $CV_R = 0.22$ (22 %) for $m \leq 0.12$ mg/kg, and

  $CV_R = 2^{(1-\frac{1}{2}\log(m))/100}$ for 0.12 mg/kg $< m <$ 138 g/kg

  Where m is the measured concentration of a substance that is to be evaluated against the legislative limit, and the uncertainty $u(m)$ shall be determined as follows: $u(m) = CV_R * m$.

In addition, the rules in Chapter 1- 4 of this Annex shall apply.'

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Clarification of stability rule

(b) Point 2.1.6 of Chapter 2 of Annex V is replaced with the following:

'If the material or article is intended to come into repeated contact with foods, the migration test(s) shall be carried out three times on a single sample using another portion of food simulant on each occasion. Compliance of the material or article shall then be verified on the basis of the level of the migration found in the third test and on the basis of the stability of the material or article from the first to the third migration test.

To the purpose of the first paragraph, the sample shall be considered non-compliant if:

$m_3 >$ SML, or,

$m_1 < m_2$ OR $m_2 < m_3$ OR $m_1 < m_3$,

where m_1, m_2, and m_3 are respectively the measured concentration in the first, the second and the third migration test.

These criteria shall be evaluated as follows, as applicable:

– IF $(m_i - m_j)/[(u(m_i) + u(m_j)] > 1.64$ THEN $m_i < m_j$
– IF $(m_3 -$ SML $)/[(u(m_3)] > 1.64$ THEN $m_3 >$ SML,

where i=[1, 2], j=[2, 3], and $u(m) = CV_R * m$

in case a measured concentration $m < R_L$* SML, m shall be considered equal to R_L * SML with the corresponding measurement uncertainty for the purpose of the evaluation of these criteria.

However, if there is conclusive scientific proof that the level of the migration decreases in the second and third tests and if the migration limits are not exceeded on the first test, no further test is necessary.

Irrespective of the above rules, a material or article shall never be considered to comply with this Regulation if in any of the tests a substance that is prohibited from migrating or from being released in detectable quantities under Article 11(4) is detected.'

Labelling provisions

- Discussed as part of old 16th amendment

4. Plastic materials and articles not yet in contact with food that are manufactured with substances included in the Union list for which column 10 of table 1 of Annex I sets out restrictions related to one or more of the following conditions of use of the final material or article, conditions limiting the use to

   – age or other population subgroups,

   – specific foods or groups of foods,

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

   – to heating conditions such as oven and microwave use,

   shall only be placed on the market if labelled with instructions of use directed at the final user of that material or article, and in accordance with Article 15 of Regulation (EC) No 1935/2004, ensuring that the user is provided with adequate information to prevent using the material or article under conditions exceeding the applicable limitations.

   If such a material or article is intended for repeated use, and by derogation to Article 15(7) of Regulation (EU) No 1935/2004, such labelling shall be indelibly affixed to the material or article by techniques such as printing or embossing, and a minimum font size of 3 mm (9 pt.) shall apply, unless for technical reasons, that information cannot be affixed with such techniques to the material or article, in which case the information shall displayed in accordance with Article 15(7) thereof.'

Article 14

- Article 14 to introduce migration testing
- Ensure safety in a changing market, particular in view of recycled materials

Paragraph 4 in Article 14 is replaced by the following:

'4. By derogation from paragraph 1, Articles 11 and 12 of this Regulation do not apply to multi-material multi-layer materials and articles when the layer that is in contact with the food or the food simulant during tests used to verify compliance in accordance with Article 18 is not a plastic layer or a coated or printed plastic layer'

Paragraph 6 in Article 14 is replaced by the following:

'6. In a multi-material multi-layer material or article, specific and overall migration limits for plastic layers and for the final material or article may be established by national law for multi-material multi-layer materials and articles to which the derogation provided for in paragraph 4 applies.'

Annex III

- Update of Cheese assignments
- Also discussed under 16th amendment

"07.04	Cheeses:					
	A. Whole cheese with inedible rind					X
	B. Unripened soft cheese (fresh cheese), e.g. cottage cheese, quark, ricotta, cream cheese, fromage frais, and similar cheeses		X(*)		X	
	C. Sliced ripened soft, firm or hard cheese or whole with edible rind, e.g. gouda, cheddar, gruyère, parmesan, stilton, tallegio, beaufort, tomino, brie, camembert, and similar cheeses					X/3
	D. Processed cheese, e.g. wedges, spreads and slices					X/3
	E. Brined or fresh cheese in a liquid medium e.g. feta and mozzarella:					
	I. in an oily medium					X
	II. in an aqueous medium		X(*)		X	

Annex IV

- Update to DoC

'9. when a functional barrier is used in a multi-layer material or article, the confirmation that the material or article complies with the requirements of Article 13(2), (3) and (4) or Article 14(2) and (3) of this Regulation;

10. when the plastic material is a batch of material intended for reprocessing the confirmation that it complies with Article 10(1) and that it has been obtained in accordance with point C of Regulation (EC) No 2023/2006, and, as appropriate a specification of its composition and instructions for reprocessing;

11. when the plastic material has been manufactured with one or more substances included in the Union list of authorised substances in accordance with Article 5 that have been recovered from waste materials in accordance with Article 1(3) of Regulation (EU) 2022/1616, the written declaration shall include the following:

– a confirmation that the level of individual contaminants present in these substances at the moment they have been first added to the manufacturing process subject to this Regulation was compliant with point (4)(iv) of Article 8 of this Regulation; and,

– an indication of the total content of such substances in the plastic material or article calculated as weight of recycled substances per weight of the total material or article and expressed as percent.

In case such a substance is not for 100% originating from recovery from waste this calculation shall only include the percentage of the substance which has been recovered from waste. If this percentage of recycled content in a substance is calculated using a mass-balance method a reference to the method used.'

Point B of Annex to R 2023/2006

(4) The title of section B and point 1 is replaced with the following

'B. Minimum requirements for a quality assurance system to be operated at recycling facilities where recycled plastic in manufactured in accordance with Regulation (EU) 2022/1616

1. The quality assurance system implemented by the recycler must give adequate confidence in the capability of all recycling operations taking place at the facility to ensure the recycled plastic meets all applicable requirements set out in Regulation (EU) 2022/1616, including those set out in Annex I thereof.'

(5) The following paragraph 3 is added to the end of section B

'3. The quality assurance system implemented by the recycler shall include specific operations in the recycling process, 'Quality Assessment Stages', at which the recycler shall assess the quality of each batch of material directly originating from a manufacturing stage.

This assessment shall verify the quality of each batch of material directly originating from that stage by verifying:

– whether the applicable critical limits referred to in point 2(c) have been met at each unit operation part of the manufacturing stage; and,

– whether the quality of the resulting material meets pre-defined criteria, using the tests, protocols and evidence referred to in point 2(e) applicable to that stage.

The assessment shall result in a decision on whether the quality of the batch is considered conform and suitable for further processing, or whether its quality requires correction before further processing or, alternatively, whether it is discarded or used for non-food applications, in accordance with point 2(d)'

Article 17(2)(a)

2. By derogation from paragraph 1 for:

(a) containers and other articles, containing or intended to contain, less than 500 millilitres or grams or more than 10 litres,

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

- Question from Member State on less then 500 ml derogation:
  - how to interpret in case already in contact with food – ie. quantity measured in food?
  - this underestimates real migration – a lot of packaging is actually smaller?
  - should we maintain this derogation?

DoC at Retail

- Correction of Recycling DoC question over Article 15
  - (Discussion correction Article 5(2) tomorrow)
- Should a DoC go to retailers?
- Interpretation of Article 15(1)
- Retailers do not need to issue, but receive it?

1. At the marketing stages other than at the retail stage, a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004 shall be available for plastic materials and articles, products from intermediate stages of their manufacturing as well as for the substances intended for the manufacturing of those materials and articles.

6.2 Table 2 – Business operators and their obligations in relation to DoC, supporting documents and labelling

Role	Goods	Receive Info	Keep Supporting documents	Next actor	Issue DoC	Labelling Art. 15
Non-plastic Manufacturer	Substance	No	Yes	Manufacturer	Adequate Information	No
	Intermediate	Adequate information	Yes	Distributor	Adequate Information[62]	No
Plastic Manufacturer	Substance	No	Yes	Manufacturer	Yes	No
	Intermediate	DoC	Yes	Distributor	Yes	No
Manufacturer	Article	DoC and Adequate Information	Yes	- User	Yes	Yes
				- Distributor	Yes	Yes
				Retailer + distribution centres	No	Yes
User	Article	DoC + labelling	Yes	na[63]	na[63]	na[63]	Consumer	No	Yes

17th amendment planning

- Please send us your feedback by 20 February
- Finalisation of text
  - drafting of recitals
- Internal discussion/consultation in Commission
  - review by lawyers
- Discussion in next WG – significant change expected

→ Vote in April unlikely

Other Amendment to Regulation (EU) No 10/2011 on plastic FCM

18th amendment

- ~~Precautionary measure that lays down a limit for styrene.~~
- ~~TiO2 interdiction~~

- Authorisation of one new substance

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18th amendment

Authorisation of one new substance

Substance bis(2-ethylhexyl)cyclohexane-1,4-dicarboxylate (DEHCH, FCM No 1079)

- Additive (plasticiser) in poly(vinyl chloride) (PVC) at up to 25% w/w in contact with in contact with foods for which simulants A (10% ethanol) and B (3% acetic acid) are assigned, at room temperature or below (refrigerated and frozen).
- SML 0.050 mg/kg food

19th amendment

State of play

- **Precautionary measure that lays down a limit for styrene**

Guidance value of 20 ppb determined by the WHO for drinking water on the basis of a TDI and a 10% allocation factor (exposure from food is half of that from drinking water).

➔ **precautionary limit of 40ppb**

- **Testing methods => ongoing discussion**
- **Transition period (36th months / 9 months to include the amount of styrene monomer in DoC)**

Future

- Bisphenol A – opinion expected in March
- FCM 93 – new migration limit for wax
- …

Morning discussion 10/02

Recycling register

Authorisation Decisions

Register and MSs contribution

- Cooperation with the **MSs Authorities in order to double** check and evaluate the Forms received so far per MSs – Pls send us your feedback **by 23rd of February**

  ➢6 . MSs overview

  ➢7. List of RIN,RFN & RON per MSs
  - Installations
  - Facilities
  - Companies
  - Scheme

- Comments and questions to be forward SANTE-FCM-RECYCLING-REGISTER

Register and MSs contribution

(ex. Austria 12 Rec Installations)

The Register: Forms received from EU Recyclers (slide 3)

EU Countries	Recycling installation	Recycling facility	Company name	Scheme
Austria	12	9	10	1
Belgium	7	3	3	3
Bulgaria	3	2	2	1
Croatia	2	1	1	
Czech Republic	2	1	1	
Denmark	28	12	2	1
Estonia	1	1	1	
France	22	8	9	4
Germany	44	20	15	3
Greece	1	1	1	
Ireland	1	1	1	2
Italy	58	41	39	8
Latvia	2	1	2	
Luxembourg	3	1	1	1
Netherlands	14	6	5	
Poland	11	8	8	
Portugal	10	4	4	2
Romania	4	4	4	
Spain	41	24	25	7
Sweden	1	2	1	
Grand Total	267	149	135	33

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Register and Registration

Year 2023

- Next steps in the Register:
  - **EU Survey: All forms under one**
    - 1, 2, 3, Forms merged in one
    - 4 Form to be part of the above once finalised
    - https://ec.europa.eu/eusurvey/runner/123RECYCForms
  - Novel Technology form available
    - https://ec.europa.eu/eusurvey/runner/5RECYCLNovelTechnology

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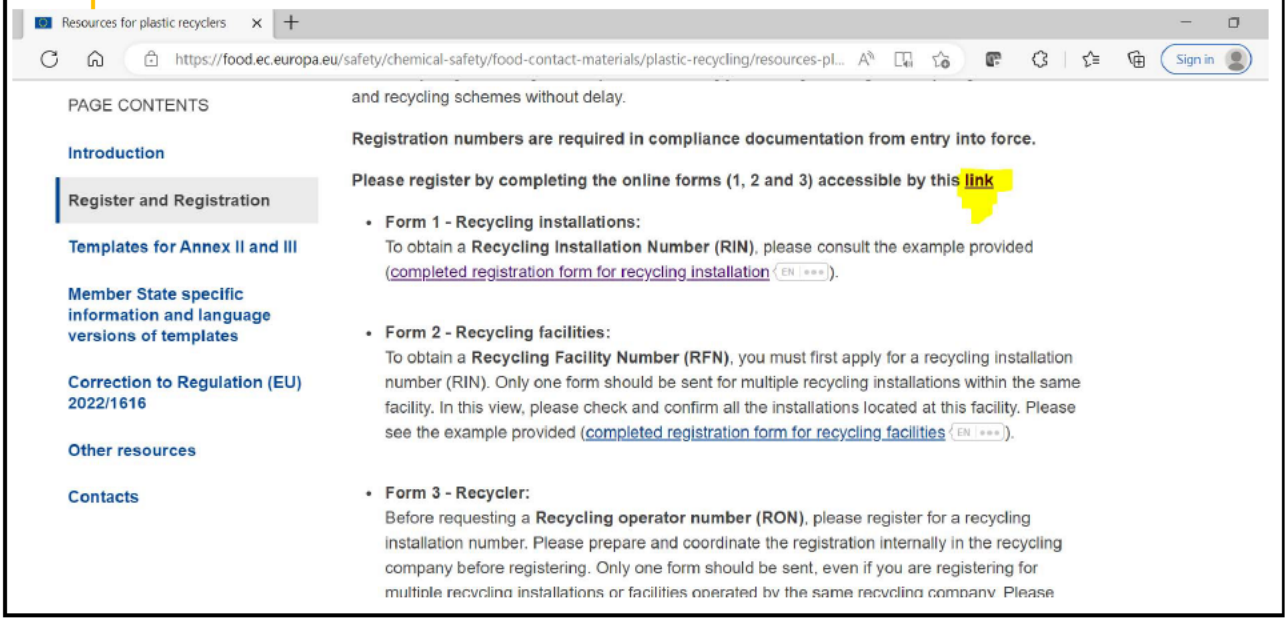
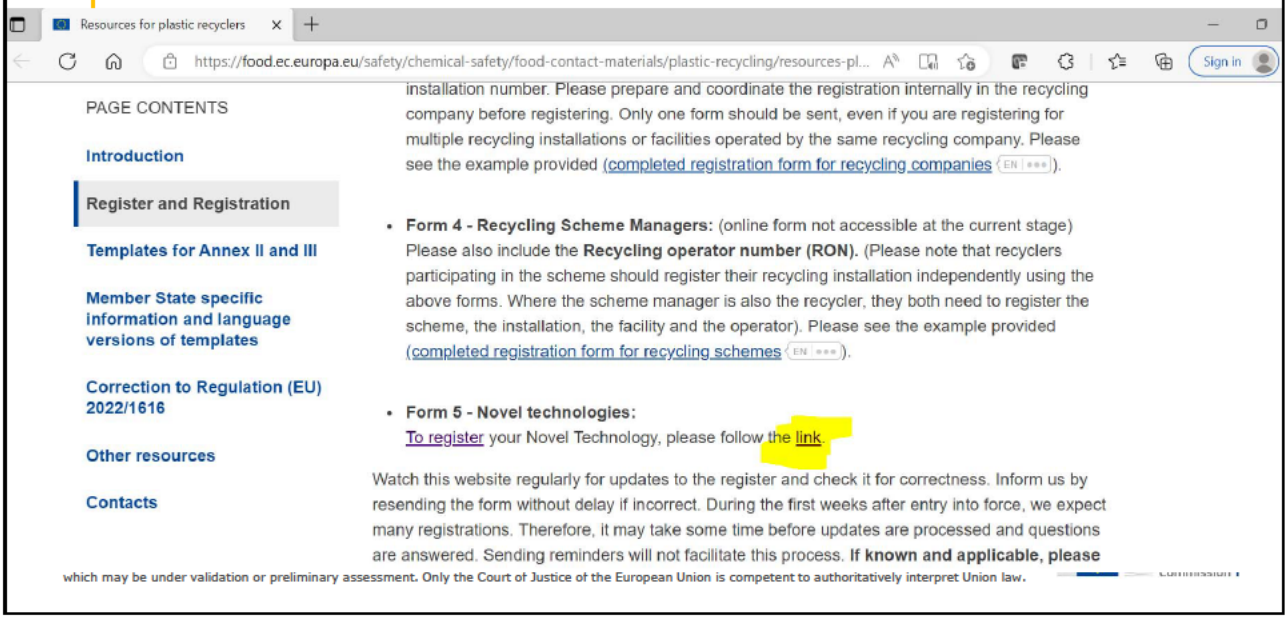
The Register: Eu Survey – Form 1,2 & 3



The Register: Eu Survey – Novel Technology



Part 2: Authorisation of recycling process

- COM invited the applicants (from 2008 till today) with a valid dossier (EFSA opinion & RECYC Number) to revise their personal data
- Batch 1: Out of the 237 applicants, 175 have replied and revised their personal data
- Under evaluation of the Authorisations Decisions and MSs will be informed about the process to be followed soon

- SANTE-FCM-RECYCLING-REGISTER@ec.europa.eu

Year 2022

Part 2: Authorisation of recycling process

- COM invited the applicants (from 2008 till today) with a valid dossier (EFSA opinion & RECYC Number) to revise their personal data
  1. June & September 2022
  2. 175 replies received
- Batch separated in order to facilitate the process
  1. Batch 1: 175 Authorisations Decisions
  2. Batch 2: The other ongoing & to be finalised dossiers
- Under evaluation of the Authorisations Decisions, MSs will be informed about the process to be followed soon

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Authorisation of recycling process

- Under evaluation: COM & MSs
  1. All EFSA opinions evaluated and separated in categories
  2. Categories selected due to their similarities, recommendations & conclusions
  3. Draft templates to be finalised & kick off the process
- Evaluation Process: COM & MSs
  1. COM will prepare drafts from all the categories to be shared with MSs
  2. Evaluation period to be followed
     - COM internal services
     - MSs evaluation
- Finalising & Voting the Authorisation Decisions

Year 2023

Authorisation of recycling process

- WG Documents shared with MSs
  - 1. MSs Authorisation Decision distribution
  - 2. MSs Authorisation Decision distribution + RECYC Number per MSs
  - 3. Evaluation Categories
  - 4. ex. of Recycling EFSA Opinion RECYC001
  - 5. ex. of Recycling Authorisation Decisions for RECYC001

❖Comments and questions to be forward SANTE-FCM-RECYCLING-REGISTER@ec.europa.eu

Afternoon discussion 10/02

CMSS

Authorisation Decisions

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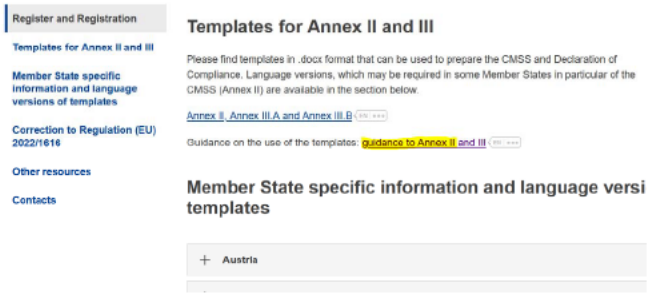
CMSS

- Discussion of Guidance:



- No CMSS documents were send by MS for explicit discussion

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Thank you

Happy to receive ques ions…