Working Group on FCM

19-20 September 2022

European Commission; DG SANTE E.2

Agenda

- 19 September
  - General introduction
  - Regulation (EU) No 10/2011
    - 16th – 17th – 18th amendments
    - outlook
  - Update on Bamboozling
  - Regulation (EU) No 284/2011
  - Revision
  - AoB
    - irradiation of packaging (SI)
    - copper(II)carbonate in AIM
    - EFSA mandate on phthalates

12:00 styrene industry
14:30 Bamboozling

- 20 September (Recycling)
  - Discussion and explanation of final text
  - Hands-on discussion of main procedures
    - Registration and Commission Register
    - Article 26 + Annex II (CMSS)
    - Authorisation
    - Compliance documentation
    - Enforcement
    - Recycling schemes
    - Novel Technologies
  - Discussion on draft guidance

Welcome

- Thank you for joining!
  - particularly those in the room
  - from now on we strive to continue this approach
    - i.e. hybrid meetings with interpretation (no interpretation tomorrow though)
    - we may schedule short remote discussions for flexibility (but without interpretation)
- New Plastic Recycling Regulation adopted
  - Publication soon – entry into force 20 days later – recycling fully harmonised
- The FCM team is now working on
  - the revision of FCM legislation – consultations and studies starting
  - recycling – preparation of register + 234 authorisation decisions
  - plastic Regulation
  - (follow other Commission files, substances, general activities, questions)

16th amendment

- Standing Committee was postponed to 19 October
  - changes to the text are still possible
- Discussion of the text – please raise your points
  - First annex
  - Then recitals, Article 3
- Discussion on wood
  - comments from Member State (wood), business operator (cork)

16th amendment deletion wood

- Comments from Member State on procedure
  - 9 months period to apply, stop-the-clock
- Questions from Member State on wood evaluation
  - How to deal with the evaluation on migrants?
  - Case-by-case basis – what is a different case (e.g. processing, intended use, …)?
  - What is a different plant species? There are sub-species?
  - What is meant with Origin?
    - (answer – not necessarily geographic origin, but new/recycled/reused)
  - Application for the wood species, or really for the final plastic containing the wood?
  - What about variations in the composition, how much would be accepted to be one use?
- Business operator on Cork
  - masterbatches of “plastics (PE, PP, PVC) mixed with finely ground recuperated cork (e.g., cork stoppers from empty wine bottles)”.
  - is cork wood? Should “finely ground recuperated/recycled cork” be considered as “wood flour”? “plastics additive from plant origin”?
  - note additional complication – if the ‘recuperated’ cork is additive to the plastic, recycling regulation applies
- Questions firstly to be addressed by EFSA
  - discussions on natural materials have started, COM request following opinion on bleached cellulose
  - natural materials to become specific subject under revision

17th amendment

- planned update in view of new recycling regulation
- we are considering to:
  - clarify that the Regulation applies to the manufacture of plastic without recycled content
  - introduce purity requirements
  - clarify rules on natural materials (nothing to do with recycling, but with purity)
  - set limitations on off-cuts and scraps (composition)
  - adapt rules on migration testing concerning multi-layer multi-material materials (!)
- It also adds rules on quality control and the handling of offcuts and scraps to Regulation (EC) No 2023/2006 on good manufacturing practices for FCMs.

17th amendment

- clarify that the Regulation does not apply to plastic with recycled content
  - the new recycling Regulation applies; precise wording still being developed
- Updated purity requirements
  - particularly when recovered from waste
  - no oligomers, full depolymerisation
  - no contaminants (impurities allowed)
  - possibility for documentary checks
  - possibility for samples

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.

- Why? → To ensure clear separation with new Regulation on recycled plastic
- Contaminants are random, from previous use, impurities subject to Article 19

17th amendment

- rules on reprocessed plastic
  - 'off-cuts' and 'scraps'
- previously consulted with industry
  - printing inks commonly present
- Regulation (EU) No 10/2011:
  - rules on composition in Article 10
- Regulation (EC) No 2023/2006:
  - new point C
  - handling of collected plastic to avoid contamination
- Rules to ensuring the plastic still meets Regulation 10/2011

'Article 10

general restrictions 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 for all substances contained those residues compliance with the conditions referred to in point (d) is demonstrated on the basis of an assessment in accordance with Article 19;

17th amendment

- We are considering to add migration testing requirement in Article 14 if layer on the food side is a plastic
  - Presently multi-layer multi-material materials exempt from migration testing
- To ensure safety when recycled plastic is combined with another material, such as when coated with plastic
  - Consequence: industry to ensure the limits under R 10/2011 are met, also if migrants originate for instance from paper and board behind a plastic layer
- possibly related clarifications deleting reference to 'plastic layers'
  - in Article 5(1), Article 6(1), (2) and (4)
  - also clarification exempting coatings and printing inks from compositional requirements
- All subject to further analysis

17th Amendment

- Following discussion on bamboo and coffee husk better definitions
  - unrelated to recycled plastics
- Organic substances listed in Annex I considered authorised only when pure
  - no presence of long list of substances that were present in the plant materials
  - purification techniques to be used (e.g. regenerated cellulose)
  - unless clearly authorised
- Listed organic materials (e.g. 'cotton fibres')
  - may not be contaminated (e.g. mineral oils) (note, if recovered subject to recycling)
  - Verification of aging of the material beyond three migration tests
- Subject to further analysis (unintended consequences?)

17th amendment to amend R 2023/2006

- New point C – already discussed, handling off-cuts and scraps;
- New point B.3
  - better support of compliance monitoring summary sheet
  - 'quality assessment stages'

ANNEX II

Template for the Compliance Monitoring Summary Sheet in accordance with Article 26 of Regulation (EU) …/…

Quality Assessment stages:

For the purpose of the compliance monitoring summary sheet, a Quality Assessment ('QA') stage shall refer to a specific operation in the recycling process during which the quality assessment takes place of batches of material resulting from the manufacturing stage immediately prior to the QA stage.

At a QA stage, one or more tests in accordance with point 2(e) of Annex B to Regulation (EC) No 2023/2006 shall be performed on the batch, and/or the production parameters used during that manufacturing stage for the manufacturing of the batch shall be verified. The analysis and/or verification shall establish whether the assessed material meets the quality standards applied in the recycling process.

There shall always be a QA stage where material enters the recycling process located at the facility, and where recycled plastic or plastic materials and articles leave the facility.

At the QA stage, a record with the outcome of the QA shall be compiled and kept in the recording system.

17th amendment planning

- Drafting expected to be finished mid-October
  - text is already advanced, but some questions
  - needed for certainty over alignment with recycling regulation
- Feedback period in November – vote 24 November seems too ambitious
  - very tight planning, competes with authorisation decisions for recycling processes
  - discussion of text with Member States needed
  - industry not expected to be quiet
- Likely voted in SC early 2023

18th amendment

- Considering to lay limits for Styrene + TiO2
  - (likely used to authorise substances as well)
- E-mail send on 29/08 to prepare you for this discussion
- Exchange on positions to determine our approach

TiO_2

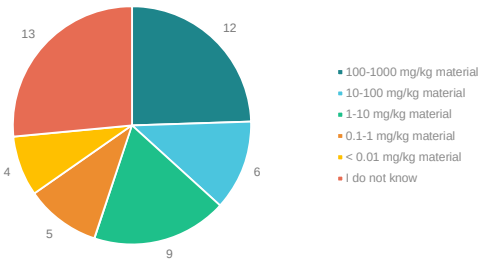
- TiO_2 authorised without a limit (but cannot be used in nanoform)
- Present basis for authorisation originates from old SCF opinion
  - concerning food additives
- Use in food additives now banned following updated view on toxicology
  - our present basis is consequently questionable
  - modern reasoning used by EFSA appears to be that it doesn't migrate, so not of concern
- Should we lay down a ND limit on TiO_2? Probably, yes, 10 ppb
- Key question: what method to use to verify compliance, hence how to express limit?
  - Method for determining TiO_2 migration?
  - Method for determining titanium migration?
  - Titanium not of a concern toxicologically, has other uses (e.g. catalyst) and may be impurity

Styrene discussion

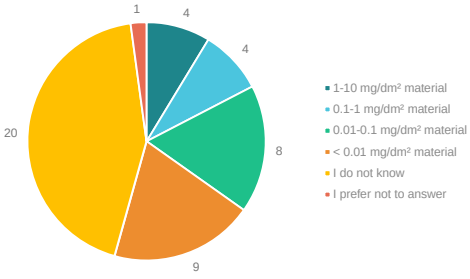
- Several times discussed in the past; no doubt we need a limit
- Two key questions:
  - Shall the limit be 10 ppb, which is (according to EFSA) achieved in majority of foods?
  - How to approach verification of compliance, as simulants are problematic?
- Foreseen approach 10 ppb specific migration limit (that is not 'ND')
  - verification in the food
  - food matrix too complex? then determine residual free styrene in plastic, 100% migration
- Significant amounts of residual styrene reported, up to 1g/kg
  - 100g yoghurt in 5g polystyrene cup with 100mg/kg free styrene: 50 ppb migration
  - 100 mg/kg free styrene appears to be rather normal; scenario would seem typical

Residual styrene and styrene migration

Residual free styrene concentration in the materials



Migration under typical testing conditions



Additional information provided by stakeholders

- Presence of free styrene monomer can be above 500 mg/kg polystyrene, which leads to a theoretical maximum amount of migratable styrene above the regulatory limit.
- Testing the migration into food is possible but very challenging, especially since there are no defined standards.
- There can be a high variability between laboratories when measuring the free styrene content of the same sample with the same method.
- Migration of styrene into food was analysed for following product categories:
  - Dairy products (migration from PS below 10 ppb – 30 ppb, from ABS around 100 ppb, from SAN below 10 ppb)
  - Fish and meat (migration from EPS below 10 ppb – 30 ppb)
  - Oil (migration from ABS around 200 ppb, from SAN below 20 ppb)

Some unknowns

- The real toxicology of styrene (‘genotoxicity cannot be ruled out’)
  - Commission mandate under preparation – answer may come in a few years only
- In what food matrices styrene can be determined reliably
- To what extend it is really possible to reduce residual styrene in polymers by using better manufacturing techniques
- Not unknown:
  - simulants do not work
  - high content / migration occurs from all styrene based plastics, EPS worst

FCM Revision

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 regulation 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
- 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

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Possible options for FCM rules B: Prioritisation of substances

- **All substances** that may pose a risk to consumers, regardless of origin, including non-intentionally added substances (NIAS) and groups of substances as relevant
- **Tiered approach, with precedence given to certain hazard classes**

EU/ public risk assessment bodies

1. Generic risk approach/ hazard-based: CMRs, EDs, PBTs and vPvBs.
2. Generic risk approach/ hazard-based or specific risk assessments: Other substances with specific properties such as neurotoxins, immunotoxins or e.g. substances in nano-form or that migrate in high amounts

Self-assessment

3. More benign substances and those migrating in low amounts

- **Dialogue with and input required from EFSA and MS/ national risk assessment bodies** to inform on priorities and capacity for future risk assessments
- **Continuation of cross-cutting exercises** e.g. **CSS** (GRA and essential use, EDs, combination effects, OSOA including interaction with evaluation of substances for materials in contact with drinking water)

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Some key issues for discussion – risk assessment

- On what basis should FCM substances be prioritised for risk assessment and subsequent EU risk management?
  - Hazard classes inc. genotoxicity, CMRs, EDs, PBTs/ vPvB, immunotoxicity, neurotoxicity
  - Material types
  - Use and exposure
- How to tackle ‘natural’ materials, taking into account the potential unknown substances present? See recent EFSA opinions on wood and bleached cellulose
- What approach should be used to better address the combination effects of different [FCM] substances?

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Some key issues for discussion – risk assessment

- EU risk management needs to be based on independent and transparent risk assessment processes, taking into account the requirements of the TR
- Who should do this? Capacity for risk assessment
  - EFSA
  - ECHA in the context of 'one substance, one assessment'
  - Member State level
  - What should be the responsibility of business operators?
- What data needs to be made available eventually and by whom?
  - Currently plastic substances for which an authorisation is not required should be risk assessed according to "internationally recognised scientific principles on risk assessment"

Some key issues for discussion – risk management

- Which current tools are important for risk management of FCMs?
  - SML
  - OML
  - 10ppb limit
- What does it meant to prohibit/ ban a substance?
- Who should be responsible for determining whether the use of an FCM substance is essential or not?
- Analytical capabilities: individual substances or multi-analyte methods
- What testing requirements are necessary?
- What is the ultimate capacity of Member States to carry out official controls to verify FCMs on the market are compliance and therefore safe?

Next steps

- Publication of **Public Consultation** (to be published shortly, 12 weeks duration)
  - Questions for citizens on scope of the legislation, the safety of FCMs, consumer information and labelling and aspects relating to re-use and sustainability
  - Questions for stakeholders (MSs, business associations, businesses, NGOs etc) on scope, including more focus on final articles, prioritization of substances, supporting safe and more sustainable FCMs and improving supply chain information, compliance and enforcement
- Parallel/ follow-up work → **citizen engagement group** (autumn 2022)
- **Study** to support objectives A, D and E
  - Develop options for an IT infrastructure required for information exchange
  - Define the roles of the various actors (operators participating in the FCM production chain, food business operators, competent authorities in the EU and abroad, notified bodies, delegated bodies and consumers)

Next steps

- Further work on options for **sustainability** (objective C) and possible supporting study, taking account of other developments e.g. on SUP and packaging and packaging waste revision; Sustainable Products Initiative and Green Claims; Framework for Sustainable Food Systems (FSFS)
- Define **analytical (laboratory) methods** that can support efficient verification of compliance and controls of final FCMs with the safety requirements
- **Further consultation work** foreseen (e.g. expert working group, targeted questionnaires, case studies, focus groups, discussion forum)
- Further discussions with MSs on risk assessment approaches in the context of EFSA's FCM FIP Network

Commission Regulation (EC) No 284/2011

Commission Regulation (EC) No 284/2011

- Contributions to fill in the data gaps
  - Concerns all but 2 MSs
  - Most Member States responded
  - Some data overridden – reduction in consignment numbers
  - Remaining blanks = zero consignments?
- Article 9: Reporting to the Commission
  - Competent authorities shall keep records of each consignment checked, including size in terms of number of articles; the country of origin; the number of consignments subject to sampling and analysis; the results of the documentary, identity and physical checks
  - Member States shall submit to the Commission a report including the information above, quarterly by the end of the month following each quarter

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Commission Regulation (EC) No 284/2011

- SANTE Data Collection Platform:
  - Editor → person from MS who can input data
  - Senior user → person from MS who can input data and submits reports
  - Requires EU login profile
- Action for MSs
  - Ensure those who are responsible for carrying out the controls have at least an 'editor' profile and can generate a report
  - Ensure at least one person responsible for submitting the report(s) to the Commission and therefore has 'senior user' access
  - Retrospective completion of data via the SANTE Data Collection Platform autumn 2022
- Discussion:
  - Issues encountered?
  - Future of the Regulation

Thank you

Happy to receive questions/discuss…

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