Update on the revision of EU FCM legislation and other activities

EFSA NETWORK ON THE COOPERATION AND HARMONISATION OF RISK ASSESSMENT OF FOOD CONTACT MATERIALS (FCM)

12th meeting

21 – 23 October 2025

DG SANTE
European Commission

Contents

1. **The Revision of EU FCM legislation**
   - What are the objectives?
   - How might approach future policy
   - How will we work

2. **Short feedback on topics regarding the implementation of**
   - the plastics Regulation (substance authorisations)
   - the recycling Regulation
   - the BPA Regulation

1. Revision of EU FCM legislation

European Commission

Revision

- We are currently accelerating the work on the revision
- The purpose of the following slides is to:
  - Briefly recall the reasons for the revision
  - Outline how we view possible future FCM legislation
    - objectives / aspirations
    - as a starting point for further discussion
  - Explain how we will work

Problems identified: Why revise FCM legislation?

- Evaluation and study activities from 2017-2022: action is needed
  - For detail, please see our dedicated evaluation webpage
- Issues raised
  - Beyond plastics, little or no harmonisation → **lack of functioning of EU market and uncertainty over safety**
  - Harmonisation made difficult by issues with authorised list approach, inc. **lack of assessment capacity and prioritization of substances**, **up-to-date assessments** and **lack of focus on the final article**
  - **Exchange of safety and compliance information** in the supply chain is poor and ability to ensure compliance is compromised; enforcement of rules on FCMs is generally poor
  - Rules do not sufficiently take into account the **specificity of SMEs**
  - Rules do not encourage development of safer and more **sustainable alternatives**
- Causes are inherent to the present regulatory system
  → **fundamental change to present system required** to address issues

FCM Revision: Primary objectives

1. Ensure appropriate **harmonisation** across all materials
    - improve certainty over **food safety**
    - improve **functioning of the EU market**
2. **Simplify** – make rules more practicable, enforceable and achievable
3. Achieve **accountability** regarding (final) materials and articles
4. Improve **competitiveness and legal certainty**

- for all primary objectives we keep in mind
    - SMEs (particular focus on **traditional** and **artisanal manufacturing**)
    - tools for compliance and enforcement
    - level playing field (including internationally)
    - sustainability

FCM Revision: Main principles / aspirations

1. Ensure **safety of final food contact articles** (FCAs)
   - Requirements to **share information** throughout supply chain
   - **Transparency** on composition of final articles and on migratable substances
   - **Accountability –** clarity over business operators' responsibilities
   - **Final responsibility with producers** of final FCAs who must have all necessary information
2. Common **approach for risk assessment** and level of safety for **all FCMs**
   - including how to demonstrate and verify the level of safety
   - Difference between intentionally and non-intentionally added substances disappears
3. In general, **rules to apply equally regardless of materials type**; some distinctions and adapted approaches may be needed (e.g. recycled materials)
4. the use of **GMP** as a tool to know and control composition of materials

FCM Revision: Main principles / aspirations

5. Prioritise risk assessment of substances and risk management at EU level
   - Aim to **ban the most harmful substances** and increase uptake of more benign substances and materials
   - Chemicals classification outside FCM legislation to gain in importance (REACH, CLP)
6. Promote inertness of FCMs
   - it should be cheaper to manufacture more inert materials for a given application
7. Take account of ageing and foreseeable use
   - information and knowledge to consumers
8. Support **sustainability** of materials
9. make use of **digitisation of information** on FCMs to the furthest extent possible
10. enforcement of **compliance of the compliance process** rather than of the product

Organisation in main policy themes and pillars

Safety and sustainability of food contact materials (FCMs)

A + B together represent the core possible approach

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

C. Support more sustainable alternatives

Information exchange, compliance and enforcement of FCMs

To support A+B (and C): verify safety, sustainability and ensure smooth functioning of the internal market

D. System for exchange of information in supply chain

E. System for verifying compliance and official controls

F. Further develop analytical methods

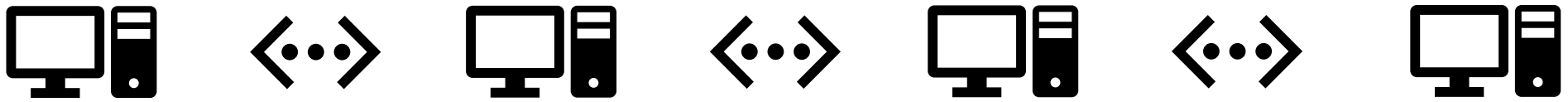
Pillar A

1. Business operators to have **complete knowledge on composition of FCM**
   - intentional and unintentional substances, throughout the supply chain
   - potential for migration (‘migratable substances’) in final food contact article (FCA)
   - exception for for manufacturers of starting substances, preparations and materials, that are not specifically intended for food contact and declared as such
   - small print to be defined; which business operators must have what knowledge
2. Use of **GMP** to control manufacturing processes
   - Improve knowledge on composition of substances, preparations and other intermediate materials declared as suitable for food contact
   - customers only procure intermediate substances, preparations and materials that are suitable for food contact.
   - possibility for scheme or self-responsibility for validating or certifying materials

Pillar A

3. Undertake a **risk assessment** of migratable substances
   - techniques including analytical verification or migration modelling needed to ensure real migration levels under foreseeable/intended conditions of use do not have an adverse effect on human health
   - ensure compliance with specific restrictions (e.g. ban of substance)
   - link with Pillar B

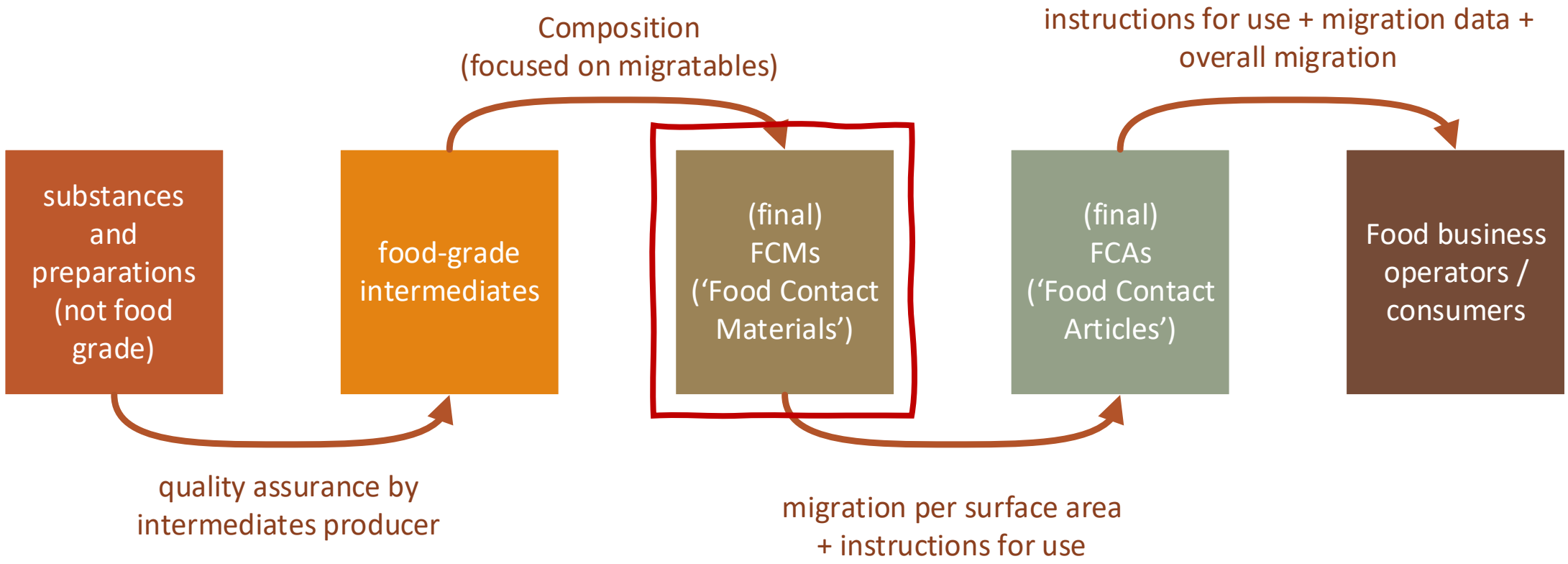
4. Make **information available!**
   - in full to enforcement authorities
   - all information necessary to ensure safety to be passed from business to business, respecting defined legitimate business confidentiality
   - in principle, communication only on substances present in amounts that may cause risk



Pillar A

5. Ensure **technological innovations** are taken into account as they become available over time to improve certainty over safety
   - appropriate design of the final article and production practices that improve inertness of FCMs and minimise migration
   - limitations of use of the article (e.g. restrictions to certain food types)
6. System to ensure that only verified safe FCMs/FCAs can be placed on market
   - note difference approach to FCM versus FC Articles
7. FCAs must be accompanied by communication (instructions) on safe use; user of final FCA must use it in accordance with the instructions
   - manufacturers of final FCA to ensure appropriate communication
   - producers and processors of food, as well as caterers must follow instructions
8. Operators to have **sufficient expertise** to carry out the tasks under points 1 – 7

Pillar A: a view on complete knowledge



Simplification of Materials

- In principle **rules to apply the same to all materials**, regardless of 'type'
- Some distinction and need to tailor approach: but not to set different safety standards, to reflect practicable and achievable approaches for RA and RM
- Main considerations
  1. Synthetic organic type materials (plastics, rubbers, coatings, adhesives, inks..)
     Known substances: monomers, additives, PPAs, reaction and degradation products, impurities
  2. Natural organic type materials (wood, fibres, plant-based)
     Largely unknown substances
  3. Inorganic based materials including metals
     Known metal ions
- Special considerations
  4. Active (and intelligent) materials
     New substances arise when in contact with food
  5. Recycled materials
     Need to reduce contamination
  6. Composite (paper and board, multi-material)
     Combination of 1 + 2 + 3

Pillar B: Prioritisation of substances

1. Substances are no longer prioritised for risk assessment and risk management purely based on the need to authorise their use in the manufacture of FCMs
2. Tiered approach, with **precedence given to certain hazard classes**
    1. Generic risk approach/ hazard-based: CMRs, EDs, PBTs and vPvBs.
    2. Specific risk approach
        - Substances with other hazard properties e.g. immunotoxicity, nano-materials + other criteria e.g. substances that migrate in high amounts
        - Exceptions for tier 1 when sufficient justification
    3. More benign substances and those migrating in low amounts
    - Criteria for prioritization to be discussed and elaborated: Use, migration, exposure, grouping, cumulative and combination effects, vulnerable populations
3. Dialogue with and input required from **EFSA and MS/ national risk assessment bodies** to inform on priorities and capacity for future risk assessments

EU/ public risk assessment bodies

Industry self-assessment

Pillar B: other relevant legislation

- **Optimise efficiency**
  - utilise existing data sources e.g. REACH if possible, ensure existing data available to EFSA
  - sharing of information between agencies – 1S1A Regulation establishing a common data platform on chemicals
  - cooperation across RA bodies, harmonized approaches and consensus e.g. hazard properties – 1S1A Regulation to enhance cooperation among EU agencies in area of chemicals
- **Ensure consistency**
  - e.g. approach for hazardous substances in other products legislation such as cosmetics and toys
  - Rules for substances used in drinking water materials
- **Consideration of other EU legal requirements**
  - e.g. PPWR to prioritise ‘substances of concern’ and ensure safety of recycled materials

Pillar C: Sustainable FCM

- Work so far done as a separate study
  - help define what we consider ‘sustainable FCM’
  - possible measures that help achieve a higher level of sustainability
- Potential measures under future FCM legislation
  - Harmonised standards and guidance for reusable FCMs
  - Eco-design guidance for FCMs
  - Product essentiality test
  - Sector-wide science-based sustainability targets
- Further discussion needed to understand if sustainability as a third objective of legislation makes sense and has added value

Pillar D: Information in the supply chain

1. Ensure that the objectives of pillars A and B can be met
   A. transfer information in supply chain **digitally** / provide access to supporting documentation
   B. provide access to existing risk assessments
2. Challenges: To design a system and manage proprietary information
   - the information is (largely) to be provided by the supply chain - high level of transparency required
3. Implicit requirement on supply chain: **no information, no market**
4. Knowledge of FINAL producers
   - Expertise in chemistry or of consultants

Pillar E: Compliance and controls

- Role of **business operators in compliance**
  - What can be achieved by business operators?
  - Greater responsibility, greater flexibility, but also greater transparency
  - what about SMEs, in particular traditional and artisanal production
  - Possible use of **Notified Bodies** tasked with conformity assessment
- Role of **Member States in controls and enforcement**

Current

- Documentary checks
- Physical checks and lab controls
- Available resources → Need for prioritisation

Future

- Enforce the *process* rather than *products*? e.g. to check if
  - BOs have the capability to carry out risk assessment (RA)
  - BOs actually carry out the RA, including the standard and quality
  - Notified Bodies do their work as expected
  - Escalate RA to be done by public authorities, if necessary

F: Future of Analytical methods

- Current situation: only a very limited number of substances are routinely subject to verification of compliance on the basis of analytical methods, for which in many cases methods or accreditation does not exist

Intentionally used substances

- Introducing new technologies and methodologies to increase accuracy or efficiency
  - Multi-analyte methods
  - complex substances, e.g. MOAH
  - competencies of NRLs?
- Migration testing with food simulants
  - Need to re-assess current simulants and testing conditions for plastics?
  - Specific simulants and testing conditions for e.g. paper and board?

Non-intentionally used substances

- Non-targeted analysis required as substances cannot be predicted
  - Comparability of non-targeted screening between laboratories?
  - How to further harmonise the analytical methodologies?
  - How to ensure that harmonized libraries, needed for identification, are being used?
- Coupling with bioassays for risk management
- non-Targeted is growing
  - increasingly used by Industry and NGOs
  - recycling Regulation requires its use to monitor contaminants for novel recycling technologies
  - more formal method development, proficiency testing, and standards are essential

How will we work now?

- The previous slides are our starting position
- Main steps
  1. **Targeted dialogue and consultation with individual experts**
  2. (increasingly) Wider consultation on outcome with stakeholders when appropriate
  3. Finalisation of policy through impact assessment when appropriate
- About step 1 (which we have **now** started):
  - Format:
    - **Small group of experts** are consulted on basis of their **individual expertise (**not to represent the interests of a particular sector, business or viewpoint), through interviews, joint discussion, and documentation of ideas
    - Discuss issues and formulate solutions that work in a future regulatory system → document
    - Initial focus on pillars A+B
  - DG SANTE led; experts are being individually selected; solution driven

Important Disclaimer!

- The slides describe the ‘aspirations’ of the revision
- These do not necessarily reflect the reality of what will be the final legislation
- Some of these aspirations may not be achieved, or be differently achieved
- Discussions with EFSA, Member States and Stakeholders will be very important
- Success also relies on you!

2. Topics related to implementation

Plastics (Regulation (EU) No 10/2011): Substance authorisations

Recycled Plastics (Regulation (EU) 2022/1616)

BPA (Regulation (EU) 2025/3190)

Regulation (EU) No 10/2011: substance amendments

- 14 substances have received a favourable EFSA opinion and for 4 substances it was not possible for EFSA to conclude on the safety of the use of the substance
- 1st batch composed of 6 substances (based on 5 opinions)

FCM No	Name of substance	EFSA Question No
FCM 1084	Phosphorous acid, triphenyl ester, polymer with 1,4-cyclohexanedimethanol and polypropylene glycol, C10-16 alkyl esters	EFSA-Q-2022-00613
FCM 1089	Calcium *tert*-butylphosphonate	EFSA-Q-2022-00526
FCM 1092	Amines, di-C14-C20-alkyl, oxidised, from hydrogenated vegetable oil	EFSA-Q-2021-00555
FCM 1093	Wax, rice bran, oxidised	EFSA-Q-2022-00452
FCM 1094	2,2′-oxydiethylamine	EFSA-Q-2024-00102
FCM 1096	Wax, rice bran, oxidised, calcium salt	EFSA-Q-2022-00452

- The amendment with these substances was voted on favourably at PAFF 19 Sept 2025 and can be accessed via the Comitology Register. Now subject to scrutiny period of EP and Council

Regulation (EU) No 10/2011: substance amendments

- Other substances with a favourable EFSA opinion in preparation for additional amendments for vote in PAFF in 2026

FCM No	Name of substance	EFSA Question No
FCM 1086	Chopped carbon fibres, from carbonised polyacrylonitrile	EFSA-Q-2021-00006
FCM 1088	Poly(2-hydroxypropanoic acid), n-octyl/n-decyl esters- (oligomeric lactic acid)	EFSA-Q-2021-00006
FCM 1090	Mixture of 1,9-nonanediamine (NMDA) and 2-methyl-1,8-octanediamine (MODA	EFSA-Q-2019-00533 EFSA-Q-2019-00534
FCM 1095	N,n'-(2-(4-(2-aminobenzamido)butyl)pentane-1,5-diyl)bis(2-aminobenzamide)	EFSA-Q-2023-00721
FCM 19	N,N-bis(2-hydroxyethyl)alkyl(C8-C18)amines	EFSA-Q-2019-00483
FCM 1087	Nano precipitated calcium carbonate	EFSA-Q-2019-00232
FCM 93	Waxes, paraffinic, refined, derived from petroleum-based or synthetic hydrocarbon feedstock, low viscosity	EFSA-Q-2018-00558
	Silver nanoparticles	EFSA-2018-00640

- Other matters: styrene and non-authorisation decisions being prepared separately

Regulation (EU) No 10/2011: Wood applications

- Wood can no longer be used in plastic
  - unless in accordance with Regulation (EU) 2023/1442: only for uses for which application was received
  - also applies to wood-like products
  - example: lignocellulose is pure substance authorised as starting substance, not wood
- Transition period is being extended
  - precisely, the date for the validity check by EFSA of 1 February 2025 is to be extended by one year
  - Applicants to submit the necessary information to EFSA soon
- Future: specific applications, specific species of wood
- Again, wood and wood-like products are not presently authorised
  - specific substances are authorised, e.g. ground sunflower seed hulls

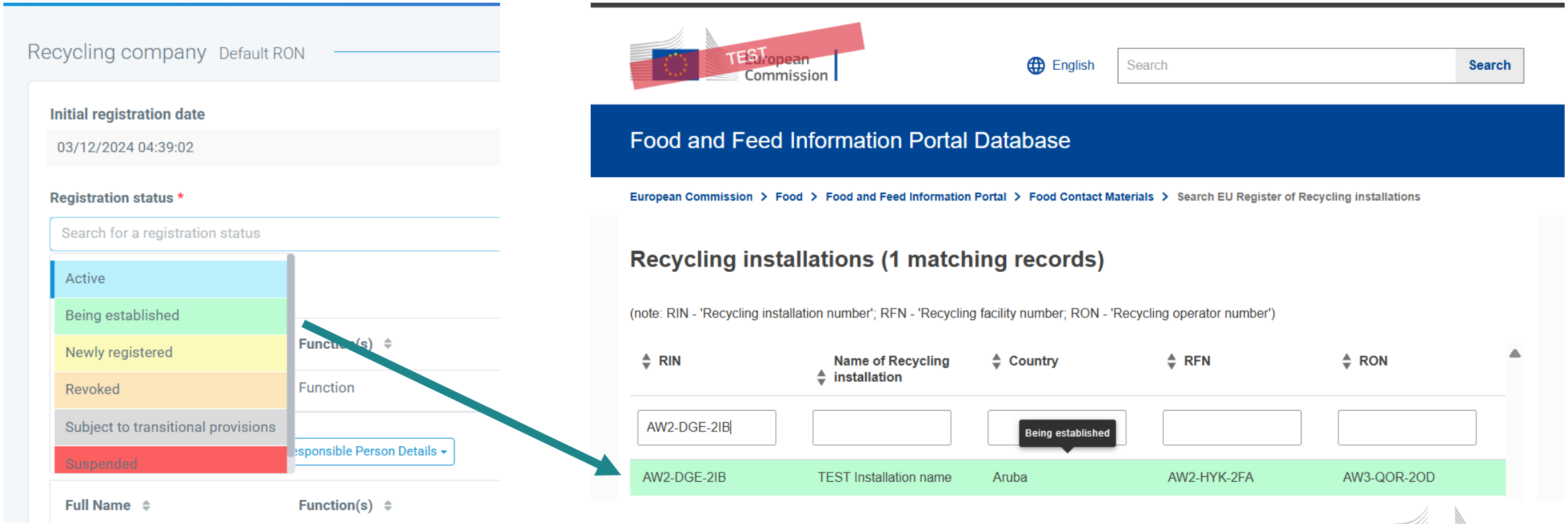
Recycling Regulation (EU) 2022/1616

- Three relevant discussions

1. **Amendment of the Regulation** (being considered and developed)
   - better procedural support for EU Register
   - clarification of declarations of compliance (2 new templates)
   - presentation of document upon release into free circulation
2. **Audits of registered installations**
   - Installations that have not been audited to be suspended; target end of year
   - colour coding to indicate draft status
3. **Novel Technologies (and schemes)**
   - Important, but will be taken forward with some delay

Draft registration status on-line

- Soon to come, colour coding to provide initial view on registration status
  - Internal view
  - External view



BPA Regulation 2024/3190

- Regulation bans the use of Bisphenol A in a number of materials
  - Regulation also addressed other hazardous bisphenols
- A correcting Regulation was voted on favourably 19 September 2025
  - focus mostly on corrections to the transitional provisions – may have impact!
  - https://ec.europa.eu/transparency/comitology-register/screen/documents/109222/1/consult?lang=en.
- A Q&A document is being finalised (official guidance)
  - soon to be adopted

Contact

European Commission webpages on FCMs
http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm

Contact us: SANTE-FCM@ec.europa.eu

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