Update of EU activities on Food Contact Materials (FCMs)

Food Contact Regulations Europe 2020

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What is a Food Contact Material?

Any material:

• already in contact with food and intended for that purpose

• intended to be brought into contact with food

• can reasonably be expected to be brought into contact with food or to transfer constituents to food under normal or foreseeable conditions of use
EU legislation - rationale

• Food Safety: FCMs must not
  • endanger human health
  • bring about an unacceptable change in the composition of the food
  • bring about a deterioration in the organoleptic characteristics

• Internal market: effective functioning
  • no barriers to trade

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EU legislation applicable to all FCMs

- sets out general rules and procedures for FCMs
  - objectives: safety and internal market
  - describes scope of what an FCM is
  - sets out main principles and procedures
- Basis for specific measures

- requires Good Manufacturing Practices for all FCMs
  - quality assurance system
  - quality control system
  - documentation
- Annexes with rules for printing and recycling
5 steps to an authorised substance

1 - Positive list of substances is established for a material (e.g. plastic)
   - substance may only be used in the material if listed – business operator should apply
   - applications should be submitted via Member State to EFSA

2 - EFSA assesses the safety of each substance in the specific material
   - EFSA publishes its scientific opinion on the safety of the substance

3 - Commission prepares draft Decision authorising the substance
   - taking the opinion and other relevant matters into account

4 - The decision is voted in Standing Committee
   - Parliament and Council have a 2 or 3 month period for scrutiny
   - the Commission adopts the Decision and publishes it in the Official Journal

5 - The substance may be used in the specific material
   - subject to restrictions, and to requirements set out in the Regulation under which it is listed

(14) The safety assessment of substances should be followed by a risk management decision as to whether those substances should be entered on a Community list of authorised substances.
Present Commission activities on FCM

• Evaluation and Impact Assessment of overall FCM legislation
• Implementation of rules for plastic recycling
• New limits of Ceramic and vitreous materials
• ‘Minor’ present activities include:
  • implementation of Regulation (EU) No 10/2011, measure on Glymo
  • follow-up of EFSA evaluation of Phthalates, Bisphenols and Styrene
  • activities on official controls with our European Union Reference Laboratory (EURL)
  • coordinated control plan, Regulation (EU) No 284/2011 (‘China measure’)
  • support to Member States and business operators – on questions and other matters
Future of FCM legislation

Evaluation

Impact Assessment
Future of EU FCM

• Basic FCM legislation is 43 years old (originally Directive 76/893/EEC, now Regulation 1935/2004) and has never been systematically evaluated

• Many issues identified by stakeholders (e.g. industry, NGOs) and in the management and implementation of the legislation such as:
  • lack of specific rules at EU level for materials other than [mainly] plastic,
  • lack of focus on all substances that may migrate from FCMs,
  • ability to demonstrate compliance and enforcement
  • new development such as REACH not taken into account
  • coherence with other relevant legislation

• Is it still effective, efficient, coherent, and relevant?
Evaluation: Stakeholder consultation 2018 – 2019 - study

• Evaluation considered first step towards a possible new FCM approach

• Study based on public consultation, workshops, interviews, focus groups, and case studies now completed

• Staff working document (‘SWD’) summarising the findings of the first step is under way

• However Commission is considering to start 2nd step prior to SWD publication, i.e. to do impact assessment in parallel
Impact Assessment

1. Inception Impact Assessment (‘IIA’): consultation on policy options + problem definition (start mid 2020)
2. Impact Assessment (‘IA’): Assessment of policy options (Q4 2020 – Q4 2021)
3. Publication of Evaluation + IA results (likely together, beginning 2022)
4. Drafting of new legislation

Approach + Timeline tentative
Potential Elements for future FCM policy

1. Further Harmonisation

2. Efficient way of assessing a very large number of substances
   • prioritisation – substance categories, real exposure
   • better use of REACH

3. Increased transparency and responsibility for businesses
   • possibly registration and digital dossiers

The inception impact assessment (IIA) will consult on actual policy options;
   • do nothing, or develop new specific legislation are likely to be included as policy options
plastic Food contact materials

Regulation (EU) No 10/2011

upcoming amendments
Regulation on Plastic FCM

- Regulation (EU) No 10/2011 on plastic FCM
  - Sets out compositional requirements
    - positive list of substances
    - derogations
    - special rules
  - Regular amendments
    - to add substance
    - to improve rules
15th amendment

• Addition of 3 authorized substances with restrictions

• Other changes include:
  • new restrictions for certain metals such as arsenic, cadmium, chromium, lead, and mercury
  • new level of detection: 0.002 mg / kg food (or simulant) for primary aromatic amines (PAA)
  • changes to compliance testing for entire appliances/food processing equipment
  • changes to test requirements for repeated use (subsequent tests cannot be higher)
  • changes to some test conditions for overall migration
  • adequate information to strengthen the Declaration of Compliance to facilitate, for example, the requirements of new metals and PAAs

• target entry into force Q2 2020 → text nearly finalised
16th amendment

- matters considered for the Forthcoming (16th) amendment; it may…
  - take account of EFSA opinions on phthalates and wood
  - add substances on basis of new EFSA opinions (at least 2 at present)
  - take a first step towards addressing biocides in plastics
  - address structure of DoC – use of obligatory template
  - address reprocessing of plastics (uncontaminated scraps and off-cuts)

- target: entry into force Q3 2020
long term: improving test methods

• method development together with EURL-FCM

• generic 10 ppb assignment for ‘ND’ being slowly replaced
  • never a health based migration limit, but an assignment of an analytical specification, the level of detection
  • new substance specific limits – always lower than 10 ppb
  • applying Article 11(4) of the Regulation based on present analytical capabilities

• move to multi analyte methods
  • methods by which the migration of several substances can be determined in one step
  • modular aspects
RECOMMENDATION (EU) 2019/794

on a coordinated control plan to establish the prevalence of certain substances migrating from food contact materials
‘monitoring’ recommendation

• Officially: coordinated control plan to establish the migration of substances

• Focus is on monitoring (obtaining data) not necessarily controls (compliance)
  • voluntary participation, only Member States Competent Authorities

• Rationale
  • on-going discussion on future of FCM
  • various policy needs
  • to prepare for replacing Regulation (EU) no 284/2011 on certain FCM from China and Hong Kong
  • gain experience for formal control plan

• Results due end of February

• Continuation in 2020 will be discussed with Member States

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Which substances are monitored?

- Primary aromatic amines (PAA)
  - Plastic tableware and kitchenware and printed FCMs including paper and board

- Formaldehyde and Melamine
  - Plastic tableware and kitchenware including reusable coffee cups using additives in the plastic derived from natural sources such as bamboo

- Phenol
  - Plastic kitchenware and tableware; varnished or coated materials and; printed plastic and paper and board packaging materials

- Bisphenols including BPA and BPS
  - Polycarbonate and polyethersulfone plastic; coated metal packaging (e.g. cans, lids)
Which substances are monitored?

- Phthalates and non-phthalate plasticisers
  - Plastic materials and articles, in particular those manufactured using polyvinylchloride (PVC) such as thermoformed sheets, flexible packaging and tubing; closures and lids

- Fluorinated compounds
  - Paper and board based materials and articles, including those used to wrap fast-food, takeaway and bakery products and microwave popcorn bags

- Metals
  - Ceramic, enamel, vitreous and metal kitchenware and tableware including artisanal and traditionally produced materials and articles

- Overall migration
  - Non-conventional plastic kitchenware and tableware, such as reusable coffee cups using additives in the plastic derived from natural sources such as bamboo
Other matters

Glymo, Plastic Recycling, Ceramics
Glymo

- FCM No. 1068 ‘Glymo’ [3-(2,3-epoxypropoxy)propyl]trimethoxy silane:
  - Potentially problematic migration levels in several materials

- Commission considers to regulate epoxysilanes
  - Possibly in force in Q3 2020, positive list of safe use, template based Declaration of Compliance
  - essentially all FCMs (but use in plastic FCM covered under Regulation (EU) No 10/2011)

- Lesson: laboratories to be careful when using ‘10 ppb’ testing approach
Regulation (EU) 10/2011 on plastics FCM controls composition

Recycled plastics are affected by incidental contamination

Recycled plastic must be assessed in a different manner

decontamination efficiency

Only recycled plastics without contaminants should be placed on market → EFSA evaluation

- specks, greying, yellowing, clouding → visible
- smell, taste → perceivable
- harmful impurities → measurable
- genotoxic impurities → undetectable

Since two years Plastic strategy → reduce and recycle

- FCM plastics are a very significant part of the total plastic use

- targets on recycled content
  - 25% in PET beverage bottles by 2025

Consumer trust and uptake

Safety assessment by EFSA
Foreseen Approach to amend recycling Regulation

Present
- > 140 applications for the authorization of individual processes; mostly PET
- need to ensure proper transition + clear obligations
- need to deal with other materials and different kinds of processes

Q2 2020
- Foreseen adoption of Amendment to Regulation (EU) No 282/2008
- Transition: PET first, the rest later
- Obligations on the operation of the process, administration, enforcement

Q3 2020
- Authorization decisions notified to applicants
- Publication of Register of authorization holders, recyclers, recycling sites

2021
- Further amendments to Regulation (EU) No 282/2008
- All recycled plastics into scope, including chemical recycling
- Updated 2-step application process

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Ceramic and Vitreous Materials and Articles

- Present Lead and Cadmium limits appear way to high
  - reduction by a factor 1333 (lead) or 400 (cadmium) could be required
- Significant impact expected to traditional and artisanal production
- IIA completed, IA under preparation, to take place in 2020.
- Independent of developments to FCM legislation (evaluation and IA)
Contact and further information

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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