



Review of EU legislation on EU food contact materials

MAC (Seafood) Working Group 3 meeting
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DG SANTE
European Commission

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Content

- brief introduction on food contact materials – no details on the legislation
- revision of FCM legislation including short reflection on MAC position
- other relevant developments (recycling)

Regulation (EC) No 1935/2004

- Applicable to all FCMs:
 - already in contact with food (e.g. packaging), intended to be in contact (kitchenware, food processing equipment) or likely to transfer constituents
 - a specific list of FCMs does not exist: if transfer of substances is foreseeable → FCM
- Ensure
 - **a high level of protection of human health**
 - the effective functioning of the internal market
- Basis for specific measures e.g.
 - Regulation (EU) No 10/2011 on plastic FCM authorising substances with restrictions e.g. SMLs
 - Regulation (EU) 2022/1616 on recycling of plastic
- Provide for General rules and procedures
 - the role of EFSA, definitions, labelling, traceability, inspection and control



EU legislation on FCMs

Regulation (EC) No 1935/2004 (objectives: human health and functioning of EU market)
Basic rules on safety, labelling, traceability, inspection and control, authorisation process



Guidance
on plastic FCM &
documentation

**Regulation (EC)
No 10/2011**
on plastic FCM

**Regulation (EC)
No 282/2008**
on plastic recycling

**Regulation (EC)
No 450/2009**
on AIM

**Directive
84/500/EEC**
on ceramics

**Directive
2007/42/EC**
on RCF

**Regulation
(EC) No
2023/2006**
on good
manufacturing
practices

**Directive
93/11/EEC**
on nitrosamines

**Regulation (EC)
No 1885/2005**
on epoxy derivatives

**Regulation (EU)
No 2018/213**
on bisphenol A

**Directive
78/142/EEC**
on VCM

Regulation 284/2011
on plastic
kitchenware

**Recommendation
2019/794**
on FCM controls

**Recommendation
2017/84**
on MOH

Seafood, Seafood supply chains and food contact materials

- Food contact materials are all materials that are intended or may foreseeably come into contact with food
- ‘*Food*’ is defined in the general food law (Regulation (EC) No 178/2002)
- Present interpretation agreed with competent authorities:
 - fish becomes food from the moment it is killed for that purpose
 - anything in contact with fish from the moment they have been killed including the equipment intending for killing the fish is a food contact material
 - fishing nets are intended to catch live fish (not to kill them) so nets are not a FCM
(the actual interpretation is a bit more complex – it can be argued differently)
- Food contact legislation very relevant to the seafood supply chain
 - the seafood supply chain are FCM users, not producers

Revision of FCM Legislation

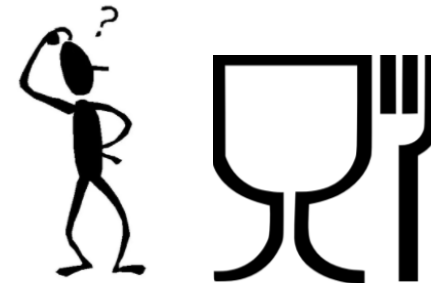
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FCM Evaluation

- Staff Working Document published
 - 9 June 2022 (https://ec.europa.eu/food/safety/chemical-safety/food-contact-materials/policy-initiatives/evaluation-eu-rules_en) includes summaries in FR and DE)
- Conclusions:
 - Overall the current FCM Regulation functions as expected, but to a certain extent
 - It partly fulfils its objectives, in particular for plastic FCMs for which specific EU rules apply
 - There is EU added value and it also remains relevant for all stakeholders
- The evaluation provides the basis for the revision

FCM Evaluation: Identified problems (summary)

- No full harmonisation
- Complex, resource intensive, lack of prioritisation and focus on final product
- Not sufficiently transparent
 - in the value chain and beyond



European Commission's commitments

**Circular Economy
Action Plan (CEAP)**
March 2020

Farm to Fork strategy
Revision of FCM legislation
May 2020

**Chemicals Strategy for
Sustainability (CSS)**
October 2020

Recycling:
sorting, quality
and safety

Compostable,
biodegradable
natural, FCMs

**proposed
PPWR
30/11/2022**

Support use of innovative
sustainable packaging
including re-use

Reduce over-
packaging and
packaging waste

Reduce use of most
hazardous chemicals:
ban CMRs, EDs, PBTs

Coherence of
assessment: "OSOA"

Address
combination effects
of chemicals

"Safe and sustainable"
materials by design

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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 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

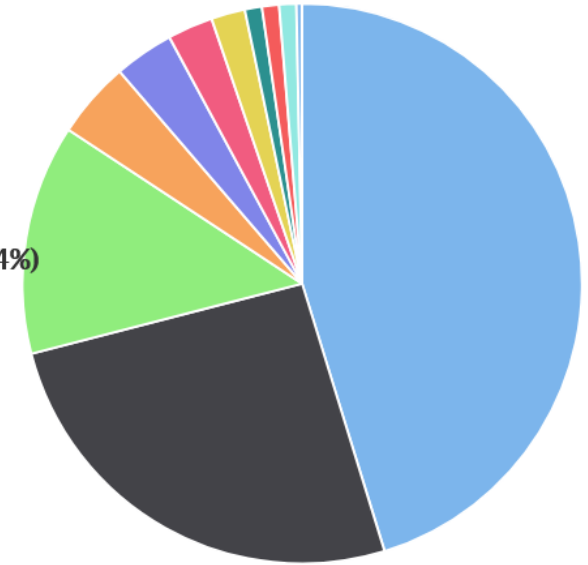
E. System for verifying compliance

- Delegated bodies under Official Control Regulation 2017/625
- Notified Bodies tasked with conformity assessment
- Further development of test methods and technical standards as required

open public consultation – now closed

- 610 valid contributions
- analysis in progress

By category of respondent



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



During 2023 we will seek to consult frequently with stakeholders

MAC Recommendations (17/02/2021)

- The MAC issued recommendations on our roadmap
- Our objectives include to
 - take into account the interests of seafood operators and the supply chain
 - seek full harmonisation of rules on compliance and analytical methods
 - take into account SMEs, focus on FCM producers, not users
 - (rules focus mostly at the production of FCMs, much less at the use)
 - improve information available to FCM users, both professional and consumers
- In addition
 - new legislation on plastic recycling published in September, focus on safety, not on 'ease'
 - It is unlikely that Regulation (EC) No 1935/2004 will remain, but this is a serious option

Other matters

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Introduction of limit for Styrene

- Given health concerns a limit for styrene is being considered
 - EFSA could not rule out a risk for Genotoxicity
 - presently no limit, limit to be established at 0,04 mg / kg food (40 ppb)
 - testing primarily in the food
- Affects all plastics made with styrene under Regulation (EU) 10/2011 on plastics
- Fishing industry high user of polystyrene, particularly expanded PS
 - **Large boxes** with fresh unprepared fish in ice **unlikely to be affected**
 - **Small packaging** in contact with sliced fatty fish **possibly significantly affected**
 - may also affect some work surfaces and processing equipment
- Discussion on-going, no definite measure yet

New Regulation on recycled plastic

(Regulation (EU) 2022/1616)

- All recycled plastic to be produced with suitable recycling technology
 - at present: mechanical PET recycling and **recycling from a closed production chain**
 - also some forms of chemical recycling → if the monomer is recycled
 - all other forms of recycling are only permitted for development purposes (with 'novel recycling technologies')
- Detailed rules on:
 - what plastic may be collected, how it must be recycled, and for which use it is suitable
 - **instructions for use,**
 - compliance documentation – provides those instructions and ensures traceability and enforceability
- Recycling from a closed production scheme
 - Requires a recycling scheme, managed by a central organisation, in which users and recyclers of plastic articles participate
 - typically users of reusable crates to transport food products from producer to retailer → includes seafood

Concluding on use of FCMs in Seafood supply

- Many materials and articles used by seafood supply chain are FCM
 - Subject to Regulation (EC) No 1935/2004
- Possible impacts from revision of FCM legislation
 - New harmonised rules, potential extension of scope, rules for re-use
- Recycling Regulation
 - not all plastics can be recycled under FCM legislation – primarily PET can be recycled
 - for other plastics you may be required to participate in recycling scheme
- Introduction of limit on styrene may have consequences

Thank you

Happy to receive questions...

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