European Union update on Food Contact Materials

FIP scientific network for the cooperation and harmonisation of risk assessment of FCM, the 'EFSA FCM Network' meeting
10 – 11 July 2018

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This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion and understanding of existing and potential new legislation as well as ongoing activities, but should not in anyway be seen as giving a final interpretation of existing legislation or a proposal of new legislation.

Main ongoing activities

Evaluation of the FCM legislation

Plastic recycling for FCMs

Ceramics

Other ongoing activities

- Management of Commission Regulation (EU) No 10/2011 including authorisation of new substances
- Commission Regulation (EC) No 284/2011 (imports from China and HK) and FCM monitoring
- Follow up on Regulation (EC) No 528/2012 (biocides)
- Update of online database of substances

Evaluation of FCM legislation: Why?

- *Basic FCM legislation is 40 years old (Directive 76/893/EEC), and has not been systematically evaluated*
- *Issues that are perceived today:*
  - ***Materials other than plastic do not have specific rules at EU level***
  - ***Questions regarding the current approach***
    - *Positive authorised lists*
    - *Risk assessment approach*
    - *Information exchange in the supply chain*
    - *Ability to demonstrate compliance and enforcement*
  - ***Coherence with other relevant legislation***

Need to substantiate perceived problems and how legislation is functioning with concrete documented evidence, transparency and accountability

Evaluation of FCM legislation: What?

Tool defined under better Regulation framework
http://ec.europa.eu/smart-regulation/guidelines/ug_chap6_en.htm

Principles and concepts:

- **Comprehensive** 5 criteria (others as appropriate)
- **Proportionate** tailor to intervention and data available
- **Independent and objective** no undue pressure, full access to relevant data, autonomy during conduct
- **Transparent judgement** clear evidence trail and specific answers
- **Evidence-based** use diverse range of methods and sources

- ***Effectiveness*** *-To what extent has FCM legislation achieved its objectives i.e. ensure effective functioning of internal market and; providing the basis for securing a high level of protection of human health?*
- ***Efficiency*** *- What are the costs and benefits associated with the legislation?*
- ***Coherence*** *- To what extent are the provisions of Regulation (EC) No 1935/2004 internally coherent and coherent with other relevant legislation?*
- ***Relevance*** *-To what extent is the Regulation and available tools still relevant*
- ***EU added value*** *- What has been the EU added value of the Regulation?*

Evaluation of FCM legislation: How?

Existing information

- *JRC Baseline report*
- *Other COM fitness checks, evaluations*
- *Correspondence from stakeholders*
- *EFSA opinions*
- *DG SANTE work*
- *Feedback on the evaluation roadmap*

Supporting study

Four phases foreseen

- *Inception - definition of research strategy and methodology*
- *Data collection - desk and field research (stakeholder consultation)*
- *Analysis of all information collected*
- *Synthesis - drawing conclusions*

Evaluation of FCM legislation: How?

Stakeholder consultation

- ***Targeted interviews addressed to:***
  - *MSs' Authorities, including enforcement bodies and control laboratories;*
  - *Businesses including specifically SMEs and microbusinesses*
  - *Scientific experts in the field of FCM (e.g. EFSA, analytical laboratories, etc.)*
  - *Consumer representatives*
  - *NGOs*
- ***Surveys** mainly targeting SMEs*
- ***Focus group meetings** gathering representatives*
- ***Workshops***
- ***Case studies***
- ***12 week public consultation***

Staff Working Document

*The SWD will be delivered by the Commission at the end of the evaluation communicate the **results and conclusions** of the evaluation:*

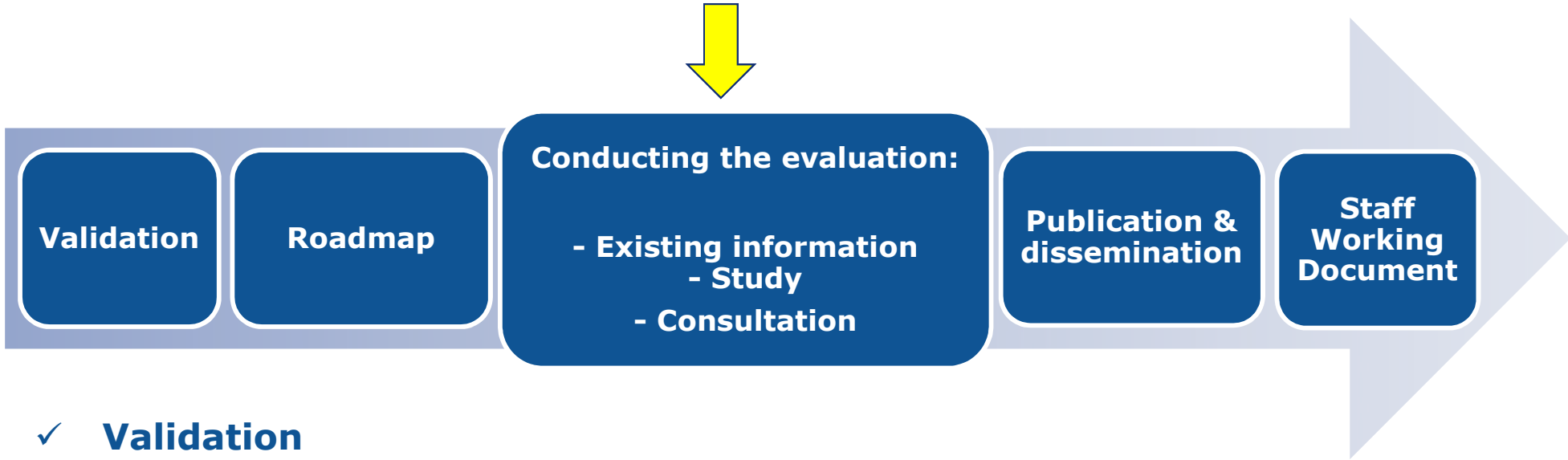
- To policymakers, to **inform decision making, priority setting and justify any new initiatives**
- To stakeholders, sharing the method, evidence base and analysis used for the evaluation.

It will provide:

- A description of the **intervention** (refined intervention logic) and the **current situation**
- A description of the adopted **methodology**, assumptions, limitations and robustness of findings;
- **Analysis** and answers to the evaluation questions addressing the **5 evaluation criteria** of effectiveness, efficiency, relevance, coherence and EU-added value.
- Main **conclusions** drawn from the evaluation identifying possible steps for the improvement of the current legal framework for FCM.

Provides a basis for the Commission "to consider what, if any, possible steps need to be taken in the future concerning the regulation of FCM in the EU"

Evaluation of FCM legislation: Timeframe



- ✓ **Validation**
- ✓ **Roadmap** open for comments from 28 November to 26 December 2017. 30 feedbacks received, reaffirming the existence of a number of perceived issues in relation to the functioning of the Regulation. All comments are available at https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429_en
- ✓ **Publication of evaluation website** May 2018 https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/evaluation_en
- ✓ **Study** to support evaluation July 2018 ➔ September 2019
- ✓ **Consultation** main part September 2018 ➔ July 2019
- ✓ **Publication and dissemination activities** September 2019 ➔
- ✓ **Staff Working Document** early 2020

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Recycling for plastic FCM

Commission Regulation (EC) No 282/2008 requires authorisation of recycling of plastic for FCM

Authorisation decisions on ~140 recycling processes

- **Decisions will be simple**
  - Rely on EFSA opinion and dossier
  - Support self-assessment by operators
  - Compliance monitoring summary sheet
- **Adoption and application early 2019**

Should ensure safety in practice

Monitoring of incidental contamination

Unpredictable presence of potentially toxic and unidentified substances originating from

- Production of plastics (e.g. decomposition products)
- The use phase (e.g. a pesticide)
- Misuse (e.g. paint thinner stored in a PET bottle)
- Cross-contamination during collection (e.g. leaking fluid)
- Used non-FCM plastics (e.g. non-FCM additives)

Limited knowledge leads to conservative risk assessments

- Need for decontamination of recycled plastics
- EFSA assessments assume potential presence of genotoxic contaminants
- Difficult to recycle materials other than PET

Monitoring to centralise data on occurrence of recurring contaminants in uncleaned and cleaned flakes

- To have knowledge on contaminant levels in view of a changing market
- To inform risk assessment
- To enforce and eventually improve and standardise waste collection

Wider picture and future for recycling

Europe-wide strategy on plastics, adopted January 2018 - part of the transition towards a more circular economy

- All plastic packaging on the EU market will be recyclable by 2030
- Consumption of single-use plastics will be reduced

Situation for FCMs not compatible with recycling targets

- Low recycling rate of polyolefins (e.g. PE, HDPE, LDPE)
- Presently nearly only PET + closed loop plastics

What does this mean for FCMs?

- Work with ESFA and industry to increase recycling of non-PET
- Standardisation of waste streams
  - 'Food grade waste' can we achieve this?
  - Advantages lower burden, higher safety
- Monitor shifts and ensure safety of other materials
  - Recycled paper and board
  - "Non-plastic" materials

Bottom line: SAFETY FIRST

Ceramics

Directive 84/500/EEC sets out limits for Pb and Cd from ceramic

- EFSA Opinions indicate present limits far too high
- Discussions started in 2012 but need to undertake testing work identified

JRC work undertaken 2013 – 2017 to ensure analytical capabilities

Discussions recommenced in 2017. Points under consideration:

- Actual limits
- Possible mitigation measures to protect traditional and artisanal industries including SMEs and availability of these products on the market
- Labelling and communication to consumers
- Transitional periods
- Specific testing rules to prevent unnecessary compliance work
- Addition of other metals (e.g. cobalt, chrome, nickel, aluminium)
- Addition of glass FCMs

Biocides Regulation 528/2012

Note on interim approach for establishment of migration limits

- *Published 2017*

Main objectives for FCMs:

- *Establish processes of assessment and implementation at EU level concerning the authorisation/ approval and where necessary, setting of migration limits or residual content of biocidal substances in FCMs*
- *Clear process for all – Member States, industry, assessment bodies*
- *Coherent and complementary data requirements (no duplication, overlap).*

Ongoing work:

- *Verify status of Ag substances in Provisional List under ECHA and coherence with 2004 – 2005 EFSA opinions*
- *Identify and progress adaptation and adoption where necessary of measure(s) at EU level*
- *Information on substances and use in FCMs other than Provisional List*
- *Decision and elaboration on situation for substances that are not included in PT4 and which may present a risk from the final FCM*

Other ongoing activities

Commission Regulation (EC) No 284/2011 and future monitoring

- Recent data shows significant decrease in non-compliance of consignments from China and Hong Kong
- Non-compliance remains on the market – also products from other countries
- Voluntary monitoring program under discussion to coordinate Member States' activities, to prioritise and better establish levels of compliance

Update of database of substances (currently offline)

- To reflect numerous amendments to Regulation 10/2011
- More user friendly
- Include possible list of substances regulated at national level

Updates and amendments to Regulation 10/2011

- Entry into force of new limits on BPA, Zinc and Aluminium, and new testing rules for dry fruits and vegetables in September 2018

- *Commission Regulation 2016/1416*
- *Commission Regulation 2017/752*
- *Commission Regulation 2018/79*
- *Commission Regulation 2018/213*
- *Commission Regulation 2018/831*