Trusted science for safe food

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Workshop to discuss the role that REACH could have in assisting with regulation of chemicals in Food Contact Materials

Current risk assessment of chemicals in plastic FCM

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Outline

1. Engagement with stakeholders
2. ECHA-EFSA cooperation
3. Current risk assessment
4. FCM peculiarities

Main objectives of stakeholder engagement

EFSA's aim is to

- improve the opportunities for stakeholders to contribute to the different stages of generic **scientific assessment**, ensuring balanced representation of views of different interest groups (e.g. BPA protocol, ED, emerging risk, sugar protocol)
- enable society to contribute more widely to EFSA risk assessment work and thereby, to **become more trustworthy,**
- engage with society to **inform on science** (*via open calls for data and public consultations and discussions, e.g. public consultation on opinion on phthalates*) and **ensure the accessibility and relevance of our work**.

EFSA's cooperation with Stakeholder Organisations

Permanent mechanisms

- **Stakeholder Forum**
- **Stakeholder Bureau**

Targeted mechanisms

- Discussion Groups
- Roundtables
- Info sessions
- Communicators Lab
- Framing of Questions

For more information on Stakeholder engagement, please contact Goran Kumric (Goran.Kumric@efsa.europa.eu)

ECHA-EFSA cooperation

- ✓ Memorandum of understanding
- ✓ *Ad hoc* joint activities
  - ✓ Endocrine disruptor (guidelines for identification)
  - ✓ Biocides used in FCM (PT4 surface biocides)
  - ✓ Phthalates (2 hearing experts in the EFSA Working Group)
  - ✓ FCM Network since 2017 (observer; exchange on plastic additives)
  - ✓ Bisphenol S (ongoing discussion)
- ✓ April 2019, agreement to move from *ad hoc* joint activities to strategic partnership (priorities areas: structured data, assessment methodology, research)

EFSA safety assessment of regulated FCM

- ✓ **Based on guidance** for submission of an application (dossier) for safety assessment of substance/process prior to its authorisation
  - Recycled plastics (Reg. (EU) 282/2008) => EFSA guidance for plastics recycling (2008) and EFSA criteria for PET recycling (2011)
  - Active and Intelligent Materials (Reg. (EU) 450/2009) => EFSA guidance (2009)
  - **Plastics (Reg. (EU) 10/2011) => SCF guidelines (2001)** and EFSA Note for Guidance
- ✓ EFSA Scientific Committee opinions and cross-cutting guidance documents (TTC, nano, genotoxicity…)

Plastics: what is evaluated?

- ✓ In accordance with Regulation (EU) 10/2011,
  - **The regulated intentionally added substance (IAS)** and its impurities
  - The expected (and/or intentional) reaction and transformation products coming from use of the substance. An antioxidant will be oxidised, a monomer will form oligomers. These are predictable products that are formed and can be analysed for and evaluated. They may be present in the restriction but are not entries in the Union list.
  - Other main reaction and degradation products coming from the use. They may be present in the restriction but are not entries in the Union list.
  - Colorants, solvents, aids to polymerisation are not evaluated.

Principle for tox. data requirement (SCF, 2001)

✓ The higher the "exposure/migration" into food,
the greater the amount of data is required

Migration (mg/kg food)	<0.05	0.05-5	5-60
2 genotoxicity tests *in vitro*	+	+	+
90-day oral study in rodents		+	+
Accumulation information		+	+
ADME study			+
Reproduction study			+
Developmental study			+
Long term/carcinogenicity study			+

Default exposure Assumptions (SCF, 2001)

- ✓ In 2001, human exposure data were not available
  - A person (60 kg bw) consumes daily and throughout whole life-time, up to **1 kg** food packaged in 6 dm^2 FCM always releasing the substance at full SML
  - Exposure ⇔ migration per kg food (simulant)

- ✓ **"One major area to revisit is the estimation of consumer exposure" (EFSA CEF Panel, 2016)** as it does not take into account **infants and toddlers** who have the highest consumption per kg bw; also toxicological tiers should take this into account

Non Intentionally Added Substances (NIAS)

- ✓ Evaluation follows **the same approach as for regulated substances** with more consideration/flexibility for addressing the genotoxicity potential (EFSA CEF Panel, 2016) by using e.g.:
  - TTC (0.0025 µg/kg bw per day)
  - SAR/QSAR, read-across

- ✓ **Limitations/challenges**
  - Chemical analysis (identification and quantification)
  - To get enough quantity of material for testing the potential toxicity
  - NIAS may change with process, starting substance, etc.

FCM peculiarities

- ✓ EFSA's evaluation is required before EU authorisation
  - Timeline is 6 months + possibly 6 more months; clock-stop mechanism
  - Opinion is the outcome of an independent Panel (supported by Working Group + EFSA's staff) and is coordinated by EFSA
- ✓ Assessment based on intended/requested uses
- ✓ Data
  - Toxicological dataset requirement and hazard identification/characterisation are driven by migration potential through a tiered approach, it is not a full 'RA'
- ✓ Conclusion/outcome
  - Based on the extent of the dataset and on the assessment of the substance and its related migrating chemicals
  - A restriction in migration and/or uses to comply with is proposed

FCM peculiarities

✓FCM legislation constrains for EU-regulated chemicals

- Data sharing
  - The Union list is positive but data are the property of the applicant
  - The use of data from other applicant(s), other evaluations is limited
- Recognition (not only for FCM)
  - Need for an EFSA opinion even when a sister Agency published one
- The constrains are different for EU-harmonized (regulated) *vs* non EU-harmonized areas and for IAS *vs* NIAS chemicals

REACH and EFSA FCM

What REACH information could be relevant for FCM regulations / risk assessment of chemicals in FCM?

Sub-questions notably triggered by FCM peculiarities: what context, what chemicals, what information?

- Chemicals: IAS, NIAS, EU-regulated (listed chemicals), re-evaluation, crisis, etc.?
- Information/data: studies, and/or hazard identification outcome, and/or hazard characterisation outcome and/or evaluation?
- Can the information be legally used for the purpose?
- For EU-regulated chemicals, how this could impact the timeline and the restrictions?
- Are exposure and assessment specific to each area?

REACH and EFSA FCM

- Would common guidance/methodologies (e.g. for the hazard identification) facilitate the recognition/endorsement of the evaluation made by the other party?
- Could a better identification/awareness of the chemicals under evaluation, already evaluated in the two areas, of the conclusion/outcome, and its basis help/avoid duplication?
- Could expertise in prioritisation, screening tools help (for re-evaluation, for lists of non-EU regulated areas e.g. for the printing ink Swiss List B)?

Thank you

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EFSA:
http://www.efsa.europa.eu/

EFSA Journal on Wiley:
https://efsa.onlinelibrary.wiley.com/journal/18314732

EFSA Scientific Network on FCM:
https://www.efsa.europa.eu/it/food-ingredients-and-packaging/networks