Current state of play on FCMs, including the risk assessment

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efsa
European Food Safety Authority

EFSA safety assessment of 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)
  - AIM (Reg. (EU) 450/2009) => EFSA guidance (2009)
  - **Plastics (Reg. (EU) 10/2011) => SCF guidelines (2001)** and EFSA Note for Guidance
- ✓ EFSA Scientific Committee opinions (TTC, nano, genotoxicity…)

Plastics: what is evaluated?

- ✓ In accordance with regulation (EU) 10/2011,
  - the regulated substance and its impurities
  - The expected (and intentional) reaction and transformation products coming from use of the substance. An antioxidant will be oxidised and a monomer will form oligomers. These are predictable and can be analysed for and evaluated.
  - Main reaction and degradation products coming from the use should be considered (evaluated) & included in restrictions of substance. They are not listed.
- ✓ **Not** colorants, solvents, aids to polymerisation

Principle for tox data requirement

- The higher the "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 highest consumption per kg bw ; also toxicological tiers should take this into account

NIAS, a challenge

- Evaluation follows **the same approach as regulated substances** with more consideration for addressing the genotoxicity potential (EFSA CEF Panel, 2016)
  - TTC (0.0025 µg/kg bw per day)
  - SAR/QSAR, read-across
- **Limitations/challenges**
  - Chemical analysis (identification and quantification)
  - To get enough material for testing the potential toxicity
  - May change with process, starting substance, etc.
  - Evaluation is lost even though considered in the evaluation of the regulated substance and in the restriction (e.g. in use)

Biocides

- EFSA **evaluation of the safety & efficacy** of approx. 15 chemicals
  - Last opinion dates back 2011, substances are not added to the positive list but in the provisional list of additives
  - One application under validation: what to evaluate?

- The situation/articulation is not clear
  - 'Biocide regulation' requires a full risk assessment -> ECHA
  - For FCM, the setting of 'MRL/SML' is required -> EFSA
  - Is EFSA opinion needed to set a SML when full RA by ECHA?

- Ongoing collaboration with EC (E2 & E4), ECHA and EFSA on how to address the situation

Active and Intelligent Materials (AIM)

- Regulation (EU) 450/2009
  - To extend shelf-life or maintain/improve conditions of packaged food / to monitor conditions of packaged food or surrounding environment
- Evaluation of the migration & toxicity of substances that contribute to function & its/their reaction products; not of the passive parts
  - In most cases, it makes use of chemicals already evaluated and authorised for plastics (10/2011)
  - In many cases, it is a compliance evaluation
- No list of authorised substances/materials yet

Recycling processes

- Regulation (EU) 282/2008
- EFSA doesn't assess
  - Re-uses of articles
  - Offcuts and factory scraps
  - Open loop **chemical** processes
- EFSA assesses
  - Closed and controlled loop processes
  - Open loop **mechanical** processes

Closed and controlled loop processes

- "input must originate from a product loop… ensuring that only materials and articles which have been intended for food contact are used and **any contamination can be ruled out"** (Art. 4)

- Approx. 10 processes evaluated (on polyolefin)
- Evaluation of 'closure and control' based on the description
- Evaluation of the impact of repeated recycling on the formation of reaction/degradation products; often the same published study

- It is largely discussion about GMP rather than chemical risk assessment

Open loop mechanical processes

- Recycling of post-consumer articles **that can be contaminated**
- Consideration of steps from the input to the output
- In particular, evaluation of the decontamination efficiency
- EFSA CEF Panel 'PET criteria' (2011)
- Approx. 130 processes evaluated (mostly PET, 2 HDPE)
- Majority was operating before the Regulation (submitted by 12.2009)
- Not yet a list of authorised processes and inspection regime for control
- Multiple applications on processes using the same evaluated technology (and the same parameters) and need an opinion

Ad'hoc questions

- BPA (mostly can coating), phthalates (plastic, inks)
- RASFF, crisis, plastic and non-plastics
  - SEM (plastic)
  - BADGE, NOGE (coating)
  - Methyl-benzophenone, ITX (printing inks)
  - Melamine (plastic, can coatings, paper and board, adhesives)
  - Mineral Oils (paper and board, recycling, printing inks)
- Evaluation is based on available data (public domain & Industry), it may require production of data - it requires a lot of resources

Other FCM types

- 4/17 are EU specifically regulated/harmonised
- **EFSA FCM Network** since 2013 to promote cooperation and RA methodology harmonisation (e.g. partnering grant on coating)
- Some **Members States** are performing safety assessment, e.g.
  - Printing inks - CH & DE – 6 applications vs 30 new chemicals/year
  - Coatings - NL - very few new chemicals/applications /year
  - Rubbers – FR & DE - ongoing work
- Work at Member State level is crucial - it feeds EFSA data and expertise - synergies exist

Cooperation, synergies

- With Member States and sister Agencies (e.g. phthalates, biocides)
- What about more/better harmonisation and/or recognition
  - At EU level with MS & Agencies -> legislation constrains
  - at the international level, building with FDA?
- Data sharing -> legislation constrains
- EU (international) database with all MS and EU assessments, all areas

THANK YOU FOR YOUR ATTENTION

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