Current state of play on FCMs, including the risk assessment

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EFSA safety assessment of FCM

- **Based on guidance** for submission of an application (dossier) for safety assessment of substance/process prior to its authorisation
  - 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

<table>
<thead>
<tr>
<th>Migration (mg/kg food)</th>
<th>&lt;0.05</th>
<th>0.05-5</th>
<th>5-60</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 genotoxicity tests <em>in vitro</em></td>
<td>+</td>
<td>+</td>
<td>+</td>
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<tr>
<td>90-day oral study in rodents</td>
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<tr>
<td>Accumulation information</td>
<td>+</td>
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<tr>
<td>ADME study</td>
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<tr>
<td>Reproduction study</td>
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<tr>
<td>Developmental study</td>
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<td>+</td>
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<tr>
<td>Long term/carcinogenicity study</td>
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</tbody>
</table>

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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 dm² 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: