Plastics Coordination Group
FCMs Framework Evaluation
Sept 24th 2018
Overview Regulation (EU) No 10/2011

- Harmonized regulation and guidance
- Legal certainty of a list of evaluated substances
- Opportunity to petition
- Recognition of Industry Risk Assessment (Art. 19)
- Scientific approach including migration modelling and worst case calculation concept
- Migration testing

Description on how and what to communicate

BUT,…
Authorization of substances migrating from Plastics are harmonized

- Positive list for Intentionally Added Substances (IAS)
- Art 19 for others

Issues:

- Further need to describe requirements along the supply chain and vis-à-vis enforcement authorities:
  - Analytical methods used to identify/quantify substances
  - Risk assessments performed, incl toxicological evidence
- Subsidiarity principle still allows Member States (MS) measures,
  - e.g. Warenwet, contradicting the spirit of 10/2011 (Aids of Polymerization listing),
  - BPA ban in France
- Diverging Risk Assessments Understanding on Art 19 enforcement
  - Lack of mutual recognition on Enforcement

Missing agreement on risk assessment outcome supporting industry derived limits
Positive Lists: Petitioning and Authorization

Opportunity for industry to petition

Evaluation by food safety authorities (legal certainty)

Available list of evaluated substances and additives with Specific Migration Limits (SML)

Issues:

- Long authorization process
- More stringent restrictions
- Complexification of migration testing
- Limited/no acceptance of in-silico tools for hazard assessment for IAS.
- Conservative assumptions for exposure assessment
- Missing pre-submission meetings to
  - ensure a more precise interpretation of industry’s dossiers,
  - enable industry to answer quickly any question from the Panel
  - would allow overall for a more effective and timely risk assessment process.

High barrier for new product development (limit innovations)
Industry risk assessment & recognized scientific principles

- Industry risk assessments according to internationally recognized principles
- EFSA report 2016 on acceptance of use of TTC approach
- FACET exposure tool hosted and published on JRC website

**Issues:**

- Article 19 interpreted as EFSA note for guidance only
- No workable approach for risk assessment of complex mixtures
- Conservative risk assessment approach for unidentified peaks
- Limited acceptance of probabilistic exposure models and tools
- No database with exposure thresholds
- Non acceptance of no migration principle
- Insufficient opportunities for direct consultation (EFSA/COM)
  - Difficulty to have exchange of opinion on specific scientific matters
  - No possibility to resolve conflicting scientific opinions
- Lack of trust (Authorities/Industry)

**Needs accepted rules and guidance for Industry risk assessment**
Examples of Concerns to be discussed with EFSA/Authorities,…

- 10/2011 recent amendments lower SML below 10 ppb
  - Without information on reference substances & analytical method
  - Substance limits have to be specific to be enforceable
- “Generic” 10 ppb limit for all migrants not included in Annex I,
  - Despite available assessment that would allow higher limits
- Restrictions in Annex I narrowing monomer petition
  - e.g. restrictions on oligomers
- Allocation factors lacking discussion/publication

Risks of developing highly stringent requirements with limits becoming challenging
Compliance testing

- Migration conditions and simulants are clearly defined in Annex V & III
- The concept of migration modeling and worst case calculation (Art. 16)
- Analytical methods are harmonized in CEN standard EN 1186 series

Issues:

- The JRC technical guidelines for compliance testing (still) not published
  - Analytical tolerances in migration testing are now missing
  - Use of alternative and substitute simulants is missing
  - Unnecessary additional testings

Waiting official publication
Communication

Union Guidance on Regulation (EU) No 10/2011 as regards information in the supply chain (2013) provides clear description on:

• Content of Declaration of Compliance and “adequate” information
• Roles and obligations of each actor in the supply chain

Issues:
- Industry frightened by loss of Confidential Business Information
- Attention required to avoid communication disruption along the complex value chain
- Ensure harmonized understanding on enforcement requirements and needs

Continuous improvement by learning & developing common approaches
GREAT to be harmonized

- Please,
  - while keeping at minimum identical consumers safety,
  - keep the regulation:
    - Workable, Pragmatic, Practicable
    - Enforceable,…
- Plastics Coordination Group members have ideas and suggestions

We will be more than happy to present & discuss during the consultation
THANKS

Plastics
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