

Plastics Coordination Group FCMs Framework Evaluation Sept 24th 2018



Association of Plastics Manufacturers

Overview Regulation (EU) No 10/2011

- Harmonized regulation and guidance
- Legal certainty of a list of evaluated substances
- Substitution 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



Harmonization and Guidance

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- 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

- Substitution 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.



Industry risk assessment & recognized scientific principles

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- 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

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- 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:

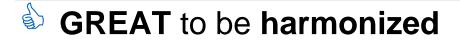
- Industry frightened by loss of Confidential Business Information
- Attention required to avoid communication disruption along the complex value chain
- Ensure harmonized understanding on enforcement requirements and needs



Continuous improvement by learning & developing common approaches

Conclusion

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- 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 The Material for the 21st Century









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