



**Plastics Coordination Group**  
FCMs Framework Evaluation  
Sept 24<sup>th</sup> 2018



**PlasticsEurope**  
Association of Plastics Manufacturers

- 👍 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 **I**ntentionally **A**dded **S**ubstances (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 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

- 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



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

The Material for the 21st Century

