

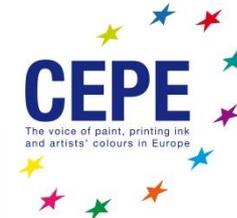
**Position of the
Packaging Ink Joint Industry Task Force (PIJITF)
on the planned EU Measure
on Printed Food Contact Materials
("pFCM measure")**

Version 4th April 2018

The PIJITF represents the value chain from the manufacturers of ink raw materials to food business operators.



A sector of CEPE aisbl



Introduction

- TRIS notification of the “Printing Ink Ordinance” by Germany
 - Objections expressed by a considerable number of MS
- European Parliament Resolution sees the need for harmonized legislation for all FCM’s
- JRC baseline study identifies patchwork of (different) FCM regulations across the EU
- Commission announces its intention to adopt – in 2018 – new Union legislation on printed FCM in form of “specific measure” according to Art. 5 of the Framework Regulation
- Commission invites the PIJITF to contribute to the process
- Germany suspends the adoption of its draft ordinance until further notice

Definition “Printing Ink”

see Union Guidelines on the Plastics Regulation

- "Printing inks" are mixtures of colourants with other substances which are applied on materials to form a print design on this material.
- *footnote:*
 - Printing inks are preparations (mixtures) which may be manufactured from combinations of colourants (pigments, dyes), binders, plasticisers, solvents, driers and other additives.
 - They are solvent-borne, water-borne, oleo-resinous or energy-curing (UV or electron beam) systems.
 - They are applied by a printing and/or a coating process, such as flexography, gravure, letterpress, offset, screen, non-impact printing or roller coating.
 - Printing inks on food packaging are generally applied on the non-food contact side of primary food packaging, and – accordingly – are often referred to as “food packaging inks”.

Clarification “Printing Ink”

Printing inks:

- a. Mixtures of colourants with other substances which are applied on materials to form a graphic or decorative design together with or without
- b. Other coloured or uncoloured overprint varnishes/ coatings or primers which are normally applied in combination with a) in order to enable the printed design to achieve specific functions such as ink adhesion, rub resistance, gloss, slip/friction, durability etc.

Printing inks do not include coatings which are applied with the prime objective of enabling the material or article to achieve a technical function such as heat sealing, barrier, corrosion resistance etc., as opposed to a graphic effect, even though they may be coloured.

Scope of pFCM measure

- To cover the printing ink layers as part of printed food contact materials
 - ensuring that any substance transfer from the print layer into food occurs only at levels that do not endanger human health in accordance with the Framework Regulation (EC) No 1935/2004
- To principally address any print layer, regardless of whether the print layer is directly in contact with the food or not.
 - Certain applications may have to be addressed at a later stage

Exclusion from scope

- Materials where migration from the print to the food is impossible (when an absolute barrier is present) and set-off or gas phase transfer can be excluded

Starting point

- Large number of substances not officially evaluated
- If all such substances were to be officially evaluated, this would require enormous resources.
- The Commission acknowledges that such resources are only available to a limited extent
- Plastics started in 1980s (monomers), additives 20 years later, still only ca. 1000 authorised substances
- Long timelines stifle innovation
- Avoid positive list approach

Inks under the current legislative regime

- All FCM are covered by Framework Regulation
 - Article 3 (including GMP requirement)
 - Article 17 (traceability)
- For plastic FCM: Plastic Regulation including positive list (Union list)
 - Covers printed plastic FCM as well
 - If a substance contained in the Union List is used in inks applied onto a plastic material, then this material has to meet the relevant restrictions of this substance
 - For Non-Listed Substances (NLS): compliance assessment in accordance with internationally recognized scientific principles on risk assessment (Art 19)
- Today, the Art 19 process is used for non-listed migrants coming from the print layer in printed plastic FCMs

Suggested approach to regulate pFCM

- Follow the established practice for dealing with inks in printed plastic food contact materials
 - Leads to more appropriate migration limits for not officially evaluated substances than e.g. in the Swiss Ordinance (10 ppb)
 - Limits based on scientific evaluations improve safety compared to applying default detection limits without further evaluation

Suggested approach to regulate pFCM

With regard to intentionally added substances: 2 elements

- Part 1 – database of officially evaluated substances
 - Plastics Regulation, EFSA Opinions, National Competent Authority evaluations following the relevant EFSA guidance (e.g. BfR, FSVO)
- Part 2 – self-assessed substances
 - replicates Art 19 approach for NLS under the Plastics Regulation
 - Principles for Risk Assessment should be developed by the European Commission, in collaboration with relevant stakeholders (The PIJITF offers its support !)
 - option should remain to submit dossier to EFSA / Member State competent authority for official evaluation and inclusion of the substance in part 1

Non Intentionally Added Substances (NIAS)

- Compliance shall be assessed using internationally recognized scientific principles on Risk Assessment

Suggested approach to regulate pFCM

Transparency:

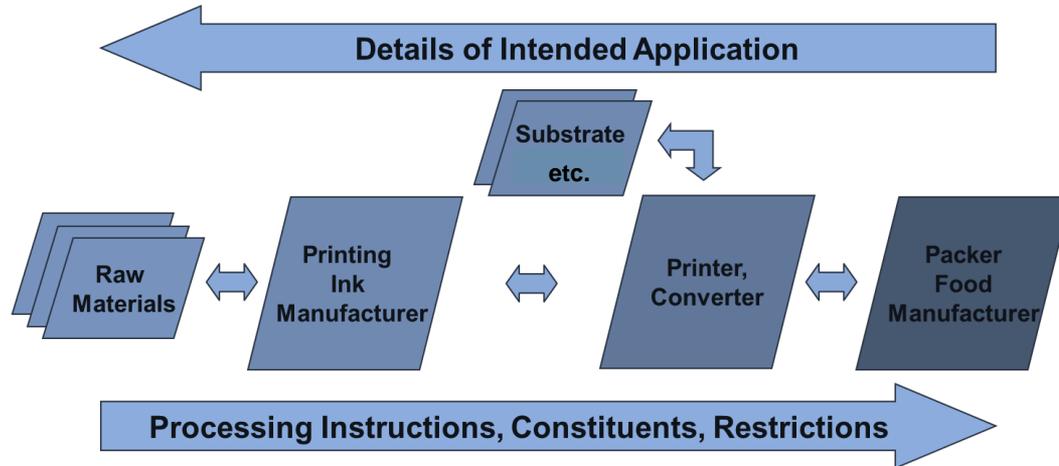
- Industry happy to work with the Commission on the development of tools on how to enhance transparency in addition to B2B communication in the supply chain.
- The PIJITF has established a working group which is tasked to develop proposals

Exposure Consideration

- EU default 1 kg food per day in 6 dm² packaging & 60 kg body weight
 - Simple
 - Allows the derivation of any required limits on a substance
 - Existing approach for plastics
- Allow use of alternative exposure scenarios
 - to refine risk in use for particular exposure situations

Demonstrating Compliance – Exchange of information

Co-operation and information sharing among all partners in the food packaging supply chain



- For plastic FCM: Union Guidance on Regulation (EU) No 10/2011 on plastic materials intended to come into contact with food as regards information in the supply chain
- Similar guidance should be developed for any type of FCM, not just plastics

Demonstrating Compliance – Compliance Testing

- Only got Plastics Regulation testing methodology so far
- Issues in translating this to other materials
- If test conditions cause changes to material not seen during use, then too severe (not appropriate)
- EuPIA Guidance on Migration Test Methods (07/2017)

Demonstrating Compliance – Compliance Testing

- General principles could be included in Regulation (Annex)
- Specific details may need to be in Guidance to meet timeline
- Also need to allow Worst Case Calculation and migration modelling

Process steps to demonstrate compliance:

- First WCC
 - if doubts then use modelling
 - if doubts then use simulants
 - if still doubts then measure in food

Compliance checks - enforcement

- Audits: The **processes** used by industry should be audited by third parties
- third parties should be accredited by the control authorities as capable to carry out such audits.
- Checklists: use checklists modelled on those currently used by the food industries to qualify their suppliers.

Summary of the Proposal

- Capable of swift implementation
- Compatible with the existing Framework Regulation
- Utilises the existing assessments of substances done by EFSA and other official bodies
- Reflects the best known current practices for ensuring the safety of printed FCM
 - And will extend that practice throughout the industry
- Ensures that limits for the migration of substances are based on toxicological evaluation rather than default limits
- Allows for the transparency of industry's assessment and compliance processes