



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

The EU Commission has announced its intention to adopt new Union legislation regulating the printing ink layer as part of printed food contact materials (FCMs) in 2018.

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

The PIJITF proposes a harmonized approach which ensures high levels of consumer protection and which can be delivered within a relatively short time frame.

Executive Summary

The EU Commission intends to adopt new Union legislation regulating the printing ink layer as part of printed food contact materials (FCMs). The Packaging Ink Joint Industry Task Force (PIJITF) represents the members of the food packaging supply chain that are concerned with the production of such materials and their subsequent use. The proposals in this document would ensure that substances in the ink layer of a printed FCM do not transfer to the food in quantities which could endanger human health. The objective is a high degree of consumer safety whilst being pragmatic and workable for industry.

This proposal envisages that official evaluations and listings will be used where available. However, if a FCM contains a material for which there is no such evaluation, it will be necessary for industry to conduct a risk assessment in order to demonstrate compliance with the relevant requirements of the Framework Regulation 1935/2004.

Thus the proposal has two elements:

Part 1. A Database of Officially Evaluated Substances. This consists of those substances already evaluated by official bodies, such as EFSA, and will include any SMLs, TDIs or other restrictions already established. These substances are allowed to be used in the manufacture of inks for FCMs (subject to their restrictions).

Part 2. Industry risk-assessed Substances. Substances which are not listed in Part 1 may be used provided that they have been properly risk assessed “in accordance with internationally recognised scientific principles”, in line with the Article 19 approach laid down in the Plastics Regulation. The risk assessment process should be developed by the European Commission.

There should be a duty, outlined in a Guidance Document, to communicate the results of the risk assessment, including any self-derived SMLs, TDIs etc., to the next actor in the supply chain.

Worst case calculation, migration modelling and migration testing into simulants and into real foods may all be used to demonstrate compliance with any restrictions. General principles for testing could be included in the text with specific details in a Guidance Document.

In order to verify compliance in an efficient way, the focus should be on processes for risk assessment. These processes used for compliance work performed along the value chain should be defined and documented so that they can be audited, either by the Control Authorities, or, if this is not possible, by accredited independent third parties delegated to by Control Authorities.

Detailed considerations

The EU Commission has announced its intention to adopt – in 2018 - new Union legislation which has in scope the printing ink layer as part of printed food contact materials. This will be done in the form of a specific measure according to Art. 5 of the Framework Regulation (EU) No 1935/2004. The Commission has declared that the legislation should be efficient, effective, enforceable, workable and pragmatic.

The Commission invited the Packaging Ink Joint Industry Task Force (PIJITF) to contribute to the process, and the PIJITF is happy to assist the Commission.

The PIJITF represents the members of the food packaging supply chain that are concerned with the application of printing inks onto food contact materials and their subsequent use. The members of the PIJITF are listed in the appendix 1.

While it is important to consider the safety of food contact materials as a whole, it is our understanding that this measure only addresses the safety compliance of the printing ink layer as part of the printed food contact materials.

With this position paper, the PIJITF wishes to outline the key elements that should be considered when drafting the EU measure. These elements ensure a high degree of consumer safety whilst they are pragmatic and workable for industry.

1. Definition: What is a “Printing Ink”?

The Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food [4] define “printing inks” as “mixtures of colorants with other substances which are applied on materials to form a print design on this material”. The related footnote gives information about the main components and the types of printing ink, as well as the printing processes through which the printing ink is applied onto a substrate:

“Printing inks are preparations (mixtures) which may be manufactured from combinations of colorants (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”.

This definition, however, does not advise which types of coatings, lacquers or varnishes are covered by the term “printing ink”, and which are not. The PIJITF therefore suggests the following clarification:

“Printing inks¹ are:

- 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.”

2. What should be in scope of the pFCM measure?

The pFCM measure should cover the printing ink layers as part of printed food contact materials, and ensure that transfer of substances from the print layer into food does not occur at levels that could endanger human health, in accordance with Article 3 of Regulation (EC) No 1935/2004.

In principle, the measure should address any print layer as part of a printed food contact material, regardless of whether the print layer is directly in contact with the food or not. It may be necessary, though, to address certain applications at a later stage.

The applications detailed below shall be out of scope of the pFCM measure:

Printed food contact materials, for which migration of ink ingredients from the print layer to the food is impossible and set-off or gas phase transfer can be excluded, should not be in scope of the pFCM measure. An example for this would be printed labels on a glass bottle.

3. The starting point

Official evaluations have not been carried out on many of the large number of substances which are used in the manufacture of printing inks for food contact materials.

If all such substances were to be officially evaluated and safe limits established, this would require enormous resources. The Commission has however acknowledged that such resources are only available to a limited extent.

The development of the positive list for food contact plastics illustrates the downside of a positive list approach. Establishment of that list started with the monomers in the 1980s, followed by additives 20 years later. Still the list comprises only about 1000 authorized substances. From experience, it takes about four years from the submission to EFSA of the dossier on a new substance until the publication of an amendment to the Plastics Regulation and inclusion on the Union List. These long timelines clearly stifle innovation.

¹ Decorative inks for ceramic and glass food contact materials and articles, applied in a firing process (>500°C), shall not be regarded as printing inks.

Therefore, if this positive list approach were followed for the pFCM measure, either one would need very long transitional periods, until all the substances were officially evaluated, or the positive list would be incomplete, and therefore unworkable.

For these reasons, neither the Commission nor the affected industries favour an approach based on an exhaustive list of authorised substances (positive list).

4. How does industry currently meet the requirements of the Framework Regulation with regard to printing inks?

All food contact materials are covered by the Framework Regulation (EU) No 1935/2004. They are required to fulfil the provisions of Article 3 of the Framework Regulation, they must be manufactured in accordance with Good Manufacturing Practices² (GMP), and traceability must be ensured at all stages of the production of FCM (Art. 17). Furthermore it is good practice that adequate information is exchanged along the supply chain in order to enable the next actor in the chain to demonstrate compliance. Where there are no specific measures, compliance with Article 3 of the Framework Regulation is assessed in accordance with internationally recognized principles on risk assessment.

The Plastics Regulation (EU) No 10/2011 sets out the specific provisions for the manufacture of food contact plastic materials. It contains a positive list (Union List), which sets specific migration limits or other restrictions for listed substances. Printed plastic materials are also plastic materials, and are in scope of the Plastics Regulation. If a substance listed in the Union List is used in a printing ink applied onto the plastic material, then this material must meet the relevant restrictions of this substance as set in the Regulation, even if it is only contained in the print layer. Article 19 of the Plastics Regulation requires that the compliance of substances which are not covered by an inclusion in the Union List shall be assessed in accordance with internationally recognized scientific principles on risk assessment to be compliant with Article 3 of the Framework Regulation.

Today, the same Article 19 process is used for the non-listed migrants coming from the print layer in printed plastic FCMs.

5. Suggested Approach to regulate printed food contact materials in general

The PIJITF suggests that the measure for printed food contact materials follows the established practice for dealing with inks in printed plastic food contact materials, per Article 19 of the Plastics Regulation. This would lead to more appropriate migration limits for not officially evaluated substances than, for example, in the Swiss Consumer Goods Ordinance [1] (10 ppb). Limits based on scientific evaluations improve safety (safe use) compared to applying default detection limits without any further evaluation.

With regards to intentionally added substances, there are two elements to the suggested approach:

² See appendix 2 for European publications and references to industry guidelines to manufacturing practices

Part 1: Database of officially evaluated substances

A database should be established comprising all substances for which official evaluations already exist, together with all relevant information (TDIs, SMLs etc.). Sources for these evaluations are the Plastics Regulation, EFSA Opinions, or National Competent Authority evaluations following the relevant EFSA guidance. Regarding the latter, use should particularly be made of the substance evaluations done by the German Federal Institute for Risk Assessment (BfR) in preparation of the draft German “Printing Ink Ordinance”, as well as the evaluations performed by the Swiss Federal Food Safety and Veterinary Office (FSVO) in relation to section 12 on food packaging inks of the Swiss Consumer Goods Ordinance.

Substances listed in this database should be allowed to be used in the manufacture of inks for FCM.

Part 2: Industry risk-assessed substances

Substances which are not listed in part 1 should be permitted to be used provided that their use has been properly risk assessed. This would replicate the Art. 19 approach of the Plastics Regulation for non-listed substances. The principles of the risk assessment of substances should be developed by the European Commission, and either incorporated in the legal text itself, or reflected in a related Union Guidance.³ Industry should be responsible for conducting the risk assessments according to these principles.

There should remain an option for industry to submit a dossier to EFSA or a Member State competent authority to have the substance officially evaluated and listed in part 1.

Non Intentionally Added Substances (NIAS)

Compliance with Article 3 of Regulation (EC) No 1935/2004 of NIAS shall be assessed using internationally recognized scientific principles on risk assessment.

Transparency of industry risk assessments

The results of the industry risk assessments shall be communicated to the next actor in the supply chain, to allow him to use this information in the further risk assessment for his material.

Industry would be 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.

³ Note: In the current absence of an official EFSA process, EuPIA has detailed such an approach in its “Guideline for Risk Assessment of Non Intentionally Added Substances (NIAS) and Non Listed Substances (NLS) in printing inks for food contact materials” [2]. This guideline is based on recent guidance and opinions by the European Food Safety Authority (EFSA).

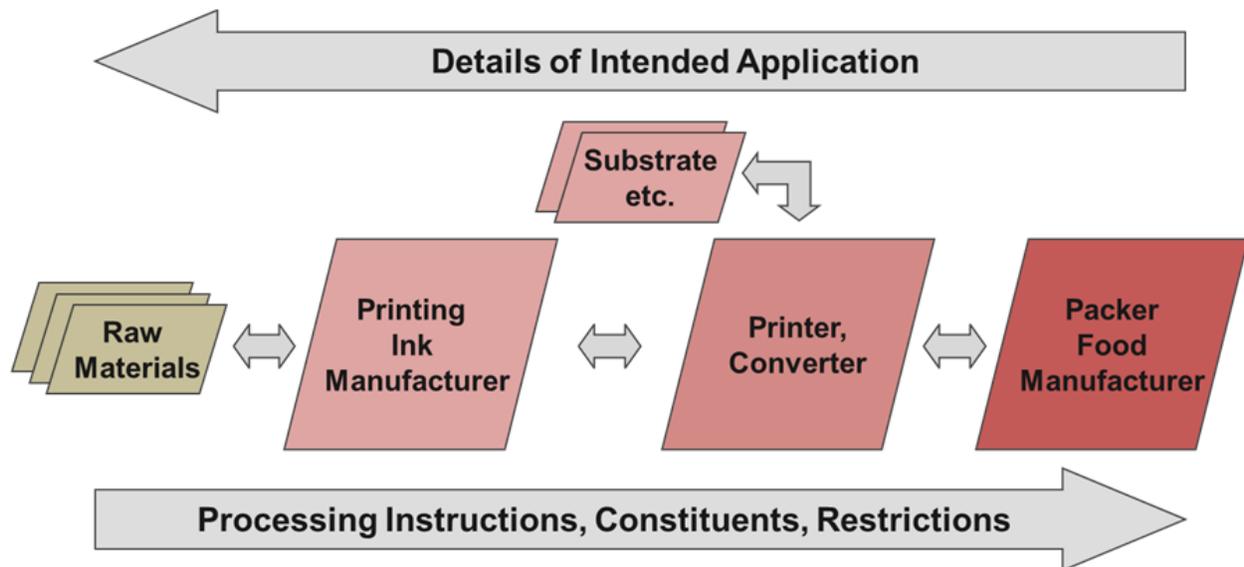
6. Exposure considerations

In the absence of specific exposure information, it is suggested to use the existing approach for food contact plastics as the default model: 1kg food per day in 6 dm² & 60 kg bodyweight. This well-established model can be simply applied for the derivation of any required limits on a substance. However, it should also be allowed to use alternative exposure scenarios, if, by doing so, the risk assessment can be refined.

7. Demonstrating Compliance

7.1 Exchange of relevant information in the Supply Chain

The responsibility for the compliance of the final printed FCM in relation to its intended use remains ultimately with the converter and packer/filler. To allow shared and final responsibilities to be met there needs to be co-operation and information sharing among all partners in the food packaging supply chain, from raw material suppliers, ink manufacturers, printers and/or converters, the packers/fillers through to the food manufacturer. Relevant information has to be shared both ways – up and down the supply chain.



Details of relevant information to be shared down the plastic FCM chain are given in the Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain [5].

Similar guidance should be developed for information requirements for any type of food contact material, not just plastics.

7.2 Compliance testing

Currently available EU guidelines provide detailed information on compliance testing for plastic FCM in scope of the Plastics Regulation only. In the absence of harmonized regulations for other FCM, the conditions used in the Plastics Regulation are often also applied to non-plastic FCM. However, food simulants for testing plastic materials and/or conditions may cause physical damage or changes to the non-plastic FCM leading to erroneous results. This is also true for printing inks. Hence, testing conditions better suited to the specificity of each FCM need to be proposed. EuPIA has recently published its Guidance on Migration Test Methods for the Evaluation of substances in Printing Inks and Varnishes for Food Contact Materials [6]. These are suggested to be used in connection with the EU measure, by including the general principles into the legal text, and publishing specific details in EU Guidance documents.

Clearly, it should not be mandatory to test each and every printed food contact material: Due to the relatively low application weight of most inks, the Worst Case Calculation technique is particularly well suited to demonstrate the compliance of substances which are added to ink formulations in defined amounts. As a second choice, migration modelling should be performed. And only if modelling fails or is not possible, then actual tests using simulants should be conducted. If there are still doubts, then measurement in food needs to be undertaken. Appropriate selection of samples can be used to group FCMs in order to reduce testing.

8. Compliance Assurance

The Commission and Member States may want additional assurance that industry is managing the (a) risk assessment of substances and (b) compliance work described above. To address this, it is proposed that:

a) The industry risk assessments, as described in section 5, should be completely transparent to the authorities. They are part of the supporting documentation ((SD) of corresponding manufacturers. Declarations of Compliance (DoC) and SD are accessible and auditable to enforcement authorities, as well as GMP 2023/2006 documents depending on the position in the supply chain. Other options to increase the visibility towards the authorities are also under discussion.

b) In order to verify compliance in an efficient way, the focus should be on processes for risk assessment. These processes used for compliance work performed along the supply chain should be defined and documented so that they can be audited, either by the control authorities, or, if this is not possible, by independent third parties delegated to by Control Authorities.

The results of an audit performed in a Member State should be acceptable throughout the European Union. For companies with multiple production sites, centralised auditing should be considered.

Auditing criteria could be described in guidelines and based on experience with existing schemes such as ISO standards or similar. Industry can help Control Authorities to develop such auditing criteria; the food industry has developed considerable experience in auditing processes, which can be used as a basis for a more general approach.

The (a) risk assessment of substances and (b) compliance work could be done by individual companies or contracted external laboratories or consultants; in the latter case, the contracting industry would maintain the liability of the assessment. Whatever auditing or outsourcing of assessment work is performed, the industry operator retains full responsibility for its products.

Finally, and to avoid conflicts of interest, those laboratories, consultants or other institutions which provide services to a business for the risk assessment shall not act as delegated third party auditor acting on behalf of control authorities for that business.

PIJITF, 9th August 2018

PIJITF Members

- **ACE:** The Alliance for Beverage Cartons and the Environment, www.ace.be

ACE – The Alliance for Beverage Cartons and the Environment – provides a European platform for beverage carton manufacturers and their paperboard suppliers to benchmark and profile cartons as renewable, recyclable and low-carbon packaging solutions. Engaging with stakeholders and partners seeking high environmental stewardship, it contributes expertise to EU policy, legislation, and standard-setting.

ACE members include beverage carton producers Tetra Pak, SIG Combibloc and Elopak; they develop, manufacture and market systems for the processing, packaging and distribution of food, and produce packaging material at 20 plants in Europe. About 98% of the paperboard used by ACE members in beverage cartons in Europe is produced by Stora Enso in Skoghall (Sweden) and Imatra (Finland), and BillerudKorsnäs in Gävle and Frövi (Sweden), who are also members of ACE.



- **CITPA:** International Confederation of Paper and Board Converters, www.citpa-europe.org

The International Confederation of Paper and Board Converters in Europe (CITPA) was established in 1961 to represent the interests of the European Paper and Board converting industry. CITPA's membership comprises European level associations such as EUROSAC, FEFCO, EuroWaxPack, FINAT, ECTA and ECMA, as well as several National Federations in Austria, Belgium, Germany, Italy and Portugal, together with Associate Members such as ProCarton and Cepi Eurokraft. CITPA represents multinational companies and small and medium-sized firms. The Paper and Board Converting Industry in the EU member states produces Paper and Board products with an annual production value of around 60 billion €.



- **ECMA,** www.ecma.org

ECMA is the international network of folding carton organisations; carton businesses, national carton associations and suppliers to the carton industry.

With its seat in The Hague, The Netherlands, and an office in Brussels, ECMA represents 500 carton producers in nearly all countries in the European Economic Area. Around 70% of the total carton market volume in Europe, and a current workforce of about 45.000 people are represented in ECMA.



- **ESIG/Cefic** European Solvents Industry Group, www.esig.org

ESIG's mission is to promote oxygenated and hydrocarbon solvents industry in Europe and we are representing the major manufacturers in Europe.

We strive to ensure that the regulatory framework relevant to the manufacture, storage, distribution and use of these solvents is based on sound science and best practice.

We provide our members and main downstream users with the advice and guidance to comply with the latest legislation, while encouraging members to share insights and advice.



- **MPE:** Metal Packaging Europe, www.metalpackagingeurope.org

Metal Packaging Europe gives Europe's rigid metal packaging industry a unified voice. We proactively position the positive attributes and image of metal packaging through joint marketing, environmental and technical initiatives. We represent the industry's views so that stakeholders understand how metal packaging contributes to the Circular Economy.



- **EuPC:** European Plastics Converters Confederation, www.eupc.org

EuPC is the leading EU-level Trade Association, based in Brussels, representing European Plastics Converters. EuPC now totals about 51 European Plastics Converting national and European industry associations, it represents close to 50,000 companies, producing over 45 million tonnes of plastic products every year. The European plastics industry makes a significant contribution to the welfare in Europe by enabling innovation, creating quality of life to citizens and facilitating resource efficiency and climate protection. More than 1.6 million people are working in about 50,000 companies (mainly small and medium sized companies in the converting sector) to create a turnover in excess of 220 billion € per year.



- **EuPIA,** a sector of CEPE: European Printing Ink Association, www.eupia.org

EuPIA, the European Printing Ink Association, represents the interests of the printing inks and varnishes industry in Europe. Operating under the umbrella of CEPE, it represents 75 companies generating about 90 % of ink sales in Europe (close to 1 million tons in volume to a value of 3 billion Euros). 90% of EuPIA's members are SMEs.



- **FCA / CEFIC,** Food Contact Additives, (<http://fca.cefic.org/>)

FCA (Food Contact Additives) is an Industry Association organised as a Sector Group under the umbrella of Cefic (European Chemical Industry Council). FCA represents producers of additives used in the various food contact applications



- **FEFCO AISBL:** European Federation of Corrugated Board Manufacturers, www.fefco.org

The European Federation of Corrugated Board Manufacturers (FEFCO) is a non-profit organisation representing the interests of the corrugated packaging industry across Europe and addressing a wide range of issues, from technical topics to economical questions. Headquartered in Brussels, FEFCO was established in 1952 and regroups 24 National Associations as well as Corresponding members and Sympathizing members (suppliers). It represents 412 companies operating 701 plants in total employing around 91 100 employees



- **FEICA:** Association of the European Adhesive & Sealant Industry, <http://www.feica.com>
FEICA, the Association of the European Adhesive and Sealant Industry, is a multinational association representing the European adhesive and sealant Industry. This specialty chemical sector represents more than 2% of the total European chemical industry's turnover and contributes more than 14 billion euros to the EU economy. Our industry invests about 370 million on R&D yearly and employs more than 41,000 people. FEICA represents close to 800 adhesive and sealant producers in Europe.



- **FoodDrinkEurope:** Confederation of the food and drink industries of the EU, <http://www.fooddrinkeurope.eu>

FoodDrinkEurope is the organization of Europe's food and drink industry, the largest manufacturing sector and leading employer in the EU and a key contributor to its economy (289 000 companies, 99% SMEs, 4.2 million employees). Its membership comprises 27 National Food and Drink Federations, 27 European Sector Associations and 21 large companies



- **FPE:** Flexible Packaging Europe, www.flexpack-europe.org

Flexible Packaging Europe (FPE) represents manufacturers of flexible packaging who convert plastics, paper and aluminium foil using extrusion, printing, coating and laminating processes. With more than 80 member companies on 400 sites all over Europe, FPE is responsible for about 80% of European flexible packaging turnover (for pre-packed retail foods). Members include large, multi-site, multi-national organisations as well as medium and small companies. 6 national flexible packaging associations are associated members.



- **Intergraf:** European Federation for Print and Digital Communication, www.intergraf.eu

Intergraf is the European Federation for Print and Digital Communication. Its main task is to promote and protect the interests of the European graphic industry. The graphic industry in the 28 European countries comprises some 120,000 firms and employs around 630,000 people. The turnover in the printing industry is about € 80 billion. The industry throughout Europe consists mainly of small enterprises, as 90% of them employ fewer than 20 persons.



- **I&P:** Imaging and Printing Association, www.ip-europe.com

I&P Europe – Imaging and Printing Association is a European association of product manufacturers and technology providers for the imaging and printing industry. I&P Europe members' products include conventional and digital materials and their processing solutions. This includes for example inks for digital printing applications, toners, pressroom chemicals, printing plates and equipment. The association currently has 33 member companies (45% SMEs). The sum of total annual turnover within the EU of all companies represented in I&P Europe is round about 7 Billion Euro.



References to European publications and Industry Guidelines to Manufacturing Practices

- [1] “Ordinance of the FDHA on materials and articles intended to come into contact with food-stuffs (Consumer Goods Ordinance),” 12/2016.
- [2] “Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food,” 11/2013.
- [3] “Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the suppl chain,” 11/2013.
- [4] EuPIA, “Guideline on Risk Assessment of Non Intentionally Substances (NIAS) and Non Listed Substances (NLS) in printing inks for food contact materials,” 08/2017.
- [5] EuPIA, “Good Manufacturing Practice: Printing Inks for Food Contact Materials, 4th completely revised version,” 03/2016.
- [6] EuPIA, “Guidance on Migration Test Methods for the evaluation of substances in printing inks and varnishes for food contact materials,” 07/2017.
- [7] ESG Guideline for Paper Sacks in Contact with Food, Issue 2, Based on compliance with the EU legal status as per 01/2013
- [8] FEFCO GMP International Good Manufacturing Practice Standard For Corrugated & Solid Board
- [9] FEICA Guidance for a food contact status declaration for adhesives, 09/2014
- [10] FEICA Guideline for Good Manufacturing Practice of food packaging adhesives in Reference to Regulation (EU) No 2023/2006, 03/2015
- [11] CITPA Code for Good Manufacturing Practices for flexible and fibre-based packaging for food, 07/2011

