9 January 2023

Position of the Packaging Inks Joint Industry Task Force (PIJITF) on the review of Framework Regulation on Food Contact Materials & Articles

The European Green Deal aims to develop the EU's circular economy and drive sustainability in all industrial activities. The current review of the Framework Regulation on food contact materials (FCMs) provides a unique opportunity for further harmonisation of the requirements on food contact materials and articles, thus supporting the green transition of the internal market. The effective functioning of the European Single Market and the free movement of goods and raw materials is fundamental to ensure the sustained growth and competitiveness of the European economy.

Food packaging plays a key role in the sustainability of food systems. The printed packaging for food value chain (PIJITF) represented by the undersigned associations supports the transition to sustainable food systems and contribute to climate neutrality.

All FCMs are covered by the EU Framework Regulation 1935/2004 and its review will impact both harmonised and non-harmonised materials and articles. The PIJITF asks that the following points are considered:

1. Risk assessments should be the primary method for the evaluation of final FCMs, all starting substances and intermediate products, considering the hazard assessment and the exposure data.
2. Available data on hazard should be used for the hazard assessment of starting substances and mixtures, according to “one substance one hazard assessment” approach.
3. The “one substance one hazard assessment” should be followed by a risk assessment for food contact where EFSA should retain responsibility.

4. Self-assessment by industry should be central in the assessment process, this will be especially important for NIAS and innovative substances. Industry guidelines are already in use and provide a good foundation.
5. The most hazardous substances (e.g. CMR, vPvB, PBT), with the potential to migrate in amounts relevant for human health through oral exposure should be subject to specific risk assessment.
6. The use of a Generic Risk Assessment (GRA) is not appropriate to address substances in FCMs as it does not properly consider the migration and exposure of those substances.
7. Essential use concept should only be considered after an evaluation of safe use and minimising undesired trade-offs.
8. Known Non-intentionally Added Substances (NIAS) should be risk assessed similar to Intentionally Added Substances (IAS) following internationally recognised principles.
9. Accumulation of different substances should be evaluated at every stage of the production process where difference substances/materials are used and it should be controlled via good manufacturing practices (GMP).
10. If chemical data repository is developed, it should be managed by an EU authority and made available to EU agencies, national authorities and industry to streamline the assessment process, while protecting confidentiality and with appropriate safeguards.
11. Declaration of Compliance (DoC) should be mandatory for all FCMs and articles. Specific measures should be developed to allow compliance evaluation. In the absence of specific measures, an EU guidance is needed.
12. Specific provisions are needed on exchange of information to enable more transparency throughout the supply chain, using industry experience as much as possible. This should include clear and consistent rules on data requirements and information transfer.
13. Existing positive lists from EFSA and competent national authorities should be integrated and used when developing harmonised EU specific measures.
14. Enforcement at national level and border control should be improved by providing a harmonised EU approach and clear guidance to Member States. Member States should make available sufficient resources to enable the control.

The European printed packaging for food value chain represents mostly non-harmonised FCMs and has successfully implemented international principles to ensure consumer protections and food safety for its products.

The Packaging Ink Joint Industry Taskforce (PIJITF) proposes a blueprint for printed food contact materials and articles (pFCM) that could be applied to develop harmonised measures for all materials or as a general approach set out in the Framework Regulation. See Annex 1. The approach is based on the principle of industry self-evaluation and control of the process to ensure compliance of the final article.

ANNEX 1

Blueprint for printed food contact materials and articles (pFCM) that could be applied to develop harmonised measures for all materials or as a general approach set out in the Framework Regulation

Background

The proposals in this annex suggests an approach for substances in the ink layer of a printed FCM to ensure that they do not transfer to the food in quantities which could endanger human health. The objective is to achieve 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 or national authorities, and will include any SMLs, TDIs or other restrictions already established. These substances should be allowed for use 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 and methodology should be developed by the European Commission to ensure consistent application among Member States and across industries.

Data needs related to the risk assessment of substances could be supplied by a new repository system developed at EU level, which would allow the use of REACH data for FCM assessment by authorities and other stakeholders.

There should be a DoC obligation, outlined in the Framework Regulation, to communicate the results of the risk assessment, including any self-derived SMLs for substances of concern, TDIs etc., to the next actor in the supply chain. This should be also elaborated via increased transparency in the supply chain, while respecting confidentiality. The industry needs regulatory rules or guidance documents according to which the compliance can be evaluated.

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 a Guidance Document.

In order to verify compliance in an efficient way, the focus should be on processes for risk assessment and good manufacturing practices. These processes used for compliance work performed along the value chain should be defined and documented so that they can be officially audited. While it is important to consider the safety of food contact materials as a whole, the following example addresses the safety compliance of the printing ink layer as part of the printed food contact materials.

1. Precondition for harmonized measures

We suggest all materials to be explicitly defined in the Framework Regulation even if they currently do not have a specific EU measure, as a precondition for future development. Here is a specific example for the definition of printing inks (see below).

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”. 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 inks[1] 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.”

Example of a printed layer as part of a final article

Considering the EU intention to evaluate the safety of FCM based on the final article, this requires careful assessment of all FCM and articles, for example the substrate (monomaterial or multimaterial), printing ink layer, adhesive layer, etc. Any specific measure that covers the printing ink layers as part of printed food contact materials, should ensure that transfer of substances, including those 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.

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 be out of scope. An example for this would be printed labels on a glass bottle. The assessment of the final article should still take place.

2. Suggested Approach to regulate printed layer on final article that can be used as a general approach to all non-harmonised materials

The PIJITF suggests that a specific measure involving a printed layer on a final article 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 (referring to tier 2 and 3 from the Commission’s Inception Impact Assessment):

[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.

Part 1: Database of officially evaluated substances as part of a repository or independently (based on existing positive lists)

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 for use in the manufacture of inks for FCM.

Part 2: Industry risk-assessed substances

Substances which are not listed in part 1 should be permitted for use 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 and methodology for the risk assessment of substances should be developed by the European Commission, and either incorporated in the legal text of the Framework Regulation, or reflected in a related Guidance document.[2] 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.

The industry self-assessments could be also valuable information to share with enforcement authorities in a form of databases or under another agreed format, respecting the intellectual property rights.

Non-Intentionally Added Substances (NIAS)

Known NIAS should be risk assessed either by EFSA/competent authorities or self-assessment by industry in the same way as IAS. Compliance with Article 3 of Regulation (EC) No 1935/2004 for NIAS shall be assessed using internationally recognized scientific principles on risk assessment.

Access to a central repository will be necessary for the industry to use the available data under REACH for their own self-assessment.

3. 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 dm^2 & 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.

4. Demonstrating Compliance

4.1. Exchange of relevant information in the Supply Chain

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 Practices[3] (GMP), and traceability must be ensured at all stages of the production of FCM (Art. 17). Furthermore, it is good practice that

[2] 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).

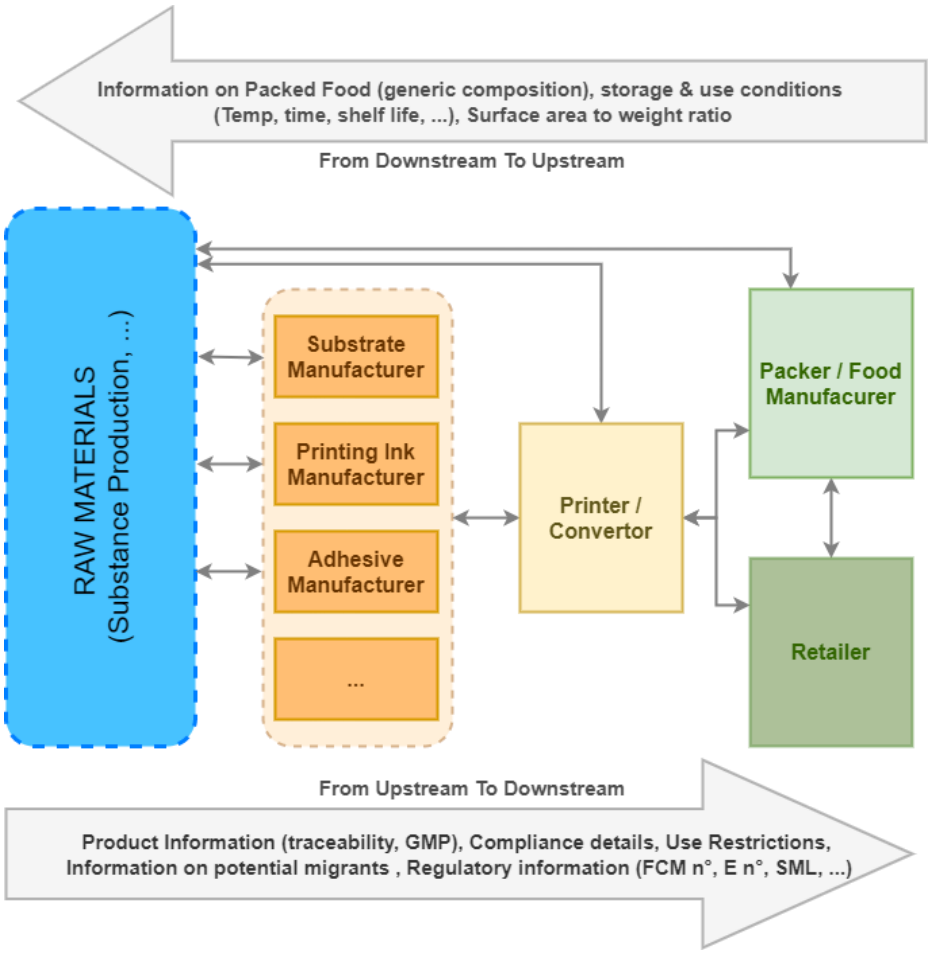
[3] See annex 2 for European publications and references to industry guidelines to manufacturing practices.

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 responsibility for the compliance of the final article 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 parties in the food packaging supply chain, from raw material suppliers, ink manufacturers, printers and/or converters, the packers/fillers to the food manufacturer. Relevant information has to be shared both ways – up and down the supply chain.

An EU guidance on compliance communication in the supply chain in addition to the mandatory DoC requirement will support transparency of information and ensure safety of the final product.

The PIJITF value chain has developed a guidance matrix for communication in the supply chain identifying the minimum necessary information needed at each step of the process to assess compliance. 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.



4.2. Compliance testing

Currently available EU guidelines provide detailed information on compliance testing only for plastic FCM in scope of the Plastics Regulation. 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 and other materials. 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.

Compliance of the final article can be achieved if all used materials comply. Specific testing conditions have to be considered for the different materials used in the final article.

It should not be mandatory to test each and every final article: In the case of printed layer, 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.
This tiered approach can be applied to all food contact materials and articles.

5. 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 2, 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 documents depending on the position in the supply chain.

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 officially audited.

The results of a compliance audit performed in a Member State on industry risk assessment should be acceptable throughout the European Union.

Auditing criteria could be described in guidelines and based on experience with existing schemes such as ISO standards or similar. Industry can support the work of Control Authorities to develop such auditing criteria; the food industry has 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 official auditors on behalf of control authorities for that business.

Annex 2

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 supply chain,” 11/2013.

[4] EuPIA, “Guideline on Risk Assessment of Non Intentionally Added 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 International Good Manufacturing Practice Standard For Corrugated Board, 2020

[9] FEICA Guidance for a food contact status declaration for adhesives, 2022

[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

[12] Intergraf and FTA Europe guide to applying food contact materials legislation, 06/2021.

PIJITF Members supporting this position paper

- **ACE:** The Alliance for Beverage Cartons and the Environment, www.ace.be
- **CEPI:** Confederation of European Paper Industries, www.cepi.org
- **CITPA:** International Confederation of Paper and Board Converters, www.citpa-europe.org
- **ECMA:** International networ of folding carton organisations www.ecma.org
- **ESIG/Cefic:** European Solvents Industry Group, www.esig.org
- **MPE:** Metal Packaging Europe, www.metalpackagingeurope.org
- **EuPC:** European Plastics Converters Confederation, www.eupc.org
- **EuPIA**, a sector of CEPE: European Printing Ink Association, www.eupia.org
- **FEFCO:** European Federation of Corrugated Board Manufacturers, www.fefco.org
- **FEICA:** Association of the European Adhesive & Sealant Industry, http://www.feica.com
- **FoodDrinkEurope:** Confederation of the food and drink industries of the EU, http://www.fooddrinkeurope.eu
- **FPE:** Flexible Packaging Europe, www.flexpack-europe.org
- **Intergraf:** European Federation for Print and Digital Communication, www.intergraf.eu
- **I&P:** Imaging and Printing Association, www.ip-europe.com