The PIJITF feedback on the ECORYS final report
"Study supporting the evaluation of food contact materials legislation"

The undersigned associations of the Packaging Inks Joint Industry Task Force (PIJITF) acknowledge the work performed by Ecorys and taking in consideration the feedback given by the printed packaging supply chain. We would like to offer comments and solutions to key points identified in the report regarding food contact materials (FCM).

1. Coherent framework

We agree with the conclusion that the Framework Regulation 1935/2004, in principle, "provides a basis for securing a high level of protection of human health…". However, the general rules give a lot of room for different interpretations which creates difficulties and uncertainty for all stakeholders.

We propose that the Commission issues a more detailed guidance document to promote a more effective and consistent interpretation and implementation of the Framework Regulation. Additionally, it can provide more transparency, particularly relating to the application of the requirements of Article 3.

2. Assessment of starting substances vs. final articles and combination effects

It is paramount to know which starting substances are used in the manufacture of FCMs which can give an indication of the likelihood of migrating substances which could end up in food and consequently exposing consumer. For the determination of safety, it is also of vital importance to know the composition of the final article and assess which components could migrate into food. This includes the NIAS which may come from several sources (residual substances used in the manufacture of substances and materials, contaminants, decomposition substances, transformation products, etc.).

The potential for combination effects is a question that concerns all exposures to substances. For FCMs it becomes very difficult to investigate since both the packaging and the packaged foodstuffs are complex mixtures of ingredients. However, the exposure to migrants from FCMs is often so low as to be below the threshold of toxicological concern. We also note that substances used in FCMs with similar chemistry and functional groups, with a common toxicological mode of action, are already assessed together and typically assigned a group migration limit or restriction as part of the EFSA evaluation protocol.

3. Insufficient resource allocated to risk assessment, risk management and enforcement

The lack of resources at public authorities has been identified as a critical limitation. We also note that the distribution of resources reflects the priorities and concerns of the public authorities, indicating the FCMs are a relatively low societal concern. This is supported by the information provided by the RASFF system – problems arising from FCMs are low and largely linked to imports.

The capacity issue, however, cannot be solved by the introduction of more legislation which will easily exacerbate the lack of resource and capacities of control authorities. Consequently, it will be necessary that any new legislative initiatives are aimed at improving efficiency, rather than introducing additional burdens to both public authorities and business operators. A way forward can be that industry, the supply chain and the public authority share responsibility for the risk assessment and risk management. This will allow public authority resources to be used more effectively and allocated to the verification of the assessment and enforcement activities.

We propose that the Commission considers the possibility to allow industry and the supply chain to perform risk assessment and risk management for substances not yet evaluated. This would stimulate innovation and allow faster replacement of substances of concern. Another measure to alleviate the burden on enforcement authorities and support on better understanding of FCM requirements would be the recognition by the Commission of industry and sector guidelines.

4. EU positive list approach

We agree that as part of an integrated approach to risk assessment positive lists may help in communicating developed toxicological data and harmonized migration limits. Furthermore, the very large number of substances used in FCMs that are not covered by a positive list means that the internal market is not functioning effectively. At the same time, it is estimated that between 7,000 and 9,000 substances still need to be assessed, requiring substantial financial resources. Consequently, it would take the official authorities considerable time and resources to perform all risk assessments. The report concludes that “it is very unlikely that it will be possible to establish positive lists of authorised substances for all FCM”. The positive list approach used to regulate substances used in plastic FCMs is not workable for other FCMs. In conclusion, a different approach is required.

We propose a hybrid and more flexible system, where evaluations of substances authorised for existing positive lists are used. This would include those made by national bodies according to the EFSA protocols that would be supplemented by industry evaluation of non-evaluated substances, self-derived migration limits for those substances and the appropriate restrictions. Public authorities would still be tasked to evaluate substances, particularly difficult cases or where they would challenge the industry self-derived limits. However, the numbers would be substantially reduced, with industry taking on the bulk of the substance assessments. Over time, the authorities could also work through the list of industry derived limits/substances, to establish ‘official’ limits, as the available resource allows. Where there is a conflict, for example with different limits established by different Member States, EFSA should be asked to make an evaluation to determine the appropriate limit (and it may be that there are different limits for different applications of the same substance).

This approach would require a suitable EU guidance for industry to follow and to facilitate deriving appropriate migration limits to ensure safety. This joint stakeholder approach will make best use of the available information and resources.

5. Good manufacturing practices

We fully agree with the crucial role GMP plays in the production of safe food contact materials. Good manufacturing practices are paramount for businesses in their production process and guide them through the compliance and safety assessment of food contact materials and articles.

Several sectors already established GMP-guidelines which are widely implemented by the industry. With the verification of the GMP-system and production process of a business, the competent authority could evaluate a broad range of articles produced by that business and thus ensuring these are compliant with the applicable legislation.

PIJITF remains committed to work with the European Commission and support the efforts to establish a coherent, efficient and improved framework for the regulation of food contact materials, one that continues to guarantee the safety of consumers and contribute to healthier food system.

Signatory associations:

ACE – The Alliance for Beverage Cartons and the Environment
CEPI – Confederation of European Paper Industries
CITPA – International Confederation of Paper and Board Converters
ECMA –The European Carton Makers Association
ESIG/Cefic - European Solvents Industry Group
EuPC - European Plastics Converters Confederation
EuPIA, a sector of CEPE – European Printing Ink Association
FCA / CEFIC – Food Contact Additives
FEFCO – European Federation of Corrugated Board Manufacturers
FPE – Flexible Packaging Europe
Intergraf – European Federation for Print and Digital Communication
I&P Europe – Imaging and Printing Association
MPE –Metal Packaging Europe
MPMA – Metal Packaging Manufacturers Association

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