

The Need for Harmonised EU Legislation on Food Contact Materials

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This consultation paper has been jointly prepared by the Alliance for Beverage Cartons and the Environment (ACE), representing the beverage carton industry, and Flexible Packaging Europe (FPE), representing the flexible packaging industry.

ACE members include Tetra Pak, SIG Combibloc, Elopak, Stora Enso and BillerudKorsnäs.

FPE members represent companies that manufacture all types of flexible packaging including pouches, sachets, liquid packaging, confectionery and pharmaceutical packaging applications, and much more. FPE comprises all major European producers of flexible packaging for all materials.

The members of these associations face many of the same challenges in the context of the assessment of food contact materials to be placed on the market across Europe. Our two associations have regularly been in contact with the European institutions and we are pleased to outline in further detail the challenges that the European packaging supply chain is currently facing due to a fragmented internal market. In our view, these facts make a clear case for a more harmonised approach across Europe.

The Market for Beverage Cartons and Flexible Packaging.

The packaged food and beverage industry is led by multinational companies which operate on a pan-European or even global basis. The packaging supply chain delivers value to these companies by ensuring food preservation, food safety, and prolonged shelf life for fresh produce, ultimately contributing to the lowering of food waste. Ranging from large companies and groups of companies to a high number of SMEs, the sector operates across national boundaries and is characterised by a truly European identity and method of operation.

Within this sector, beverage cartons account for some 6% and flexible packaging for 50% of packaging in the field of food contact materials for consumer applications¹.

The Current Situation

Legal Framework

Framework Regulation (EC) No 1935/2004 Article 3 prescribes that food contact materials (FCM) must be “safe” in order to be allowed for placing on the market.

For plastic materials and articles intended to come into contact with food Regulation (EU) No 10/2011 lays down specific rules for demonstrating the safety of these materials. Hence, for these materials, the safety requirement and detailed compliance assessment rules are largely laid out.

¹ These, and the following market data, are based on industry estimates, partly derived from information gathered for the FACET project

Materials for which such EU harmonised measures have not been established, the situation is more complicated. It is practically impossible for the majority of companies to start from first principles and demonstrate that their FCM comply with Article 3 of Framework Regulation (EC) No 1935/2004. To prove for millions of FCM on the market that there is no or minimal risk associated with a FCM is extremely challenging, in particular for SMEs with limited expertise and resources

Clarity is sought by consulting various national pieces of legislation. However, these are often limited in scope, outdated or not suitable for the relevant material at hand. This can lead to a situation where materials can be legally placed on the market although there is no legal process for compliance with the food safety principle as these rules are simply missing.

Companies try to fill this “safety gap” by following other guides such as Council of Europe recommendations, industrial codes of practice or national legislation of third countries (e.g. US FDA, Swiss Ink Ordinance).

Beverage cartons and flexibles in the legislative environment

In practice, the plastic layers in beverage cartons must have compositional compliance with Regulation (EU) No 10/2011. However, other components such as inks, paper and board lack harmonised measures.

For flexible packaging, manufacturers are faced with the following gaps in EU legislation:

- Full compliance with Regulation (EU) No 10/2011 - 10%
- Regulation (EU) No 10/2011 does not apply to some components – 80%
- Regulation (EU) No 10/2011 does not apply at all - 10%

Overall, some 50% of all food for consumer applications is packed in beverage cartons or flexible packaging for which the industry has not been adequately equipped with harmonised rules for demonstrating the safety of all their components.

Consequences

1. **The burden of 28 national legal systems:** A typical converter of flexible packaging handles around a hundred different products. In the absence of workable mutual recognition, demonstrating compliance of each of these products with the legislation of 28 different MS is often highly challenging due to:

- Lack of accessibility: unclear access to national legal texts, timings for updates
- Language barriers – limited number of national regulations are available in translation
- Lack of resources: in particular SMEs may not have/cannot afford specialised staff/legal firms for assessing FCM legislation across 28 Member States
- Lack of transparency: Consultation on the development of new national legislation is often confined to the MS concerned. The result will naturally be national legislation that does not take into account the European nature of the supply chain and may give competitive advantages to national manufacturers.

- Lack of clarity of legal status: Some MS publish “recommendations” on FCM rather than providing legislation. However, a failure to comply with such “recommendations” may raise questions over the safety of FCMs.

In practice, compliance can therefore often only be established with two legal regimes.

2. **Ineffective mutual recognition:** Producers are often unclear when a product is compliant in one Member State (MS) but not in another, whether the product is compliant across the EU. As in many other sectors, mutual recognition has many shortcomings in practice and is often unworkable.
3. **Perceived “choice”:** There is an increasing perception that companies can and do undertake forum shopping for regulatory standards on FCM.
4. **De-selection of materials:** A regulation of substances in a single MS may lead to the de-selection of materials, because packaging manufacturers cannot easily control their supply chains. Examples include
 - a. the French BPA ban now being addressed by the EU Commission,
 - b. the proposed mineral oil regulation in DE which has already led to a de-selection of recycled paperboard for food contact applications, and
 - c. the DK work on fluorinated compounds in FCM which cannot be met by materials that are approved food contact applications and legally compliant in other MS.
5. **Distortion of the internal market:** In formulating national legislation stakeholder consultations and engagement is largely confined to the country itself. There is no practice to consult stakeholders beyond their national boundaries.

In consequence, national legislation may address mainly national circumstances and lose sight of diverging conditions and FCM applications in other MS and therefore hinder the free movement of packaging materials and packaged food with the EU.

6. **Loss of consumer trust:** It is due to this regulatory context and implementation in practice that civil society stakeholders and the general public perceive FCMs as:
 - a. largely unregulated and
 - b. more seriously, as a risk to consumers.

While the beverage carton and flexible packaging industries take due care and thoroughly assess and ensure materials’ safety, the current legislative environment does not contribute to instilling trust and reassuring consumers and civil society stakeholders. This has been confirmed at the January 2016 hearing in the European Parliament.

Examples

The following examples illustrate the variety of legislations and recommendations to be taken into account for widely used food packaging materials.

1. **Inks** – Inks are used on the majority of packaging materials. Although printed on the non-food contact side, there remains a risk of their components transferring to the food, either through

migration or, in the case of beverage cartons and flexible packaging, through set-off in reels. Applicable national rules include:

- a. FR positive list for pigments
- b. BE and NL purity requirements for pigments
- c. DE BfR recommendations on purity requirements for pigments (used as colorants in plastics)
- d. Swiss Ink Ordinance (section 8b of the Ordinance of the FDHA on Materials and Articles (RS 817.023.21)): only legislation comprehensively covering ink components and therefore used as *de facto* reference

Currently, the Swiss Ink Ordinance is the only legislation that comprehensively covers ink components and has become a commonly used *de facto* reference. The Council of Europe Resolution AP(2005)2, even though still used, has become less relevant.

The ongoing German assessment of specific measures on ink may lead to additional legislation adding to the mix. It is likely to supplant the Swiss Ordinance even though it is indeed to be complementary.

These examples of national legislations shown above do not necessarily imply that all MS legislations are incompatible with each other. In the past however, industry has faced issues due to diverging interpretations of EU principles by member states and the absence of community law. For example, for photo-initiators, ITX and TAA, the interpretation of migration levels and the judgment on a breach of Art. 3 (EU Framework Regulation 1935/2004) varied widely across the EU.

During the ITX case in 2006, some MS did not see any reason to claim materials on the market while others had driven court cases against food producers and packaging companies.

2. Coatings²

Applicable national legislation on food contact coatings which include positive list:

- a. IT – Annex II, Section I of Ministerial Decree of 21 March, 1973
 - b. ES – Annex I, Royal Decree 847/2011
 - c. GR – Art. 28, Greek Food Code
 - d. CZ – Annex 10, Part I of Decree No. 38/2001
 - e. SK – Annex 4, Decree No. 1799/2003 – 100
 - f. NL – Chapter X of Appendix A of the Dutch Packaging and Utensils Regulations, 1979
- In practice, compliance with Regulation (EC) No 1935/2004 is most often demonstrated by reference to:
- g. FDA 21 CFR 175.300 or 320
 - h. DE BfR Recommendation XIV or XXI
 - i. Council of Europe Resolution AP(2004)1

In addition, companies must take account of the French suspension of the use of BPA and a specific EU measure on certain epoxy derivatives, Regulation 1895/2005.

² Information largely based on a presentation at PIRA Conference 2013 by Rachida Semail of Keller and Heckman LLP

3. Paper³

Applicable national legislation on food contact papers include:

- a. NL – Chapter II of Appendix A of the Dutch Packaging and Utensils Regulations, 1979
- b. IT – Annex II, Section I of Ministerial Decree of 21 March, 1973
- c. GR - Art. 24, Greek Food Code
- d. CZ – Annex 12 of Decree No. 38/2001
- e. SK – Annex 8, Decree No. 1799/2003 – 100

In practice, compliance with Regulation (EC) No 1935/2004 is most often demonstrated by reference to:

- f. DE BfR Recommendation XXXVI
- g. Council of Europe Resolution AP(2002)1

Examples of conflicting Member State legislation:

- Italian legislation limits the use of light weight pigment coated paper and paperboard because of a regulation on ash content. Ash content above 10 % limits the use of the FCM to dry and non-fatty foodstuff. Low grammage pigment coated board fails to fulfil the 10 % limit. This material would be legal in other member states.
- The German BfR recommendations permit the use of certain stilbene derivatives as Optical Brightening Agents in food contact papers. These are not permitted under Italian legislation.
- The Danish Food Administration Authorities “discourage” the use of fluorinated substances in cardboard and paper that is intended for food, and has set an indicative maximum level. The use of such substances is permitted in many other Member States.

4. **Migration Test Methods** - In the absence of community law and in certain cases national law, MS tend to use rules prepared for plastics and their specific migration test conditions. These may be completely unsuitable for other materials such as paper.

Recommendation

We trust that with these examples we illustrate the general need for further EU harmonisation of FCM regulation. We are fully aware of the fact that there might be more sectors facing similar issues and do therefore not suggest to prioritize the areas highlighted above.

Nevertheless, we hope for a thorough Commission review of the current EU and MS regulatory framework for FCMs and would be happy to provide further information, as appropriate.

Whatever next steps the Commission may decide to take, it should aim at

- Ensuring a level playing field for FCMs in general, regardless of their origin;
- Enhancing the available scientific fact base so that increasingly refined questions concerning consumer protection can be answered adequately and with relevant information about food consumption, the use of food contact materials and the substances used in manufacturing them;
- Setting a simpler and fully harmonised regulatory framework providing economic actors with more flexibility in employing various tools in ensuring food contact safety and compliance.

³ Information largely based on a presentation at PIRA Conference 2012 by Rachida Semail of Keller and Heckman LLP