

**ECMA Comments**  
**Revision of the EU rules on food contact materials (FCM's)**  
**Inception Impact Assessment**

The European Carton Makers Association has for many years closely following the FCM legislative developments, providing input into different reports and studies by European institutions. We welcome the opportunity to further contribute to the discussion on the policy options as referenced in the inception impact assessment.

As an industry association, our members are typically manufacturing product packaging using different food contact materials, typically cartonboard, inks and adhesives.

ECMA represents 80% of the total carton volume in Europe and has around 500, direct and indirect members. Of the folding carton makers, 90% can be considered as SMEs, with 70% below 50 employees and 20% between 50 and 250 employees.

**Comments related to the identified fundamental issues in the evaluation of the FCM legislation.**

Lack of functioning of the internal market and possible safety issues for non-plastic FCMs.

ECMA is strongly in favour of harmonised food safety legislation instead of a patchwork of national measures. Harmonised legislation creates a level playing field, avoids operational uncertainty, decreases the costs and complexity for demonstrating compliance and enhances the internal market and the overall level of FCM safety.

Mutual recognition is essential for the internal market and businesswise, but a well-accepted harmonised legislation should be the pursued end goal.

The positive authorised list approach and lack of focus on the final product.

It is obvious, with the current resources it will not be possible to come to closed positive lists with fully assessed substances for all, so far not specifically regulated FCM materials. The second-best option is in our view to come to transparent inventory lists with all substances somewhere regulated with the adopted limits, indicating also in which FCM the substances may appear.

Such a transparent general list - as announced by the Joint Research Centre when presenting the Baseline Study - offers public authorities the possibility to screen the included substances and for the industry such a list would provide a reference overview. At the time, the creation of an IT tool with full access to the developed general list and a database with all translated national food safety legislation, was mentioned in presentations.

It seems not appropriate to abandon the “starting substances” approach because this is “not feasible” and to present an increased focus on the safety of the final article as the alternative.

Any safety issues appearing only at the final article stage, need to be addressed but a good view on the starting substances facilitates the understanding of what may happen.

Lack of prioritisation of the most hazardous substances and up-to-date assessments.

ECMA shares the view that prioritisation is important. In the impossibility to go through a full toxicological assessment for all not evaluated substances, it is with the use of advanced in silico tools, possible to obtain a good indication on the substances of the highest concern. Taking into consideration the overall exposure from different sources, authorities and industry may, in a trustful science-based context, set pragmatic plans to tackle the prioritised substances.

Exchange of safety and compliance information in the supply chain is poor and the ability to ensure compliance is compromised.

To fill the still existing gap in required information sharing, ECMA developed questionnaire templates which may be used by its members when discussing food safety with the suppliers of the different FCMs.

The most advanced level of information sharing is obtained from the suppliers, the chemical identity of the used substances with the specific migration limits, residual content restrictions or other limitations

(EU, national legislation or evaluation by an official authority) and alongside the concentration of the used substances in the delivered FCM.

An advanced information sharing contains also information on the used self-evaluated not listed substances, the dual use substances, the NIAS and accurate use instructions.

In case this detailed level of transparency on the used substances can't be reached, ECMA is strongly in favour of the communication requirements included in the published Council of Europe Resolution CM/Res(2020)9 on the safety and quality of materials for contact with food.

According to the resolution, declarations of compliance need to be issued at all stages of the supply chain.

"The declaration of compliance means that the manufacturer of the food contact material or article assumes responsibility for the suitability for food contact, including the safety of all released substances or whenever applicable, explicitly informs the next business operator in the supply chain of the compliance work that needs to be completed. ..."

"A declaration of compliance ... includes at least (if applicable) : ... Information on substances used, impurities and reaction and degradation products, including those known or foreseen to be generated at later production stages, for which the business operator has identified that further compliance work needs to be conducted at the next stages in the supply chain."

#### Rules do not sufficiently take into account the specificity of SMEs.

The Ecorys report identified the particular difficulties SME's are encountering. With a lower leverage they are often not able to obtain the required adequate information to perform cost-effective worst-case calculations for the final carton and some SME's don't have the resources to effectively monitor the food safety issues into the full detail.

Especially from the SME perspective we believe the DOC wording referred to above, would be a significant step forward.

Looking back into the sector experiences over the last ten years, the outcome of certain court cases with SMEs involved, has been particularly unfair. The full chemical knowledge about substances is with the suppliers. They know which reactions may take place, which impurities can be expected. It is unfair to hold SME carton makers responsible for safety issues which may appear, in case no clear information was provided. It is for an SME not feasible to follow all scientific publications related to the safety of substances.

#### Rules do not encourage development of safer and more sustainable alternatives.

This paragraph identifies well the need to bring clarity in relation to the use of new barrier technologies on paperboard. The 4Evergreen project is currently covering this type of issue.

### **Comments related to the different possible measures under consideration.**

#### Ensure the safety and sustainability of the final FCM

##### Shifting the focus onto final materials

ECMA fully supports the need to assure the safety of the final article. The overall safety of the delivered packaging needs to be guaranteed, taking in account the migration which may come from the different materials used. Based on accurate information obtained from the different suppliers the converter/carton maker is in a position to perform overall worst-case calculations for the substances which may come from different sources.

As expressed earlier the "starting substances" remain however an essential cornerstone !

An increased focus on compliance of the final article should not lower the responsibility of the upstream suppliers. Converters have to verify what needs to be further checked, need to respect the use instructions and have to work according appropriate good manufacturing practices.

##### Prioritising the assessment and management of substances.

Aligned with previous comments ECMA supports a prioritising approach. Transparency about the flow of information in the supply chain can never be 100%, but by tackling the unassessed substances in a responsible pragmatic way - taking in account hazard and exposure - further progress may be made. The tiered approach allowing also business operators to perform - well communicated - risk assessments is another contribution to overcome the vast remaining evaluation task and to speed up the introduction of innovative solutions.

##### Supporting safer and more sustainable alternatives

ECMA welcomes the intention, to incentivise the use of safer and more sustainable materials and to support safe recycling.

Ensure exchange of information in the supply chain, support for SME's and enforcement of the rules.

Improving quality and accessibility of supply chain information for compliance and enforcement

Accurate communication and a clear determination of responsibilities in the supply chain is essential for making progress regarding the safety of FCMs.

As indicated earlier it is critical to know what needs to be verified. Just an indication that the delivered FCMs are compliant with specified reference legislations is, for converters, not sufficient.

Safety assessments are about which substances are present and may migrate or react ! This allows cost effective compliance work and is feasible for SME's.

Imported materials need to be as compliant. The same DOC information needs to be available.

System for ensuring compliance of the final FCM

There may be a role for third parties offering an additional compliance guarantee towards business operators.

As the inception impact assessment mentions an extensive further consultation process, ECMA hopes to be also invited for a stakeholder working group discussion.

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