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SHAPING A SUSTAINABLE FUTURE FOR PACKAGING

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# Contribution to the public consultation on the draft Commission Regulation amending Regulations 10/2011 and 2023/2006

EUROPEN, the European Organisation for Packaging and the Environment, representing the packaging value chain in Europe, would like to take the opportunity of this paper to provide feedback on the draft Commission Regulation amending Regulation (EU) No 10/2011 on materials and articles intended to come into contact with food and Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Our feedback on the draft Regulation is as follows:

## 1. Articles 3a & 8 - High degree of purity

The introduction of the requirements of Article 3a, which define where a substance used in the manufacture of plastic materials and articles can be considered as having a high degree of purity, raises the following concerns regarding practical compliance demonstration:

- The requirement in point (iii) to conduct testing for genotoxicity according to 'the relevant guidance adopted by the Authority' would rule out the possibility of referring to other internationally recognised assessment tools, such as for instance ECHA's Assessment of Genotoxicity Under REACH.
- The obligation in point (iv) to demonstrate that unknown contaminants and non-intentionally added substances do not exceed the threshold of 0.15 ppb is extremely challenging. Indeed, it is not technically possible to detect all the unknown substances. The identification of a substance is essential for conducting proper root-cause analysis on sources and toxicological assessments. Although the identification and semi-quantitative estimation of substances in screenings is possible for the low ppb range, currently there is no analytical method for the identification and estimation of the majority of the peaks. As the detection limit for the unknown substances is so low, it is unclear whether these substances originate from the packaging material or occur due to environmental contamination (e.g. during sample taking, laboratory work, etc.). The uncertainty is further worsened by the peaks hidden in the background noise of the chromatograms. Because current analytical capabilities are insufficient, the identification of substances at the lower ppb ranges is extremely difficult and therefore burdensome.
- The risk assessment limit for unknown substances suggested in point (iv) seems unjustified for substance for which genotoxicity is not yet known and it should be noted that it is significantly lower than the approved detection limits for known substances of concern. The regulation should recognise that compliance with such limit is not technically feasible considering current limitations of analytical chemistry.

Furthermore, and in order to ensure a clear interpretation of the proposed obligations, we call on the European Commission to clarify that the reference to 'a substance' in the introductory paragraph of Article 3a exclusively refers to the substances type listed in Annex I to the draft regulation. We would also welcome the publication of technical guidelines to support the practical implementation of Article 3a(iv).

Article 8 of the proposed Regulation introduces a requirement for "*Substances used in the manufacture of plastic materials and articles, including those manufactured from waste*" to be "*of a high degree of purity and (…) of a technical quality suitable for the intended and foreseeable use of the materials or articles.*" For the same reasons

mentioned above, it is not feasible for the definition of "high degree of purity" to apply to substances used in the manufacture of plastic materials and articles.

## 2. Article 14a - Labelling

While we support the objective of educating consumers on the safe use of plastic food contact articles, we would like to point out several concerns regarding the practicability of Article 14a.

Paragraph 1 of the Article states: *"1. The manufacturer or other operator responsible for placing on the market a* ***material*** *or article intended for repeated use shall provide information about its the maximum life span to its users by means of labelling or instructions, including appropriate instructions designed to slow down deterioration of the material or article, as well as a description of observable changes of the article or material that may indicate the deterioration of the article or material and that it has reached its maximum life span."*

The use of the word "material" in the paragraph could suggest that intermediate materials, such as plastic pellets, are also subject to the requirement. Given that various operating steps take place during the converting process (e.g. mixing pellets with other materials, heat treatment), a manufacturer of materials may not be able to adequately inform consumers. We therefore suggest deleting the reference to "material" from the labelling requirement.

Furthermore, should articles be too small to bear all the requested information, it should be allowed for those to be communicated via other information tools, for example via digital solutions.

Finally, we do not support the obligation for the manufacturer of materials or articles intended for repeated use "*to describe observable changes of the article or material that may indicate the deterioration of the article or material and that it has reached its maximum life span."* Indeed, misuse cannot be predicted, and the obligation opens to liability of the manufacturers for any possible unforeseeable misuse that consumers can make. Manufacturer can inform on the intended use and possible limitations of the articles introduced in the market, but it should be consumers' responsibility to follow the instructions.

## 3. Article 17.2 point (a) - Removal of derogation for containers with volume less than 500ml

The derogation of containers with volume less than 500ml from the calculation of migration results using the actual S/V ration was introduced in order to compensate for the gross overestimation made by assuming that consumers eat food packaged in small containers in a quantity equal to 1 kg per day, all containing the same migrating substances. The entire foundation of the food contact legislation is based on the accumulation of worst-case scenarios and exposure overestimation.

Removing this derogation is not supported by evidence of safety problems and would have significant impacts, as many articles perfectly compliant with the current legislation would be set out of the law without any evidence that they represent a problem. We oppose this amendment and we call for maintaining the current text.

## 4. Article 3 - Transitional measures

The transitional periods set out in the draft regulation are unrealistic. The re-evaluation and risk assessment of affected substances will be significant and time consuming. Considering the complexity of affected supply chains and formulations, we call for the establishment of longer transitional arrangements.

## 5. Annex V - Compliance testing

While we appreciate the effort to provide clarity on the technical requirements of the analytical method for testing compliance of migration from plastic food contact materials and articles, we believe that such technical specifications should rather be included in the *"Union Guidelines on Regulation (EU) No 10/2011 on plastic*

*materials and articles intended to come into contact with food",* preventing Annex V from becoming overly burdensome with specific technical details.

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