

## Plastics Europe View: Food Safety – Plastic Food Contact Materials (Update to Quality Control Rules)

Plastics Europe wishes to express its concern regarding the proposed change to the “eurocube” model / surface-to-volume requirements for Article 17(2), in the forthcoming 18<sup>th</sup> amendment of Commission Regulation (EU) No 10/2011. Moreover, as this change was introduced after conclusion of the public consultation on this proposed legislative amendment, we believe it is essential to highlight our preliminary assessment of the impact that a change in the surface-to-volume ratio from 6 dm<sup>2</sup> per kg to 12 dm<sup>2</sup> per kg will bring about. We foresee significant practical implementation challenges that we believe will increase the regulatory compliance obligations on intermediate food contact material producers, with little appreciable increase in consumer protection. Therefore, we call on the Commission to defer this change and to conduct a more thorough assessment of the values used in the “eurocube” model as part of the forthcoming revision of the wider Food Contact Materials Regulation.

The surface-to-volume ratio is a fundamental parameter in the risk assessment of food contact materials when calculating and modelling the amount of a substance that might migrate from the material or article into food. The proposed doubling of this ratio would increase the theoretical surface area in contact with the food per unit volume and lead to a higher calculated migration rate. Such a change would add significant conservatism into the regulatory assessment framework. In some instances, it would result in substances, that are currently regarded as being used in a safe manner for food contact applications, being calculated as exceeding their specific migration limit (SML). This would result in a safety evaluation failure, even though neither the real-world migration of that substance and nor the food contact application has changed.

For intermediate producers, this change would trigger a significant body of work to ensure that safety evaluation failures do not occur, and currently compliant materials remain so. At a low end, the foreseeable impact of this change is that all current migration calculations and models that use a 6 dm<sup>2</sup> per kg surface-to-volume ratio would have to be reassessed and revised to account for the new value. This process would be extensive and resource intensive across all intermediate producers, despite no change in real-world migration from food contact material to food. At a high end, the impact on intermediate producers is an obligation to conduct additional real food testing to demonstrate that materials currently compliant with Regulation (EU) No 10/2011 remain in compliance and are entitled to stay on the market.

In addition, and for some intermediate producers, a downstream producer of food contact materials and articles may be wholly or partially reliant on the intermediate producer to ensure that downstream producer achieve compliance with Regulation (EU) No 10/2011 due to their limited regulatory capability and/or expertise. In such cases a change of surface-to-volume ratio will create

an unintentional commercial pressure from the downstream producer as they seek a surface-to-volume ratio of twelve regardless of suitable real-world migration data provided by the intermediate producer. Such market pressures would only amplify the regulatory pressure of this change. Additional assessment, cost, and supply chain communication demands are foreseen to be imposed on intermediate producers on top of those already highlighted.

On a first order basis, Plastics Europe considers that potential impact of surface-to-volume requirements for Article 17(2) in the forthcoming 18<sup>th</sup> amendment of Commission Regulation (EU) 10/2011 will be significant on intermediate producers. Whilst we understand that there is an intention improve consumer safety, we believe that to proceed at this time would impose significant practical implementation challenges and costs on intermediate producers. We believe that a more thorough assessment of benefits and costs needs to be undertaken on this proposal. Therefore, we call on the Commission to defer this change and to conduct a more thorough assessment of the values used in the “eurocube” model as part of the forthcoming revision of the wider Food Contact Materials Regulation. Such an approach will ensure that the Commission’s desire to improve consumer safety can be achieved in a way that aligns with science and does not excessively burden intermediate producers.

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**Please contact:****Plastics Europe**

Sabine Lindner

Senior Expert Consumer Affairs

+49 69 25561308

sabine.lindner@plasticseurope.de

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Plastics Europe is the pan-European association of plastics manufacturers with offices across Europe. For over 100 years, science and innovation has been the DNA that cuts across our industry. With close to 100 members producing over 90% of all polymers across Europe, we are the catalyst for the industry with a responsibility to openly engage with stakeholders and deliver solutions which are safe, circular and sustainable. We are committed to implementing long-lasting positive change.

