



**LEBENSMITTELVERBAND**  
Deutschland

## Position

# Draft Commission Regulation banning the use of bisphenol A and other bisphenols in food contact materials and articles<sup>1,2</sup>

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Lebensmittelverband Deutschland e. V./ represents the interests of the German food industry as entire chain in close contact with the supplier industries. A ban on bisphenol A in the food industry does not only affect the packers of certain foods and importers of packaged products; there are users of BPA-based process materials throughout the industry, some of whom will be massively affected by the proposed bans, such as confectionery manufacturers.

Efforts and substitution processes have been underway in the supply chains for many years; where possible, the intentional use of BPA in products with direct and intensive food contact and migration risk has been replaced by suitable substances with comparable functionality. However, very lengthy qualification processes are generally required; the time and effort required and the limits of substitutability for materials such as polycarbonate have often been pointed out in statements and technical discussions.

In May 2023, the Commission announced that it would ban the intentional use of BPA in food contact materials in light of the opinion of the European Food Safety Authority (EFSA) lowering the TDI value for BPA. We expressly point out that scientific divergences between EFSA and the German Federal Institute for Risk Assessment (BfR) and the European Medicines Agency (EMA) have not yet been resolved. From the point of view of German industry, it is regrettable that the process of resolving of the scientific assessments has not been given further scope. By nevertheless proposing a risk management measure so promptly, the Commission is ignoring the divergences instead of creating the conditions for a credible chemicals strategy and supporting the objective work of the scientific authorities.

On February 9, 2024, the consultation process on the specific draft regulation for a ban on the use of bisphenol A, bisphenols and bisphenol derivatives and for the manufacture of food contact materials and articles was launched<sup>1,2</sup>.

The regulatory concept resulting from the proposed regulation includes the new regulation of the targeted use of BPA/bisphenols in the manufacture of certain food contact materials through specific bans in conjunction with the repeal of authorizations for use in plastics (Regulation (EU) No. 10/2011) as well as changes to the scope of use for BADGE and the repeal of the authorization of BPA in varnishes and coatings (Regulation (EU) No. 2018/213). The obligation of manufacturers to

<sup>1</sup> COMMISSION REGULATION (EU) .../... of XXX on the use of bisphenol A (BPA) and other bisphenols and their derivatives with harmonised classification for specific hazardous properties in certain materials and articles intended to come into contact with food, amending Regulation (EU) No 10/2011, amending Regulation (EC) No 1895/2005 and repealing Regulation (EU) 2018/213, Brussels, XXX PLAN/2023/1013 (POOL/E2/2023/1013/1013-EN.docx) [...] (2024) XXX draft

<sup>2</sup> ANNEXES to the COMMISSION REGULATION (EU) .../... on the use of bisphenol A (BPA) and other bisphenols and their derivatives with harmonised classification for specific hazardous properties in certain materials and articles intended to come into contact with food, amending Regulation (EU) No 10/2011, amending Regulation (EC) No 1895/2005 and repealing Regulation (EU) 2018/213, Brussels, XXX PLAN/2023/1013 ANNEX (POOL/E2/2023/1013/1013-EN ANNEX.docx) [...] (2024) XXX draft ANNEXES 1 to 3



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monitor recycled paper materials, polysulfone membranes and BADGE coatings is included as a regulatory element.

We consider the proportionality, the important limitations and the weighting according to contributions to exposure acknowledged in the Commission's proposal. With this opinion, however, questions and inconsistencies in the regulation need to be discussed. In particular, the concept of "monitoring" with regard to paper/cardboard as a completely new element is not applicable in practice for the affected industry and it is not a solution for reducing BPA in the waste paper cycle. The food industry, as a packaging sector that is increasingly focusing on sustainable, recyclable packaging materials and will also have to meet the requirements of the European Packaging Ordinance in this regard in the future, shares and supports the criticism voiced by the paper associations.

In the following, we comment on the wording of the regulation and ask for improvements for clarification and for changes:

- Article 1 „Subject matter and scope“

As explained above, it is not feasible for the paper industry to implement the entire monitoring concept set out in Article 5 in conjunction with the associated obligations and, as a result, is not beneficial to the packaging industry. In Germany, the recommendations of the BfR Plastics Commission XXXVI, which specifically limit the migration of BPA/bisphenols for "*paper, cardboard and paperboard for food contact using recycled fibers as raw materials*", have become established as voluntary specifications. A testing recommendation only exists for papers that are intended "*for contact with moist or fatty foods*". [Annex to BfR Recommendation XXXVI, as of 1.2.2023]

We propose that this EU-wide recognized recommendation be taken into account and that corresponding changes be made to Article 1 and Article 5:

*„... if the finished paper and board products **are foreseeably intended for use with moist and fatty foodstuffs.**“*

- Article 2 „Definitions“

Nr. 2 a)

A "*final food contact article*" may consist of several units, not all of which come into direct contact with food. These items may also be easily separable. It is therefore important to clarify that only the parts of a composite article with direct food contact fall within the scope.

Nr. 2 d)

The restriction in the definition for "*BADGE-based heavy-duty varnishes and coatings*" to "*synthesized only from BADGE and its derivatives as monomers*" is incomprehensible; in practice, these exclusivities do not exist, which is why "**only**" should be deleted.

- Article 3 „Prohibition of the use of BPA“

We ask for clarification to express the objective that only the "*intentional*" use of BPA is subject to the ban; to add this term creates legal certainty and clarity:

*„The **intentional** use ...“*

Furthermore, the authorization of use in the manufacture of polysulfone membranes is mentioned in Article 5. For reasons of clarification, a delimitation and exception should also be described in Article 1, paragraph 2.



- Article 5 „Monitoring and reporting of results“

The concept of monitoring the use and release of BPA by the "manufacturers" of certain heavy-duty paints and coatings and polysulfone membranes as well as paper and cardboard with recycled content is highly questionable in terms of clarity, practicability and proportionality. We take a critical view of the following points:

- There is no significant entry of BPA into food via the products mentioned.
- The three product categories are not comparable and not to be subjected to the measures under no. 3 and 4.
- The conditions and material flows in the production of varnishes/coatings and membranes differ significantly from recycled paper.
- In the case of paper and cardboard, only the relevant food contact papers for moist and fatty foods can play a role.
- In waste paper cycles, it is a matter of inputs and carry-over of BPA, not intentional use.
- In multi-stage manufacturing processes, it is unclear who is the addressee for the monitoring tasks. Coatings usually consist of several components that are initially mixed - who is the manufacturer?
- The reporting obligations lead to a high level of bureaucracy.
- There is a lack of standardized measurement methods for the different matrices.

We ask that all points be considered and amended in accordance with Article 5 in order to make the concept affordable and understandable. However, the exceptions for heavy-duty paints/coatings and polysulfone membranes are very welcome and, from the point of view of the industry, mandatory. They must not be allowed to be changed.

- Article 7 "Declaration of Compliance"

For all materials and articles covered by the regulation, a written declaration is required at all marketing stages to ensure compliance. It is important to clarify whether the retail stage is included in the definition of "all marketing stages". However, the benefit of this formal document for retailers is minimal. It is the responsibility of the supply chain and manufacturer to ensure the conformity of food contact materials as defined in EU Regulation 10/2011 for plastics. The introduction of additional documentation for the retail stage only leads to additional bureaucracy.

- Article 10 "Transitional Provisions"

The transitional provisions of 18 and 36 months are to be welcomed in principle and are very important periods for generally longer technical adaptation processes.

In addition to the foodstuffs mentioned point 2 a) should necessarily include aggressive filling materials with a high acid content:

*„... to be filled with **high acidic food**, processed fruits, vegetables and fish products;“*



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The 36-month period is not feasible for certain applications in the polycarbonate sector. These are usually installed process materials (valves, seals, containers), equipment for production with consumption and maintenance, such as the molds for confectionery and chocolate production. For such process materials, there are currently no adequate substitutes that ensure functionality (e.g. bending stability). The extension of the time limit beyond 36 months or the creation of a general exemption for specific and low risk polycarbonate process materials is urgently required from an economic perspective.

The wording in point 7 is not conclusive; it must be assumed that full protection is granted for installed parts integrated into systems or tanks and containers in use. In our understanding, the time limit of 10 years relates to the sale of material that is produced during the transitional period and held in stock in stores (e.g. spare parts for machines). Clarification is urgently needed:

*„By derogation from paragraph 5, final food contact articles to be used in professional production equipment not complying with this regulation **shall be removed from the market stocks at the latest 10 years ...**“*

Dr. Sieglinde Stähle  
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