

AmCham EU's reaction to France's Annex XV dossier proposal on BPA

A dangerous precedent that will decrease regulatory predictability and negatively impact the Single Market

Executive summary

AmCham EU is worried that some elements of France's Annex XV dossier on BPA are in contradiction with the principles of the EU Single Market. The new legal interpretation of monomers put forth by French authorities is creating a considerable amount of uncertainty and an unpredictable environment for future investments in Europe. Our members believe that an inconsistent implementation of EU chemicals policy at national level as well as regulatory overlap undermines the Single Market.

This paper highlights the elements of this legal interpretation that our members find to breach the principles of the Single Market and calls on the European Commission to assess this case against a potential breach of EU law.

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AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €2 trillion in 2015, directly supports more than 4.3 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

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POSITION PAPER

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The American Chamber of Commerce to the European Union (AmCham EU) has long called for greater predictability, transparency and legal certainty when it comes to EU chemicals policy. We also ask for greater consistency in its implementation.

We note with surprise that the French authorities are putting forward a **new legal interpretation of monomers, saying they do not qualify as intermediates** in the context of the REACH Annex XV dossier on Bisphenol A (BPA). We would like to caution the European Commission and the French authorities against such a difference in legal interpretation which creates a considerable amount of uncertainty and an unpredictable environment for future investments in Europe.

The EU Single Market is the basis of European economic success and a key determinant of US foreign investment in Europe. Completing the Single Market will increase productivity, investment, trade and job creation, helping to ensure Europe maintains its position as a global player.

Inconsistent implementation of EU chemicals policy at national level undermines the principles of the Single Market. The EU and its Member States should work hand in hand and take steps to build a real Single Market for chemicals. This means avoiding unconstructive national initiatives which undermine economies of scale as well as the legal certainty which should come from a market of 500 million people.

We find that elements of France's Annex XV dossier on BPA are in contradiction with the principles of the EU Single Market.

Firstly, France **explicitly questions, or even denies, that uses as a monomer to make polymers fulfil the REACH definition of intermediates** when it comes to the authorisation process. This is in direct contradiction with what is commonly accepted, namely, that uses as a monomer to manufacture polymers should be qualified as intermediate uses, and are thus outside the scope of authorisation¹.

Secondly, BPA is not yet addressed under any restriction or authorisation procedure in the framework of the REACH regulation. Nevertheless the French authorities imply in their dossier that not only BPA as a monomer, but also the **resulting polymer uses, could become subject to authorisation** (Annex XIV) and/or restricted for certain future uses (Annex XVII). This would set a precedent with far-reaching consequences and create uncertainty for industry at this stage.

Thirdly, when it comes to the introduction of **alternatives**, industry is making efforts to investigate possible alternatives to BPA for uses in their products. Potential alternatives to BPA-based epoxy (including acrylic-based epoxy) currently being investigated require different manufacturing process technologies, and have significantly higher prices than BPA-based epoxy. Alternatives to BPA in polycarbonates are in the very early stages of being assessed. However, **the vast majority of known**

¹ see the ECHA guidance, p. 8 and 13: https://echa.europa.eu/documents/10162/13632/polymers_en.pdf

alternatives have a similar hazard profile to BPA. Due to the numerous types of components involved across products (with each having its own set of functional requirements), it is likely that multiple alternative materials would have to be identified in order to meet the appropriate safety and technical requirements of each product. A polycarbonate replacement, if possible, would take several years (for one product) to reach the regulatory approval stage – from alternative material assessment and feasibility work to subsequent product development work.

Finally, we find this development to be a classic example of regulatory overlap within REACH, as BPA is currently undergoing the substance evaluation process (conducted by Germany). Proposing to add BPA on the SVHC list before the evaluation is concluded presumes that its results are already known. This is a breach of industry's right to be heard and to defend its substances and discredits the entire Substance Evaluation process.

We encourage the European Commission and its Legal Services to look at this case and to assess it against any potential breach of EU law and the principles of the EU Single Market. Europe needs a balanced and coordinated legal framework to accelerate business developments that meet citizens' needs and foster growth.