

# AmCham EU position on the proposed PAHs restriction

INFORMATION PAPER

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## Background and Analysis

For members of the American Chamber of Commerce to the European Union (AmCham EU), safety is a key priority and safety has built the reputation of our members' products, services and brands for decades.

Our members invest considerable resources to ensure that their products meet or exceed relevant legislation and related standards of health, safety and environmental protection.

As part of that effort, our members keep abreast of the peer-reviewed scientific literature concerning the potential health impacts associated with polycyclic aromatic hydrocarbons (PAHs).

AmCham EU would like to emphasise that PAHs are not substances that are intentionally added in products. PAHs are created during the production of certain raw materials, particularly when high temperatures are involved e.g. burning. Consumer goods may sometimes contain traces of PAHs depending upon the types of raw materials that were used in their manufacture. It is also well known that PAHs can be found in barbecued food, roasted coffee and vegetable oil for cooking as a result of exposure to high temperatures.

AmCham EU is concerned that the policy debate on PAHs is currently driven by emotion and political motivation and therefore lacks a rigorous scientific basis. Furthermore, we are worried about the precedent that would be set by rapidly moving forward without the due process that is in place and which requires a scientific review of such wide-ranging proposals.

**AmCham EU calls for the normal REACH procedure provided for in Article 68(1) for restrictions to be followed, and supports the Member States that do not find the fast track procedure appropriate for this proposed PAH restriction.**

**In this regard, the AmCham EU members would like to request robust scientific and socio-economic impact assessments before a decision on REACH restrictions is taken.**

**AmCham EU warns that political considerations must not overcome the science.**

### ***Procedure***

AmCham EU supports policy initiatives that seek to protect the consumer, particularly those that are based on a sound scientific basis.

AmCham EU is concerned that the call for a fast track procedure to address PAHs under REACH for such a broad scope of products has never been used to date, and may be an attempt to avoid a deeper scientific scrutiny of the German dossier's Annex XV. AmCham EU also questions why PAHs deserve such a unique treatment compared to other substances currently under review. AmCham EU supports the Member States that have challenged this procedure for PAHs.

AmCham EU believes that a normal REACH procedure would provide the opportunity to gather additional scientific and technical knowledge to the benefit of consumers and manufacturers alike.

**AmCham EU's alternative proposal would be to follow the REACH normal procedure for restrictions under Annex XVII as set out in Title VIII, Chapter 2 of the REACH Regulation.**

REACH Annex XVII restrictions for PAHs already exist in relation to extender oils used in the production of tyres. This restriction is accompanied by references to harmonised test methods. Any extension of the scope of PAHs restrictions to other consumer goods should also be accompanied by reference to harmonised test methods in order to provide a high degree of legal certainty in the results obtained.

**AmCham EU would also like to take this opportunity to stress the importance of a clear definition of consumer goods proposed for the scope of the PAHs restrictions.**

### ***Scientific flaws***

AmCham EU is concerned that the proposal represents a compromise proposal stemming from intense political pressure from one Member State. The weak scientific basis of the German Annex XV dossier has resulted in an excessively severe draft proposal that is disproportionate with the real life risks to consumers. The restriction ignores the scientific fact that not all PAHs have an equivalent toxic potential (potency). This further increases the disproportionate nature of the draft proposal.

The proposal does not make it clear that the restrictions apply only to materials that are accessible to a consumer. There can be no risk from materials that are inaccessible to a consumer.

Even the German proposal - Annex XV dossier - notes that its findings are often unsound and could benefit from additional research: *'The knowledge about release of these compounds needs to be improved. Standardised migration*

*methods that cover the typical uses of the consumer articles investigated should be developed by further projects' (German Annex XV dossier, p.20).*

### ***Implications of a very low content limit for PAHs***

AmCham EU is concerned that the extremely low limit of 0.2mg/kg, in the absence of harmonised, accurate and reproducible testing method(s) that are suitable for each category of consumer goods falling within the scope of the restriction, will make it impossible for our members as well as for market surveillance authorities to reliably test compliance with the PAH requirement. This will lead to significant legal uncertainties as to product compliance and will not allow a level playing field between all players.

AmCham EU is also concerned that the proposed low limits do not take into consideration factors that are external to the manufacturing process, e.g. contamination from other PAH sources during shipment and storage.

This highlights the need for further work and research.

### ***Transition period***

The proposed limits for PAHs are based on the ALARA principle (as low as reasonably achievable). They imply the need to search for new materials. This cannot be done overnight and has design, production and supply implications.

In addition, the product development life cycle for some of our members is such that up to 18 months is needed between the design of the product and when it is placed on the market. For highly technical products, requiring specific and complicated performances, the product development life cycle will be much longer. For tyres for instance, several years were needed to replace extender oils containing PAHs with safe low-PAH oils. In addition, this does not take into consideration any process for approving new raw materials and new suppliers. Most of our members do not produce the raw materials themselves and use what is available on the market. New raw materials must be carefully assessed to ensure they are fit for purpose and provide continuing all-round safety in the products in which they are used.

It is important for all stakeholders that harmonised standardised test methods are available. A reasonable transition period would allow the standardisation process to proceed.

### ***The principle of proportionality***

AmCham EU supports policy initiatives that are proportionate and focus on the risk of exposure to PAHs and not the possible hazard. A risk can only arise if certain PAHs migrate out of the material matrix.

AmCham EU is concerned that the main sources of exposure to PAHs are not consumer goods. However, they would still bear the burden of the restrictions,

the significant increase in testing costs, and be discriminated against even though there are no proven safety improvements for the consumer.

Furthermore, any decision on restrictions should be proportionate to the risk for consumers. The mere presence of a chemical substance in a material does not mean that consumers will be exposed. The substance must find its way into the body of the consumer before it could present a risk to health, i.e. there must be some kind of exposure. The well known risk equation holds true:

$$\text{Risk} = \text{Hazard} \times \text{Exposure}$$

If there is no exposure there is no risk, even if the substance under consideration is classified as hazardous.

### ***The crucial importance of proper enforcement and market surveillance***

Any regulation, no matter how well designed, would fail to deliver the desired results for health and environmental protection if it is poorly enforced. Therefore it is essential that a robust surveillance programme accompany any restriction.

The experience so far with the high aromatic extender oil restriction in tyres shows that even after two years of the law's application there is still a relatively high percentage of non-compliant tyres – some 11% of all tyres tested<sup>1</sup>. All the non-compliant tyres had been imported into the EU.

AmCham EU currently disagrees with the PAHs dossier as it stands. However, if after a sound and robust scientific analysis, exposure risks to PAH in specific goods were to be confirmed, AmCham EU calls on the EU and national market surveillance authorities to ensure that any new legally binding requirements are accompanied by a solid monitoring programme for compliance.

**In conclusion, AmCham EU would like to address the following key messages in relation to the current proposal for PAHs restrictions:**

- **A further extension of the REACH ban on PAHs in consumer goods should follow the full procedure foreseen in Article 68(1), with scientific and socio-economic impact assessments [performed by the EC bodies];**
- **Any PAHs restrictions should be accompanied by a harmonised test method to ensure that the restriction is enforceable for both manufacturers and market surveillance authorities;**

<sup>1</sup> 'Second testing program confirms: REACH compliance tests continue to give failing grades to tyre imports', ETRMA (European Tyre and Rubber Manufacturers' Organisation), <http://www.etrma.org/newsroom/13/75/REACH-compliance-tests---2nd-campaign/>

- **The restriction should set limits for PAHs that are in proportion to any potential risk to consumers. This should lead to limits that are based upon exposure and measured using a harmonised migration method;**
- **The EU and Member States should install a robust market surveillance programme for compliance with any new restrictions, and in general for compliance with REACH; and**
- **AmCham EU also calls for an appropriate transition period to implement any new measures.**

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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 U.S. investment in Europe totaled \$2.2 trillion in 2010 and directly supports more than 4.2 million jobs in Europe.*

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