AMCHAM EU
AMERICAN CHAMBER OF COMMERCE TO THE EUROPEAN UNION
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

AmCham EU position on the REACH restriction process and certain phthalates

INFORMATION PAPER

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Executive Summary

AmCham EU speaks for European companies of American parentage which invest in Europe and contribute substantially to European economic growth. We promote and are committed to a coherent and balanced approach to environmental legislation, based on sound science and the better regulation approach.

We are writing to raise our concerns with the recent REACH restriction proposal by Denmark for DEHP, DBP, BBP or DIBP contained in articles.

These substances are already subject to the REACH authorisation process and subjecting them to the REACH restriction process in parallel raises a series of concerns, in particular as to the possibility for companies seeking authorisation to have their request duly considered.

In addition, the restriction proposal is based on the combined exposure and effect of the four phthalates, which Denmark recognises as being 'a new method'. Introducing a restriction on this basis, for which no methodology and criteria have been developed or approved at EU level, runs counter the principles of legal certainty and science-based decision-making.

Our membership represents a large spectrum of industry sectors, which have all made significant investments to comply with REACH, and will do so in the future. We therefore have a keen interest in ensuring that the application of the REACH processes avoids duplication and overlaps and are based on sound science.

Background

REACH has entered into a new phase with the application of the authorisation and restrictions processes and it is important to ensure that each of these processes is applied in full respect of the underlying principles of sound science, the understanding of socio-economic impact and due process.

The low molecular weight phthalates DEHP, DBP, BBP and DIBP have been included in the list of substances subject to authorisation (Annex XIV Authorisation List), which means that they will not be allowed on the market, used or incorporated into articles in the EU after the 'sunset date' (2015), unless authorisations are granted to those companies seeking authorisation for specific uses.

While the authorisation process is underway, Denmark is seeking to restrict the use of the same phthalates '*in articles intended for use indoors and articles that may come into contact with the skin or mucous membranes containing one or*

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more of these four phthalates in a concentration greater than 0.1% by weight of any plasticised material'.

While Denmark's initial attempt in April last year was rejected, their revised proposal has passed the European Chemicals Agency (ECHA) conformity check and the restriction process has thus been formally instigated, in parallel to the authorisation process.

It is questionable, however, whether the new proposal addresses the critiques made by the Netherlands, as rapporteur, that the dossier failed to demonstrate that the proposed restrictions were appropriate or proportionate. Indeed, the proposed restriction as drafted is very broadly defined and will mean a ban on almost all products containing these phthalates.

1.Overlaps between the REACH processes of authorisation and restriction

As discussed above, the four phthalates are already subject to the REACH authorisation process and subjecting them to the REACH restriction process at the same time, before the completion of the authorisation process, raises a series of concerns.

As discussed in the attached AmCham EU position paper on the REACH authorisation and restrictions processes, REACH contains several articles that address the relationships between the authorisation and the restriction processes (Articles 56(1); 58(5); 58(6); 60(6) and 69(2)) and it is important that these articles are interpreted and applied in a way that ensures legal certainty and prevents duplication and overlap.

AmCham EU believes that Article 58(6) should only be used in exceptional circumstances to avoid duplication of efforts, legal uncertainty and confusion in the supply chain, and suggests that the Commission elaborates a policy as to the circumstances that may justify the application of this Article, such as for example in case where restrictions must be adopted on articles containing Annex XIV listed substances that cannot wait the completion of the authorisation process.

2.Restriction requests should be made based on sound science

Any ban or restriction that may result from the authorisation and restriction processes must be based on sound scientific evidence. As required under international trade rules, any ban or restriction adopted by the EU should not be more trade restrictive than necessary to achieve a policy goal. This requirement entails a thorough examination of all scientific evidence justifying a ban or restriction for each and every use of the substances concerned and claimed to be harmful.

The Danish Annex XV restriction proposal is based on the combined exposure and effect of these phthalates. The science behind this phenomenon remains in

its infancy and no scientifically validated criteria and methodology have yet been developed to measure this potential effect.

The EU is still discussing how to better address the combined effects of chemicals. In July 2011, the European Commission published, for consultation, a preliminary opinion on the toxicity and assessment of chemical mixtures which has been formulated jointly by the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).

AmCham EU members believe that any decision taken on the combined effects of these phthalates should only be taken after an agreed EU approach on this subject.

As regards sound science, we also would like to point out to the conclusions of the UK's Committee on Toxicity (COT) of 1 November 2011 on the proposed restrictions that '*The risk characterisation for combined exposure to DEHP, DBP, BBP and DiBP that is reported in the Restriction Report should be viewed as a first tier assessment. Given its conservatism and the levels of the RCRs calculated, it does not necessarily indicate a need for risk reduction measures beyond those that are already in place. To refine the risk assessment, it would be most useful to collect further biomonitoring data from representative populations. If necessary, there should also be a more thorough risk assessment for other products which might be used as substitutes should additional restrictions be imposed on DEHP, DHP, BBP and DiBP*'.

3.Practical issues related to the proposed Phthalate ban

Substitution and time to market

The Danish proposal is based on the basic premises that (1) alternatives are available for all uses, and (2) the cost of substitution is minimal. These are not correct. Indeed, the proposal itself acknowledges in its main assumptions (section E.4.) that '*the information is not necessarily representative for all markets within EU and for all companies operating in EU*'.

More specifically, the restriction bases its cost of substitution analysis on available information, assuming the direct replacement of a single chemical constituent within all formulations. This methodology does not account for the significant costs associated with the initial development of each new formulation, material testing, scale-up, qualification, implementation and certification within articles.

Many small volume uses of specialty materials have not yet been formulated, qualified or certified for use in articles. For each material that requires the substitution of these phthalates, the time and cost associated with developing alternative materials, and the subsequent cost and flow time for implementation, have not been accounted for in this proposal. The indirect costs of this

restriction on specialty materials must be understood and accounted for in the final outcome of this process.

The report suggests a transitional period of 12 months from the entry into force of the phthalate ban. This is based on the assumption that simple, existing substitution materials exist for industry. This timing does not allow sufficient time for some materials, used in certain articles, to be qualified and certified by federal agencies prior to implementation within the supply chain, and final inclusion in finished articles.

Rather, the global supply chain is a complex and multi-tiered system for many US and EU producers of articles, particularly for articles that are not consumer products. While for simple products the concept of stock depletion sounds reasonable, the restriction as proposed does not allow adequate time for those instances where new materials must be developed, tested, qualified, certified and implemented throughout a complex supply chain. Typical time-to-market flow time for complex articles is three years when alternative materials are available.

Recycling

We also fear that if allowance is not made for recycling when these restriction requests are made, these restrictions will have a significant effect on recycling with associated impacts on resource efficiency and sustainability. These four classified phthalates have been in use for several decades and as such there is widespread use of flexible PVC made with them. As part of sustainability and resource efficiency initiatives, flexible PVC articles are being recycled into useful articles. In 2010, the voluntary initiative of the European PVC industry (Vinyl 2010) recycled approximately 260,000 tonnes of PVC of which about half was flexible PVC. Over the last 10 years, close to 1 million tonnes of PVC has been recycled (approximately half being flexible PVC). A significant proportion of the flexible PVC will have contained the four classified phthalates. In view of these arguments, when developing the proposed restrictions, careful consideration should be given to recycling to ensure that sustainability and resource efficiency is not unnecessarily impacted.

Skin contact does not lead to significant exposure

The proposed restriction would apply to 'articles that may come into direct contact with the skin or mucous membranes'.

This implies that skin contact and mucous membrane contact with articles, predominantly made of flexible PVC, can lead to significant exposure of LMW phthalates, which should be demonstrated through appropriate migration and dermal contact data using realistic use conditions. AmCham EU believes that this has not been adequately demonstrated in the Danish dossier. It should also be noted that the manufacture of flexible PVC articles involves a high temperature process that results in binding of the phthalate plasticiser within the PVC matrix. As a result, dermal contact with flexible PVC articles does not lead to significant dermal exposure to the phthalates. In addition skin absorption

studies on the neat phthalate plasticiser show that they are poorly absorbed via the skin. Skin contact with flexible PVC articles is therefore not a significant source of internal exposure to these phthalates as implied by the Danish proposal.

Conclusion

To conclude, AmCham EU believes that the Danish proposal does not properly take in to account the inherent difficulties in running the authorisation and restriction processes in parallel and is not based on full economic and scientific evidence.

AmCham EU requests that (1) the Commission adopts a policy on the application of Article 58.6 of REACH, and that (2) the EU authorities involved in the review of the proposed restriction (i) refuse to adopt a restriction based on the combined effects of chemicals until an EU policy is adopted on the subject and (ii) take into account the practical considerations discussed in this paper in order to ensure that any restriction would take account of to economic and practical realities.

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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 totalled €1.4 trillion in 2009 and currently supports more than 4.5 million jobs in Europe.

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