

## **ECHA conclusion to list DEHP as an Endocrine Disruptor for the environment is not based on science and will undermine innovation and investment**

It is with deep concern that ECPI notes the ECHA Member State Committee has concluded that DEHP is an endocrine disruptor of equivalent level of concern for its environmental properties. The science on DEHP does not support such a conclusion as the weight of evidence shows that DEHP does not cause adverse endocrine effects in fish and other aquatic organisms. This was also the reason for non-classification for environmental hazards in the conclusion of the EU DEHP RAR (Risk Assessment Report) which at the time has been agreed by all member states. In addition, lack of reproductive effects in primates and species differences for rat, mouse and humans is not in agreement with a concern for mammals in the environment. Moreover, DEHP does not bio accumulate and therefore DEHP cannot pose a hazard to higher mammals in the environment. ECPI does not agree with the Member State Committee that the WHO/IPCS definition of adverse effects consequent to an endocrine mode of action, for the environment, has been met and demonstrated in the dossiers submitted. "We can only conclude that the decision has been political rather than science based" stated Dr. Stephane Content of ECPI.

This conclusion will likely lead to a second listing of DEHP on the REACH Candidate list with the potential for a second Authorisation process, with the uncertainty, complexity and cost for European producers and with no environmental benefit. Producers are just completing the first Authorisation application which has taken three years and major investments of time and money for the dossier preparation and process.

"It is with serious concern that ECPI notes that the full scientific data has not been taken into account and a robust weight of evidence evaluation of all the data, both positive and negative, has not been performed by the ECHA Member State Committee. The scientific data on DEHP does not support the conclusion that it is an endocrine disruptor of equivalent level of concern for its environmental properties. In addition this decision may mean that DEHP producers, medical devices producers and recyclers of flexible PVC are faced with a new challenge regarding the Authorisation process but this time based predominantly on political grounds" stated Stephane Content ECPI manager.

While alternatives for PVC applications are available and have been developed by the plasticisers industry over the last 20 years, this does not justify the non-science based overregulation of DEHP. The future of any chemical substance will be put in doubt when a non-science based, political approach is taken. This leads to a complete lack of the regulatory predictability needed for investments and to a slowdown of the industrial, economic and social growth which is detrimental to European competitiveness and prosperity.

Therefore ECPI urges the European Commission and ECHA to:

- Conduct an in-depth review of the scientific justification for the conclusion of the Member State Committee on DEHP and its environment ED properties and put on hold the listing until that review is completed.
- Avoid duplication of regulatory requirements (re: double Authorisation) for substances like DEHP which increase the already significant costs of REACH compliance without any clear benefit.
- Ensure that, in the future, there is appropriate scientific review and discussion before substances are referred to the Member State Committee for consideration as substances of equivalent concern for endocrine disrupting properties. A first scientific review in the relevant Expert Group or Committee would help avoid political decisions on substances.

**About ECPI:** The European Council for Plasticisers and Intermediates is a Brussels-based trade association representing the common interests of European manufacturers of plasticisers, alcohols and acids. Member companies are BASF, Deza, Evonik, ExxonMobil, Grupa Azoty and Perstorp. ECPI is a sector group of Cefic, the European Chemical Industry Council, which represents the interests of the European chemical industry.

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