European Council for Plasticisers and Intermediates
COMMITTED TO THE SCIENCE OF SAFETY

High phthalates are not endocrine disruptors

At the recent event "*Hold-up sur la fertilité! Phtalates et perturbateurs endocriniens, de la recherche scientifique à l'action*" organised by Reseau Environnement Sante (RES) and Women in Europe for a Common Future (WECF) at the French National Assembly in Paris on 10 April, participants repeatedly presented all phthalates as a category of toxic substances with potential endocrine disruptive effects. However, the European Council for Plasticisers and Intermediates (ECPI), representing the main EU phthalate producers in the EU, would like to point out that phthalates are a large and diverse family of chemicals divided in two main groups with very different properties and effects: high molecular weight phthalates, or simply high phthalates, which are the most widely used in Europe, and low molecular weight phthalates. To use the generic term "phthalates" in this context is simply not correct.

High phthalates (known under acronyms such as DINP, DIDP or DPHP) are not endocrine disruptors. Recent independent studies have shown no evidence of adverse effects mediated via an endocrine mode of action for high phthalates in animal studies and, equally, there is no evidence for such effects in humans. It is important to emphasise that high phthalates have undergone individual and comprehensive risk assessments completed by the European Union. The results of this risk assessment have confirmed that they are not reproductive agents, are not classified for any health or environmental hazard, and can be safely used in all current applications. The same conclusion has been reached by ECPI's expert scientists who, using OECD's endocrine evaluation framework, have clearly shown that high phthalates are not endocrine disrupters.

At the Paris event, the speakers, and in particular Dr. Shanna Swan and Prof. René Habert, presented the results of some of their studies and investigations conducted on DEHP and other low molecular weight phthalates. Prof. Habert for example, dealt exclusively with the effects of DEHP's metabolite known as MEHP.

However, during their interventions, they repeatedly and wrongly used the general term "phthalates" implying that they all are endocrine disruptors. ECPI would like to call upon scientific rigour in order to avoid making unjustified and undifferentiated and generic claims when referring to the effects of one single substance and not its entire family. There is ample research published on plasticisers and the safety of high molecular weight phthalates which should not be ignored, whether the debate is scientific or political. The results of scientific research have led to classified low molecular weight phthalates (DEHP, DBP, BBP and DIBP) being stringently regulated via the REACH regulation, under both the Authorisation and Restriction processes. Based on the statements from RES and WECF they would appear to be unaware of this fact.

In this regard, ECPI recognizes the importance of research and has supported independent studies over the last 30 years, investing approximately 130 Million Euros in scientific research. We understand that certain organisations are suffering from the decrease in public funding available for research but this should not be a reason for making alarmist statements with respect to the safety of entire chemical families in order to obtain additional research funding.

The protection of consumers is of paramount importance to the plasticisers industry. ECPI and its members are committed to product safety, and will continue to support the use of sound science and risk assessment when analysing and assessing phthalate plasticisers.

For more information on plasticisers and phthalates, please visit: **www.plasticisers.org** where you can find comprehensive information on risk assessments, current research and also learn about common misconceptions around phthalates

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 Arkema, BASF, DEZA, Evonik Oxeno, ExxonMobil, Oxochimie, Perstorp and ZAK. ECPI is a sector group of CEFIC, the European Chemical Industry Council.

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ECPI response to frequently made non-scientific claims

At public events and conferences on the topic of endocrine disruptors such as the one held in Paris, a number of arguments are being heard over and over again but, quite often, they lack the necessary scientific validity or are being used to extrapolate conclusions which can often be misleading.

Substance specific studies: All the studies presented as showing potential endocrine disruptive effects for phthalates focus on, DEHP and other low molecular weight phthalates and their metabolites. Claiming that all phthalates are reprotoxic based just on the analysis of one main molecule would be like saying that all cholesterol is bad, whereas it is well known that there is good and bad cholesterol. Generalisations, although frequently used to make a concept more easily understood, can be misleading when talking about complex scientific issues and should therefore be avoided.

Phthalate migration: **High phthalates do not readily migrate** or leach into the environment from articles because they are physically bound within the PVC matrix. Even in abraded particles that may be collected in the form of dust, phthalates would remain tightly locked. It is a misconception that all phthalates used in PVC readily migrate. If this was the case, flexible PVC would not remain flexible and perform as intended. Essential applications such as wire and cable, where electrical safety is paramount, would crack and break rendering them unusable and potentially unsafe for consumers.

Indoor air and dust: It is very important to emphasize that the presence of flexible PVC particles in house dust does not pose any risks to human health. Recent scientific studies have concluded that household dust does not correlate to human exposure levels for phthalates, and is not an indicator of indoor air quality[1]. It is therefore not scientifically sound to conclude that levels in dust equate to exposure and therefore exceed safe limits.

Presence of phthalates in cosmetics: Regarding the use of EU classified low phthalates, only DBP and DIBP were ever used in cosmetics or body care products but are no longer found in products manufactured and commercialised in the European Union due to provisions of the European Cosmetics legislation, which prohibits the use of substances classified for carcinogenic, mutagenic and repro-toxic (CMR) hazards. This EU legislation does not apply in other regions of the world, such as the US, where classified low phthalates are still permitted, although some companies have voluntarily stopped using them. High phthalates are not used simply because their technical properties and molecular structure do not make them suitable for these applications. Today, only the non-classified phthalates, DMP and DEP are used in cosmetics in the EU. They have not been classified or restricted because they do not pose any risks for our health or the environment

Animal studies: Those bundling together all phthalates and labelling them as endocrine disruptors often refer to animal studies showing adverse effects even for high phthalates. Comprehensive animal studies have shown that high phthalates do not cause adverse effects via an endocrine mechanism. Whileeffects are seen on rats' liver at very high doses (3000 to 20,000 times higher than the maximum potential exposure to humans), these are not endocrine related effects.

REACH regulation: Amidst growing concerns regarding exposure to chemicals, some groups are calling for new legislation to limit their use in Europe. However, it is important to recall that phthalates are some of the most widely researched and strictly regulated substances. The EU Regulation on chemicals and their safe use, **REACH**, is the most comprehensive product safety regulation in the world. The classified low phthalates (DEHP, DBP, and BBP) are tightly regulated by the existing Authorisation and Restrictions processes. As a result of EU legislation and market

[1] H. Fromme et al., "Occurrence of phthalates and musk fragrances in indoor air and dust from apartments and kindergartens in Berlin (Germany), Indoor Air 2003, 1-8. Kerstin Becker et al. "DEHP metabolites in urine of children and DEHP in house dust". International Journal of Hygiene and Environmental Health 207 (2004); 409-417. Tobias Schripp et al. "Chamber studies on mass-transfer of di(2-ethylhexyl)phthalate (DEHP) and di-n-butylphthalate (DnBP) from emission sources into house dust", Atmospheric Environment 44 (2010)
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pressures, the use of classified phthalates has reduced significantly over the last 20 years and today, over 80% of all phthalates produced in Europe are non-classified high molecular weight ones which have been registered under REACH.

Industry's responsibility: The entire chemical industry takes responsibility for ensuring the safe use of its products and for complying with all relevant legislation very seriously. Plasticisers in general, and phthalates in particular, have been extensively tested and evaluated including for potential adverse effects via an endocrine mechanism. The industry, which has a lot at stake in the endocrine debate, continuously sponsors broad and product specific research to address this important issue. Funding is available via the Long Range Research Initiative managed by CEFIC and from specific product sector groups.