



55 EUROPEAN AND INTERNATIONAL CIVIL SOCIETY ORGANISATIONS ASK COMMISSION TO REJECT AUTHORISATION OF HAZARDOUS DEHP IN PVC PLASTIC

By early 2015, the Commission must decide whether or not to grant authorisation for the continued use of the plasticizer DEHP in PVC plastic (for both raw and recycled) articles in Europe [1] many of which end up in consumer products. This follows the delivery of opinions on this substance by the European Chemicals Agency's (ECHA) Risk Assessment Committee (RAC) and Socio-Economic Committee (SEAC).

We, the undersigned human health and environment public interest groups, strongly oppose any authorisation for the use of DEHP in PVC articles for the following reasons:

By granting authorisation for the use of DEHP in a wide range of PVC products and in recycled PVC plastic, the Commission will fail the main objective of REACH

One of the main aims of the authorisation procedure is to ensure that substances of very high concern are "progressively replaced by suitable alternative substances or technologies where these are economically and technically viable."

Furthermore, Article 1 of REACH establishes that the aim of the Regulation is to ensure a high level of protection of human health and the environment, and that substances that are placed on the market do not adversely affect human health and the environment.

The recommendation of ECHA to grant authorisation seriously undermines the REACH goals of protection and promotion of safer substitutes. Moreover, the principle of substitution did not have sufficient weight during the ECHA Committees' deliberations. We therefore call into question the commitment of the EU public Agency, ECHA, to make this a priority focus over and above 'toxic business as usual'. Without a strong substitution focus in the authorisation process, the European public and economy will not benefit from innovation in safer chemicals use.

Furthermore ECHA's assessment is not consistent with other pieces of legislation in the EU, such as the Directive on the Restriction of Hazardous Substances in electrical and electronic equipment which has recently called for a ban on four phthalates (including DEHP). This decision is broadly supported by the Commission and Member States because industry has demonstrated the availability of technically and economically feasible alternatives. Their socio-economic impact analysis indicates that a restriction of DEHP would have benefits for human health, the environment and safer waste management.

DEHP is highly toxic and hormonally active

DEHP is a well known toxic substance. It has already been listed on the REACH candidate list due to it being toxic to reproduction. Denmark has also proposed its listing on the REACH list of substances of very high concern (SVHC) as an endocrine disruptor. DEHP is a phthalate, a member of this group of "gender-bending" chemicals which because of their anti-androgenic / estrogenic properties and can cause feminization in males of several species. There is a growing body of evidence that certain phthalates, including DEHP, are implicated in causing breast cancer, testicular cancer, birth malformations in baby boys and infertility. Given that DEHP can act as a hormone disruptor, it is likely that there is no safe level of exposure. Moreover, this chemical is a suspected carcinogen and neuro and immune toxicant, and is associated with neurodevelopmental disorders in children.

DEHP is widely used such that there is ongoing exposure

DEHP in PVC is widely used in everyday consumer products-usually together with other phthalates, (textiles, furniture, shoes, building materials, etc.), as well as in PVC products in the work place (plasticizers, paints, work cloths, boots, etc.). Citizens and the environment are continuously exposed to DEHP from multiple sources on a daily basis. DEHP (and its chemical counterparts) is found in PVC articles in high concentrations (10-60% by weight) and because DEHP is not chemically tightly bonded to the plastic, it easily leaches out. Therefore, DEHP is a ubiquitous contaminant that can be found throughout the European environment (air, water -even rainwater - and soil) as well as in the blood and urine of sampled European populations. At

particular risk are pregnant women, newborns and children who are subjected to this chemical at key stages of development.

DEHP is so hazardous that it continues to be the chemical that is most commonly notified to the RAPEX system - the EU's rapid alert system on measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers.

Alternatives to DEHP are widely available

Alternative plasticisers for PVC and alternatives to PVC itself are available on the European market, for the whole range of current DEHP use in substances, materials, processes and technologies. In fact during the ECHA's public consultation for these applications, companies ranging from suppliers to downstream users provided more than ample information on availability, technical and economic suitability of safer non-DEHP alternatives.

The applicants did not fulfil the conditions necessary for granting an authorisation

The applicants did not scientifically and robustly demonstrate that all the risks from the uses of this chemical can be, or are adequately controlled. Furthermore they did not make a compelling argument that the socio-economic benefits of ongoing use of DEHP in PVC plastic outweigh the risks to European consumers, families and the environment from ongoing exposure to DEHP. Nor did they provide adequate justification that suitable alternatives were unavailable to them.

ECHA's opinion to allow the ongoing use of DEHP in a wide range of PVC plastic products is the result of a secretive and procedurally flawed process

During the public consultation on these applications, the European Chemicals Agency deemed relevant information 'confidential business information', hindering stakeholders' meaningful and effective participation in the authorisation process. The public had no access to the information which resulted in the Risk Assessment Committee's (RAC) opinion that adequate control could be achieved for this chemical with respect to exposure of the general population. RAC did not take into account the actual exposure of the European population to DEHP and dismissed both its endocrine disrupting properties and its impacts on adults, newborns and children, as well as dismissing information on the proven mixture toxicity of exposure to DEHP and other related phthalates.

ECHA's Socio Economic Assessment Committee (SEAC) rubber stamps 'business as usual' over innovation and safer products

The applicants' socioeconomic analyses is deeply flawed. However, instead of rejecting the application for authorization or instructing the applicants to do a more robust study (including taking into account the economic impact on Europe's entire population from ongoing exposure to DEHP), the socio economic analysis committee (SEAC) carried out its own flawed 'worst case scenario' calculations. This concluded, with little real evidence, that the benefits for these few applicants outweigh the risks to society as a whole. This is even more disturbing considering ECHA acknowledged that the risks are not adequately controlled and that significant uncertainties and information gaps were identified in their assessment.

Therefore, we the undersigned organisations ask the Commission not to grant authorisation for the continued use of DEHP in PVC plastic products. The Commission needs to support the goals of REACH; the Commission is accountable to the European public for protecting citizens and the environment from hazardous chemicals, whilst promoting innovation including safer chemicals and products to ensure a resilient economy.

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Three companies Arkema (France), ZAK (Poland) and Deza (Czech Republic) have applied to continue using this substance of very high concern (DEHP) in plastic (PVC) consumer articles such as flooring, upholstery, footwear, car seats and children's clothing – all products to which the population is routinely exposed to on a daily basis.

Three other companies: VINYLOOP FERRARA, Stena Recycling and Plastic Planet have applied for the use of DEHP in recycled soft PVC containing articles.