



To: Members of the REACH Committee

Brussels, 23 April 2018

Dear Sir/Madam,

We are writing to you regarding the REACH Committee Meeting that will take place this week on 25-25 April. At this meeting crucial discussions, and potentially votes, are planned on:

- (1) the amendment of REACH Annexes for nanomaterials
- (2) the Article 68(2) restriction on CMRs 1A and 1B in textiles and clothing
- (3) the amendment Annex XVII REACH as regards bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP)

We ask you to:

(1) Support/vote in favour of the Commission's proposal to amend the REACH annexes but to:

- a. move the proposed amendment 7.18 from annex IX to Annex VI and
- b. modify the REACH act preamble accordingly

so that ECHA is able to require sufficient additional information in order to ensure safety to companies registering nanomaterials.

(2) Support/vote in favour of the Commission's proposal to restrict CMRs in textiles and clothing for consumer uses but to:

- a. cover all CMR category 1A and 1B substances with a harmonised classification in the restriction, and not just those 40+ substances for which the European Commission was able to find evidence of use in the textiles sector;
- b. set concentration limits and expand transition periods (e.g. formaldehyde, NMP, DMAC and DMF) so that these offer a similar level of protection as Oekotex 100 or the EU Ecolabel for textile products in a way to ensure a high level of consumer protection;

- c. **guarantee sufficient protection for small children by establishing separate limits for baby products up to the age of 36 months;**
- d. **acknowledge the urgent need to protect consumers by further using article 68(2) to other consumer products and to note within the REACH Evaluation process that other chemicals of concern beyond CMRs (e.g. sensitisers or endocrine disrupters) should also be restricted under article 68(2). The development of specific product legislation concerning textiles within the EU may be also needed.**

(3) Support/vote in favour the European Commission's restriction proposal for the four phthalates but to:

- a. **reject the proposed exemption to articles exported to third countries for the sake of ethical considerations;**
- b. **reject the exemption for outdoor, industrial and agriculture uses as it may still pose a significant threat to human health and the environment;**
- c. **reduce the Commission's deferral proposal of 60 months for automotive and aerospace articles used in the interior of aircrafts and motor vehicles since children and adults can be exposed to high levels of these four phthalates;**
- d. **reject the general exemption for spare parts both for the automotive and aircraft sectors. Although we understand that a deferment may be needed, it should be time limited.**

More details on each of the above points are provided below (see annex).

Yours faithfully,



Tatiana Santos Otero
Senior policy officer - Chemicals and nanotechnology, European Environmental Bureau

On behalf of:
Center for International Environmental Law (CIEL)
ClientEarth
ECOCITY
Ecologistas en acción
European Environmental Bureau (EEB)
Health and Environment Alliance (HEAL)
Women Engage for a Common Future (WECF)

In view of the public interest in this matter, we intend to make this letter publicly available.

ANNEX I. Amendment of REACH Annexes for nanomaterials

The latest proposal for a modification of REACH annexes to adapt the REACH framework to the specificities of nanomaterials includes a new addition in the form of a new section 7.18 to be added to Annex IX. This proposal indicates that:

“Further testing for nanoforms covered by the registrations shall be considered by the registrant or may be required by the Agency in accordance with Art. 41, if there is an indication that specific additional particle properties significantly influence the hazard or the exposure to those nanoforms.”

We welcome the inclusion of this additional provision in the REACH annexes but consider its placing in Annex IX is contrary to the letter and spirit of REACH and defeats the purpose of finally adapting the REACH Annexes to the specificities of nanomaterials after a 6 years process and making the REACH framework future proof.

We also question the claim that the placing of this provision of this provision in Annex IX is warranted by the results of the impact assessment (which has still not been made public and should therefore not be used as a justification for limiting the level of protection of human health and the environment).

On the proportionality of placing this provision in Annex IX:

In that respect, we would first highlight that placing this provision in Annex VI would not impose any additional costs on registrants that would not be justified by the overarching objective of the regulation to provide a high level of protection of human health and the Environment. In effect, that provision would only impose *the consideration* of additional physico-chemical parameters in the event they have an impact on the risk profile of the nanoform of a substance. ECHA would only be able to require additional information if it could scientifically justify the need to collect this information to assess the safety of the material. This request would furthermore be subject to the ECHA board of appeal scrutiny that has so far interpreted ECHA’s competence in relation to nanoform registration in a manner that is both restrictive and highly protective of the rights and interest of registrants.

As a result, this provision would only have the effect of imposing additional costs on registrants if, and only if, the provision of this additional information was necessary to assess the safety of the nanoforms, in line with the REACH objectives. It is therefore inaccurate to claim that inserting this provision in Annex VI, would impose a unreasonable costs on registrants.

On the future proofing of the REACH annex revision:

As commonly agreed, this modification of the annexes has suffered very long delays that have prevented ECHA from fulfilling its mission to guarantee the safety of materials coming on the market (see for example: *“Echa says it cannot verify if nanomaterials are being used safely”*¹). As a result of these delays, the Annex revision currently being discussed will also not enter into force before 2020. Nanotechnology, nanoscience and material science are fast evolving domains, and it is commonly accepted that in the coming years new generation of nanomaterials and advanced materials will be developed and come onto the market. While there is a general consensus that the physico-chemical properties currently listed under annex VI 2.4.1 to 2.4.5 are considered adequate to characterize a material in order to assess its safety, it is most likely that these physico-chemical properties may not

¹ *Chemical Watch*, 18 Jan 2018: <https://chemicalwatch.com//63212/echa-says-it-cannot-verify-if-nanomaterials-are-being-used-safely?q=nanomaterials+ECHA+registration>

be enough to adequately characterize future generations of nanomaterials and advanced materials. In the event that additional physico-chemical properties were identified as necessary to properly characterize these future materials, placing this provision in Annex IX instead of Annex VI would make it virtually impossible for ECHA to collect the necessary information to adequately identify these materials if they were produced in volume under a 100t and assess their safety, until the REACH annexes were further revised. Thus recreating the current unacceptable situation where materials would come on to the market without their safety being properly guaranteed or even assessed for an indefinite amount of time. It should be noted in that respect that the vast majority of new materials are produced in volume significantly lower than a 100t (see for example, information from the French registry).

Inserting this provision in Annex VI, instead of Annex IX would therefore make the REACH regulation more future proof at no extra costs for registrants.

ANNEX II. Article 68(2) restriction on CMRs 1A and 1B in textiles and clothing

Please find enclosed the [ANEC and BEUC comments to draft reach restriction of CMR substances in textiles.](#)

ANNEX III. Amendment Annex XVII REACH as regards bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP)

We welcome the restriction proposal which will contribute to the reduction of the exposure of European citizens and environment to these four well known reprotoxicants and endocrine disrupting substances.

RAC and SEAC opinions estimate that the restriction may avoid annually 2,110 cases of infertility, 480 cases of cryptorchidism and 540 cases of hypospadias in European boys. In addition, the restriction will prevent other male and female reproductive diseases as well as children suffering from immunological effects. Therefore we support the general deferral time for entry into force of 18 months.

We also welcome the group approach followed by the dossier submitters. Although the restriction tackles only four of the wide group of phthalates, we consider this as an improvement compared to the traditional substance by substance approach and encourage Member States, the Commission and ECHA to continue advancing in the restriction of groups of SVHC.

Regarding the scope of the restriction we are concerned that it will allow continue manufacturing and exporting these SVHC to third countries, and therefore putting citizens health and the environment at risk in other countries. These double standards are completely unacceptable and we encourage you to ensure that exports of these four phthalates are banned.

Also, the exempted outdoor, industrial and agriculture uses may still pose a significant threat to human health and the environment. Articles and materials for agriculture use, such as films, canvasses, irrigation and draining pipes and fittings may be an important source of these four phthalates to the environment and to man via the environment. It is estimated that over 280.000 t of

PVC was used in agriculture in Europe in 2004. Even a low content of phthalates (15%) in these PVC articles is considered, would represent a total use of 42.000 tonnes of phthalates in agriculture uses per year. Phthalates can leach out from agriculture articles during use, and contribute to significantly contaminate the environment and the food chain. Therefore we ask you to reject the proposed exemption to these articles.

Furthermore, outdoor, industrial and agriculture articles containing these four phthalates are easily accessible in the market to consumers at garden and building materials stores. If exempted from restriction, there should be at least an obligation to label the articles in order to avoid indoor use and clearly inform consumers about use restrictions and waste management obligations.

We firmly oppose the Commission's proposal to defer 60 months the entry into force of the restriction for automotive and aerospace articles used in the interior of aircrafts and motor vehicles. It is well known that children and adults can be exposed to high levels of these four phthalates in the interior of vehicles due to their use in different parts, including carpets and seats. There is no justification for this derogation. As RAC opinion reflects, *"there are no known uses for which there are no alternatives for the four phthalates and additional consultation with aviation industry representatives did not reveal specific cases for which recertification may be required."* (Page 44, RAC and SEAC opinion).

Regarding automotive parts, RAC opinion states that *"Although industry has provided information that they have transitioned to alternatives and very few article types still contain the four phthalates, sufficient information (e.g., volume of phthalates used, number of vehicles impacted, definition of "hidden" articles, etc.) for an assessment of such a derogation was not provided."*

RAC concludes *"From a risk assessment perspective the requested derogation is however not considered justified by RAC, in the absence of information on the degree of inhalation exposure and the contribution to the risk. RAC further noted that the automotive industry indicated they can transition to alternatives within the foreseen transition period."* (Page 47, RAC and SEAC opinion).²

Finally, we also ask you to reject the general exemption for spare parts both for the automotive and aircraft sectors. Although we understand that a defer may be needed, it should be time limited.

² Committee for Risk Assessment (RAC) Committee for Socio-economic Analysis (SEAC) Opinion on an Annex XV dossier proposing restrictions on FOUR PHTHALATES (DEHP, BBP, DBP, DIBP) ECHA/RAC/RES-O-0000001412-86-140/F ECHA/SEAC/RES-O-0000001412-86-154/F