



To: Members of the REACH Committee

Brussels, 6 July 2018

Dear Sir/Madam,

We are writing to you regarding the REACH Committee Meeting that will take place next week (11-12 July). At this meeting crucial (preliminary) discussions, and potentially vote, are planned on:

- (1) the amendment Annex XVII of REACH as regards bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP)**
- (2) the decision for (partially) granting an authorisation under the REACH Regulation to (among other uses) produce PVC articles of bis(2-ethylhexyl) phthalate (DEHP) to Grupa Azoty Zakłady Azotowe Kędzierzyn S.A. and DEZA a.s.)**

The amendment Annex XVII of REACH as regards bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP)

We welcome the fact that the EU is now proposing to restrict these phthalates, but we are very concerned that the proposed restriction excludes the use of these chemicals in food contact materials although the majority of exposure to DEHP comes via food.

In our view there is no scientific or policy justification for excluding Food Contact Materials (FCM) from this Restriction. REACH restrictions are permitted to cover FCM uses, and RAC and SEAC state¹ that a restriction is needed due to the risks posed by these chemicals.

It is true that the EU has a separate regulatory system for the regulation of chemicals in food contact materials, but we consider that it is more logical, administratively efficient, and likely to be more rapid if these uses are included in the REACH restriction.

These chemicals are proven endocrine disrupters, and RAC and SEAC have decided that they pose risks that need to be controlled through a Restriction. How is it possible to justify a ban on their use in our living rooms when permitting continued use in our kitchen?

Regarding the scope of the restriction we are concerned that it will allow continue manufacturing and exporting these SVHC to third countries. Furthermore, the exemptions and derogations proposed by the Commission are not properly justified and pose a significant threat to human health and the environment.

¹ https://echa.europa.eu/documents/10162/22286145/rest_four_phthalates_compiled_rac_seac_opinion_en.pdf

The decision for (partially) granting an authorisation to produce PVC articles of DEHP

The EEB and CHEM Trust firmly reject the authorisation of DEHP used to produce PVC articles. Granting authorisations for these applications would not be in keeping with the provisions of Title VII of REACH, in particular Articles 60, 62 and 64 of REACH and would undermine the main objective of REACH “to encourage and [...] to ensure that substances of high concern are eventually replaced by less hazardous substances or technologies where suitable economically and technically viable alternatives are available”.

We would like to highlight to the competent authorities that for these applications:

- **The risks related to the uses of DEHP are not adequately controlled**
- **There are suitable alternative substances and technologies**
- **the socio-economic benefits of continued use are not demonstrated to outweigh the risk to human health or the environment**

As you can see, the decisions that you will take during upcoming REACH Committees will have a substantial impact in reducing the exposure of people, including vulnerable populations such as babies in the womb and young babies and children, and the environment to these well known toxic substances.

These decisions will also either reflect the spirit of the REACH law, or contradict its main purpose. We therefore ask you to:

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

- a. include food contact materials in the scope of the restriction**
- b. reject the proposed exemption to articles exported to third countries for the sake of ethical considerations;**
- c. reject the exemption for outdoor, industrial and agriculture uses as it may still pose a significant threat to human health and the environment;**
- d. 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;**
- e. 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.**

(2) Reject the authorisation for the use of DEHP in PVC consumer articles

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

Yours faithfully,



Tatiana Santos Otero

Senior policy officer - Chemicals and nanotechnology, European Environmental Bureau

On behalf of:

CHEM Trust

European Environmental Bureau (EEB)

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

Annex I: 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.

We welcome the fact that the EU is now proposing to restrict these phthalates, but we are very concerned that the proposed restriction excludes the use of these chemicals in food contact materials. This is in spite of the fact that the Annex XV risk assessment² concludes that the majority of exposure to DEHP comes via food, and that a significant portion of the exposure to the other phthalates is via food. Not all this food-based exposure will be due to food contact materials, but DEHP, DBP and BBP are all authorised for use in food contact materials.

In our view there is no scientific or policy justification for excluding Food Contact Materials (FCM) from this Restriction. REACH restrictions are permitted to cover FCM uses, and RAC and SEAC state³ that a restriction is needed due to the risks posed by these chemicals.

It is true that the EU has a separate regulatory system for the regulation of chemicals in food contact materials, but this system is widely acknowledged to be insufficiently protective and does not properly regulate chemicals in many food contact materials such as paper, card, inks, glues and coatings. There are discussions ongoing regarding possible controls on the use of these chemicals in food contact, but we consider that it is more logical, administratively efficient, and likely to be more rapid if these uses are included in the REACH restriction.

These chemicals are proven endocrine disrupters, and RAC and SEAC have decided that they pose risks that need to be controlled through a Restriction. How is it possible to justify a ban on their use in our living rooms when permitting continued use in our kitchen?

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.

² <https://echa.europa.eu/documents/10162/522e2fdf-d48d-bca2-6ac1-ebcfffab2287b>

³ https://echa.europa.eu/documents/10162/22286145/rest_four_phthalates_compiled_rac_seac_opinion_en.pdf

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).

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.

Annex II. authorisations for the use of DEHP in PVC consumer articles

See also the a letter sent to the Commission by 55 civil society organisations⁴

DEHP is a well known substance of very high concern due to its toxicity for the reproductive system and as an endocrine disruptor. DEHP is a phthalate, a group of "gender-bending" chemicals which cause the males of species to become more female. These chemicals have disrupted the endocrine systems of wildlife and potentially of humans too. DEHP can cause breast and testicular cancers,

⁴ <http://eeb.org/publications/31/chemicals/92964/letter-to-european-commission-on-hazardous-dehp-in-pvc-plastic.pdf>

birth malformations and infertility, to name just a few. Due to its endocrine disrupting properties, no safe exposure threshold can be derived with sufficient certainty for DEHP. Moreover, it is also a suspected carcinogen and a neuro and immune toxicant.

Environment, health, doctors, cancer prevention advocates and green chemistry professionals have come together with women's organizations, and medical organisations to strongly oppose the authorisation of the use of DEHP in PVC items on the grounds of toxicity and the significant and long term health risks to humans. It is already restricted in toys and childcare articles under other EU regulations. However, children are still highly exposed to consumer products containing phthalates, such as textiles, footwear or car seats.

Grupa Azoty Zakłady Azotowe Kędzierzyn S.A. and DEZA a.s. applied in 2013 for authorisation of the use of DEHP in soft PVC-containing articles and still today use and produce it. Granting authorisations for these applications would not be in keeping with the provisions of Title VII of REACH, in particular Articles 60, 62 and 64 of REACH and would undermine the main objective of REACH "to encourage and [...] to ensure that substances of high concern are eventually replaced by less hazardous substances or technologies where suitable economically and technically viable alternatives are available".

The risks related to the uses of DEHP are not adequately controlled as RAC has clearly stated in its opinion.

There are suitable alternative substances and technologies. As highlighted in the SEAC's opinion, the applicants, when providing their analysis of alternatives, ignored alternative materials, substances and techniques claiming that they cannot produce the alternatives, even though authorisation is sought for many downstream uses, not for manufacturing.

Furthermore, DEHP has, to a large extent, already been replaced by other plasticisers and materials. During the public consultation, manufacturers of alternatives as well as downstream users applying these alternatives have provided overwhelming information which shows that readily available and technically and economically feasible alternatives do exist.

The applicants could not demonstrate that the socio-economic benefits of continued use outweigh the risk to human health or the environment. SEAC's opinion confirms that there were significant deficiencies in the socio-economic analysis presented by the applicant, including the lack of any health impact assessment identifying the remaining risk to workers' health.

Therefore, the legal requirements of Article 60(2) and 60(4) are not met and the authorisation must not be granted.

You can find further details regarding the procedural and substantive flaws of the ECHA Committees' opinions on DEHP in a letter sent to the Commission by 55 civil society organisations⁵ and in the EEB's report "A Roadmap to revitalise REACH"⁶. Moreover the unjustified delay of these authorisation decisions, foreseen in 2015 is unacceptable since EU citizens have been meanwhile unduly exposed to this extremely hazardous chemical.

⁵ <http://eeb.org/publications/31/chemicals/92964/letter-to-european-commission-on-hazardous-dehp-in-pvc-plastic.pdf>

⁶ http://eeb.org/wp-admin/admin-ajax.php?juwpfisadmin=false&action=wpfd&task=file.download&wpfd_category_id=31&wpfd_file_id=2349&token=03cd006b70c33cc7882ffd225c8b1455&preview=1

As you can see, the decisions that you will take during an upcoming REACH Committee will have a substantial impact in reducing the exposure of people, including vulnerable populations such as babies in the womb and young babies and children, and the environment to this well known toxic substance.

These decisions will also either reflect the spirit of the REACH law, or contradict its main purpose, the protection of health and environment. We therefore call upon you to oppose the authorisation.