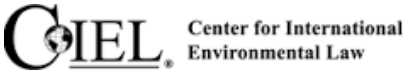
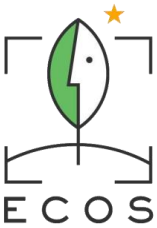

EUROPEAN
ENVIRONMENTAL
BUREAU


Health Care
Without Harm


CHEMTrust
Protecting humans and wildlife
from harmful chemicals


CIEL
Center for International
Environmental Law


ECOS


HEAL
Promoting environmental policy
that contributes to good health


GREENPEACE


ClientEarth


WECF


CEO


ECOLOGISTAS
en acción


cancer
prevention


Friends of
the Earth
Australia


BCUK
Breast Cancer UK
Preventing breast cancer


Bund für
Umwelt und
Naturschutz
Deutschland
BUND
FRIENDS OF THE EARTH GERMANY


AWHHE
Armenian Women
For Health and Healthy
Environment


FUNDACIÓN
ALBORADA


générations
FUTURES


ZERO
associação sistema terrestre sustentável


Alliance for
Cancer Prevention


ecocity


DET ØKOLOGISKE RÅD
Fremtidens miljø skabes i dag


Avicenn
Association de Veille et d'Information Civique
sur les Enjeux des Nanosciences et des Nanotechnologies


S.E.P.A.N.S.O.


ARNIKA


wemos
HEALTH UNLIMITED


Naturskyddsföreningen


CPZPZ


hej!support
health · environment · justice


AGIR
pour
l'environnement


Inštitut
za
trajnostni
razvoj

To: Members of the REACH Committee

Brussels, 8 February 2017

Dear Sir/Madam,

We are writing to you regarding the REACH Committee Meeting that will take place next week on 16-17 February. At this meeting crucial discussions, and potentially votes, are planned on:

(1) the restriction proposal of Octamethylcyclotetrasiloxane (D4) and Decamethylcyclopentasiloxane (D5),

(2) the identification of Diisobutyl phthalate (DIBP), Dibutyl phthalate (DBP), Benzyl butyl phthalate (BBP), Bis(2-ethylhexyl) phthalate (DEHP) as substances of very high concern (SVHCs) according to REACH article 57(f) for their endocrine disrupting properties and

(3) the Commission's proposal to amend the REACH annexes for substances with nanoforms.

We ask you to:

- **Note the limited scope of the proposal for restriction of D4 and D5 in personal care products that are washed off in normal use. This scope will not be sufficient to address the specific environmental concerns related to the PBT and/or vPvB properties of these substances. Additional measures under authorisation will be therefore needed.**

- **Support/vote in favour of the Commission's proposal to identify four phthalates (DEHP, DBP, BBP and DIBP) as substances of very high concern, according to Article 57(f) of REACH, due to their endocrine disrupting properties and consequent implications for <u>human health</u>.**

- **Note that the process used by the European Commission in its proposal to amend the REACH annexes for substances with nanoforms does not respect the competent authorities represented in the CASG nano group, bypassing them almost completely despite having shared previous revision proposals with this group in the past.**

- **Note the long and unjustified delay and total absence of legal action on nanomaterials to ensure the protection of health and environment by the European Commission since 2012.**

- **Demand that the Commission ensures a more transparent, accountable and inclusive decision-making process that is designed on effective participatory practices.**

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

Yours faithfully,

Jeremy Wates,
Secretary General of the European Environmental Bureau

On behalf of:

European and international organisations:
Center for International Environmental Law (CIEL)
ClientEarth
Corporate Europe Observatory (CEO)
European Environmental Bureau (EEB)
European Environmental Citizens Organisation for Standarisation (ECOS)
Greenpeace
Health and Environment Alliance (HEAL)
Health Care Without Harm (HCWH)
Women Engage for a Common Future (WECF)

National organisations from:

Czech Republic:
Arnika – program Toxické látky a odpady
Centrum pro životní prostředí a zdraví (CpŽPZ)

Denmark: Det økologiske Råd

France:
Agir pour l'Environnement
Avicenn
Générations Futures
SEPANSO Aquitaine

Germany:
Bund für Umwelt und Naturschutz Deutschland (BUND)
HEJSupport

Greece: ECOCITY

The Netherlands: Wemos

Portugal: ZERO – Associação Sistema Terrestre Sustentável

Slovenia: Institut za trajnostni razvoj

Spain:
Ecologistas en acción
Fundación Alborada

Sweden: Naturskyddsföreningen

United Kingdom:
The Alliance for Cancer Prevention UK
Breast Cancer UK
The Cancer Prevention and Education Society
CHEM Trust

Other national organisations outside the EU
Armenian Women for Health and Healthy Environment (AWHHE)
Friends of the Earth-Australia

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

ANNEX

Restriction proposal on the use of D4 and D5 in personal care products that are washed off in normal use

The UK has prepared a restriction proposal for personal care products, that are washed off in normal use, if they contain more than or equal to 0.1 % by weight of D4 or D5. We support the restriction proposal and welcome the fact that both D4 and D5 are included in the restriction proposal so as to prevent the replacement of D5 by D4.

However, we note the limited scope of the proposal. As it stands, the proposal will not be sufficient to alleviate the specific environmental concerns related to the PBT and/or vPvB properties of these substances. The scope of the restriction proposal is limited to a very minor use fraction (the use of D4 and D5 in personal care products that are intended to be washed off the hair or body with water within a few minutes of application). **The environmental emissions of all other uses are not addressed by this restriction proposal**. The restriction is also silent on the application in household cleaning products and personal care products with leave-on application such as hair gels and skin creams. **Therefore, in addition to the current restriction proposal, these substances should enter the REACH Authorisation process**. This would help minimise the environmental emissions from the other uses of D4 and D5.

We would also like to remind competent authorities that REACH Art. 58(3) requires that especially substances with PBT or vPvB properties should be prioritised for inclusion in Annex XIV.

D4 and D5 are substances of very high concern, meeting the PBT and/or vPvB criteria. D4 and D5 are high tonnage substances, each registered at > 100.000 t/a and > 10.000 t/a respectively. D4 and D5 have wide dispersive uses, including uses in a very wide variety of consumer products. **The current restriction proposal covers only emissions from a very minor use**.

The undersigned NGOs are also concerned about the long-range transport in the atmosphere to remote areas, which is confirmed by monitoring data. **The major part of the environmental emissions of D4 and D5 occur into the air compartment but these are not addressed in the restriction proposal**. In fact the atmosphere is assumed to act as a safe long term sink for D4 and D5 from which the substances slowly disappear via atmospheric degradation and subsequent wet deposition. This needs further consideration in the future given the many uncertainties in the underlying assumptions.

Support the identification of four phthalates (DEHP, DBP, BBP and DIBP) as endocrine disrupting chemicals (EDCs)

It has already been agreed that DEHP will be listed as an EDC for the environment (REACH 57f) in addition to its reprotoxic properties (REACH 57c). During this meeting, Member States will possibly vote on whether these four phthalates should be listed as EDCs due to their effects on human health.

Member States have already unanimously agreed in the Member State Committee (MSC) that these four substances have endocrine disrupting properties for the environment. Moreover the majority of Member States agreed that because the level of concern about the effects on human health is equivalent to CMRs, the four phthalates should be listed according to Art 57(f) as human health EDCs.

We strongly believe that it is very important that the four phthalates should be identified in the Candidate List (and Authorisation List) as SVHCs both according to Art 57(c) (toxic for reproduction) and Art 57(f) (EDC). The Commission's proposal clarifies that **Article 57 does not preclude identifying a substance as being of very high concern based on the same effect on human health several times, in order to specify the mode of action**. In fact, other chemicals are listed as carcinogenic and mutagenic, and this is not considered double counting.

We agree with the majority of Member States and the Commission on the importance of specifying the mode of action of these phthalates as endocrine disruptors by identifying them as SVHCs according to Art 57(f). This better reflects existing scientific knowledge on these substances.

Listing DEHP, DBP, BBP and DIBP as EDCs for human health, as compared with keeping them only listed as reprotoxicants, will lead to different risk management considerations in the REACH applications for authorisation and restriction processes. For example, the REACH Review of how EDCs should be assessed noted that "it may be difficult (albeit not impossible) to determine a safe threshold with reasonable certainty for endocrine disruptors, taking into consideration all uncertainties related to EDs".

ECHA submitted in September 2016 a restriction proposal for these four substances in articles, in order to avoid the exposure of people and the environment through imported articles. The identification of the four phthalates as EDCs for human health is a crucial consideration in this restriction process because as EDCs for human health any level of exposure would constitute a risk to be addressed.

Therefore, officially listing that a reproductive toxicant is also an EDC is important because it properly reflects the state of the science on the nature of the hazards, and will be useful to further inform how these chemicals should be dealt with.

If the European Authorities fail to agree to list these four phthalates as endocrine disruptors for human health, despite having acknowledged and officially classified the impact of these four phthalates on human reproductive health due to the disruption they cause in the endocrine system, we fear that Member States will never be willing to identify any human health EDCs. European national authorities are responsible for protecting the European public from hazardous chemicals such as EDCs. We therefore strongly urge all Member States to support this proposal.

Commission's proposal to amend the REACH annexes for substances with nanoforms

In 2011, the Commission rejected the idea of a nanomaterials-specific separate piece of legislation on the basis that it would be quicker to revise REACH Annexes to adapt the REACH framework to the specificities of nanomaterials.

After five years of delay[1], the European Commission will present its proposed legal act to amend the REACH annexes for substances with nanoforms at the upcoming REACH Committee meeting.

A draft proposal on the Annex revisions was discussed at a REACH competent authority sub group on nanomaterials (CASG nano) meeting in May 2014 and then not again until March 2016, with no explanation for this delay.

[1] This process was announced by the Commission in its Communication on the 'Second Regulatory Review on Nanomaterials' (COM/2012/572) in 2012.

At both meetings, the Commission imposed very short deadlines for Member States and Stakeholders to provide comments on this complex proposal, promising that they would respond equally quickly to the comments, suggestions and questions. **As of today, no response to specific questions or suggestions was provided and no revised document has been shared with CASG nano members despite numerous requests by Member States and stakeholders alike.**

In addition, **the Commission has recently announced that it will now bypass the CASG nano and present its updated proposal directly to the REACH Committee without responding to the CASG nano experts' comments, questions or suggestions**. Moreover, the Commission has not yet shared the so called RCOM document, where the Commission answers and explains to the CASG Nano members the reasoning behind taking or not taking some comments further.

We are dismayed by the apparent disrespect shown by the Commission to the members of the CASG nano group and its mandate, and note that because of the continued delays in the process, **the REACH annex revision may indeed have been longer than the development and adoption of a stand-alone nano specific regulation that would have ensured the safe use and development of nanomaterials in Europe**.

We regret the very poor participatory process, and the absence of transparency and accountability, made even worse by the long and unjustified delay and lack of any legal action to ensure the protection of health and environment by the European Commission. While the Commission was neglecting the process it had itself established, these materials still cannot have their hazard profiles and exposure scenarios characterised, and risk assessment remains impossible.

Furthermore, **as a result of the long and unjustified delay, the proposed annex revision will not be in place in time for the last REACH registration deadline in 2018**. The Commission is effectively failing to solve the main problem this initiative aimed at addressing: to ensure that nanomaterials are properly addressed and safety demonstrated in REACH registration dossiers. This situation questions the validity of the Commission's claim in 2012 that "REACH sets the best possible framework for the risk management of nanomaterials".

It appears that the European Commission is prioritising business interests over the health of EU citizens and environment, putting them both at serious and unnecessary risk. Civil society organisations demand governance of nanomaterials that respects EU objectives of a high level of protection of environmental and human health and consumer safety, as required in the Treaty on the Functioning of the European Union.

The undersigned NGOs call for a more transparent, accountable and inclusive decision-making process that is designed on effective participatory practices.

Further information:
NGO position paper 'Reset Governance: Nanomaterials as a case study on negligence. NGO demands for adequate EU governance of nanomaterials'