



Brussels, 7<sup>th</sup> September 2016

Dear Sir/Madam,

The Commission will soon present a draft regulation regarding the restriction of PFOA, its salts and PFOA-related substances to the REACH Committee. The undersigned civil society organisations would like to express their support for the restriction of these toxic, persistent and bioaccumulative chemicals. We would also like to draw your attention to the major changes that the scope of the original proposal submitted by Germany and Norway would undergo and the derogations that would be introduced if the proposal from the ECHA Committees were approved. Indeed, these proposed changes would render the restriction meaningless.

PFOA is classified as toxic for reproduction (category 1B), affects cholesterol levels and may cause cancer in humans. A recent published study from the C8 Health Project survey showed a dose related increase in both kidney and testicular cancer with PFOA among 32,254 participants. It is so persistent, that there are no measurable environmental half-lives. PFOA is widely found in remote areas, including the Arctic, demonstrating long-range environmental transport. A recent review of the toxicity of perfluorinated compounds found adverse effects after developmental exposure, including immunotoxicity and endocrine disruption, at very low doses—1,000 times lower than the EU Tolerable Daily Intakes for PFOA. In humans, PFOA is also associated with inflammatory diseases, ulcerative colitis, thyroid disease, pregnancy-induced hypertension, and

impaired neuro- as well as reproductive development.

The restriction originally proposed would have prevented these substances from being manufactured, used or placed on the market on their own, or as constituents of other substances, in mixtures, or in articles at concentrations greater than 2 ppb (2000 ppt). Note that PFOA exposure is considered to be so serious that US EPA has set a health advisory limit for combined concentrations of PFOA and PFOS in drinking water at 70 ppt and the US state of Vermont has set an even lower limit of 20 ppt PFOA due to health concerns.

However, after claims from some companies during the public consultation that the 2 ppb concentration limit was too low, ECHA's Committees have proposed new limits of 25 ppb (for PFOA and its salts), and 1000 ppb (for PFOA-related substances in constituents of other substances, in mixtures, and in articles). The committees have provided no justification about the environmental and health impacts of these important changes to the scope of the proposal, and appear to be merely rubber-stamping industry proposals in contrast to their mandates.

RAC and SEAC also added in their opinions a large number of derogations that were submitted by industry during the public consultation, including derogations for semiconductor photolithography processes, photographic coatings, implanted medical devices, spare parts, latex printing inks, textiles treated for worker protection, filtration systems, nano-coated materials, and firefighting foams. These derogations include open applications that would result in direct environmental pollution of a PBT substance and would permit the use of products containing PFOA for up to 20 years in some cases. Some of the SEAC derogations are even proposed without a time limit. Again, no justification about the environmental and health impacts of these derogations nor availability of alternatives was provided by the committees. This is unacceptable and undermines protection of human health and the environment.

Should they be adopted, these derogations would lack an appropriate legal basis because of the lack of justifications provided by the REACH committees and would undermine the effect of the restriction, which is to reduce the global consumption and emission of PFOA.

At the same time that scientists are warning about the low-level effects of PFOA, RAC and SEAC are proposing to dramatically and arbitrarily increase the allowable limits. Therefore, we ask you to support the dossier submitters' original concentration proposals and to support only specific (for example, in implantable medical devices) and time-limited derogations for essential uses, following the example of the Stockholm Convention, which sets brief (five-year) derogations after which reevaluation is required. Allowing very long transition periods -- up to 20 years! -- contains harm to human health and removes any incentive for European manufactures to develop new, innovative and safer products. Derogations for latex printing inks, firefighting foams, spare parts, and articles produced from recycled materials should not be allowed.

Finally, we also ask you to ensure that the restriction proposal requires all new articles that contain PFOA as a result of any exemptions granted to be labelled. This will be critical for the handling of these parts under the Stockholm Convention obligations at the end of life and has precedent in the

treaty's listing of HBCD.

The PFOA regulation proposal from the ECHA Committees not only undermines the original submission from Germany and Norway, but also the EU's own proposal for listing PFOA in the Stockholm Convention. The EU correctly nominated PFOA for global action under the Convention and now must exert leadership in its own regulatory response to truly protect human health and the environment.

You can find further details in the attached briefing.

Yours faithfully,



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On behalf of:

The Cancer Prevention and Education Society

CHEMTRUST

CIEL

The Danish Ecological Council

ECOCITY

Ecologistas en Acción

The European Environmental Bureau (EEB)

Friends of the Earth Germany-BUND

Fundación Alborada

GREENPEACE

Health and Environment Alliance (HEAL)

Health Care Without Harm (HCWH) Europe

IPEN

Women in Europe for a Common Future (WECF)

ZERO – Associação Sistema Terrestre Sustentável