To: Mr. Geert Dancet, Executive Director, European Chemicals Agency (ECHA)
CC:
Mr. Jukka Malm, Deputy Executive Director, European Chemicals Agency (ECHA)
Mr. Klaus Berend, Head of Unit, REACH, Internal Market, Industry, Entrepreneurship and SMEs, European Commission
Mr. Björn Hansen, Head of Unit, Chemicals, Environment, Maritime Affairs and Fisheries, European Commission

Brussels, 21 March 2017

Dear Mr Dancet,

Thank you for your letter of 21 December 2016 and for your willingness to meet with us in order to further discuss the many concerns we share about REACH implementation, as you noted in your answer.

We believe that our seven questions from 8 November 2016, which for the most part have yet to be answered, remain pertinent and valid. While progress has been made in some areas, a lot of work is still to be done to better understand the gaps and challenges and to improve the implementation strategy.

Ten years after the entry into force of REACH, we believe it to be legitimate and reasonable to expect the Agency to know the degree of compliance of the registration dossiers received and, given that the compliance gap is apparently very considerable, that ECHA would have started deploying its most important enforcement tool: the refusal of inadequate registrations and revocation of registration decisions for non compliant dossiers. If ECHA does not take a more active role in ensuring the quality of registration dossiers, it is impossible to know whether the information provided by registrants is at all reliable, and therefore whether industrial or professional chemical users and consumers can safely use registered chemicals.

Similarly, we believe that ECHA should be ready to answer our fundamental question about the number of registration dossiers submitted by industry to date for which ECHA has found that the risks are not

adequately controlled. We would like to emphasize that the Agency has binding obligations when it finds that a registration dossier shows that the use of the substance poses a risk to society. It is therefore very important to know how ECHA is implementing REACH obligations in order to ensure a high level of protection of human health and the environment.

Your letter states that ECHA puts all its instruments in place to ensure the reversal of the burden of proof, onto industry, during registration. However, the extremely poor information provided by industry, in particular on uses and exposure, in the registration dossiers actually shifts the burden to Member State authorities and to ECHA Committees to complete the information needed in the subsequent REACH processes (i.e. candidate listing, restriction, authorisation, evaluation). By contrast, the challenging information demands from ECHA to Member States when submitting a restriction dossier is an illustration of how the burden of proof is placed on public authorities to prove that a substance should be restricted, even though REACH was designed to ensure that action is taken when doubt exists about industries' demonstration of safety.

Of particular interest to us would be to see an in-depth discussion on how the Agency can better contribute to the application of the precautionary principle in the decision making on individual chemicals. This requires a comprehensive description of all potentially adverse effects as well as highlighting the extent of the scientific uncertainty.

Unfortunately, the actual practice of ECHA is to request undeniable evidence on hazards as a pre-requisite to recommend action. Examples of this are RAC's refusal to consider scientific evidence on immunotoxicity of PFOA, breast cancer, metabolic and immunotoxic effects of BPA, or endocrine effects of phthalates, among others. In several cases the Committee establishes thresholds based on the highest values, giving preference to data from industry-funded studies. We would therefore like to invite ECHA to discuss which measures (including grouping, extended scope of restrictions, etc) could be taken to make the processes more effective in ensuring a high level of protection of environment and health.

We welcome your invitation to convene a round table dialogue with the organisations that have co-signed this letter and we would invite ECHA to present some of the information relevant to the questions in our letter of last November as a basis for this dialogue.

Yours sincerely,

Jeremy Wates,
Secretary General of the European Environmental Bureau

On behalf of:

BUND- Friends of the Earth Germany
The Cancer Prevention and Education Society
Center for International Environmental Law (CIEL)
CHEM Trust
ClientEarth
The Danish Ecological Council
ECOCITY
Ecologistas en acción
European Environmental Bureau (EEB)
Greenpeace

Health and Environment Alliance (HEAL)
Health Care Without Harm (HCWH)
HEJSupport
Women Engage for a Common Future (WECF)
ZERO – Association for the Sustainability of the Earth System
Zero Waste Europe

In view of the public interest in this matter, we intend to make this letter and ECHA's response publicly available.