Brussels, 8 November 2016

To: Geert Dancet, Executive Director, European Chemicals Agency (ECHA)
CC:
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

Dear Mr Dancet,

The 10th anniversary of the approval of the REACH Regulation is a good occasion to demonstrate the benefits of this regulation to Europe's population and environment. It is all the more timely given the fast changing political context and the different assessment exercises being conducted for chemical regulations. Regulators have assigned ECHA a major role in the implementation and delivery of REACH. In order to contribute to protecting people and the environment from harmful chemicals, to the further development of REACH and to strengthening ECHA's deliverables in the future, we invite ECHA to respond to the following questions regarding the implementation of REACH and its underlying principles and aims. Your responses will help us in developing our positions in support of more effective protection of people and the environment from the harmful effects of chemicals and will, we believe, be of wider public interest. If possible, we would appreciate your reply by the end of November or the first week of December.

1. Precautionary principle
How is ECHA ensuring that its actions and outputs are in line with the precautionary principle? In particular how do the Member States Committee, Risk Assessment Committee and Socio Economic

Analysis Committee systematically consider the application of the precautionary principle and communicate their findings to the Commission?

2. Closing the information gap

One of the main aims of REACH was to close the gap regarding available chemical safety information. Ten years on, for what percentage of chemicals, per tonnage band, is safety data sufficiently available to allow for robust and reliable risk assessments? How does ECHA intend to handle incomplete and/or outdated registration dossiers?

3. Adequate control of risks

In how many of the registration dossiers submitted by industry to date are the risks not adequately controlled according to ECHA? What are the binding obligations to which ECHA has to conform when it finds that a registration dossier shows that there is a risk for society from the use of the substance?

4. Reversal of burden of proof

A main principle in REACH is that the burden of proof is put on the companies. To what extent is the principle actually applied – on a scale from 1 (very weak) to 5 (very strong)? What are the top three incentives for a) registrants and b) applicants for authorisations to accept and embrace the burden of proof and how do ECHA and the committees ensure that those incentives are reinforced? What could be done to guarantee the effective implementation of the principle?

5. Inclusive governance

How is ECHA encouraging the involvement of "third parties" and as such promoting the "inclusive governance" elements of REACH? Specifically, looking at the socio-economic opinions could you please explain how the following aspects are included, taken into account, and weighted: (a) the overall benefit to society of the regulatory measures under discussion, (b) companies providing safer alternatives and (c) the EU economy as a whole?

6. Authorisation

REACH provides for two cumulative criteria for authorising substances of very high concern (SVHCs) for socio-economic reasons: the benefits should outweigh the risks ***and*** no suitable alternative should exist for the uses applied for. How does ECHA assess that these two criteria are separately and cumulatively met? As all authorisations have been granted to date, how does ECHA assess that no suitable alternatives exist in broad scope applications?

7. Use of information generated by REACH in the application and implementation of Community legislation

How is ECHA supporting the use by relevant actors of the information generated by REACH? In other words, what is the pertinence of REACH-generated information regarding the substitution of SVHCs in other EU policy initiatives to achieve the 7th Environmental Action Programme and the Sustainable Development Goals objectives? Specifically how is REACH-generated information dealt with in the Carcinogens and Mutagens Directive, product policy, Industrial Emissions Directive, Seveso III Directive and the new Medical Devices Regulation?

We are looking forward to your response.

Yours faithfully,

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)
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.