EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR THE ENVIRONMENT
DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES

The Directors-General

Brussels,
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Danny Jacobs, Director Bond Beter Leefmilieu
Vicky Cann, Campaigner Corporate Europe Observatory (CEO)

Dear signatories,

Thank you for your letter highlighting the need to update the REACH information requirements. We share your view that the revision of both REACH and CLP are a crucial opportunity to speed up regulatory action on harmful chemicals. In fact, the recent amendments of the CLP-Regulation will allow the classification of substances with endocrine disrupting properties, with persistent and bioaccumulative as well as persistent and mobile properties and enable their appropriate risk management.

As the Commission outlined in its Chemicals Strategy for Sustainability, the European Commission is preparing an update of the information requirements that allows the

identification, in particular, of more carcinogenic, reprotoxic and endocrine disrupting chemicals. This may include a requirement for the notification of all polymers and a registration requirement for polymers meeting certain criteria that are predictive of relevant hazard properties. Importantly, we are now considering how best to increase the information on low tonnage substances for both human health and the environment and require a chemical safety assessment for them.

In this modification of the information requirements, new approach methods (NAMs) will be referred to where these methods are sufficiently robust for regulatory use. In other areas, for the reasons that your letter points out, animal data may still be needed to ensure that information is available for the protection of humans and the environment from chemical risks, such as for the newly added hazards in the CLP regulation. Nevertheless, we are also assessing options to limit animal testing in those cases via some triggering systems and by strengthening the testing proposal procedure.

In parallel, the Commission is working together with ECHA and the EPAA (European Partnership for Alternative Approaches to Animal Testing) on a roadmap towards chemical safety testing in the EU without animals. This roadmap should identify the critical milestones to be met such as to allow another future update of the REACH annexes replacing more animal data requirements with alternative ones.

Concerning your recommendation to using the precautionary approach for regulating chemicals that would share similar hazard profiles in groups, based on similarity in chemical structure, NAM-data and other evidence, including academic data, this is already an option today. Currently, we are looking into ways to increase the use of grouping for the purpose of regulatory risk management and similar considerations apply to the possible future registration of polymers.

Concerning your request for a meeting, we invite you to contact ENV-B02-ARES@ec.europa.eu to arrange a meeting on these important matters.

Yours sincerely,

e-signed *e-signed*

Florika Fink-Hooijer Kerstin Jorna