

Helsinki, 10 March 2022

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**Subject: ECHA's scientific and technical support to the European Commission in 2021 on the Chemicals Strategy for Sustainability**

Your ref: Ares(2020)7814743 and Ares(2021)2470219

Dear Directors,

During 2021, we at the European Chemicals Agency (ECHA) have supported the implementation of the Chemicals Strategy for Sustainability (CSS) in our scientific and technical role as requested by the Commission<sup>1</sup>. With this letter we would like to honour our commitment to transparency and give a public summary of the input, as well as confirm our commitment to continue supporting the Commission during 2022. This letter will be shared with ECHA's Management Board and published on the ECHA website and we will also make available other key contributions there once the respective legislative proposals are adopted, for transparency purposes and to satisfy information requests from stakeholders.

These *ad hoc* contributions, that come on top of the Agency's regular work, have been made possible thanks to the exceptional commitment and hard work of our staff, and due to efficiencies gained and increased risk tolerance in our regulatory work.

### **Revision of hazard criteria**

As the Commission aims to develop additional hazard criteria we organised two *ad hoc* meetings to consult the PBT expert group. We continued our active support to the Commission on developing criteria for endocrine-disrupting substances, especially through the CARACAL subgroup on endocrine disruptors (CASG ED)<sup>2</sup>.

Based on this work, we established a mechanism to retrieve information on hazardous properties of substances and established a list to estimate the number of substances qualifying for any of the hazard classes/criteria relevant for CLP impact assessment and for REACH actions identified in the CSS.

### **Revision of the CLP Regulation**

The Commission intends to amend the CLP Regulation so that it has the right to initiate harmonised classifications and, when doing so, request ECHA to develop proposals for harmonised classification for prioritised substances. We provided an estimate of the resources required by the Agency to develop and prioritise such proposals.

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<sup>1</sup> See the Commission [note](#) of 21 December 2020 and [letter](#) dated 12 April 2021.

<sup>2</sup> Competent Authorities for REACH and CLP ([CARACAL](#)).

Furthermore, we provided input to the contractor who prepares the impact assessment of the CLP revision on many topics such as the possible harmonisation of derived no-effect levels or predicted no-effect concentrations (DNELs/PNECs), improvement of self-classification and the C&L Inventory, possible updates of labelling requirements, the CLP scope exemptions review, online sales of chemicals and poison centres.

### **Revision of the REACH Regulation**

To contribute to the revision of REACH, we made use of the [report](#) on the operation of REACH that had to be submitted to the Commission by June 2021. This included our practical experience and critical analysis of the state of the operation of REACH.

In addition, we provided input to the contractors in charge of numerous studies launched by the Commission to prepare the impact assessment of the REACH Regulation. This includes, for instance, contributions on the possible introduction of a mixture assessment factor and the derivation of a derived minimal effect level (DMEL) for certain non-threshold substances.

With regard to possible amendments to registration requirements, we participated in the steering committee of a Commission study to give options for amending the legal provisions for supplying information on volumes, use and exposure in registrations and the possible impact on chemical safety reports. We also took part in the steering group of a project led by the Commission's Joint Research Centre (JRC) to develop possible sustainability criteria. In this work, one option could be to request registrants to provide information on the environmental footprint of their substances in their registrations. Similarly, the Agency contributed to a collaborative project led by the JRC on extending REACH information requirements, with a focus on non-animal approaches to reduce and replace animal testing.

We also continued supporting the work of the Commission by taking part in a dedicated CARACAL subgroup on extending the registration duty to certain polymers.

Several discussions with the Commission took place on improving the evaluation process as well as the enforcement of REACH provisions, for example, through the establishment of a European Audit Capacity. We gave our scientific and technical input on different options to reform the restrictions and authorisation chapters in REACH. Linked to the latter, we supported the Commission's work on essential uses and in extending the use of the generic approach to risk management. Until the generic approach to risk management is introduced and applicable in REACH, work on restrictions should focus on the most harmful (groups of) substances and all their uses. We contributed to the Commission's Restrictions Roadmap, which includes prioritisation criteria and an initial list of prioritised (groups of) substances. The final roadmap will be published in the coming weeks by the Commission and our contributions are summarised [here](#).

### **CSS working groups**

At the invitation of the Commission, we contributed to the work of several CSS working groups, including those on 'one substance, one assessment' (1S1A), indicators, a strategic research and innovation agenda, generic risk assessment, endocrine disruptors, mixtures, enforcement, safe and sustainable by design, and global issues. These contributions were made by participating in working group meetings and by giving input to draft documents circulated in the groups.

The work of the 1S1A working group is particularly relevant to ECHA, as it aims to streamline the scientific advice provided to the Commission from different sources and under different pieces of legislation. Besides the Commission's inter-service group, we have also been requested to join a dedicated 1S1A expert group with Member States and EU agencies.

In addition, the planned regulation on reattributing scientific tasks to EU agencies, the ECHA founding regulation, the data regulation to remove legal barriers to data sharing, and the plan

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to establish an Open Data Portal for chemicals data may all have an important impact on the future mandate and workload of the Agency. Therefore, substantial time has been dedicated to early discussions on such initiatives. For the Open Data Portal, we contributed to the work of the contractor to perform a feasibility study.

Besides the new tasks that may be assigned to the Agency through the regulation on the reattribution of scientific tasks, we have been put forward to take on additional work in two more Commission proposals, namely the draft Battery Regulation and the draft Cross-border Health Threats Regulation. For these, we provided technical input to the Commission to prepare for such tasks.

For the working group on indicators, we took an even more prominent role, as technical co-lead together with the European Environment Agency, towards the development of an indicator framework on chemicals as part of the Zero Pollution and 8<sup>th</sup> Environment Action Programme monitoring framework. This was made possible by the provision of two additional posts under the 8<sup>th</sup> Environmental Action Programme.

We contributed to the newly established Partnership for the Assessment of Risk from Chemicals (PARC) to develop EU-wide human and environmental biomonitoring. In the same context, we gave our input to the Commission's study and pilot project on establishing an EU chemical early warning and action system.

### **Continued commitment in 2022**

While heavy investment to support CSS activities may require us to rethink certain priorities or come up with different ways of working for our regulatory work, we remain fully committed to supporting the Commission also in 2022. This reflects our commitment to the EU's Green Deal and recognises the importance of our scientific and technical expertise in the implementation of the CSS.

The longer-term impact on the Agency of the planned changes to legislation and the introduction of new requirements will have to be carefully assessed, including in the context of our next strategic cycle. The impact may be profound, and it will be important to match the resources of ECHA and our regulatory partners to the high ambition levels of the CSS.

Yours sincerely,

*[e-signed]*<sup>3</sup>

Bjorn Hansen  
Executive Director

Cc: C. de Avila, B. Berger, E. Montani, K. Berend, G. Casella, A. El Ameli, H. Ingels

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<sup>3</sup> This communication has been approved according to ECHA's internal decision-approval process.