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Ecosystems I: Chemicals, food, retail

DIRECTORATE-GENERAL FOR ENVIRONMENT
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NOTE FOR THE ATTENTION OF

MR BJORN HANSEN, EXECUTIVE DIRECTOR, ECHA

Subject: **Request for support to the impact assessment on the planned revision of the REACH Regulation**

Following Florika Fink-Hooijer's note 7814743 of 21 December 2020 on the implementation of the Chemicals Strategy for Sustainability, we have further analysed our need for support by ECHA in the context of the planned targeted revisions of both the CLP and the REACH Regulations. As you are aware, the Commission plans to undertake comprehensive impact assessments to underpin the revision proposals. Moreover, the Commission intends to present a roadmap for restrictions until the REACH revision will be adopted. In this context, we request your assistance in the areas indicated in the Annex, pursuant to REACH Article 77(1). ECHA will also be invited to participate in the steering groups for both relevant supporting studies and for the impact assessments.

We would also like to point to the urgency of the matters due to the tight time schedules of adopting the legislative proposals for revision of CLP (end of 2021) and REACH (end of 2022).

Yours sincerely,

(e-sign)
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Annex: Areas in which ECHA's assistance is requested

1. REVISION OF THE HAZARD CRITERIA

In accordance with the Chemicals Strategy for Sustainability, the Commission will propose changes to the CLP Regulation. The proposal should be prepared already in 2021, which means that the support from ECHA should be provided with a short deadline, preferably mid June 2021.

1.1. Development of criteria

1.1.1. Development of criteria for PMT and vPvM

The Strategy foresees that hazard classes should be developed for Persistent, Mobile and Toxic substances and for very Persistent and very Mobile substances. ECHA is requested to work with the Commission's services developing possible sets of criteria for such hazard classes and categories. The possibility to involve the PBT ECHA expert group would be welcomed.

1.1.2. Development of criteria for terrestrial organisms

The Strategy foresees that criteria for terrestrial toxicity should be developed in CLP. ECHA is requested to work with the Commission's services developing possible sets of such criteria. The possibility to involve the PBT ECHA expert group would be welcomed.

1.1.3. Development of criteria for immunotoxicity and (developmental) neurotoxicity

The Strategy foresees the assessment of the need for specific criteria for immunotoxicity and (developmental) neurotoxicity, currently covered by the hazard endpoints 'Specific target organ toxicity' and 'reproductive toxicity'. ECHA is requested to work with the Commission's services in assessing the need of such stand-alone criteria. In particular ECHA's expertise would be requested to identify any overlaps with the existing criteria related to STOT and reproductive toxicity or to future classification of endocrine disruptors.

1.1.4. Development of criteria for ED

The Strategy foresees that hazard classes should be developed for EDs (human health and environment). This work has already started as a result of a similar call in the Commission Communication COM(2018) 734 final Towards a comprehensive European Union framework on endocrine disruptors. ECHA is requested to continue their active support of the Commission's services developing possible sets of such criteria. The need to involve CASG ED and/or the ECHA ED expert group should be discussed.

1.1.5. Development of criteria for PBT/vPvB

The Strategy foresees that hazard classes should be developed for PBT/vPvB. ECHA is requested to work with the Commission's services developing possible sets of such

criteria, in particular in the discussion for a possible category related to suspected PBT/vPvB. The possibility to involve the PBT expert group would be welcomed.

1.2. Establish a mechanism to retrieve information on hazardous properties of substances and establish 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 and establish a list of substances falling under those hazard classes

In order to enable the assessment of the impact of introducing additional hazard classes in CLP and the impact of envisaged restrictions under the planned roadmap on restrictions and the implementation of the Generic Approach to Risk Management, ECHA is requested to estimate the number of substances that could potentially be identified for these hazards. Details on a mechanism to retrieve the necessary information on the hazard properties should be discussed with the Commission.

Estimates would be required for the hazards listed below:

i. Endocrine disruptors with effects for human health
ii. Endocrine disruptors with effects on the environment
iii. Persistent, bioaccumulative and toxic substances
iv. Very persistent and very bioaccumulative substances
v. Substances with specific target organ toxicity, single exposure (differentiated based on target organ)
vi. Substances with specific target organ toxicity, repeated exposure (differentiated based on target organ)
vii. Immunotoxic substances
viii. Neurotoxic substances
ix. Respiratory sensitisers
x. Persistent, mobile and toxic substances
xi. Very persistent and very mobile substances
xii. Terrestrial toxicity

ECHA is requested to, based on available information, establish a list of substances falling into each of the above hazard classes, where relevant assigning them to CLP hazard categories that the Commission is currently developing for those hazard classes.

2. ESTIMATION OF RESOURCE NEEDS FOR CERTAIN ACTIONS ENVISAGED UNDER THE PLANNED CLP REVISION

2.1. Estimation of resources required for developing and prioritising proposals for harmonised classification

The Commission wants to amend the legislation to have the right to initiate harmonised classifications, and when doing so request ECHA to develop proposals for harmonised classification for prioritised substances. In order to assess the impact of this new task, the Commission would need an estimate of the resources required by ECHA for development and prioritisation of such proposals. The average time and other resources required per proposal, incl. uncertainty interval as appropriate, should be provided.

2.2. Estimation of resources required for harmonised DNELs/PNECs in CLP

The Commission wants to request ECHA to develop proposals for the adoption of harmonised DNELs/PNECs for some substances. In order to carry-out this task, the Commission would need an estimate of the resources required by ECHA. The average time and other resources required per proposal should be provided.

2.3. Ad-hoc support on other action points for CLP revision

The Commission wants to request ECHA to support other actions for the revision of CLP and not listed above, for which an ad-hoc consultation of ECHA would be needed rather than a specific mandate.

3. REVISION OF THE REACH REGULATION

A number of actions or studies will be carried out during 2021 and until the beginning of 2022 in support of the Impact Assessment for a targeted revision of the REACH Regulation. It is expected that the Impact Assessment will be carried out in 2022 and a proposal for a targeted revision of the REACH Regulation will be adopted by end of 2022.

The Commission encourages ECHA to make use of the report on the operation of REACH that has to be submitted to the Commission in June 2021 under Article 117 of REACH to contribute to the revision of REACH, with their practical experience and critical analysis of the operation of REACH.

Aside from the contribution via the Article 117 report, the Commission anticipates that support from ECHA would be needed for the following actions or studies. The support will be needed in 2021 and maybe early 2022.

3.1. Amendment of registration requirements

3.1.1. Hazard information

As per the Chemicals Strategy, there is a need to amend the information requirements to enable the identification of substances with critical hazard properties, including neurotoxicity, immunotoxicity, carcinogenicity, endocrine disruption. There is also a continuous need to replace animal testing with non-animal approaches. DG GROW and DG ENV are requesting the JRC EURL-ECVAM to conduct a collaborative project on extending REACH information requirements pursuant to the Chemicals Strategy for Sustainability. The Commission might also contract a study to develop a proposal for amendment of the information requirements and to estimate the costs and benefits of such amendments. ECHA is invited to contribute to these activities as appropriate.

The Strategy foresees to extend the duty of registration under REACH to certain polymers of concern. ECHA should continue its involvement in the preparation of the Commission documents for the CASG as well as in the pilot project with CEFIC.

3.1.2. Information on volumes, uses, exposure/emissions and environmental footprint

The current requirements to provide information on uses do not ensure sufficiently precise information on how the substances are used, the tonnage allocated to each use, the exposure of consumers, workers and the environment during or from each use etc., and is often outdated. Therefore, the information provided in the registration dossiers is not sufficient for allowing authorities to evaluate and assess the possible risks and to take informed decisions on the need for regulatory action. The Commission is planning to contract a study to provide options for amending the provisions for supplying information on volumes, use and exposure in registrations and the possible impact on the CSRs. ECHA is invited to participate in the steering committee for that study and to provide information from the registration database and general experiences, as needed.

The Chemicals Strategy is initiating actions on development of substances, materials and products that are safe and sustainable by design. In order to provide information for use in the assessment of sustainability, it is proposed that registrants shall provide information on the environmental footprint of their substances. DG RTD is in the process of requesting JRC to develop methods for such an assessment and ECHA is invited to participate in the steering group and to contribute, as appropriate.

3.1.3. Derivation of DMEL for certain non-threshold substances

The Commission is looking into options for introducing a Derived Minimal Effect Level (DMEL) for certain substances for which it is not possible to derive a threshold in order to allow for a quantitative risk assessment. The Commission is planning to contract a study to identify types of hazards for which a DMEL can be derived, how many substances that might comprise, how this could be introduced in REACH and the possible impact of different options for the acceptance level of risks. There is also a need to look into possibilities to derive thresholds for environmental endpoints in particular for substances for which it is difficult to estimate thresholds. ECHA is invited to participate in a steering committee for this study and to contribute, as appropriate.

3.1.4. Introduction of a Mixture Assessment Factor

The Commission is currently contracting a study on the introduction of a Mixture Assessment Factor (MAF) in REACH, Annex I. ECHA is supporting this study, including by providing results of an internal study that ECHA is currently conducting to obtain more insight into the effects of introducing a MAF in REACH on the Chemical Safety Assessments required in registrations of hazardous substances manufactured or imported in quantities greater than 10 tonnes per year under REACH. ECHA is requested to continue to support the Commission activities on MAF by participating in the project steering committee and provide support, as appropriate.

3.2. Revision of evaluation procedures

The Chemicals Strategy for Sustainability confirmed the conclusion of the last REACH review that the efficiency and effectiveness of the evaluation procedures, implemented by ECHA, its Committees, the Member States and the Commission, need to be improved. In particular with regards to dossier evaluation, the Strategy requests the Commission to strengthen the principles of 'no data, no market' and the ‘polluter-pays’

under REACH, in particular by requiring compliance of all registration dossiers and revoking the registration numbers in case of non-compliance.

With regards the different procedures (testing proposal, dossier evaluation, substance evaluation) to follow to obtain additional information, in particular from experimental testing, efficiency needs to be significantly improved. Options to be considered could include strengthening the control at the entry point for all registrations (completeness check), options for a more efficient evaluation of testing proposals including evaluation of the absence of testing proposal relying on adaptations to information requirements, streamlining the procedures in order to speed up the decision-making and the submission of information, as well as the possibility for ECHA or national agencies to directly commission tests via a financial mechanism still to be defined.

ECHA is expected to provide information on the operation and practical functioning, including a critical assessment of what is functioning well and what could be improved in all evaluation processes in its report pursuant Article 117 of REACH. ECHA is also invited to contribute to the development and refinement of options for further analysis in the impact assessment.

3.3. Extending the use of the Generic Approach to Risk Management

For all the identified substances in section 1.2, items i-ix, ECHA is requested to provide available information on uses and other information to be discussed with ECHA from registration dossiers, differentiating between consumer, professional and industrial uses. To the extent possible, the quantities of the registered substances distributed between the different uses should be provided.

Further work on identification of uses and socio-economic impacts of generic restrictions will be done by the Commission with the support of a consultancy study. ECHA is invited to support the Commission by contributing to this work.

3.4. Reform of the REACH authorisation and restriction processes

ECHA is invited to support the Commission in the elaboration of options to reform the REACH authorisation and restriction processes. The Commission intends to conduct this part of the impact assessment in house, with the support of a consultancy study. ECHA is requested to provide relevant analysis and information to allow calculations to assess the impact of various options. ECHA is expected to provide information on the operation and practical functioning, including a critical assessment of what is functioning well and what could be improved in both processes in its report pursuant Article 117 of REACH. ECHA is also invited to contribute to the development and refinement of options for further analysis in the impact assessment.

3.5. Essential uses

As part of the impact assessment, the Commission will also assess various options to define criteria for essential uses and to integrate the concept into REACH. ECHA is invited to support the Commission in this work, in particular by commenting on Commission discussion papers, contributing to discussions in workshops and providing relevant information, e.g. for case studies to be developed in the course of the work.

4. ROADMAP TO PRIORITISE RESTRICTIONS FOR CERTAIN HAZARD CLASSES

In the interim period until the Generic Approach to Risk Management is introduced and applicable in REACH, the protection of health and the environment will be increased by proposing restrictions for substances (through grouping) that fall within one or more of the following hazard classes: carcinogenic, mutagenic or reprotoxic substances, endocrine disruptors, persistent, bioaccumulative and toxic or very persistent and very bioaccumulative substances, substances with specific target organ toxicity, immunotoxic substances, neurotoxic substances, respiratory sensitisers. A roadmap will be developed by the Commission, with the support of ECHA, including prioritisation criteria and an initial list of prioritised substances and groups of substances.

ECHA is invited to develop proposals for criteria for prioritising substances and groups of substances as well as to develop an initial list of prioritised substances and groups of substances. The purpose shall be to establish a multi-year planning for restrictions under REACH Article 68(1). The planning will be discussed as soon as possible with the Member States, with a view of sharing the workload of preparing Annex XV dossiers between ECHA and the national competent authorities. In this regard, ECHA should provide the current planning of restrictions and available resources to develop and assist on further restrictions in the coming years.