



Downstream Users of Chemicals Co-ordination group

DUCC COMMENTS TO CASG-POLYMERS ON CRITERIA FOR POLYMERS REQUIRING REGISTRATION

15th October 2020

The Downstream Users of Chemicals Co-ordination group (DUCC) thanks the Commission for the opportunity to provide its input on criteria for identification and grouping of Polymers Requiring Registration (PRR) and looks forward to further discussions during the next CASG-Polymers meetings. DUCC hopes that the forthcoming discussions on the PRR criteria will facilitate the development of PRR criteria that are scientifically robust and limit registration of polymers to only those that are expected to result in a significant risk to human health or the environment.

1. Polymers of Low Concern (PLC) and PRR criteria

DUCC welcomes the proposal to include a PLC concept as an integral part of the upcoming EU legislation on polymers, in particular as the PLC concept has been already successfully implemented and used in other jurisdictions such as US, Canada, and Australia. However, it should be noted that as is currently written in the report the proposed PRR criteria create an overlap with PLC and as a result some PLCs would become PRRs in the process. In our view clear criteria for PLC should be defined in order to exclude PLCs from the scope of PRR. As a pragmatic solution, common criteria as they are defined across other jurisdictions (US, Canada, and Australia), would be acceptable. Nevertheless, in our view global harmonisation would be important for the European single market. Therefore, in the long term we believe that PLC criteria should be aligned globally as the harmonization of the criteria for an EU PLC with PLC criteria in other jurisdictions would help enhance the competitiveness of the EU market.

2. PRR criteria

DUCC supports the development of PRR criteria based on hazard or on properties typically giving rise to hazards. In our view PRR criteria have to be clear, unambiguous, and easily implemented by industry as well as understandable to competent authorities.

Anionic polymers:

In DUCC's view an approach of considering only surface-active polymers should be included in the criteria in order to prevent a large number of typically non-hazardous anionic polymers from being



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identified as PRR. The current criteria have to be made more specific and based on possible hazards on the basis of (polymer) chemistry and polymer properties.

Cationic polymers

The distinction should be made between polymers that are not water soluble and those that are, as most likely the polymer is not toxic if it is not water soluble under environmental conditions. While developing criteria, cationic charge density should also be considered. A 5,000 Da cut-off per cationic unit would be too stringent and a cut-off per cationic repeat unit of >1000 Da or >2000 Da is deemed more appropriate. The same approach would apply to amphoteric polymers.

Amphoteric polymers

This "amphoteric" category is not needed as amphoteric polymers with a net positive charge should be in the cationic group and amphoteric polymers with a net negative charge should be in the anionic group. Amphoteric polymers with a net neutral charge should be considered non-ionic. If the category is kept, mitigation factor cation-to-anion ratio should be included in criterion.

Molecular weight

For the polymers that are not PLC, the Molecular Weight could be used as pragmatic criterion in determining if a polymer should be excluded from PRR. Molecular weight, however, cannot be an efficient stand-alone criterion and should be used in conjunction with other PRR criteria.

Grouping of polymers

Grouping is very important to limit the number of redundant dossiers, not only for industry, but also for ECHA and MS CAs and efficient grouping would reduce the testing burden on industry and at the same time reduce unnecessary animal testing. Grouping principles are key to the success and workability of polymer legislation and this should not be put in place before a sound approach is defined. Currently grouping is a major source of uncertainty as a clear pragmatic procedure of how to determine group size is lacking and until it is better defined which polymers are in scope for PRR, it is difficult to suggest a grouping strategy. Exclusion of PLCs from PRR would help to simplify the grouping activity. Grouping should be a very broad concept and criteria should be dynamic to allow inclusion of new polymers into existing groups. If not, new customized polymers would not fit in any



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of the existing groups and may require a separate registration. In our view grouping should be based on polymer chemistry, hazard, exposure, and ultimately potential risk.

Safety net criterion

We are concerned about the vagueness of the safety net concept, which is in contrast with Art. 138(2) of REACH that asks for a clear report on polymer risks and the need for registration. We understand that “safety net criterion” is introduced in order to “capture” polymers that “do not fall into traditional PRR classes” and thus could be hazardous or pose a risk to humans or the environment. However, in our view it would be very difficult to define clear and understandable criteria for “possible emerging concerns” and such “unprescribed and vague” criterion will lead to inconsistencies between various registrants. *Instead of a "safety net" it may be prudent to add new well-defined criteria identified via risk analysis to the core decision tree and to address “emerging concerns” via other regulatory processes.*

About DUCC

DUCC is a joint platform of **11 European associations** whose member companies use chemicals to **formulate mixtures** (as finished or intermediary products) for professional and industrial users, as well as for consumers.

DUCC focuses on the downstream users’ needs, rights, duties and specificities under **REACH** and **CLP**.

DUCC’s membership represents several important industry sectors, ranging from cosmetics and detergents to aerosols, paints, inks, toners, pressroom chemicals, adhesives and sealants, construction chemicals, fragrances, disinfectants, lubricants and chemical distributors industries. Altogether, their membership comprises more than **9.000 companies** across the respective sectors in Europe, the vast majority being SMEs. The calculated turnover of these companies is more than **215 billion euros** in Europe.

For more information on DUCC: www.ducc.eu

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DUCC’s public ID number in the **Transparency Register of the European Commission** is: **70941697936-72**