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FEICA comments on EC proposed PRR flowchart and EU definition of PLC

FEICA, the Association of the European Adhesive & Sealant Industry, is a multinational association representing the European adhesive and sealant industry. Today's membership stands at 15 National Association Members, 24 Direct Company Members and 19 Affiliate Company Members. The European market for adhesives and sealants is currently worth more than 17 billion euros. With the support of its national associations and several direct and affiliated members, FEICA coordinates, represents and advocates the common interests of our industry throughout Europe. In this regard, FEICA works with all relevant stakeholders to create a mutually beneficial economic and legislative environment.

Background

FEICA welcomes the opportunity to comment on the PRR-Identification flowchart - Update 8 June, and the proposal for an EU-definition of polymer of low concern (PLC) shared in CIRCABC, in advance of the CASG meeting of 22 June 2021 (Agenda item 5: CASG-Polymers/07/2021).

We would like to comment on the following points:

PRR identification flowchart

Notification of PLC, precursors and non-PRR status to ECH

In previous CASG meetings, the option of registrants keeping documentation on file in-house available for inspection by MS enforcement authorities was still on the table.

In the update of 8 June, this option has disappeared, and the notification of data/assessments to ECHA has been favoured.

FEICA members believe that documentation on PLC, non-PRR and precursor status should be kept on file, available for the authorities on request.

Polymers of low concern (PLCs), polymeric precursors and non-PRR polymers are exempt from registration. The REACH Regulation does not require the submission of information to ECHA when an exemption applies (e.g., naturally occurring, less than 1000 kg/yr., etc.).

International harmonisation should also be prioritised. In other jurisdictions, such as the United States and Australia, companies should keep onsite records on PLC but do not need to share this information with the authorities.

Having to receive and process information on polymers exempted from registration would create an unnecessary burden on ECHA without any added benefit for human health or the environment. Enforcement mechanisms should be strengthened to verify information kept onsite. In conclusion,

exemptions for polymers under REACH should be consistent with other types of exemptions under REACH, and no additional requirements should be imposed, consideration being given to the less hazardous profile of polymers compared with that of registered monomers.

Polymeric precursors exemption

FEICA disagrees with the proposed wording of the polymeric exemption. The updated flowchart says, 'Is P solely a precursor handled like intermediates to produce other polymers or articles?' .

We strongly believe that the exemption for polymeric precursors should not be limited to those precursors handled like intermediates.

Some polymers are used as polymeric precursors to produce other polymeric substances or articles in a subsequent manufacturing or application step. Polymeric precursors are designed to further react after application in a very short timeframe to cross-linked polymers or articles with a very high molecular weight.

Many of these polymeric precursors are handled in industrial facilities and are not intended to come into contact with humans or the environment. In industrial installations, polymeric precursors are handled under normal industrial safety standards. The risks are controlled by high-level occupational, health and safety measures and comprehensive technical, organisational and personal protective measures that are in place in such facilities. Safety Data Sheets, available for polymeric precursors, include comprehensive information for safe handling, e.g., exposure control and monitoring as well as personal protection equipment and handling, storage, and disposal information.

For the definition of 'industrial' we refer to the ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12: Use description.



information_requirements_r12_en.pdf

In conclusion, the benefits of including an exemption for polymeric precursors handled like intermediates would be rather limited and would impose a disproportionate burden on downstream users (in particular SMEs) if they were forced to work under strictly controlled conditions. In many cases, it may be more beneficial for companies to register their polymers than to make the necessary plant changes to benefit from the exemption. This would certainly negate the usefulness of the exemption concept.

Proposal for an EU-definition of polymer of low concern (PLC)

FEICA believes the proposed EU-definition of a PLC is in line with established criteria in other countries such as Australia, Canada, the USA and Korea and appreciates the efforts of the European Commission to propose a harmonised and pragmatic approach.

We would like to suggest the following ideas for consideration:

Inclusion criterion for approved polyesters

The proposed document states that the list of approved ingredients for polyesters should be dynamic. Therefore, a mechanism to add or remove substances from the list should be foreseen. This mechanism should be clear, consistent and science-based.

Qualification as PLC on the basis of RFGs for polymers MWn ≥ 1000 Da

We would like to note that for the 'Inclusion and Exclusion Criteria' item 3, 'Qualification as PLC on the basis of RFGs for polymers MWn ≥ 1000 Da', we would propose an upper limit (MWn < 10000 Da). Polymers with a molecular weight greater than 10000 Da are not expected to be bioavailable, and so are not restricted from PLC status by the presence of reactive functional groups.

This upper limit is in line with the MWn and FGEW criteria for a PLC in Australia, Canada, the USA and Korea.

Exclusion criteria based on composition, ionicity, degradation and hazard classification

For the 'Exclusion criteria based on composition, ionicity, degradation and hazard classification' section, the 'Degradation criteria' item, it should specify under what conditions, and within how much time, the polymer would 'degrade, decompose or depolymerise'.

Conclusion

FEICA members appreciate the efforts of the European Commission to shape the PLC and PRR criteria. We remain available for any technical input that may be needed from us.

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