FEICA The European voice of the adhesive and sealant industry

Brussels, 6 March 2023

FEICA's positions on polymers requiring registration

Executive summary

As part of the ambitions outlined in the Chemical Strategy for Sustainability (CSS), the European Commission is working on a proposal to register polymers under REACH.

FEICA supports a regulatory framework for the registration of polymers under REACH that places equal weight on the protection of human health and the environment, and the competitiveness and innovation of the European Industry.

To achieve this goal, FEICA considers it important that the following points be taken into account:

1. **Polymeric Precursors Exemption:** *FEICA supports an exemption for polymeric precursors linked to adequately controlled conditions (ACC). Adequately controlled conditions should be derived from a risk-based approach.*
2. **Polyesters Exemption:** *Polyesters based on a positive list of monomers and reactants should be exempt from registration requirements.*
3. **Notification of polymers:** *FEICA supports a two-step notification process, with a concise data set for all polymers (notification unit) in the first step and a second notification step to inform on PRRs.*[1] *This process will avoid a disproportionate burden for the European Chemicals Agency (ECHA) and polymer manufacturers.*

Without exemptions for polymeric precursors and polyesters and an efficient notification system, companies would face a disproportionate burden while there would be negligible benefits to human health and the environment.

The administrative burdens on adhesives and sealants companies, many of which will become registrants for the first time, would be substantial. Especially SMEs may not be able to cope with these burdens. This could result in the market withdrawal of many categories of adhesives and sealants products, the loss of products with significant benefits to EU society and job losses.

[1] PRR: Polymer Requiring Registration.

1. Polymeric Precursors Exemption

The European Commission proposed an exemption for polymeric precursors[2] handled under strictly controlled conditions (SCC). REACH already grants lower registration requirements to intermediates handled under strictly controlled conditions.

FEICA considers polymeric precursors to be of a lower risk than current intermediates. We support the position that polymeric precursors handled under adequately controlled conditions (ACC) in industrial or professional settings should also be eligible for an exemption. We see two reasons for this:

- **Lower hazard profile:** Polymers are generally considered to have a lower hazard profile and risk than substances
    - Polymers have a negligible vapour pressure. Inhalation can be excluded if no aerosols are formed by mechanical dispersion
    - Polymers > 1,000 Da are generally assumed to not penetrate the skin barrier; thus systemic effects can be excluded
    - Polymers are often present in mixtures with more hazardous components which create the hazard and drive the risk minimisation measures

- **Lower exposure:** An exemption for polymeric precursors, as proposed by FEICA, would apply to industrial or professional settings
    - In industrial or professional settings risk management measures already apply
    - Polymeric precursors are manufactured in industrial settings, safely packaged, stored and transported until final use
    - During final use the polymeric precursors are fully consumed in the curing/hardening process within a short time span[3], the result being the formation of an article.[4] The lifecycle of the polymeric precursor ends here
    - Oral exposure is generally excluded in industrial and professional settings due to generic work hygiene procedures
    - Local skin effects are prevented by the general requirement to wear gloves when handling such products. For non-classified polymeric precursors or formulated products, a mandatory Safety Data Sheet (SDS) should stipulate the use of gloves

Examples of polymeric precursors relevant to the adhesives and sealants industry include adhesives in packaging, car windshield bonding, construction joint sealing, and automotive interior bonding.[5]

Disadvantages of applying SCC to polymeric precursors

The application of SCC to polymeric precursors as used in the adhesives and sealants industry would require fully automated and enclosed handling and application of polymeric precursors throughout the supply chain. It would require significant investment in expensive technical

[2] Polymeric precursors are polymers which are transformed along the value chain into other polymers or articles. This means that polymeric precursors exist only for a limited time.
[3] Typically ranging from a few hours to days.
[4] Polymeric precursors may also be converted in industrial settings into other polymers and thus be consumed. This is, however, less common in the A&S industry.
[5] More detailed examples can be found in the FEICA paper 'Practical Application Examples to Demonstrate the Use of Polymeric Precursors'.

automation. In industrial settings this would be technically very challenging, while it would be impossible to implement in professional settings.[6]

We consider SCC unnecessary for polymeric precursors because of their lower hazard and their lower exposure, as explained above. This reduced risk should be reflected in lower registration requirements, more specifically, adequately controlled conditions (ACC).

Adequately Controlled Conditions (ACC)

FEICA supports a definition of *Adequately Controlled Conditions* based on risk considerations and an actual assessment of the risk posed by a specific polymeric precursor. The risk management measures of the polymeric precursor will then be given by the determined risk.

To assess the risk of a given polymeric precursor, the risk to human health and the environment will be considered in a flow chart. The combined risks identified in the flow charts will then be used to determine the appropriate risk management measure.

An industry group (CEFIC, FEICA, VCI) is currently working on a proposal for a more detailed description of the definition of ACC outlined above. Once this proposal is available it will be shared.

Impact

At FEICA, we estimate that adhesives and sealants manufacturers place between 13,000 and 26,000 polymeric precursors on the market, corresponding to 65 % of our polymers. None of these polymeric precursors would benefit from an exemption linked to strictly controlled conditions.[7] Instead, an estimated 85 % of our precursors (corresponding to 55 % of our polymers) would benefit from an exemption linked to ACC.

In conclusion, the obligation to register all polymeric precursors would create a significant burden for adhesives and sealants manufacturers, especially SMEs (representing 90 % of the sector) without comparable benefits to human health and the environment.[8]

2. Polyester Exemption

The European Commission has proposed an exemption for polyesters manufactured from a defined list of approved monomers and reactants (positive list). FEICA welcomes this proposal and supports such an exemption[9], as polymers without relevant toxicological and ecotoxicological properties will be exempt from registration obligations. Similar polyester exemptions can also be found in the chemical legislations of the United States, Canada, Australia, China and Taiwan.

List of monomers and reactants

A working group at CEFIC, with participation of FEICA members, has been preparing a proposal for a set of rules and criteria to select monomers and reactants for inclusion in a list that defines necessary properties (either chemical or hazard properties). Based on these rules and criteria, the group has compiled a list of suitable monomers and reactants that are used to manufacture polyesters eligible for an exemption.

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[6] FEICA Position Paper 'Why strictly controlled conditions cannot be technically applied to polymeric precursors'.
[7] Based on feedback from our member companies.
[8] DUCC/FEICA paper 'Impact of polymer registration on downstream users - SMEs'.
[9] More details can be found in the FEICA Position Paper 'Registration of Polymers – the exemption of polyesters'.

FEICA acknowledges that this list of approved monomers and reactants should be updated regularly to remove monomers classified as hazardous at a later stage and to add new non-hazardous monomers, allowing for innovation in this field.[10]

Impact

A survey conducted among FEICA members shows that the percentage of polyesters falling under the exemption could reach up to 60 %.

3. Notification of polymers

The notification of polymers has been proposed by the European Commission and ECHA and will require polymer manufacturers and importers to submit a defined data set on polymers to the European Chemicals Agency.

FEICA supports a *Two-step Notification*. In the first step a concise data set, basically consisting of manufacturer/importer information, chemical descriptors and tonnage, would have to be submitted within three years after entry into force for all polymers. In the second step, a more comprehensive data set for PRRs would have to be submitted only 2 years later. It should be recognised that these data contain commercially sensitive information and should be treated as confidential business information by ECHA and not be made publicly available.

Impact

It is estimated that there are 200,000 polymers in the EU market (both PRRs and non-PRRs)[11], which is significantly higher than the number of substances currently registered under REACH (As of 31 January 2023 there were 22,309 substances with a valid registration).[12] Extensive data generation, as foreseen in the one-step notification for polymers that do not require registration, will not contribute to further protecting human health and the environment and may be a disproportionate burden for polymer manufacturers as well as for ECHA.

We have looked at the notification requirements proposed by the Commission and ECHA and assessed the cost implications for chemical companies. We estimate that the cost for providing the proposed data set to ECHA will be between 20,000 and 30,000 euros per polymer,[13] As a result, we estimate that the average notification cost per SME could be in the range of 1 and 1.5 million euros, corresponding to approximately up to 75 % of the turnover of an SME.[14] In addition to the cost to

[10] The rules and criteria accompanying the list shall serve as a basis to decide whether to include new monomers or reactants on the list or to exclude them from it .
[11] Wood, PFA Brussels, Scientific and technical support for the development of criteria to identify and group polymers for Registration/Evaluation under REACH and their impact assessment, Final Report June 2020, p. 146, 'Best estimate 200,000'.
[12] As of 31 Jan. 2023: https://echa.europa.eu/de/registration-statistics.
[13] The costs are a rough estimate based on the data set proposed by the Commission/ECHA in 'High-level summary of COM-ECHA proposal for the registration of polymers' 31 March 2022, Annex 1 (see also ECHA's proposal). Notification costs can vary significantly from company to company and test lab to test lab. It can be anticipated that notification costs will increase as labs will likely run at full capacity when the notification deadline approaches. For some polymers test protocols may not exist and will have to be generated. The cost of developing a new test protocol (e. g. test determining the concentration of difficult to detect impurities) may amount up to € 100,000.
[14] According to a survey among FEICA member companies, an A&S SME manufactures on average 50 polymers. We calculated that notification costs for an SME would range between € 1 and 1.5 million (50 polymers x an estimated cost of € 20,000 to 30,000 per notification), corresponding to 5 % - 75 % of the turnover of an SME (SME turnover: 2 - 20 M€).

generate the required data, companies will also need to allocate significant internal resources for the notification of polymers.[15]

About FEICA

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 16 National Association Members (representing 17 countries), 25 Direct Company Members and 25 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.

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[15] We estimate that up to 60 working hours will be required to complete the proposed notification for each polymer. Not all companies, particularly SMEs, will have the administrative staff and experienced in-house experts to produce, collate, and submit the required data. They would need to ask external service providers and consultants to do this work for them instead. Even if companies have such skilled experts in-house, they will not be able to devote their time to research and innovation due to the extensive data generation activities for notification.