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FEICA's comments on the Wood/PFA report regarding Polymers **Requiring Registration**

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 almost 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

Current regulatory status for polymers

Polymers are currently exempted from registration under Regulation (EC) No. 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). However, Article 138(2) of REACH foresees a possible further review of REACH to extend the registration requirements to polymers. If the risk posed by certain polymers can be proven and practical and cost-efficient ways of selecting polymers requiring registration (PRR) can be established, registration requirements under REACH will be extended to polymers.

Wood/PFA report

To establish sound technical scientific criteria to identify PRR, the European Commission appointed the consultant firm Wood & PFA to prepare a study. As a result of this exercise, the report 'Scientific and Technical Support for the Development of Criteria to Identify and Group Polymers for Registration / Evaluation under REACH and their Impact Assessment' was published on 6 July 2020.1

FEICA welcomes the publication of the Wood/PFA report and would like to express its gratitude to the European Commission for the opportunity to provide comments.

¹ The Wood/PFA report 'Scientific and Technical Support for the Development of Criteria to Identify and Group Polymers for Registration / Evaluation under REACH and their Impact Assessment' is available for download at: https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/66d00cb2-aa0d-47f9-a4d3-42a12798d098/details

After a detailed analysis of the report, we have prepared a list of issues which we believe require additional consideration before any final decision is made. While fully supporting the comments on the Wood/PFA report submitted by Cefic and DUCC, FEICA invites the Commission to examine these issues with respect to the impact on adhesives and sealants formulators.

Understanding the impact of polymers' registration on competitiveness and innovation is critical

Many FEICA companies manufacture or customise polymers, which results in new polymers that are currently exempt from REACH registration requirements (monomers have been registered). We would like to emphasise that these 'downstream customisations' are essential to meet end-user demands and to fulfil technical requirements (those of the user and those laid down by the regulations). The need to register such 'customised polymers' will completely shift the position of adhesives and sealants formulators from being mere downstream users to manufacturers of polymers.

FEICA and its members are concerned that, unless a suitable grouping approach is adopted, the cost of registering polymers might be excessive for the adhesives and sealants sector. This will have an impact on the capabilities of the industry to develop innovative new materials based on unique polymers. Some SMEs will not be able to bear the costs of registration and useful polymers, particularly with regards to sustainability/recyclability, might be completely withdrawn from the market.

FEICA believes that the cost/benefit ratio in the case of registration could become significantly worse than estimated in the Wood/PFA Report. For example, adhesives and sealants formulators might need to use external testing facilities to carry out required tests and might need to commission external consultants for example to write Exposure Scenarios.

Enhancing competitiveness and innovation is one of the purposes of the REACH Regulation and, as such, should be considered by the legislator.

Adhesives and sealants are an essential component of many innovative products. In a fast changing world that needs to adapt to a growing population and challenges such as climate change, adhesives and sealants are enablers for many sustainable solutions such as fixing insulation panels to houses, improving thermal efficiency of windows, enabling use of renewable materials in products and others.²

How could the risk to innovation and competitiveness be overcome?

Exemptions

While being committed to human health and environmental protection, FEICA considers that certain exemptions from registration requirements should be foreseen in cases where no adverse effects can be expected.

In particular, FEICA would like to invite the legislator to consider exemptions for polymer precursors and polymers from which monomers or ingredients cannot be separated.

² More about sustainability of adhesives and sealants can be found on the FEICA website: <u>https://www.feica.eu/our-priorities/sustainable-development</u>

We have noticed that precursor registrations are not specifically mentioned in the report. In practice, polymers may be used as polymeric precursors.

In the case of industrial uses with no or minimal exposure, where precursors subsequently cure on application, such transient species should not be considered within the Exposure Scenario. Registration of such functional polymers should be re-considered.

Regarding polymers from which monomers or other ingredients cannot be separated without affecting the stability of the product, we think that the Wood/PFA proposal would lead to the registration of the polymer together with the ingredient. This would imply a duplication of efforts and costs as these ingredients will have been already registered under the current REACH requirements. Exemptions in such cases must be taken into consideration because the toxicological and eco-toxicological effects of polymers are generally lower than those of the corresponding monomers/ingredients.

Reduced registration requirements

One key function of any risk assessment is to ascertain the risks associated with the reasonably anticipated uses of a chemical. Consequently, any inclusion of uses as a parameter in the criteria should be based on real scenarios.

Reduced requirements for polymers with low exposure hazard should be considered.

We think that risk/exposure-based criteria should be used to apply reduced registration requirements. We are not in favour of using risk-based criteria as a potential PRR criterion.

Furthermore, some polymers are already regulated under other pieces of EU legislation. For example, some polymers used within adhesives for food packaging applications have already been evaluated under EU food contact regulations.

FEICA asks that polymers already evaluated according to existing legislation are subject to reduced data requirements, while also considering exposure.

Avoiding legal uncertainty: addressing the safety net concept

The Wood/PFA report suggests that polymers suspected of presenting an equivalent hazard to a polymer requiring registration should also be considered as PRRs, even if they do not meet any of the established PRR criteria.

According to our understanding, this concept is not clearly defined and is in contradiction to Art. 138(2) of REACH, which requires a clear report on polymer risks and the need for their registration. The ambiguity of this concept could lead to polymers of low concern (harmless for human health and the environment) having the need to be registered.

FEICA thinks that the safety net concept as defined in the Wood/PFA report must be reconsidered.

Key messages on the registration of polymers

FEICA recommendation for a grouping approach

FEICA believes that more details should be provided on how the grouping approaches presented in the Wood/PFA report would work in practice.

We cannot envision how, in all cases, a polymer could belong only to one group, as suggested in the Wood/PFA report. In practice, grouping overlaps will occur due to the wide range of polymer characteristics.

From the management point of view, a broad grouping approach would result in large consortia, with all the related logistical difficulties. On the other hand, a very narrow grouping might result in a financial burden for registration not bearable for SMEs, where individual polymers might have a short life cycle of less than three years due to the dynamic nature of the end market. Grouping for adhesives and sealants needs to be flexible enough to allow customisation of polymers.

FEICA supports a wide range or family approach for grouping instead of registration requirements for single polymers. In addition, we think that the regulation should include the possibility to opt out from a group.

Requirements for the registration of polymers should be harmonised globally

The Wood/PFA report provides criteria for the identification of Polymers of Low Concern (PLC) based in schemes used in other jurisdictions, for example Australia or Canada. However, the report removes some of the exemptions applicable in other jurisdictions. FEICA would like to emphasise that, when possible, PLC criteria should be clear and harmonised globally to avoid distortions in competitiveness on the global market.

Global harmonisation is important to the European single market, which in turns allows the adhesives and sealants industry to provide citizens with safe solutions while maintaining competitiveness.

Conclusion

The members of FEICA support the efforts of the Commission to develop a comprehensive regulatory framework for the registration of polymers under the REACH Regulation that will help to protect human health and the environment, without losing the competitiveness and innovativeness of the European industry.

We reiterate our commitment to assist in the development of such effective and cost-efficient regulation.

Registration of polymers should be foreseen only when a risk to human health and the environment has been proven. FEICA suggests the development of risk-based mechanisms to assess exposure of both human beings and the environment.

Due to the unique requirements of the adhesives and sealants industry, polymers used in these applications could be subject to high registration costs. This would have a significant impact on competitiveness and innovation.

Criteria to define PRR should be clear, scientifically sound and globally harmonised. Exemptions and reduced registration requirements, in applicable cases, should be considered by the legislator.

FEICA and its members have shared their comments to the Wood/PFA with the European Commission.

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