FEICA The European voice of the adhesive and sealant industry

Brussels, 30 May 2021

FEICA position on Inception Impact Assessment REACH Regulation

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.

On 4 May 2021, the European Commission opened a public consultation for the Inception Impact assessment for the amendment of the EU legislation on registration, evaluation, authorisation and restriction of chemicals (REACH)[1].

FEICA welcomes the opportunity to participate in the Inception Impact Assessment Revision of the EU legislation on registration, evaluation, authorisation and restriction of chemicals (REACH).

FEICA would appreciate the consideration of the following issues with respect to the impact of the revision of REACH on adhesives and sealants formulators.

Revision of registration requirements

The use of polymers within the adhesives and sealants industry is very widespread. In particular, customisation of polymers is key for innovation and the circular economy and must be supported by proportionate registration requirements with a minimum of administrative burden.

FEICA supports pragmatic grouping criteria for polymers, including exemption for polymeric precursors, that would allow balancing the impact on industry and would ensure availability of everyday products. At the same time, grouping would help to reduce the potentially large number of polymer registrations, often for similar polymers customised by adhesive manufacturers.

Without pragmatic grouping, many Small and Medium-sized Enterprises (SMEs) that are adhesive manufacturers would lose their flexibility to act quickly in the market and continue investing in innovation. At the same time, SMEs may be overwhelmed by the burden to support multiple registrations.

For more detailed comments, we refer to our position papers and comments that we have shared in the Caracal Subgroup on Polymers and are available at the FEICA website.

[1] Public consultation for the Inception Impact assessment for the amendment of REACH

Introduction of a Mixtures Assessment Factor (MAF)

The MAF concept is extremely abstract, largely covering hypothetical exposures and risks rather than real-life scenarios, and would result in measures that will be difficult to implement while not having tangible added value on human health and environment.

The MAF concept should be supported by scientific evidence. The introduction of a MAF should therefore be risk-proportionate, workable, and effective.

When exposure limits are derived under REACH (PNEC[2], DNEL[3]), several conservative default assessment factors are already used, all of which contain a safety margin. Their multiplication leads to an overall factor that contains a considerable safety margin that would also cover possible additive combination effects. An additional application of a MAF would lead to a further lowering of the already quite low, conservatively derived exposure limits.

The introduction of a 'mixture assessment factor' in REACH Annex 1 will significantly affect the REACH Chemical Safety Assessment of the ingredients of our products. As a result, many ingredients may no longer be used in our products. This could destroy the established technology as adhesives and sealants widely used and their absence would be a problem for many final-use sectors.

The available data on occupational diseases does not indicate that the exposure of workers is too high in all cases and that the use of an additional MAF is justified.

Simplifying communication in the supply chains

Communication on how chemicals can be used in a safe manner along the supply chain is key to securing proper risk control by downstream users. Formulators need to ensure the safe use of substances/mixtures they receive and of the mixtures they place on the market.

FEICA reiterates its commitment to the improvement of supply chain communication and welcomes the EU COM initiative to look for ways to improve communication in the supply chain.

We support implementation of new digital solutions in the market on the basis of favourable impact assessment.

Reforming the authorisation process

The 'one substance one assessment' concept could be appropriate if it is applied only to the hazard assessment as it could streamline the process, and seemingly different outcomes due to hazard assessments carried out at different times by different bodies under different legislations could be avoided. We are of the opinion that the risk assessment is specific to uses, and expertise should remain with the existing agencies responsible.

Reforming the restriction process

The application of the 'generic approach to risk management' should be limited to the current scope of Article 68 (2) of REACH (CMR[4] and consumer).

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[2] PNEC: Predicted No-Effect Concentration
[3] DNEL: Derived No-Effect Level
[4] CMR: Carcinogenic, mutagenic and toxic for the reproduction

The equal treatment of consumer uses and professional uses is not appropriate. In contrast to the use by the general public, in the professional use sector, employees receive training and apply risk management measures such as personal protective equipment in the course of their professional activity.

A specific risk assessment is required to identify the risk management measures that may be required for safe use. An appropriate risk assessment cannot be replaced by the 'generic approach to risk management'.

Regarding the concept of essential uses, a generic 'definition based' approach to 'essentiality' is not a solution that can ensure sufficient clarity and predictability for industry and consumers.

Subjective judgement cannot replace robust regulatory processes. Minimising exposure through evidence-based policy making should be the corner stone when safe chemicals are defined.

A closed and exhaustive concept for 'essential uses' could put EU competitiveness at risk as essentiality will go through constant change following societal needs and technical developments.

Revision of provisions for control and enforcement

In a global playing field, EU competitiveness should be ensured through the enforcement of compliance with regulations within Member States but also through the prevention of material from entering the European Union that was not produced for the EU market and under European rules.

The regulatory framework should be proportionate, well-assessed and based on sound science. The CSS describes 'toxic-free' as the ultimate goal. Toxic substances occur naturally or not. The focus should be on risk, not hazard, when assessing whether a substance poses a risk to people and the environment.

Conclusion

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

While we would like to express our commitment to assist in the development of such effective and cost-efficient regulation, we encourage the regulators to consider the potential impacts regulatory changes may have on downstream users.

Contact

FEICA Regulatory Affairs:
Paula Diaz (p.diaz@feica.eu)

FEICA is registered in the **EU Transparency Register** with ID no. **51642763262-89**

FEICA - Association of the European Adhesive & Sealant Industry
Rue Belliard 40 box 10, 1040 Brussels, Belgium
Tel: +32 (0)2 896 96 00
info@feica.eu | www.feica.eu

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