FEICA The European voice of the adhesive and sealant industry

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FEICA comments about Third CASG Polymers meeting

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

On 15 March 2021, as a preparation for the third CASG Polymers meeting scheduled on 19 March 2021, the European Commission uploaded to CIRCABC the document named 'An initial thought starter on REACH information requirements for Unique Polymers Requiring Registration (PRR)'.[1]

After reviewing the document and in line with the discussions held during the third CASG meeting, FEICA would like to comment on the questions posed by the European Commission in the abovementioned document.

FEICA's input on the questions posed in the thought starter shared by the European Commission

3.1.2. Do you agree with the proposed subdivision of all PRRs into Types 1, 2 and 3 based on MW primarily as proposed by Wood as the criterium to establish the test package?

A subdivision of all PRRs into Types 1, 2 and 3 based on MW is acceptable.

Do you agree with the other criteria to be taken into account to establish the test package, e.g., tonnage, use of column 2 adaptations and Annex XI adaptation options per endpoint (as for other substances), potential reduced test package for Type 2 and 3 PRRs?

Yes, but further criteria specific to polymers should be taken into account.

[1] The document 'An initial thought starter on REACH information requirements for Unique Polymers Requiring Registration' is available for download at https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/2f699825-5e4a-4d0c-87e6-a015c4da3645/details

The possibility to test polymers in a way that allows a realistic evaluation is a key factor. The problem lies in the fact that polymers are in general of poor solubility in most common solvents, and so specific test strategy must be envisaged. This has to be adapted according to polymers' specific chemical nature.

We agree with the statement to take other criteria into account, like column 2 adaptions, considering that in some cases the adaption rule 'Testing is not technically possible' can apply. Additional adaptations are maybe necessary in some cases.

We also agree (technically) to the tonnage band conclusion that proposes to consider PRRs as UVCBs.

3.2.2 Do you agree with the presented data needs in order to allow formation of UNIQUE PRRs for joint registration?

Grouping should be done based on already existing approaches such as the ECHA Read-Across Assessment Framework. Information readily available like backbone chemistry, reactive groups, molecular weight, possible breakdown products or surface activity (some of which are in the current PRR decision flowchart) will allow an evaluation. It seems reasonable to have a limited number of easily available polymer features that can be a fair proxy for hazard and risks (based on scientific knowledge and exposure) and use those to create UNIQUE PRRs.

This will allow an evaluation without a mandatory requirement for hazard information. Available human health hazards data may be used; however, a requirement to obtain additional hazard information prior to forming UNIQUE PRRs may lead to a huge upfront testing burden.

In addition to tonnage band considerations, further criteria taking molecular weight or molecular content should be taken into account.

3.2.3. Do you agree with the proposed SIRs for physicochemical and environmental fate, and toxicological and ecotoxicological data?

The general idea of less testing for larger polymer groups by testing representative polymers is agreed. An inherent heterogeneity of data between members of a 'Unique PRR' group is certain and wanted. Some parameters appear misinterpreted in this chapter. While the physicochemical property standard information requirements appear a feasible SIR for polymer group assignment, information on other SIRs should be gathered from representative polymers only to minimize testing loads. However, it was noted that in those cases where information on fate and behaviour was considered relevant, considerations should go beyond the assessment of 'readily biodegradability', i.e., they should also include longer term biodegradation as well as abiotic testing that may be important to understand fate behaviour under environmentally relevant conditions.

If a group of 'Unique PRR' is persistent and the tonnages are accumulated in the environment, this practice could lead to significantly high exposure values, likely surpassing the PNEC of these polymers. For polymers with an indication of ecotox response, the test systems should be adapted to address potentially high tonnages of a 'Unique PRR' (i.e., a test beyond 100 mg/l). Adhesives and allied products are not intended to be dispersed in the environment, also because of their use.

According to our comprehension, data requirements for Type 1 polymers are defined (= maximum SIR) whilst reduced SIR for Type 2 and Type 3 polymers should be made more transparent. It would be suitable to establish clear waiving criteria.

3.2.3.1. Do you agree that the current adaptation options in Annex XI should apply also to PRRs?

Do you agree with the draft additional adaption options for Type 2 and Type 3 PRRs?

Yes, but the technical feasibility should be further investigated and clarified.

4.1. Do you agree with the recommendation to follow ECETOC TR133-2 concerning applicability of test methods?

The applicability of testing is adequately described and represents the current state of the art. However, one important step in Tier 0 is the prevention of higher tier testing building on the concept of bioavailability. This concept should be further investigated and clarified: Internal (systemic) bioavailability as per ECETOC 133-1 and -2 means that the polymer product is absorbed into the blood stream by an organism, thereby becoming systemically available and potentially causing systemic effects. The ECETOC report acknowledges modulating factors, such as systemic bioavailability being typically low for highly hydrophilic molecules and -vice versa- high for water soluble molecules. The ECETOC further states that the molecular weight (MW) distribution of a polymer product allows determining whether internal bioavailability is likely. In terms of a citation from the EFSA Panel on CEF (2017), a MW boundary of 1,000 Da is suggested; higher internal bioavailability is unlikely to occur because of static reasons on biological membranes (recommendation by the TF). By citing different jurisdictions on MW and water solubility (e.g., the PLC concept, Environm. Canada), the ECETOC does not give concrete consideration to which modulating factor thresholds (except MW – but here polymers are always multi-constituent substances) will build the basis for a PLC and/or for the decision for a higher tier assessment, i.e., initiate testing. In addition, for environmental investigations, external factors like DOC, TOC and humic acids were identified to potentially mitigate bioavailability – especially for charged polymers.

The conceptual framework presupposes that the physico-chemical properties of the polymer of interest indicate that external and/or systemic bioavailability of the polymer product or of a fraction of the polymer product is possible. It is stated that most of the polymers submitted to Tier 1 screening will most likely not reveal any effects and a higher-tier follow-up screening is unlikely to be relevant. We would therefore like the ECETOC to further elaborate on a suggestion of a concrete threshold parameter (and methods to establish it) applicable to polymers that would allow a better valuation of the internal bioavailability concept.

4.2. Do you agree with the considerations presented for test material selection?

Whilst we agree that the tested polymers should be representative of the UNIQUE PRR, there should be a way to limit testing, proportionate to the number of polymers included in a UNIQUE PRR.

We suggest a worst-case testing approach (e.g., testing the lowest molecular weight polymer) instead of testing both extremes of the group.

Additional comments

In addition to the suggestions listed above, FEICA would like to reflect on some additional points.

We believe that particular attention should be given to low/medium molecular weight reactive polymers. These materials in the application phase (coating, adhesive, sealant and elastomer) react to form a cross-linked polymer that has a theoretical 'infinity' MW. These kinds of products should also be taken into consideration, e.g., by applying the polymeric precursor concept.

We also consider that tonnage band requirements for polymers should be revised because polymers are generally placed on the market in higher tonnages but, at the same time, lower hazards are expected (see the table below). It has to be considered that, based on how groups are defined, the mere addition of small tonnages of many individual similar polymers will easily exceed 10 tons or even 1,000 tons in cases of customized polymers for adhesives and sealants. This is the case already in other jurisdictions such as Canada.

Moreover, one polymer CAS number may contribute to all polymer types (1, 2 and 3), and here type subdivision based on MW adds additional complexity in the registration. More clarification on how the tonnages and subdivision into 3 types will be considered by tonnage is needed.

We would suggest the following approach for polymers tonnage bands:

REACH Annex Requirements (adapted for polymers)	Tonnage band requirements for substances (current)	Tonnage band requirements for polymers (proposed)
No registration	**< 1 ton**	**< 10 tons**
ANNEX VII	**1-10**	**10-100**
ANNEX VIII	**10-100**	**100-1,000**
ANNEX IX	**100-1,000**	**> 1,000**
ANNEX X	**> 1,000**	**-**

Finally, we would like to suggest a revision of the wording 'unique PRR'. Alternatives such as 'group PRR', ,'generic PRR' or 'class PRR' might possibly be more clearly understood. In our opinion, the concept of 'similarity' to identify polymers would also be more suitable than the concept of 'sameness'.

We appreciate the opportunity provided by the European Commission to contribute to the regulatory discussion and remain available for any technical input may be needed from us.

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