



Downstream Users of Chemicals Co-ordination group

19.09.2022

IMPACT OF POLYMER REGISTRATION ON DOWNSTREAM USER FORMULATORS

Over the course of 2020-2022 the Commission has been working to “make a proposal to extend the duty of registration under REACH to certain **polymers of concern**”.¹ As part of the CARACAL-subgroup on polymers DUEG has worked to contribute constructively and collaboratively to this discussion.

At the 45th CARACAL meeting in July 2022 the [Commission outlined the options to be considered in their impact assessment](#) for polymer registration. In this paper DUEG members highlight the importance of polymers for downstream user formulators and point out key impacts for the different proposals.

As of the new polymer requirements, many downstream users will become registrants for the first time.

¹ Chemicals Strategy for Sustainability Towards a Toxic-Free Environment
<https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>



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Why are polymers used by DUCC members?

Polymers are used in Downstream User products for a wide variety of applications. The technical function delivered by a polymer will depend on the type of polymer and on the product category in which this is used. In addition, the same polymer can also provide multiple functions within the same product e.g. an opacifier influences also the viscosity. Below is a brief overview of why polymers are used by DUCC members.:

Examples of Uses of polymers by DUCC members

Viscosity modifier

Foam control/anti-foaming agent

- e.g. stops excess foaming in bottles during filling, reducing/eliminating the risk of foam generation during the washing process in detergents

Emulsifier

Dye

Opacifier

- e.g. optical differentiation of products that affects consumer choice

Rheology modifier

- offers high low-shear viscosity and pseudoplasticity (shear-thinning rheology) to formulation. This is important because it helps maintain the stability of the dispersion. Without this stability the detergent formulation is vulnerable to the separation of phases, a drawback from the standpoint of aesthetics, shelf life and performance

Reactive binders

Non-reactive binders

Curing agents

Adhesion promoters

Plasticizers

Builder/co-builder (e.g. provides functions essential for controlling water hardness)

Complexing/sequestering agent

Surface modifying agent/ Surfactant (helps control surface tension properties)

Thickener

Anti-redeposition agent

Water retention

Suspension agent

Thin soluble films

Encapsulating fragrance

- The encapsulation of fragrances in fabric enhancers, detergents and in wash scent beads helps achieve a long-lasting scent (e.g. the fragrance is still perceivable days or weeks after washing fabrics such as clothes, bedding, and towels) whilst reducing significantly the quantity of fragrance used. Encapsulation technology is the most sustainable and resource-efficient way to dose fragrances in consumer products. In addition it delivers higher satisfaction and financial benefits to consumers (through lower product prices).

The impact of the different policy options

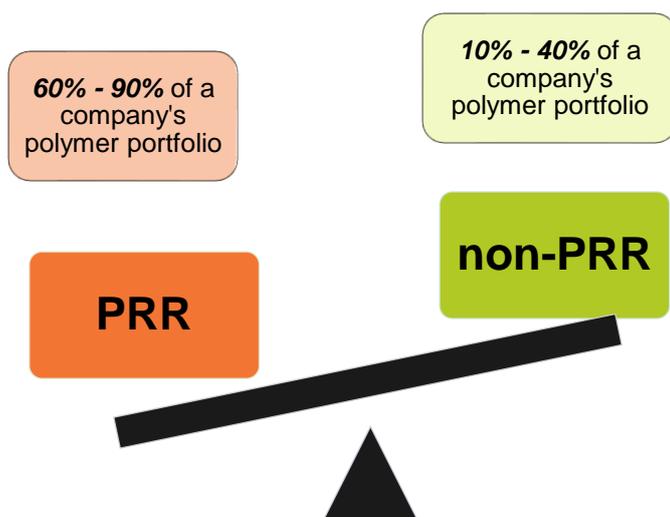
PRR vs non-PRR

Comparing

- #9a: more strict criteria to identify PRR
- #9b: less strict criteria to identify PRR

Based on the proposals outlined by Commission at the CARACAL meeting in July 2022, DUCC members have been able to identify the following impacts

The split of Polymers Requiring Registration (PRR) and those not Requiring Registration (non-PRR) is estimated to be:



Based on the data available, most companies will need to register the majority of their polymer portfolio. This will lead to a very high number of registrations, but the benefits of these are not always clear. Upon assessing the sub-options being proposed by the Commission, DUCC can also share the following:



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Option	Impact on DUCC members
#9a: Polymeric precursors exempt from registration if handled under Strictly Controlled Conditions	Very few polymers are likely to meet such strict conditions without putting in place significant additional infrastructure, which may not be practical, implementable or the associated costs would not outweigh savings in registration. In practice, the exemption will not be used.
#9b: Polymeric precursors exempt from registration if handled under Adequately Controlled Conditions (as currently handled)	Depending on the sector and the business the impact may vary, but up to 85% of polymeric precursors would be subject to the exemption. It is important to avoid creating a disproportionate burden on the industry. Stricter requirements do not ensure greater safety.
#9a: Polyesters have no special rules. To be assessed against PRR criteria like any other polymer	No exemption
#9b: Polyesters built from a list of ECHA-approved monomers are exempt from registration	Depending on the sector and business the impact may vary, but up to 60% of a company's portfolio would be subject to this exception. Polyesters are known to break down in aqueous media into their building blocks (monomers). These monomers are known and of negligible hazard. Thus, they are considered to be safe for human health and environment (as found by EPA in 1995). Similar registration exemptions have been granted in the USA, Canada and Australia
#9a: Polymers > 1000 Da with low oligomer content (< 2% of MW <500 Da, < 5% of MW <1000 Da) are PRR	The number of registrations of option #9a would increase between 25% - 50%, depending on the company, compared to #9b. DUCC clearly favours option #9b.
#9b: Polymers > 1000 Da with high oligomer content (< 10% of MW <500 Da, < 25% of MW <1000 Da) are PRR	



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Notification

Comparing:

- #10a: Detailed information for PRR and non-PRR, deadline 3 years Entry into Force
- #10b: Notification with fewer information requirements for PRR & non-PRR. Plus pre-registration with more information only for PRR, 1 year after Entry into Force for notification, 5 years for pre-reg for PRR

The comprehensive notification requirements requested for #10a would effectively result in a “registration (light)”. If detailed information is needed for notification as per #10a then companies will need a significant amount of time to gather this information.

The unintended consequences and costs linked to the provision of basic physicochemical data include:

- Re-testing of most polymers
- Shortage of polymer testing capacity due to an increased demand for testing to external contractors from SMEs
- Need to allocate skilled professionals to compliance instead of innovation - for example research and innovation leading to substitution
- Comparative lengthening of the notification process (+ 1 year) to perform the test and to deal with the reduced testing capacity

Companies will need to chase up their non-EU supply chains and generate new analytical data that will show the specific information being requested.

DUCC asks to make the notification timelines proportionate to the notification requirements.

Grouping

Comparing:

- #10a: [ECHA proposal](#)
- #10b: [ECETOC proposal](#)

The ECHA model is likely to lead to a high number of registrations as one CAS number can be split into many groups. (e.g. polyX polymer becomes – polyX polymer high Mn, polyX polymer med Mn, polyX polymer low Mn – so one CAS, three separate registrations).

If there are three years to notify, adequate time must then be allowed for grouping and subsequent registration, in order to avoid disadvantages to SMEs and first-time registrants for low volume polymers.

Other comments

If in future companies still need to register monomers in an imported polymer as well as the polymer itself, this means the regulatory cost of importing polymers may be higher than that of a non-polymeric substance. This is disproportionate. Therefore, DUCC requests:

- That for imported polymers the registration of the monomers is no longer mandatory



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- For polymers manufactured in the EU, Article 6.2 of REACH should be amended such that monomers can qualify as intermediates under the appropriate conditions for the purposes of registration.

Note: Numbers shared can only be rough estimates. Depending on their respective product portfolios, the impact on our member companies may differ significantly. We take this into account by providing a range. As the number of polymers produced by each member company will differ, the figures reported here provide an overall perspective.

About DUCC

DUCC is a joint platform of **11 European associations** whose member companies use chemicals to **formulate mixtures** (as finished or intermediary products) for professional and industrial users, as well as for consumers.

DUCC focuses on the downstream users' needs, rights, duties and specificities under **REACH** and **CLP**.

DUCC's membership represents several important industry sectors, ranging from cosmetics and detergents to aerosols, paints, inks, toners, pressroom chemicals, adhesives and sealants, construction chemicals, fragrances, disinfectants, lubricants, crop protection, and chemical distributors industries. Altogether, their membership comprises more than **9.000 companies** across the respective sectors in Europe, **the vast majority being SMEs**. The calculated turnover of these companies is more than 215 billion euros in Europe.

For more information on DUCC: www.ducc.eu

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DUCC's public ID number in the **Transparency Register of the European Commission** is: **70941697936-72**