

## Eurocolour Comments on the Essential Use Concept – Final Report

### Introduction

According to the Chemicals Strategy for Sustainability, the concept of essential use should be applied in all relevant EU legislation for both generic and specific risk assessments. The integration of the concept in REACH is one of the key components of the ongoing reform of the restriction and authorisation processes under REACH. In particular, the criteria for essential use should be used for making decisions on authorisations and on whether or not derogations to restrictions would be justified for a particular use. Additionally, the implementation of the essential use concept is to be considered in the generic risk management approach (GRA).

The now published report “Supporting the Commission in Developing an essential use concept”, published in April 2023<sup>1</sup> describes how the essential use concept could be implemented in the existing EU regulations. And this includes, in addition to the REACH Regulation, for example, the Restriction of Hazardous Substances Directive, Food Contact Materials Legislation, the Cosmetic Products Regulation, the Taxonomy Regulation, and the End-of-life Vehicles Directive.

#### **Our key remarks and message:**

- The essential use concept as stand-alone decision-making criterion for the use of substances and mixtures is absolutely disproportionate and unworkable
- The essential use concept should only be used as an option, if at all, and should not be used as the main trigger for regulatory decisions
- Turning away from proven risk-based systems ignores the safe handling of chemicals in the last decades under REACH
- The assessment of what is "essential" requires a thorough assessment, if not a case-by-case evaluation
- The actual impact of the most harmful chemicals should be qualified and quantified to support an appropriate essential use concept

Eurocolour supports the overall objectives of the CSS but has serious concerns that the measures described in the CSS would not serve the stated goals. Eurocolour is an industry association representing European manufacturers of various colourants and fillers. The continuous quality improvement of our members' products is a top priority. It is also one of our tasks to take actively part in shaping of new regulatory developments by giving scientifically sound input, based on the experience and know-how of our member companies. Therefore, we consider the essential use principle, especially in combination with the extension of the

---

<sup>1</sup> [Supporting the Commission in developing an essential use concept - Publications Office of the EU \(europa.eu\)](https://europea.eu)

generic risk approach to further hazard classes, to be fundamentally unsuitable as a stand-alone measure to be introduced into various existing regulations. We have already explained this in our policy paper "[Eurocolour's comments on the essential uses approach](#)"

Eurocolour carefully reviewed the essential use concept report and discussed internally the potential impact of the points evaluated by the publication. As manufacturers of chemical substances and coloured mixtures we consider a workable implementation and the practical consequences as key aspects of any new regulatory initiative.

The following comments and explanations are based on this specific point of view.

#### Essential Use concept under REACH – assessment of the 4 options under discussion

The most important part of the review is the evaluation of the different options for introducing the essential use concept in the REACH Regulation. The report considers 4 options:

- A) **Non-binding guidance** for the introduction of the essential use concept in authorisation and restriction, as an optional consideration, complementary to current provisions.
- B) **Binding implementing regulation and supporting guidance** for the introduction of the essential use concept in authorisation and restriction, as an optional consideration, complementary to current provisions.
- C) Introduction of legal changes in REACH for essential use under authorisation and restriction, with the essential use concept being a **complementary approach to the socio-economic (SEA) route and adequate control route (ACR) to decide the authorisation**. The essential use concept would be used to decide on all derogations from restrictions.
- D) Introduction of legal changes in REACH for essential use under authorisation and restriction, with the essential use concept **replacing the socio-economic route as an approach to decide on authorisation and derogations from restriction**. In addition, the adequate control route for authorisation would be eliminated, so that all applications for authorisation and derogations from restriction would be based on the essential use concept.

We considered each of them in detail and came to the following findings:

- Options A and B, as also underlined by the reviewers, have the same effects on the decision process on a chemical substance, although the legal status would be different. For these options, therefore, the key parameter is a check by the authorities to decide whether the administrative burden of changing a regulatory text is justified.
- Option C, which already introduces a change in the derogation mechanism in restrictions, with the essential use concept as a mandatory tool, will immediately impose a process whose application might result in even more complex evaluations as is currently the case.
- Option D, which aims to substitute the socio-economic route and eliminate completely the adequate control route, is a **complete change of the current REACH approach and from our point of view completely disproportionate**. Currently, the REACH Regulation requires companies to demonstrate the safety of their chemicals and to ensure appropriate/adequate risk management. Both the evaluation of the socio-economical aspects and the risk assessment are ways to reach a balanced conclusion on the whole substance status. This would be completely eliminated under Option D and essential use would be the only decisive criterion. In particular, disregarding the difference between hazard and risk aspects can drastically change the status of some

Eurocolour e. V.

substances, e. g., when we consider reactive substances consumed or changed during chemical processes.

- For options C and D, a strong impact is also predicted as regards the loss of essential uses, due to the possible cessation of production of specific chemicals altogether. Considering the fields covered by the “essentiality” concept, the possibility of such a loss should be taken very seriously and, again, better quantified through a first explorative approach.

Considering the potential impact on our sector of the chemical industry, but surely also on entire value chains, either one of Option A or B would be better suitable to the current understanding of the essential use approach.

### Findings of the case studies in the report

In chapter 4 of the report published, a number of case studies have been developed to assess the feasibility of the essential use concept in the different EU legislations. Looking at the conclusions reached by the test cases in the review, it is crucial that at least the initial implementation phase allows a certain flexibility to test the approach on a larger number of real cases. Contrary, option C and D would already bind to the application of the essential use approach without any possibility to test its interaction with the existing processes “in the field” and check the real relevance of the potential issues identified in the review.

As mentioned, the report presents several conclusions which support the recommendation above, and which will be explored in detail in the following paragraphs.

As a first general identified issue, the report clearly underlines two broad and extremely relevant uncertainties on the background of the performed analysis:

- the impacts of the most harmful chemicals, which the essential use concept aims to address, are largely unknown.
- the number and identity of uses and substances to be impacted by the essential use concept are unknown.

These two wide knowledge gaps are, in our opinion, already reason enough that a non-substance specific essential use concept should not be applicable to chemical substances, even if it is only intended for the most harmful substances.

Conclusions from the specific case studies address additional aspects which corroborate the necessity of a careful approach:

- In general, the analysis showed that the existing regulation already performs comparably well. In some cases, the same result is expected when introducing the essential use concept, in others the concept could just be expected to allow a fine-tuning of the existing regulatory measures. Only in the one case study, considering the substance Trichlorethylene (TCE) under the EU Taxonomy legislation, it was concluded that the currently authorised uses of TCE would unlikely fall into the essential use category.
- However, the consideration of what is ‘essential’ or not is not always evident and would in many cases require a thorough assessment, if not a case-by-case evaluation. As especially underlined, e.g., in the case study on the REACH Restriction of Cadmium

Eurocolour e. V.

and potentially involving cultural heritage, *“detailing a rigid definition for what constitutes a use that is ‘critical for the functioning of society’ on the basis of cultural heritage is very challenging, and ultimately is a case where the decision would likely be almost entirely political. This may need to be supported by additional or more extensive or targeted public/stakeholder inputs. This could make the assessment process for a case like this one more time-consuming, burdensome and controversial”.*

- In the case study on lead in alloys under the Restriction of Hazard Substances Directive (RoHS), where there is a very broad application field, it is concluded that *“For the majority of cases the necessity/criticality cannot be quickly determined and requires an in-depth analysis. As the uses are oftentimes very specific it is difficult to predict the outcome of such an analysis. Thus, the outcome from the assessment based on the essential use concept is not necessarily more predictable than from the current process”.*
- Another important factor which would have significant consequences in the communication throughout the value chain, is the acceptability of alternatives. As noted in the case study on use of cadmium and lead in ceramic and vitreous food contact materials *“In terms of lack of alternatives, while alternatives are available, their ‘acceptable’ level of performance, and what level of performance loss could be acceptable to users, would need to be determined.”* This aspect will be decisive for the future of the chemical and manufacturing industry.

## Conclusion

In conclusion, looking at the overall review results and observations, there is no clear indication that the essential use approach would improve existing processes substantially; on the contrary, many gray areas are identified which, in our opinion, speak against any too rash implementation. Therefore, the essential use concept should only be used as an option, if at all, and should not be used as the main trigger for regulatory decisions.

Regarding the proposed options for the implementation in the REACH Regulation, if necessary at all, we strongly recommend the proposed Option A or B as a better fit to deal with the different uncertainties linked to the possible effects of the introduction of this approach.

## **Your contact partner at Eurocolour:**

Dr. Heike Liewald, Managing Director  
+49 69 2556 1351  
[liewald@vdmi.vci.de](mailto:liewald@vdmi.vci.de)

Registration No. EU Transparency Register: 90219 263 4607-21

## About Eurocolour:

*Eurocolour e. V. is the umbrella association for the manufacturers of pigments, dyes, fillers, frits, ceramic and glass colours, and ceramic glazes in Europe*

Eurocolour e. V.

Mainzer Landstraße 55  
60329 Frankfurt/Germany

Phone: +49 (0)69 - 2556 - 1351  
Fax: +49 (0)69 - 2556 - 1250

[www.eurocolour.org](http://www.eurocolour.org)  
[contact@eurocolour.org](mailto:contact@eurocolour.org)