Zentralverband Oberflächentechnik e.V.

ZVO position paper on the EU Chemicals Strategy for Sustainability

Promoting a science-based approach in the EU regulatory framework on chemicals

(As of: 26.11.2020)

Zentralverband Oberflächentechnik e.V. (ZVO; engl.: Central Association of Surface Technology) welcomes the publication of the EU Chemicals Strategy for Sustainability. In particular, we consider the planned revision of the REACh restriction and authorisation procedure to be extremely important, especially in light of a necessary simplification of the legal framework as well as removal of red tape. We also strongly support the EU Commission's plan to improve the scientific understanding of chemicals.
However, ZVO criticises that the strategy sets abstract and non-quantifiable targets and foresees blanket bans on substances instead of technically determined limit values. Furthermore, the association puts into question whether the "one substance, one assessment" principle is functional. Above all else, with regard to the unprecedented challenges of the Coronavirus crisis, this strategy comes at an unfortunate time.

Context and subject

In recent years, the public image problem of chemicals has further increased: many people associate words such as “toxic” or “unnatural” with the term “chemicals. However, chemicals are an indispensable part of everyday life. Not only can they be found naturally in all everyday objects, but also in the human body, numerous vital chemical processes take place. When regulating chemicals, it is important to eliminate, as far as possible, any side effects that could endanger human health and the environment. In doing so, safe value limits should be identified based on scientifically sound risk assessments.

With the REACh and CLP regulations, the EU already has the strictest regulatory framework for chemicals in the world. While the general objective can be welcomed, the implementation of these regulations can have visible negative socio-economic effects: for instance, in recent years there have been far-reaching structural shifts in the global chemicals market, with Europe already losing a considerable share of turnover. Assumed pollution and environmental risks have merely shifted to other parts of the world.

Even after ten years, the success of REACh in attaining its stated goals is still not quantifiable, despite efforts made by industry and authorities. For instance, the number of cases of illness avoided by REACh have not yet been analysed and quantitatively evaluated. The General Report on the operation of REACh[1], published by the EU Commission in 2018, does not find any scientifically verifiable added value attributable to the regulation either.

[1] General Report on the operation of REACH and review of certain elements, 05.03.2018;
Link: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:116:FIN

Against this background and in the midst of the Coronavirus crisis, the EU Commission published its ambitious "EU Chemicals Strategy for Sustainability" on 14.10.2020. The strategy outlines, inter alia, measures to achieve the zero pollution ambition for a toxic-free environment as announced in the European Green Deal. The initiatives include:

(i) gradual phasing out from the use of substances such as per- and polyfluoroalkyl (PFAS), unless their use is proven essential for society,
(ii) minimising and substituting as far as possible the presence of substances of concern in all products,
(iii) addressing the combination effect of chemicals (cocktail effect) and
(iv) introducing information requirements in the context of the Sustainable Product Policy Initiative.

Below, ZVO will present the positive and negative aspects of the strategy from the point of view of small and medium-sized companies (SMEs) in the electroplating and surface technology industry.

1. Simplification of processes and removal of red tape

ZVO welcomes the revision of the REACh authorisation and restriction procedures foreseen in the strategy (see page 4 of the Annex of the strategy). With this initiative, the EU Commission aims to simplify and consolidate the legislative framework. Over time, ZVO has repeatedly pointed to the lengthy and costly REACh authorisation procedures. These are often delayed by several years and place a disproportionate burden on both the authorities and the companies concerned, particularly in the case of collective or consortium applications. When adjusting the framework, there is an urgent need to cut red tape of these procedures. This is because the effort required for obtaining an authorisation is currently based on the structures and capabilities of the large-scale chemical industry. The burdens are hardly bearable for small or medium-sized companies. For instance, an application for approval consists of a Chemical Safety Report (CSR), an Analysis of Alternatives (AoA) and a Socio Economic Analysis (SEA), all of which are elaborated in over 100 pages. Each requires several years of work by a highly qualified person (cf. dissertation). Medium-sized companies can only achieve this with the support of external service providers. The service providers charge up to six-figure sums for each case. These funds are therefore not available for making investments in technology and innovation.

- The authorisation and restriction procedures have to be designed in such a way that they do not impose a disproportionate burden on medium-sized companies and ensure legal and planning security.

2. Objectives must be quantifiable, realistic and concrete

ZVO fully supports the overall objective of the strategy, which is to ensure safer use of chemicals. Many companies in our industry have been investing in innovative production methods for some time now, in order to guarantee the safety of their employees and the protection of the environment. Nevertheless, it is important to take into account the progress already made in the area of chemicals regulation. Quantitative figures show that the life expectancy of European citizens has increased and infant mortality has fallen. We therefore question whether the situation is as urgent as described in the strategy. The ambitious goals of the strategy and the pressure to act should be backed up with concrete and realistic risk scenarios and data. Otherwise, the principle of proportionality is not sufficiently taken into account. In this context, the Pareto principle, which states that achieving the last 20% of a target requires 80% of the effort, should be observed. Companies are already subject to considerable burdens under the REACh regulation and other EU and national laws. Adding further regulation with the aim of making a small improvement requires efforts that many players in the industry cannot sustain. As a result, companies will move to third countries or stop production.

For this reason, ZVO remains critical of the approach taken in the strategy. By its very nature, the strategy was formulated in general terms. Many of the announced measures therefore currently lack substance and concrete quantitative and measurable objectives (this applies to the appendices of the strategy). Moreover, the strategy over-simplifies issues: there are numerous references to risks to human health and the environment, without using figures from studies that have been subject to the usual scientific control mechanisms.

On the one hand, many claims made in the strategy incite unjustified negative connotations associated with chemicals. On the other hand, successful management of chemicals and derived products is not sufficiently recognised. The safe use of hazardous chemicals has contributed to the growth of the European economy for many decades and will remain a key pillar in the future.

- When implementing the strategy, the EU Commission should further specify the overall orientation of the planned measures and define quantitative criteria to measure the achievement of the strategy's objectives. In particular, a scientifically substantiated quantification of the "current state" is a prerequisite for the evaluation of the achievement of the strategy's objectives.

3. „The dose makes the poison" – EU Chemicals Regulation should be based on scientific principles

ZVO supports a chemicals regulation that operates on the basis of scientifically sound data and risk management measures as this discourages blanket rejections of chemicals. It considers the EU Commission's commitment to improve the scientific understanding of the effects of chemicals, as outlined on page 21, to be of utmost importance. Any planned regulation should be based on epidemiological evidence.

ZVO rejects the „one substance, one assessment" principle set out in the strategy. The principle aims at assessing the risks potentially posed by a substance in general. However, in order to obtain a full understanding of the effects of a substance, different applications of that substance would have to be analysed in detail. Not the toxicity of the substance itself is decisive, but the concentration at which it is used and under what precautions. Furthermore, this approach contradicts the consideration of the risks for "vulnerable groups" identified in the strategy (see page 9 of the strategy). This is due to the fact that each group would require a separate evaluation. However, using one of these vulnerable groups as the main reference point for action is also not a viable solution, as it would have far-reaching economic implications without a vast majority of the population benefiting from additional protection. Instead, this might only bring comparatively small benefits for few people. In this context, the proportionality of means should be maintained.

Furthermore, the association views critically the fact that the EU Commission seeks to introduce a mixture assessment factor into REACh (see page 12 of the strategy). There are doubts as to whether such a factor could lead to scientifically reliable data. The assumed toxicity of many substances is based on conclusions and extrapolations of data rather than empirical epidemiological findings. The addition of a mixture assessment factor therefore increases inaccuracies and leads to even more unreliable and possibly regrettable conclusions.

In our view, blanket bans of substances without realistic and scientifically verified risk assessments are also not conducive to achieving the desired objective. The strategy intends to ban substances identified as hazardous, e.g. PFAS if their use is not essential for society (see page 14 of the strategy). This approach further contributes to the increasing unsubstantiated rejection of chemicals by the general public without measurably increasing the protection of human health and the environment. Instead, we need concrete data on the

risks posed by some chemicals that can be prevented by targeted regulation. Furthermore, the concept of “essential use” needs to be further clarified and defined.

Blanket bans or authorisation obligations are particularly unsuitable and disproportionate if they are applied to SVHC use risks, which are mostly or even exclusively present in the workplace and where, in addition, the (end) product is free of the SVHC substance. Clearly defined limit values for the workplace can cover exposures effectively, are well-established and easy to assess and measure, and therefore constitute a better regulatory instrument.

- The EU Commission should provide a legal base, which includes thorough scientific analyses of potentially hazardous substances. Regulatory measures should be goal-oriented, clearly quantified, and thus verifiable (e.g. through clear limit values).

4. Taking into account the impact of the Coronavirus crisis

In the strategy, the EU Commission writes that the transition to the use of sustainable and safe chemicals creates great economic opportunities. It also considers the transition a main component of the recovery strategy following the Coronavirus crisis (see page 4 of the strategy). This claim is difficult to understand. The ambitious investment goals and far-reaching regulatory initiatives are hard to cope with for the affected SMEs – particularly in the midst of the worst economic crisis of the post-war period. In its latest REACh report of 2018, the EU Commission claimed that the REACh regulation works well and ensures a high level of protection for people and the environment. Nonetheless, the present strategy, which is put forward in the current time of crisis, contains numerous regulatory initiatives with a far-reaching scope that threatens the very existence of SMEs.

For instance, on page 17, the strategy announces the development of another database for chemicals. As an association representing SMEs, we are convinced that one of the fundamental purposes of digital transformation should be to reduce excessive bureaucracy and to make regulatory and administrative processes easier and faster. However, the requirements of such databases have the opposite effect: they disproportionately require the limited resources of SMEs. For example, the SCIP database already significantly increases the burden on the companies concerned.

- In light of the unprecedented economic effects of the measures to combat the Coronavirus crisis, new regulatory initiatives that constitute high financial and administrative burdens should be postponed to protect SMEs. Alternatively, significantly longer transition periods should be granted to SMEs.

Conclusion

It is certainly important and appropriate to take an ambitious approach with targeted measures to reduce risks in the area of chemicals regulation. However, it hardly seems possible to produce full impact assessments for over 50 individual measures in the envisaged time period. This would be necessary in order to be able to rationally assess the effectiveness and proportionality of each measure. In the implementation of this strategy, scientific principles should not become a pretext for regulation, by selecting only parts of findings to justify actions. As a result, the unjustified and undifferentiated renunciation of chemicals as a whole would be reinforced. Moreover, high regulatory burdens would threaten the very existence of numerous SMEs in the electroplating and surface technology industry. Such an approach would neither help protect human health nor the environment.