

The new Chemicals Strategy for Sustainability **First Evaluation of the VdMi regarding opportunities and** **risks for the industry**

The EU Commission adopted the new chemicals strategy for sustainability on 14th October 2020. It is part of the zero-pollution target and thus part of the EU Green Deal, the political action plan for EU climate policy. The new EU chemicals strategy focuses on several measures in the field of chemicals management to improve environment and health safety and reinforce innovations in the field of safe and sustainable chemicals. No fewer than 54 actions are declared, which will become dominant in a flood of regulatory changes within 4 years; both in the chemicals regulation REACH, the CLP regulation as well as in numerous other legal texts such as regulations in the field of cosmetics, toys, food contact materials as well as environmental and occupational safety. Their implementation will have a significant impact on the entire chemical industry and thus also on all member companies of the VdMi.

In this first evaluation, the VdMi addresses some important aspects of the chemicals strategy and looks at opportunities and risks.

Ambitious schedule

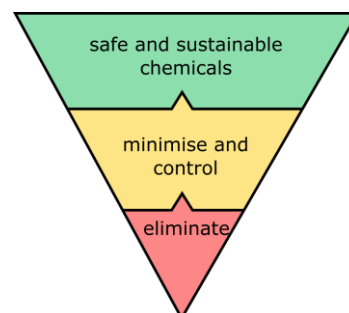
The chemicals strategy for sustainability bundles measures in the field of chemicals management, which are intended to increase the safety of citizens and the environment while at the same time strengthening innovations in safe and sustainable chemicals.

The publication of the chemicals strategy contains a description of the individual actions, a detailed schedule and some information documents that summarize the preliminary work. The first measures should start in 2020, and the measures will extend over 4 years from 2021-2024.

Due to the scope of the total of 54 proposed measures, each of which may include several stages, consultations, revisions and new submissions, the Commission's intention with regard to the chemicals strategy is very ambitious in terms of both time and content. Extensive changes to the two most influential chemical regulations in the EU, the REACH regulation and the CLP regulation, are to be started in 2021.

What is the EU planning with the new chemicals strategy - what is the goal?

The aim of the sustainability strategy for chemicals is a non-toxic environment. It is important to no longer use questionable substances and to remove them from the material cycle through appropriate measures in waste management and recycling. Hazardous substances for humans and the environment should be minimized as far as possible and, if their use is necessary, controlled by risk management measures. As a result, only "safe and sustainable chemicals" should be used wherever possible.



Focus on precautionary principle and sole hazard assessment

At the beginning of its strategy paper, the EU Commission itself states that the EU already has one of the most comprehensive and safest regulatory frameworks for chemicals. Protection for the environment and consumers is unique in terms of form and scope. Nonetheless, substantial

packages of measures are being proposed to further tighten chemicals regulation. The chemicals strategy is characterized by the precautionary principle and an approach that only focuses on the dangerous properties of a substance or mixture. The extent to which a substance classified as hazardous is safely handled or used is not taken into account. From this, the EU Commission derives extensive tightening of chemicals law and restrictions for chemicals in consumer products. Restrictions on entire groups of substances could be made in consumer or consumer-oriented products without prior risk assessment.

What specific measures are proposed?

Threat of tightening due to stronger legal framework and more data collection

- Extension of the information requirements in the REACH regulation
- Extension of the registration requirements for certain polymers
- Extension of the criteria for SVHC substances: ED, vPvM, PMT
- Group restrictions in REACH / use restrictions for groups of substances

Registration and information obligations under REACH are to be adapted and expanded. In future, polymers will also be subject to registration requirements. In addition, it is intended to significantly expand the information requirements for certain hazardous substances for smaller tonnages; it is also planned to make chemical safety reports mandatory for registrations in the 1-10 t range. This would result in considerable additional work, especially for substances with lower tonnages.

It is also planned to expand the list of SVHC criteria to include endocrine disruptors (ED), very persistent and very mobile (vPvM) and persistent, mobile and toxic (PMT) substances. Since no clear criteria have yet been defined for all of these properties, the full scope cannot yet be assessed.

In addition, combination effects in mixtures are to be given greater consideration in the future by introducing so-called MAF values (mixture assessment factor). How these are determined and how exactly this factor should affect a classification, for example, is still unclear. However, it is to be feared that mixtures will be more strictly regulated and restricted in the future.

New definitions and hazard classes in CLP Regulation

- New definitions: safe and sustainable, essential use
- New CLP hazard classes: ED, PBT, vPvB, PM
- Revision of the nano definition

In addition to the term “safe and sustainable chemicals”, the chemicals strategy also introduces other new, previously not clearly defined terms such as “essential uses” or “substances of concern”. This must not mean that the hazard classification alone is decisive. Hazardous substances can also be used safely and contribute to sustainability.

Several new hazard classes are to be introduced in the CLP regulation in order to be able to clearly communicate health and environmental risks that were previously difficult to determine. Specifically proposed were new hazard classes for endocrine disruptors (ED) as well as substances that are persistent, bioaccumulating and toxic (PBT), very persistent and very bioaccumulating (vPvB) or persistent and mobile (PM).

In addition to the newly introduced definitions, the definition for nanomaterials is also to be revised and standardized. Associations have been calling for a standardization of the nano definition across all regulations for several years. This would eliminate confusion and simplify customer communication. This would also mean that current deviations from the EU definition in product-specific regulations, such as in the EU Cosmetics Regulation, would no longer apply.

Streamlining of responsibilities on the part of authorities

- New approach: One substance – one assessment
- Re-organisation of responsibilities

Further measures provide for a reorganization of the authority's responsibilities, among other things, to simplify procedures (so-called "one substance - one assessment"). The VdMi supports a reduction of the bureaucratic effort and an acceleration in particular of approval and admission procedures. However, such a restructuring and streamlining also harbors the risk that details or specific information will receive less attention. Due to the diverse areas of application of substances and mixtures, there are also many aspects to consider. For example, migration limit values in toys or food contact materials are assessed differently than an oral ingestion of an industrially used substance. Experience already shows that applications cannot always be processed by an experienced expert. Further reduction of responsibilities must not lead to a deterioration in processing.

Evaluation

From the perspective of the VdMi, the existing instruments for classification, restriction or approval (REACH and CLP Regulation) are sufficient to regulate chemicals and ensure their safe use. This is proven by various analyzes, including the REACH Review from 2018. Instead of setting up new formal hurdles, we believe that the existing instruments should continue to be used efficiently. Therefore, a departure from the risk-based assessment approach cannot be advocated.

The expansion of the information requirements for substances, especially for tonnages <10 t, would apply to all substances that are subject to registration, such as pigments, fillers, ceramic frits, and mean considerable, extended data requirements. The effects of the expansion of the SVHC criteria cannot be quantified generally but further information obligations are generated in the supply chain. This threatens further raw material losses ("phase-out"). The consideration of mix effects will lead to an increased CLP classification of mixtures with all the corresponding consequences. This will influence the so-called downstream legislation in many ways (e. g. waste, plant approval, occupational safety); likewise, consumer and consumer-related legislation (e. g. cosmetics, packaging).

Consequences or assessments of consequences for the newly used but not yet precisely defined terms such as "safe and sustainable chemical" or "essential use" are currently difficult to achieve. This is accompanied by considerable planning uncertainty for the entire chemical industry and companies. The announcement of new CLP hazard classes for ED, as well as PBT, or vPvB or PM, will very likely lead to an increase in the number of hazardous substances or to additional and more complex classifications. The consequences are extensive communication and documentation obligations in the supply chain, an increase in (group) restrictions (e. g. in consumer products) and consequences in the downstream legislation (e. g. waste, plant approval).

We have been calling for harmonization of the EU nano definition for many years. The Commission announced the revision of the EU definition for several years but has not yet implemented it. It should continue to aim to achieve a uniform definition across all regulations.

Conclusion

With the new EU Chemicals Strategy for Sustainability

- Comes a flood of changes and tightening in chemicals law, environmental and consumer legislation.
- There is a threat of loss of essential raw materials.
- Unnecessary (planning) uncertainty is generated.

From VdMi's point of view

- There is no need for further tightening in the regulative field.
- There are serious doubts that
 - o the implementation of these measures in the present form will be practicable for the companies.
 - o the announced measures serve the stated goals. Safe and sustainable chemicals do not exclude hazardous substances!
- The precautionary principle and the CLH classification alone must not be decisive in determining whether a substance / a group of substances may be used in products.

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The Verband der Mineralfarbenindustrie e. V. represents German manufacturers of inorganic (e. g. titanium dioxide, iron oxides), organic and metallic pigments, fillers (e. g. silica), carbon black, ceramic and glass colours, food colorants, artists' and school paints, masterbatches and products for applied photocatalysis.