

Eurocolour position paper on the Commission's paradigm change of substance assessment as part of the Chemicals Strategy for Sustainability (CSS)

Introduction

With the publication of the Chemicals Strategy for Sustainability the EU Commission introduces a new paradigm of substance assessment and management consisting of four cornerstones:

- (1) Introduction of new hazard classes
- (2) Extension of the generic approach to risk management for "the most harmful chemicals"
- (3) Establishing a concept of "essential uses" and
- (4) Amplifying innovation for "safe and sustainable-by-design" chemicals.

The Commission is convinced that these elements will lead to simpler and faster assessments and provide clear signals to all actors.

Ad (1) The Commission intends to expand the current hazard classes by introducing new hazard classes in the CLP Regulation (such as endocrine disruptors, PBTs, vPvBs, PMTs, vPvMs, chemical properties affecting the immune, neurological or respiratory system or are toxic to a specific organ) to protect consumers and professional users. This will lead to a broad range of hazardous substances and an increased number of potential SVHCs. As the example of PFAS, which are highlighted in the CSS, shows, a single property of a substance – persistency – can be cause for identifying the whole group of PFASs as most harmful and transferring the whole group to a generic approach to risk management.

Ad (2) The „generic approach to risk management“ (abbreviation: Generic Risk Approach, GRA) is based on the principle that the intrinsic properties of substances or groups of substances alone determine the risk management measures through regulatory measures, such as a restriction or ban of certain uses, e.g. use in consumer products. In this case, no specific risk assessment takes place, and therefore specific conditions and specific risk management measures determined to ensuring safe use are replaced by generic pre-determined measures. With the extended generic approach to risk management the EU Commission neglects well-defined and proven risk approaches applied under the REACH Regulation and other European chemicals legislation.

Ad (3) With the generic approach to risk management (GRA) becoming the default option for several hazard classes, substances could be banned or restricted although they are proven essential for society. Therefore, the EU Commission wants to establish a concept of essential use and promises definitions of criteria for essential uses. This is to ensure that otherwise banned substances will still be allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no acceptable alternatives with regards to environment and health. Nevertheless, criteria for essential use might differ based on cultural aspects, change of societal needs or impacts like Covid 19.

Ad (4) Last but not least, innovation processes are to be triggered for chemicals, which are “safe and sustainable by design”, which will include inter alia concrete measures developing criteria for „safe“ chemicals. Terms like “safe and sustainable chemicals” are introduced and brought into focus without being further specified.

These four elements describe the Commission’s intention to change the existing chemical assessment at least for large groups of “the most harmful chemicals”, in particular for consumers and professional users.

Planned changes in the framework of the CSS contradict the current assessment of chemicals

The Chemicals Strategy for Sustainability (CSS) focuses on the Generic Approach to Risk Management and thus basically stands in contradiction to the Precautionary Principle by giving emphasis on intrinsic hazardous properties of a substance and neglecting exposure and risk. The latter is the key to a proportionate and non-discriminatory set of measures, since generally there is a risk only when there is exposure to or release of a hazardous substance.

In the CSS it is not taken into account that the chemical industry and its downstream users have good experience and know-how in the handling of chemicals classified as hazardous and have been using them safely for many years.

According to Article 68, Paragraph 2 of the REACH Regulation, the *generic approach to risk management* is already being applied in the current legal framework, whereby this is currently restricted to substances with CMR properties of Categories 1A and 1B, and to the use by the private end consumer.

The extensive package of measures under the *Chemicals Strategy for Sustainability (CSS)* includes a fundamental revision of the REACH Regulation. In this context, the application of the *generic approach to risk management* is to be extended:

As starting point for the application of the approach, it is planned to extend first the intrinsic properties of the substance from the present CMR, Cat. 1A/1B to include endocrine disruptors and substances with PBT and vPvB properties. In a second step, a further extension is to be examined to respiratory sensitisers and to immunotoxic and neurotoxic substances, as well as to substances with specific target organ toxicity (STOT).

The extension of the generic approach to risk management to other hazard classes would substantially increase the number of affected relevant substances, and therefore the number of corresponding affected products (both for end consumers and professionals). The criteria for the new hazard classes, such as for endocrine disruptors, have in part not yet been established, which leads to the scope of possible effects being hard to assess, and generates legal uncertainty.

Introduction of the new terms „safe and sustainable“ and „essential use“

Terms like “safe and sustainable chemicals” are introduced and brought into focus without being further specified. In addition, the strategy speaks of “essential/significant uses”. This is a new concept that needs to be thoroughly evaluated before being incorporated into the legal framework. A clear description of these new requirements is essential but may depend on many factors which may also change. We therefore do not consider this approach to be feasible. With continued use of specific risk assessment and conclusive risk management measures, safe handling of chemical substances is possible.

With regards to our specific products, the most prominent use of pigments is in coatings and paints. The benefits of pigments and fillers in most applications are often underestimated, they fulfill important functions in terms of functionality and sustainability.

Some Considerations for Eurocolour products

The combination of the generic approach to risk management and the concept of essential use constitutes a new paradigm for the assessment of chemicals. With this proposal the Commission seems to replace existing specific risk assessment by an incomplete and therefore misapplied use of the precautionary principle based only on hazard assessment and ignoring use and exposure. The implementation of the essential use concept across the whole industry would need many more specific justifications compared to its use in the Montreal Protocol. The Montreal Protocol which has been signed by 197 countries regulates clearly defined specific substances with proven ozone-depleting properties and has introduced the essential use concept within a strict framework appropriate to the specific scope.

The essential use question is quite complex, as the example of the colourants shows: Whereas colourants which play an important role for communication would be regarded as essential by the majority, would we consider colourants that provide aesthetic pleasure only as nice-to-have or as essential in support of mental health? Is a colourant used in art nice-to-have or essential? Long lasting discussions can be assumed regarding the categorisation into “essential” and “nice-to-have”, that would certainly not end in a simpler and generally faster implementation of this concept as supposed by its supporters.

In the field of colourants (that are used in any products) existing regulatory measures can be considered as sufficient to protect humans and the environment. Where colourants, i. e. pigments or dyes, had been identified as to be CMR Cat. 1A or 1B in the past, they have been banned from use, especially for consumer products, no matter if the end product is “classified” as essential or not. In this case it would not make any sense to keep the dye or pigment for specific consumer products that are critical for society.

Thus, for proven SVHC properties, the current system goes far beyond the new paradigm. As for suspected SVHC substances, the REACH provisions allow many options for regulatory measures – it also can be demonstrated that the authorisation and restriction procedures according to REACH Art. 55 et seq. are having an immediate effect on the value chain beyond the regulatory goal: as soon as a substance is listed on the candidate list, brand manufacturers of consumer goods request from their suppliers to phase it out as soon as possible.

Summary

Our key remarks and messages:

- The Chemicals Strategy for Sustainability fundamentally contradicts the precautionary principle by focusing exclusively on the hazardous properties of a substance and neglecting exposure and risk.
- The GRA will result in many hazard classes triggering a blanket ban of many products and chemicals used by consumers and professional users.
- Our industry's products such as pigments, dyes, fillers or ceramic materials are broadly used and strongly contribute to the quality and lifetime of many materials and thus to their sustainability.
- Substances deemed inappropriate have been already phased out, leaving only substances which can be handled safely.
- Turning away from proven risk-based systems ignores the safe handling of chemicals in the past decades under REACH. This will result in a possible loss of essential chemicals as raw materials without any benefit to consumers /society
- The introduction of the „safe and sustainable by design approach“ without appropriate standards and definitions might trigger another rise in demand for new „safe“ chemicals and „sustainable“ chemicals without proven benefit for consumers /society.
- The introduction of new terms and the departure from the tried and tested specific risk assessment would mean a change of paradigm in the entire chemicals assessment for which neither a need nor a justification is seen.

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About Eurocolour:

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

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