

Substances of Concern

A New Cornerstone for Chemicals Management in the EU

The EU Chemicals Strategy for Sustainability (CSS) shed a new light on the concept of ‘Substance of Concern’. So far, risk management measures for chemicals (in products) in the EU was risk-based, mostly preceded by an identification as ‘Substance of Very High Concern’ and/or by the demonstration of a risk to human health or the environment. By contrast, the concept of ‘Substance of Concern’, increasingly present in a variety of horizontal and sectoral EU legislations, is symbolic of a shift to a more hazard-centric approach to chemicals regulation in the EU, with important consequences in various regulatory contexts.

Background of the Concept of Substances of Concern

Historically, in the EU’s chemicals legislation (notably REACH), concerns posed by a substance only trigger the adoption of risk management measures to the extent that they reach a certain level of gravity, possibly initi-

ated by their classification in a given hazard class under the CLP Regulation, thereby qualifying a substance as ‘Substance of Very High Concern’ (SVHC). This mechanism serves as a flagging mechanism for the most hazardous substances.

Such identification does not trigger any risk management measures (RMM)

per se, but merely information requirements across the supply chain. Beyond that, it may attract authorities’ attention towards the eventual adoption of further RMM, such as for example an inclusion in the REACH Authorization List or a restriction.

A broader understanding of the notion of Substance of Concern can be found in the “sectoral” biocides and plant protection products regulations. Under both regulations, however, qualifying as such merely excludes products containing the substance from fast-track authorization and approval procedures but does not bear regulatory consequences.

The Chemicals Strategy for Sustainability

The concept was revived with the launching of the EU’s CSS in October 2020, which expanded it to include substances in the REACH Candidate



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List, as well as substances “which hamper recycling for safe and high quality secondary raw materials”. With this evolution, the concept is no longer only safety-related, as consideration is now given to circularity objectives.

The strategy recommended the minimization of the presence of Substances of Concern, and, for the most harmful, a phasing out for non-essential uses. This rationale was subsequently incorporated into a range of legislations adopted in the context of the Green Deal.

A first example is the ecodesign for sustainable products regulation (ESPR), which establishes a general framework for the definition of ecodesign requirements for different types of products and materials. Some requirements are related to the presence of Substances of Concern, which receives in that context a definition which now constitutes a central reference point for other EU legislations.

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The definition of Substance of Concern, in line with the CSS, shows an extension beyond safety considerations. The notion is indeed substantially broadened to include substances with confirmed as well as suspected hazardous properties (e.g. CMRs and Endocrine Disruptors Category 1 and 2). Substances can also be deemed ‘of





concern' if they negatively affect "the reuse and recycling of materials in the product in which it is present".

From that definition in the ESPR itself, the actual classification of substances as being 'of concern', will be defined at a later stage, within product and material-specific ecodesign requirements. Monitoring the adoption of the first set of requirements is key as they may set a precedent.

The consequences of the identification of a Substance of Concern will depend on each ecodesign requirement, but we already expect that it

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will trigger information and notification requirements of their presence throughout a products' value chain and lifecycle. This may expand to restrictions on the substances' use in a whole category of product or material.

Divergence between ecodesign requirements may potentially lead to substances being banned for use in some products but not others—without a dedicated risk assessment. The same substance may in fact even not be considered as being of concern for other product categories. This may lead to important incoherencies and subsequent hurdles for companies.

In the meantime, the ESPR definition became a reference point in other legislations, such as the Packaging and Packaging Waste Regulation (PPWR). The PPWR however sets its own procedure to determine the conditions under which a substance is deemed to hinder reuse and recycling, which could lead to other inconsistencies. The use of such substances shall be minimized in packaging, with the possibility of setting restrictions.

Another interesting reference is found in the Corporate Sustainability Reporting Directive (CSRD), which introduces reporting requirements on Substances of Concern. It foresees that an undertaking shall disclose whether and how its policies aim at the substitution and minimization of the use of such substances, present reduction targets and report on their conditions of production, use, distribution and import/export. Such reporting

requirements constitute an enormous challenge for companies as well as an important information gathering exercise for authorities.

A Shift Towards a Hazard and Sustainability-Based Management of Chemicals

The concept is increasingly present in EU legislations, beyond the remit of chemicals regulation. This comes with serious implications and somehow appears as an extension of the generic approach to risk management, whereby the mere classification of substance as Substance of Concern can automatically trigger a ban in certain types of products. This accompanies an increased reliance on hazard classification as a proxy for risk in recent EU chemicals regulatory activities, although restrictive measures should remain based on a risk assessment, as proportionality commands that they be used only as a last resort.

This approach was notably pushed forward in the revision of the CLP Regulation, which highly incentivizes new hazard classifications and straightforward processes. It first does so by incorporating new hazard classes, i.e., ED, PBT/vPvB, and PMT/vPvM. It then facilitates hazard classification by

empowering the Commission to initiate harmonized classification while this competence was so far exclusive to the industry and the Member States. Alignment between self-classifications is also incentivized and grouped classification prioritized, whenever scientifically justifiable. Considering that the Substance of Concern concept heavily

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In parallel, the evolution of the EU chemicals legislation from a risk-based to a more hazard-centric approach is also visible in the context of REACH restrictions, with authorities considering some properties (e.g., persistence) as a sufficient trigger for RMMs. The example of the PFAS restriction proposal is in this sense striking.

The Path Forward

The concept of Substance of Concern is progressively taking root in the European Union's legislation. Still, many acts remain to be adopted before it becomes fully operative and the actual consequences of a substance's qualification upon its use in products be defined.

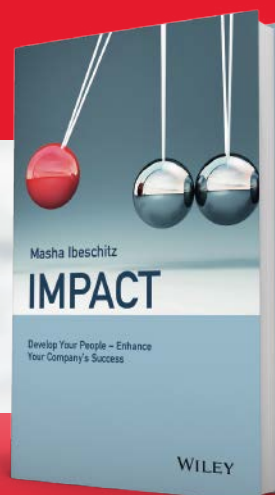
Uncertainties remain, even more so considering that the concerned policies constitute an inheritance from the previous Commission. More caution could be expected from the newly designated Commission, with the transition from the Green Deal to a Clean Industrial Deal, oriented towards reinforcing competitiveness. Nonetheless, one should not expect a full breakout from the previous approach considering the Commission's recent expressed intentions regarding the REACH revision and ongoing substances restrictions.

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