

July 2021

POSITION PAPER “CHEMICAL STRATEGY FOR SUSTAINABILITY”



CONTENT

- 03 Intro
- 04 Essential Use Concept
- 05 Mixture Assessment Factor
- 06 Safe and Sustainable by Design
- 07 Extension of Generic Approach to Risk Management
- 08 Interface between REACH and Occupational Safety and Health (OSH) Regulations
- 09 Registration requirements for polymers under the EU REACH Regulation



ISOPA shares vision of the EU Chemicals Strategy for Sustainability – polyurethanes will help deliver the Green Deal ambitions

The Chemical Strategy for Sustainability is an opportunity to drive innovation in the European Chemicals Industry towards the sustainable chemistries needed to deliver on the Green Deal. ISOPA shares the vision of the Chemicals Strategy for Sustainability and supports steps to enhance enforcement and innovation to boost the competitiveness of the European Chemicals Industry.

The Chemicals Strategy for Sustainability must be a genuine Green Deal growth strategy for Europe's industries, including the polyurethanes industry. This is required to support the economic recovery plan and for the polyurethane industry to transform its own production processes to achieve climate neutrality by 2050.

To deliver on the ambitions, the Strategy must integrate the multiple facets of chemicals management including safety, circularity, resource efficiency, environmental footprint, science and innovation.

ISOPA supports the many initiatives in the Strategy to better protect human health and the environment. Continuous improvement in chemical safety, protection of human health and the environment is embedded in many of our initiatives. These include Training on the Safe use of Diisocyanates; Working together with regulators towards a new Occupational Exposure Limit Value on Diisocyanates; Several industry guidelines on the safe use of diisocyanates and training of Drivers in the logistics value-chain.

While there is a strong focus on safety aspects, the Strategy lacks specificity and clarity on how the second objective will be met: boost innovation for safe and sustainable chemicals. This is critical as both objectives need to work hand in hand – a world-class competitive chemicals industry is needed to enable the innovations towards safe and sustainable chemistry.

Diisocyanates and polyols are the main building blocks for polyurethanes. Polyurethanes are amongst those materials which provides the key to solutions that will deliver the Green Deal, from solar panels to batteries, wind turbines and hydrogen to building insulation, to name just a few. The Chemicals Strategy for Sustainability needs to harness the essential role of technologies like polyurethanes to deliver climate neutrality and circular economy ambitions.

ISOPA will focus on the most relevant topics in the Strategy for the manufactures of diisocyanates and polyols as well as for the polyurethane industry.

A) Essential Use Concept

The Chemicals Strategy for Sustainability promises to restrict the most harmful chemicals unless their use is deemed essential. This will be achieved by introducing and operationalizing a 'concept for essential use' in the EU legislative framework, including REACH, following the model of the Montreal Protocol.

ISOPA supports the calls by several Member States made in comments to the Competent Authorities for REACH and CLP (CARACAL) expert group for further detailed assessments before introducing such a change to the way regulation of chemicals works in the EU. It is necessary to develop clear

criteria for essential use which do not hinder the chemical innovation needed to meet other parts of the Chemicals Strategy for Sustainability and the wider Green Deal. For example, the criteria could be implemented to support the risk management option analysis to first focus efforts on how to best manage risks for the non-essential uses.

It should be recalled that the European Commission's 2018 REACH REFIT Evaluation and the 2019 Fitness Check on chemicals legislation both conclude that incremental improvements are needed to the EU's chemicals regulatory framework.



B) Mixture Assessment Factor

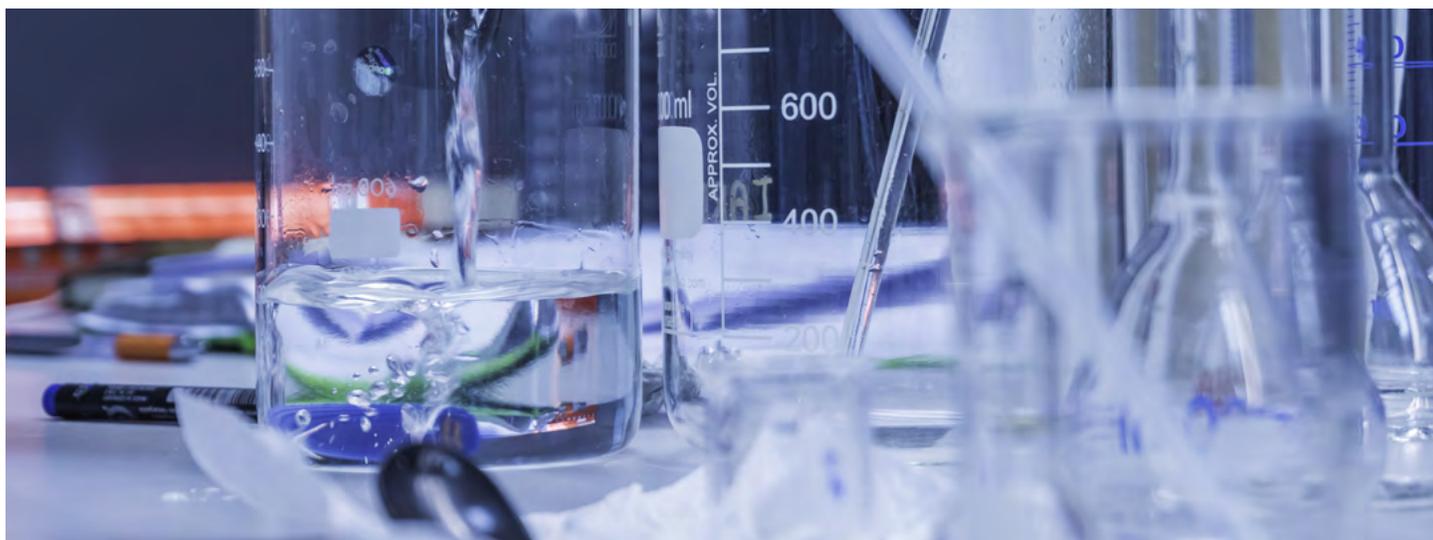
The Chemicals Strategy for Sustainability intends to address the combination effects of chemical mixtures, including unintentional mixtures, by introducing a mixture assessment factor (MAF) in REACH and provisions to consider combination effects in other legislation.

ISOPA shares the view of Cefic that the systematic introduction of a generic MAF under REACH is not the right approach to solve the issue of potential unintentional combined exposure.

Although it seems straightforward to apply, its simplicity is a significant weakness. The rationale behind a generic assessment factor includes many assumptions to cover uncertainties. There are research projects indicating that the risk of

combined exposure in Europe are driven by a very limited number of chemicals. Therefore, we believe that the MAF approach should only apply to substances where there is a potential concern for unintentional mixtures.

Any MAF introduced must holistically consider the pre-existing risk management measures in place on certain substances when the chemical safety assessment takes place to adequately reflect real-world conditions. Furthermore, a mechanism should be established to ensure that the risk assessment based on MAF is updated if new measures are introduced to ensure assumptions are consistent with real-world conditions.



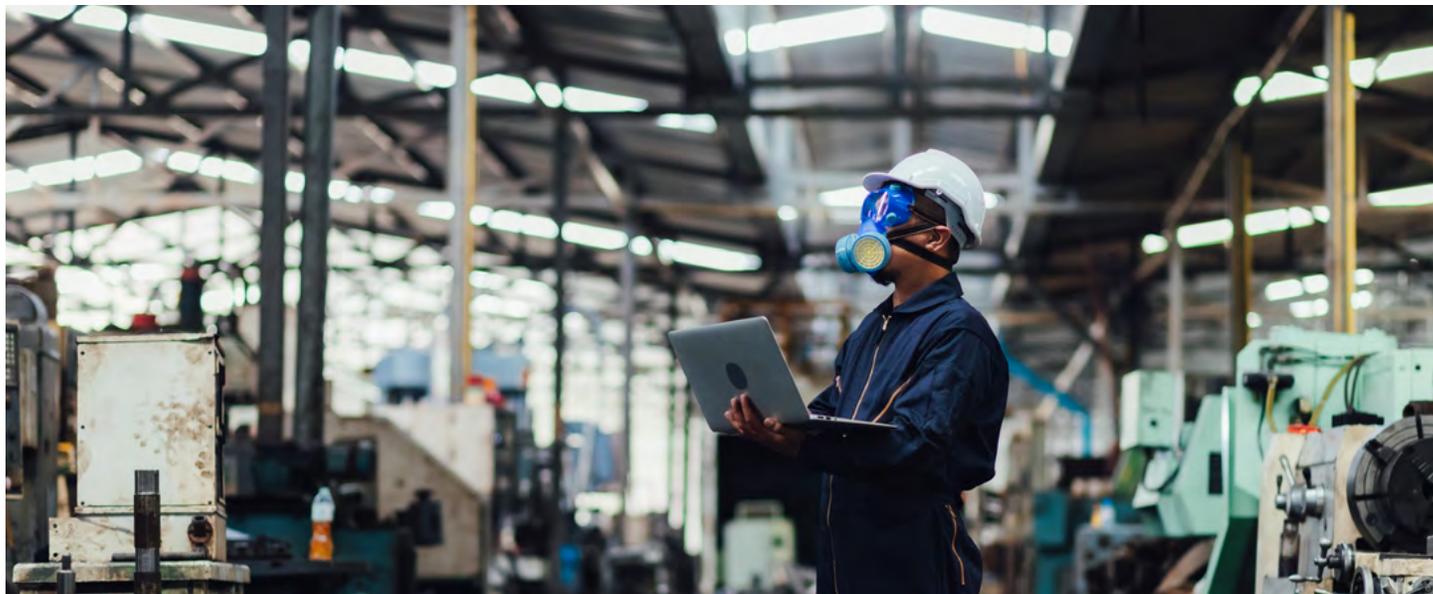
C) Safe and Sustainable by Design

The Chemicals Strategy for Sustainability highlights that the transition to 'Safe and Sustainable-by-Design' chemicals responds to a societal urgency while offering great economic and employment opportunities. The European Chemicals Industry is already a global frontrunner and has the capacity to boost the transition.

The European Commission will develop EU safe and sustainable-by-design criteria for chemicals to secure a common understanding among stakeholders to drive the transition.

ISOPA joins Cefic in welcoming the new Safe and Sustainable-by-Design paradigm, including the establishment of a support network and the development of criteria that will guide the development of 'the chemistries of tomorrow'.

It will be important to ensure that the approach is implemented in a way that enables the majority of industry to successfully manage this transition and continue to deliver performing products.



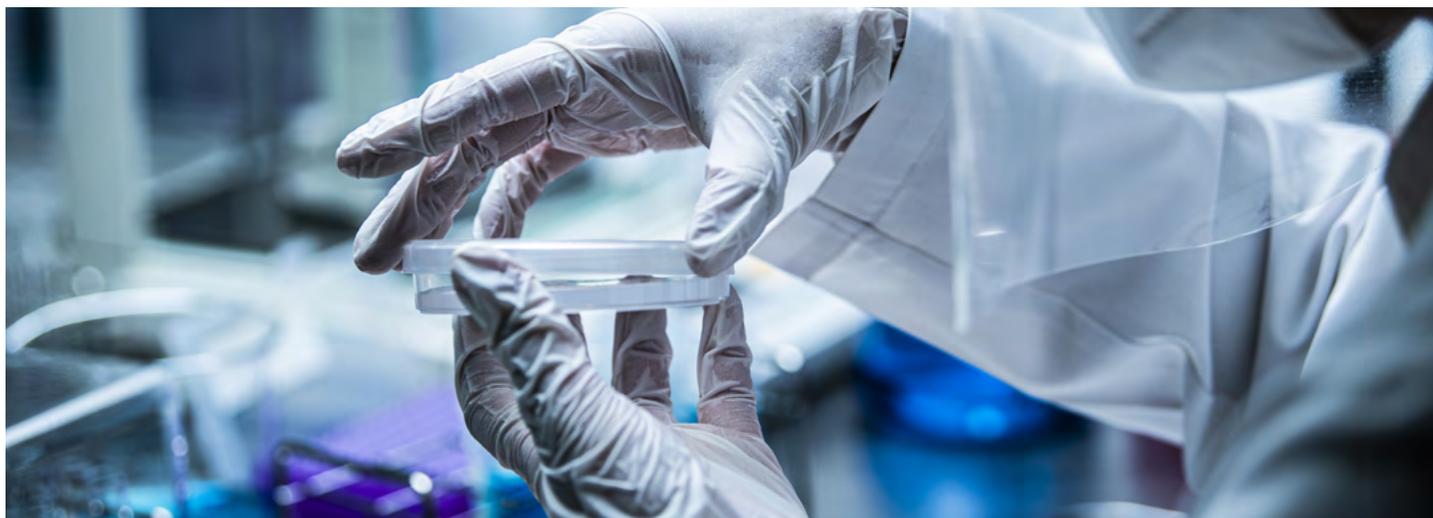
D) Extension of Generic Approach to Risk Management

The Chemicals Strategy for Sustainability seeks to extend the 'generic approach to risk management' in the EU legislative framework. It means that risk management measures, such as restrictions, are automatically triggered based on the hazardous properties of the chemical.

ISOPA does not support an extension of the approach which completely disregards exposure and use considerations. Managing chemicals based on a good understanding of their uses and of potential exposure should continue to be at the

core of risk management. This ensures that the measures taken to address risks are proportionate and effective in protection of human health and the environment.

Furthermore, ISOPA would stress that definitions and criteria setting are crucial. In particular, if a substance is assigned as "Hazardous", this does not equal that there is an uncontrolled risk nor that it is a "Substance of Concern (SOC)" or even a "Substance of Very High Concern (SVHC)".



E) Interface between REACH and Occupational Safety and Health (OSH) Regulations

The Chemicals Strategy for Sustainability in combination with the [EU Strategic Framework for Health and Safety at work 2021-2027](#) seeks to strengthen the protection of workers and professionals.

The importance of improving the interface between the EU's REACH Regulation and EU Occupational Safety and Health (OSH) rules is identified as priority in these initiatives. ISOPA welcomes any steps in this direction.

ISOPA recognizes that measures under REACH and OSH Rules can be complementary to protect workers. New mandatory training requirements for professional and industrial users of diisocyanates were recently adopted under REACH while there is

also an ongoing process to establish a binding EU occupational exposure limit (OEL) for diisocyanates. The Strategic Framework for Health and Safety commits to putting the OEL on diisocyanates in place by 2022.

In this context, the 'one substance, one assessment' approach of the Chemicals Strategy for Sustainability is a real opportunity to ensure that measures in the REACH/OSH interface are consistent, proportionate and effective. The [2021 Better Regulation Communication](#)'s commitment to offset any newly introduced burdens by removing equivalent burdens in the same policy area must be implemented when introducing new measures in the area.



F) Registration requirements for polymers under the EU REACH Regulation

The Chemicals Strategy for Sustainability promises to extend REACH Registration requirements to certain polymers.

ISOPA agrees with the need to improve availability of data on polymers. Any Registration requirements must be based on sound scientific criteria for selecting the polymers that require registration. The information requirements introduced for polymers should not replicate directly current approach for substances under REACH.

ISOPA supports that polymeric precursors are excluded from the scope of the Registration requirements. The Registration requirements must be subject to a rigorous impact assessment to ensure that these are proportionate and the registration system should avoid unnecessary testing on animals whenever possible.



Jörg Palmersheim

ISOPA Aisbl
Secretary General
Rue Belliard 65
B-1040 Brussels

Contact ISOPA:

Email: main@isopa.org

Visit us: www.isopa.org