

2nd edition

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SUCCESSFULLY NAVIGATING REACH



A guide to the restriction process applying to diisocyanates

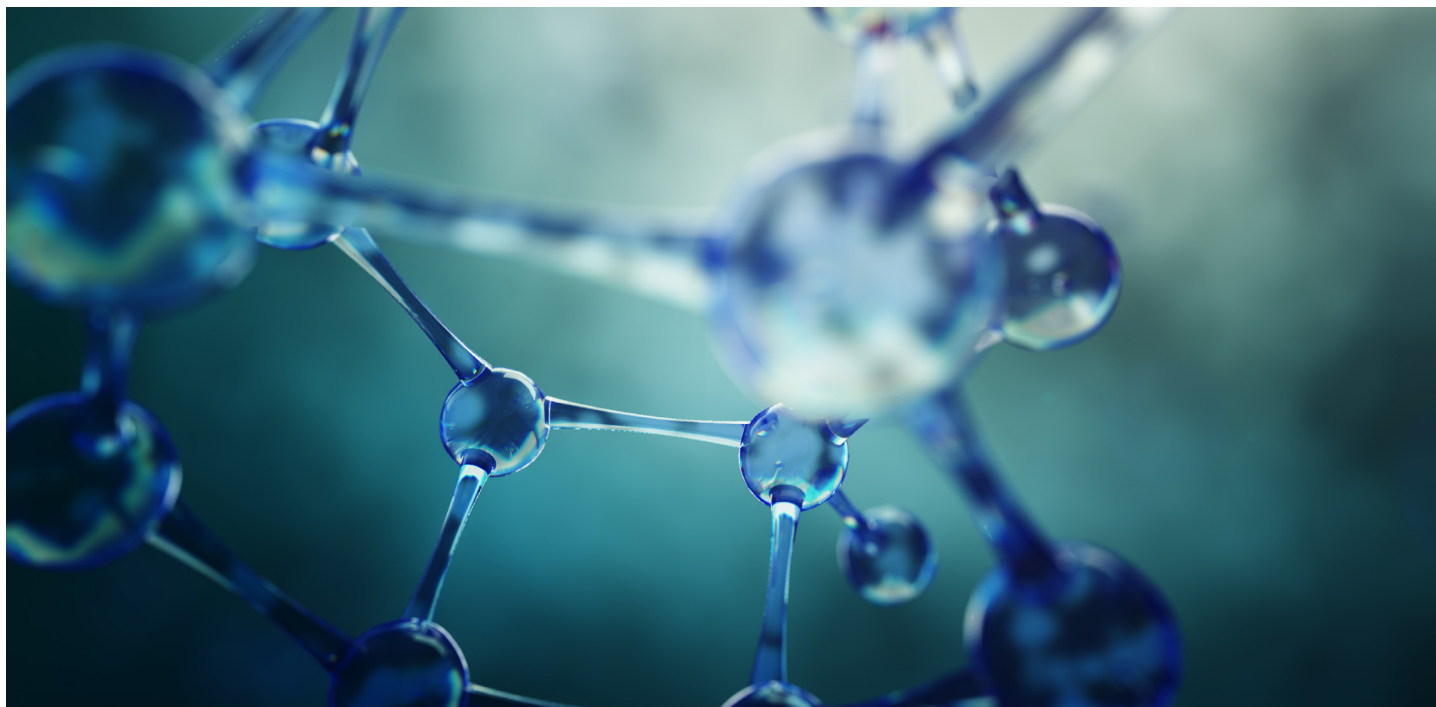


Introduction

Welcome to the ISOPA/ALIPA guide to the REACH processes applying to diisocyanates!

With this document, we aim to answer all questions the polyurethanes value chain may have on diisocyanates and their safe handling. More specifically, this guide elaborates on processes and regulatory measures taken under REACH (European chemicals regulation) that could potentially impact the manufacture and use of diisocyanates in the future.

This document reflects on the current status of the regulatory process as of May 2018 and may be subject to modifications as discussions move forward at European level.



Polyurethane

A product for the future

Polyurethanes are versatile, modern and safe. They are used in a wide variety of applications to create all sorts of consumer and industrial products that play a crucial role in making our lives more convenient, comfortable and environmentally friendly.

Whether in rigid or flexible form or elastomers, binders or coating materials, polyurethane is used in a wide variety of applications. Thanks to

its versatility and unique properties, the list of applications is long and getting longer, with new innovative applications regularly coming on to the market all the time.

Polyurethane is a product for the future. It plays a crucial role in our evolving needs, allowing us to do things that a generation ago would have seemed impossible.



Diisocyanates and polyols

The building blocks of polyurethane

Polyurethane is a plastic material (a polymer), which would not exist without diisocyanates and polyols. There are many types of diisocyanates the foremost of which are: methylene diphenyl diisocyanate (MDI) and Toluene diisocyanate (TDI) are aromatic diisocyanates, while hexamethylene diisocyanate (HDI), methylene dicyclohexyl diisocyanate or hydrogenated MDI (HMDI) and isophorone diisocyanate (IPDI) are aliphatic diisocyanates. Along with polyols, which are long alcoxyether chains, these chemicals form the building blocks of polyurethane.

Effectively polyurethane is derived from the chemical reaction between diisocyanates and polyols; when mixed together, they polymerise.

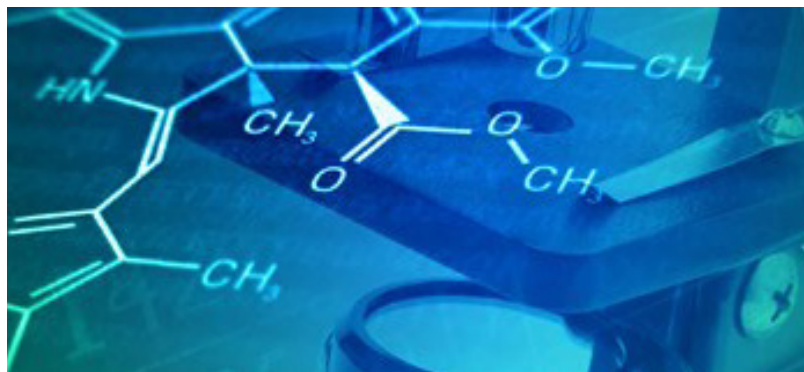
For polyurethane to live up to quality expectations and products' technical specifications, pigments and additives may be added to ensure the exact formulation of the product, be it foam, adhesives, elastomers or sealants and coatings. The varieties in density are endless. As the molecule is adapted to provide different properties, polyurethane foam can display different levels of rigidity or flexibility.

For example, a comfortable sofa requires the use of carbon dioxide as a blowing agent for the production of soft foam. In rigid foams, a gas such as pentane is "trapped" in the foam's closed cells, optimising its insulation capacity.

In addition, the durability, corrosion resistance and weather resistance of polyurethanes makes them suitable for coating all kinds of surfaces. Polyurethane can also be used to safely bind together quite different materials, such as wood, rubber, cardboard or glass.

For example, polyurethane adhesives enable the reuse of vehicle tyres in playgrounds, sports tracks or surfaces for sports stadiums after they are collected and shredded. Polyurethane coatings can protect substrates against corrosion and weather influence, by that significantly increasing their durability and saving resources.

Further applications of diisocyanates are highly durable compact materials like thermoplastic polyurethane (TPU) and elastomers. Such materials are widely used for various applications like wheels, ski boots or artificial leather.





Who are ISOPA and ALIPA?

ISOPA

ISOPA is the European trade association for producers of diisocyanates and polyols – the main building blocks of polyurethanes. ISOPA promotes the highest level of best practice in the distribution and use of diisocyanates and polyols in Europe and ensures that all stakeholders can easily access accurate and up-to-date information on these substances. ISOPA is based in Brussels, Belgium, and is an affiliated organisation of the European Chemical Industry Council (CEFIC). ISOPA members include BASF, BorsodChem, Covestro, Dow, Huntsman and Shell Chemicals.

ALIPA is the European Aliphatic Isocyanates Producers Association. It was created by the major European producers BASF, Covestro, Evonik and Vencorex in order to encourage the safe and proper use of aliphatic isocyanates.

ALIPA



REACH and Diisocyanates

What is REACH all about?

Adopted in 2006, REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation. It is a European regulation that aims at improving the protection of human health and the environment from potential risks from chemical substances; whilst ensuring the EU chemicals industry's global competitiveness is maintained. As opposed to previous legislation, REACH places the burden of proof on industry. To comply with the Regulation, companies must

correctly identify and manage risks. In turn, chemical producers have to demonstrate to the European Chemicals Agency (ECHA) how the substance can be safely used and communicate the risk management measures to their users. To deliver on such ambitious objectives, the Regulation has put in place a number of processes that have required a lot of efforts from the chemical industry and its value chains in recent years.



Registration

First and foremost, companies are obliged to collect information on the properties and the uses of the substances they manufacture or import at or above one tonne per year. This includes an assessment of their hazards and potential risks.



Evaluation

ECHA and EU Member States will then evaluate the information submitted by companies, as well as the quality of the registration dossiers and testing proposals, in order to clarify if a given substance constitutes a risk to human health or the environment.



Authorisation

The authorisation procedure aims to assure that the risks from Substances of Very High Concern (SVHC) are properly controlled, and that these substances are progressively replaced by suitable alternatives. SVHC substances are listed in the so-called 'Candidate list'. The list includes Carcinogenic, Mutagenic, Reprotoxic (CMR) substances, Persistent Bio-accumulative Toxic (PBT) substances and substances of equivalent concern (endocrine disruptors, sensitisers, etc.)



Restriction

Restriction is the process used to protect human health and the environment from unacceptable risks posed by chemicals. Restrictions may limit or ban the manufacture, placing on the market, or use of a substance. In some specific cases, like for diisocyanates, where the product is used in a large range of applications, authorities may decide to call for the development of targeted product stewardship initiatives. This will ensure that all workers who interact directly with the substances are both informed and trained in order to manage any risks associated with handling the substances.

Diisocyanates and REACH

Diisocyanates have been subject to regulatory processes in Poland, Estonia and Germany since 2012.

Evaluation led by Poland, Slovenia and Estonia

Both TDI and MDI have been added to the ECHA Community Rolling Action Plan (CoRAP). TDI was evaluated in 2013 by the Polish Competent Authority which concluded that no regulatory action was needed.

MDI has been evaluated by Estonia since 2013 and the final conclusions are expected in the autumn of 2018, as further information was requested. HDI was evaluated by Slovenia, concluding there was no need for further action.

Restriction led by Germany

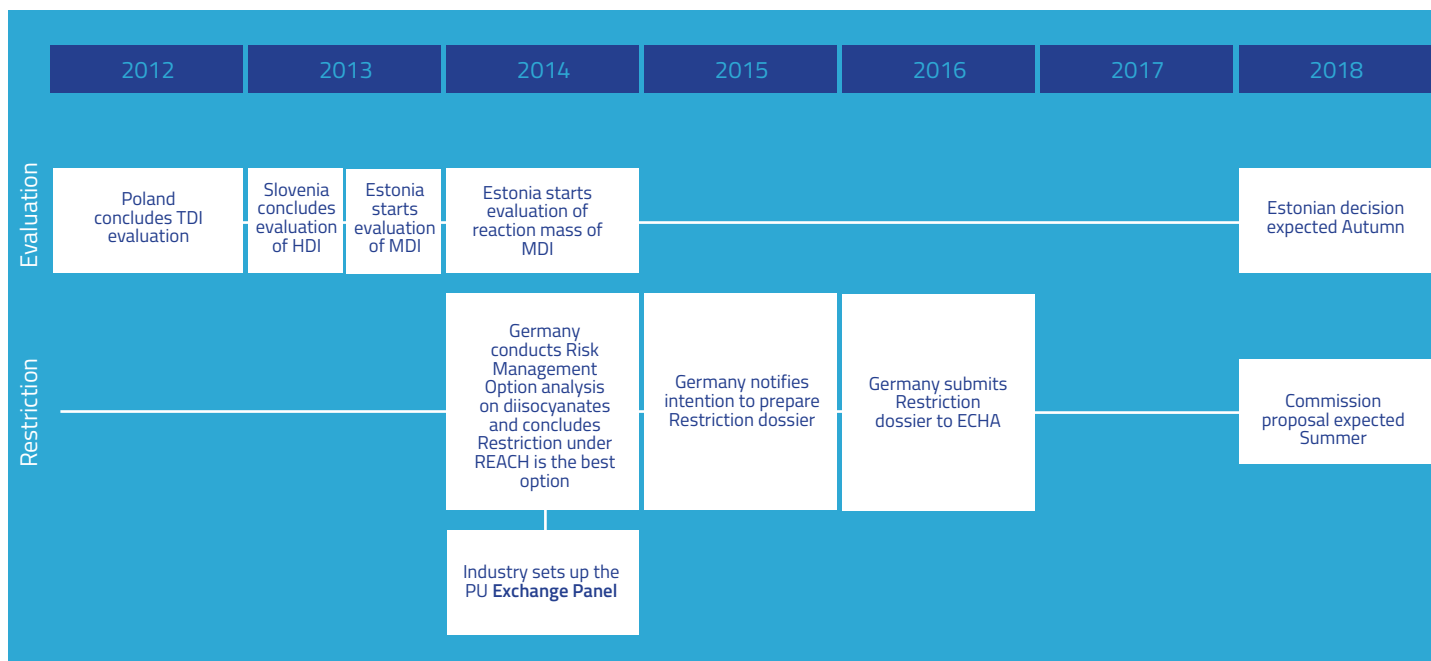
Meanwhile, BAuA, the German REACH Competent Authority, took a particular interest in the respiratory sensitising properties of diisocyanates in the workplace (if not handled properly). In order to clarify the situation and identify the best policy tool, German authorities decided to conduct a Risk Management Option Analysis (RMOA). The

exercise was completed in August 2014 and Germany recommended a more original restriction route, by proposing mandatory training that would ensure safety in the workplace for workers handling diisocyanates.

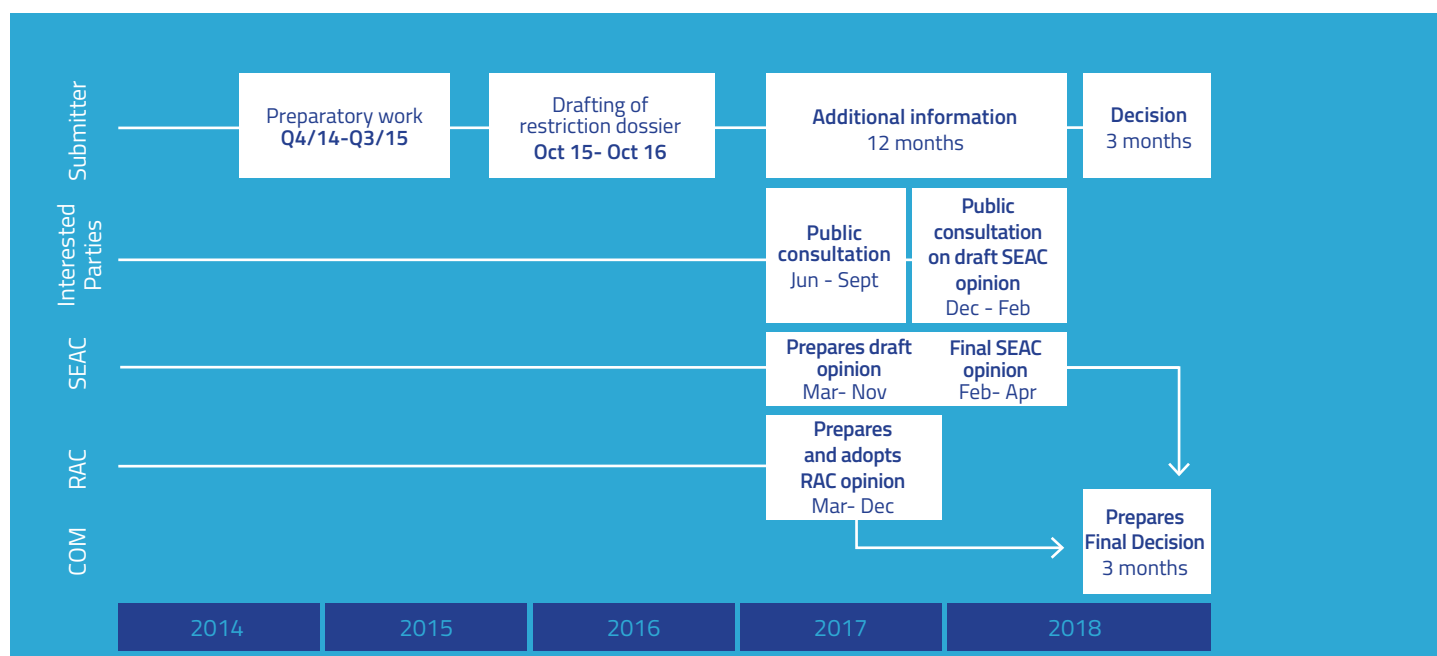
In October 2015, BAuA formally registered its intention to prepare a restriction dossier. The dossier was formally sent to ECHA in October 2016 and has since then been subject to scrutiny by ECHA's Committee for Risk Assessment (RAC) and Committee for Socio-Economic Analysis (SEAC), including public consultations on their opinions. The final draft restriction dossier is currently being drafted, compiling the RAC and SEAC opinions as well as the comments received during the public consultation. The Commission is due to put forward a proposal by the summer of 2018. You will find on page 9 a description of what provisions the restriction dossier currently contains, following the RAC and SEAC opinions.



REACH timeline for diisocyanates



Restriction process



Training

Currently, the following elements are set to be part of the restriction proposal:

- An EU harmonised set of training materials will be provided by diisocyanate manufacturers and importers in cooperation with downstream users;
- The trainings will be conducted in house, by a consultant or by public authorities. It can be conducted in various ways, including off-site/on-site training courses, E-learning, integration of training into the product presentation;
- The trainings will be conducted through train-the-trainer principle;
- Users of diisocyanates will have to document the completion of the training and check the validity once per year;
- Each employee will have to be trained once every four years, content and training duration depending on the risk of exposure;
- There will be a transition period of several years during which industry must get ready for the restriction and workers will start being trained. The exact duration of this transition period will be the subject of political discussion at the end of the regulatory process. The proposed transition period by RAC and SEAC is 4 years;
- Manufacturers and importers, as well as trade associations of relevant downstream users, have already indicated their commitment to such an approach and have started internal consultations in developing such training materials; and

Exemption: The restriction dossier will also contain a procedure allowing industry to demonstrate that product-use combinations inherently carry no significant exposure. In this case, such product-use combinations will be exempted from the need for training. We also understand training materials will be made available by the placers of diisocyanates on the market.

Trainings will depend on levels of exposure:

Level 1 training	Level 2 training	Level 3 training
<ul style="list-style-type: none"> ▪ Loading/Unloading Trucks ▪ Pumping/loading using closed systems ▪ Application of sealants and adhesives (including foam application from cans) ▪ Handling of cold fibers and composite materials after manufacturing ▪ Polyurethane operation with dedicated closed machinery like foaming, adhesives, sealants, elastomers ▪ Working in laboratory <p><i>Level 1 training can be e-learning</i></p>	<ul style="list-style-type: none"> ▪ Handling of mixtures at ambient temperature (incl. foam tunnels) ▪ Spraying in a ventilation booth ▪ Application by roller ▪ Application by brush ▪ Application by dipping and pouring ▪ Handling oligomers after manufacturing ▪ Foundry applications ▪ Mechanical post treatment (e.g. cutting) of not fully cured articles ▪ Cleaning and waste ▪ Change management 	<ul style="list-style-type: none"> ▪ Open handling of warm or hot formulations (45C and more) ▪ Spraying in open air, with limited or only natural ventilation (including large industry working halls) and spraying with high energy (e.g. foams, elastomers) ▪ Handling incompletely cured articles (e.g. freshly cured, still warm) ▪ Maintenance and repair that needs access equipment

Industry's commitment and dialogue with REACH authorities

The diisocyanates industry has been engaged in the regulatory process right from the beginning in order to provide authorities with the most robust data and information and to permit REACH regulators to have a pragmatic and harmonised approach, which could be applicable to all companies, including SMEs.

Following BAuA's RMOA on diisocyanates in 2014, ISOPA and ALIPA decided to further cooperate with downstream associations in the context of REACH-related issues. They actively provide relevant information to authorities conducting research on diisocyanates in a newly created platform, the Polyurethane (PU) Exchange Panel.

The Panel's goal is to allow the entire value-chain to better participate in the process with all relevant REACH Competent Authorities in Europe. Several downstream associations of the PU Exchange Panel are joining efforts to develop teaching materials.

Associations Involved

List of panel members

EU

ALIPA
CEC (Footwear)
CECED (Domestic Equipment)
CEPE (Coatings & Paintings)
Contance (Euroleather)
EFCC (Construction Chemicals)
EFIC (Furniture Industry)
EPF (Panel Federation)
EPDLA
Euratex
Euromoulders
Europur
FECC (Distributors)
FEICA (Adhesives & Sealants)
ISOPA
PPA (Panels & Profiles)
PU Europe
RTP Resin
PDA Europe Polyurea
Development Association

DE/BE

Deutsche Bauchemie

Fedustria

FSK

IVK (Adhesives)

IVPU (Rigid Foam Producers)

VdL (Coating industry)

ZVEI (Electric and Electronic Manufacturers)

Product stewardship programmes – Promoting the safe use of diisocyanates

The safe production, use, transport and selling of diisocyanates and polyols have always been one of ISOPA and ALIPA's core missions. ISOPA and ALIPA members as well as downstream users of diisocyanates are strongly committed to the safe use of diisocyanates and safety at the workplace at European and national levels.

For ISOPA, ALIPA and the members of the PU Exchange Panel, behaviour at the workplace is key to ensuring the safe use of diisocyanates. Therefore, the industry has for decades developed and promoted a number of product stewardship programmes.



Walk the Talk is a programme developed by the members of ISOPA with the aim of improving safety, health and environmental best practices across the European polyurethanes industry. The Walk the Talk programme focuses on the behavioural safety of industrial and professional users involved in the industry through an ongoing dialogue. The programme consists of detailed sets of training covering all the phases of the industrial process: processing, maintenance, warehousing and waste. From the arrival of chemicals to the discharge, which rely on potentially dangerous operations, ISOPA provides support to both users and logistics service providers. Two information packages are available: a Basic Safety Package and a package containing EU REACH & CLP information.



The safe transport of diisocyanates is essential for both people and manufacturers. All the participants in the supply chain, the manufacturers of MDI/ TDI, the transportation company and the receiver of the products play vital roles in ensuring that accidents are prevented. ISOPA is committed to the continuous increase of best practices in the loading, transport, unloading and storage of diisocyanates and polyols. Our aim is to assure maximum protection of health and safety and a consistent industry wide approach. ISOPA developed a series of guidelines that reflect the collective knowledge and best practice of the logistics personnel of the ISOPA member companies. They cover all aspects of the supply of chemicals.

we care that you care

ALIPA's Safeguard programme consists of information packages with recommendations and measures regarding safe handling of aliphatic isocyanates. The programme focuses on the safe use of aliphatic diisocyanate monomers and on safe use of aliphatic polyisocyanates in spray applications.

FAQ

on diisocyanates



Products

What are MDI, TDI, HDI, HMDI and IPDI?

MDI stands for Methylene diphenyl diisocyanate, TDI stands for Toluene diisocyanate. From a chemical point of view, they are aromatic diisocyanates and considered organic compounds.

Aliphatic diisocyanates are hexamethylene diisocyanate (HDI), methylene dicyclohexyl diisocyanate or hydrogenated MDI (HMDI) and isophorone diisocyanate (IPDI).

Where are they used?

Together with polyols, MDI and TDI are the essential building blocks for the manufacturing of polyurethane. It can be tailored to be either rigid or flexible, and it is the material of choice for a broad range of applications such as insulation in buildings and white goods; adhesives, coatings, automotive parts, sportswear, etc.

Aliphatic diisocyanates are light resistant substances which are preferably reacted with polyester- and polyether-polyols and used for coatings, sealants and elastomers where colour-stability is required.



Market

What are the supply chains for these chemicals?

Diisocyanates and polyols are sold to downstream companies producing flexible and rigid polyurethane foams as well as elastomers, binders or coating materials. Further down the value chain, we find manufacturers of building insulation, white goods, automotive, furniture and bedding, footwear, coatings and adhesives, etc.

How many people does the industry employ?

According to a survey conducted in 2013 by an external party, the polyurethane industry involves more than 240,000 companies (most of which are SMEs), providing almost one million jobs in Europe:

- 184,000 direct jobs (directly resulting from polyurethane chemicals production including direct and downstream customers)
- over 47,000 jobs indirectly (suppliers/subcontractors)
- 690,000 jobs that are expenditure-induced (i.e. which represents the economic contribution of the polyurethanes industry on all non-polyurethane sectors of the EU-27¹ society)

Which companies produce diisocyanates and polyols?

ISOPA represents the European manufacturers of aromatic diisocyanates and polyols, and its members are: Covestro, BorsodChem, Dow, BASF, Huntsman and Shell.

ALIPA is the European Aliphatic Isocyanates Producers Association. It was created by the major European producers BASF, Covestro, Evonik and Vencorex.

How much is produced in the EU?

In terms of raw material consumption, over 6 million tons of polyurethanes were produced in the EMEA region in 2018.

¹ Data prior to Croatia's accession.



Safety

Are diisocyanates safe?

Like any substance, the use of diisocyanates is safe when chemicals are handled according to relevant risk management and safety measures.

It is also important to stress that virtually no diisocyanates can be found in finished articles; hence, there is no consumer exposure. MDI and TDI do not migrate as they are only reactive chemicals.

Do MDI and TDI meet Substance of Very High Concern (SVHC) criteria?

Our industry firmly believes that MDI and TDI are not SVHC according to the criteria outlined under REACH, for the three following reasons:

- The threshold for respiratory sensitisation is never met when risk management measures are applied correctly. Therefore our industry is convinced that the inclusion of diisocyanates as sensitisers under the SVHC process would not be justified or proportionate to the risk.
- In case of exposure, the effects of MDI and TDI are reversible and not comparable to CMR (Carcinogenicity, Mutagenicity, Reproductive toxicity). When exposure ceases, the overwhelming majority of individuals with diisocyanate-related sensitisation show significant improvement or totally recovery.
- In the last decade, we have observed a significant decrease in cases of diisocyanate-related sensitisation against a growing polyurethane market that doubled since 1995; confirming that new sensitisation cases can be eliminated by implementing safe exposure limits and appropriate controls.

Sensitisation means that after a high level of exposure, a person could become allergic to the substance. If sensitised, each time the person is in contact again with the substance (even at very low concentrations) the person would have a strong allergic reaction with respiratory impacts (e.g. asthma).

The majority of individuals with diisocyanates-related asthma show improvement over time or total recovery after exposure has ceased.

Furthermore, it is important to highlight that the majority of diisocyanates uses are industrial or professional applications. Health complaints only occur if the person is in contact with the substance at high levels of exposure.

Are there any alternatives to aromatic and aliphatic diisocyanates?

Polyurethanes cannot be produced without aromatic or aliphatic diisocyanates. Therefore, there is no alternative for MDI, TDI, HDI, IPDI or H12MDI. To date, no other chemicals have been found to be able to replace their function in the production of polyurethane articles.

Are there alternatives to polyurethanes?

Polyurethanes provide outstanding benefits in many applications and contribute significantly to society's sustainable development, e.g. through energy and resource efficiency. Alternative technologies are not available for all applications and alternative materials might not provide the same performance in terms of durability and efficiency.



Regulation status

Why are diisocyanates considered for restriction measures under REACH?

Diisocyanates are considered for restriction measures due to the occupational sensitisation health effect they could pose to workers above a certain level of exposure. It is therefore a specific use restriction that is envisaged. Restrictions would target products containing more than 0.1% by wt monomeric diisocyanates.

Can diisocyanates still be placed on the market in the EU and can I still legally use them?

Yes, diisocyanates remain available on the EU market. Trainings proposed by ECHA will become mandatory in the future once the restriction is adopted by the European Union.

What are the next steps?

The next milestone is the publication of the final compiled RAC and SEAC opinion taking into account the comments received during the public consultation and the 38th SEAC meeting held on 13 March 2018. Once this compiled opinion has been published, the European Commission has three months to prepare the draft amendment to the REACH regulation which then will be adopted if no objection is raised by the European Parliament or the Member States.

What shape is the restriction likely to take?

The Legislators' intention is to propose measures based on BauA's proposal meant to improve the behaviour of employees at the workplace with the aim of reducing the risk of developing occupational asthma. Concretely, the RMOA should focus on integrating a training and certification scheme defining minimum conditions for the safe handling of the substances.

Detailed measures will be agreed at the European level.

Glossary

ALIPA:	European Aliphatic Isocyanates Producers Association.
BAuA:	German Federal Institute for Occupational Safety and Health (BAuA).
CMR:	Substance classified in Part 3 of Annex VI to CLP Regulation as carcinogenic, mutagenic or toxic for reproduction.
CoRAP:	Community rolling action plan (CoRAP) – CoRAP specifies the substances that are to be evaluated under REACH over a period of three years.
Diisocyanates:	Family of chemical building blocks mainly used to make polyurethane products, such as rigid and flexible foams, coatings, adhesives, sealants and elastomers. Diisocyanates are divided into two types: aromatic diisocyanates and aliphatic diisocyanates.
ECHA:	European Chemicals Agency.
EU:	European Union
HDI:	Hexamethylene diisocyanate
HMDI:	Methylene dicyclohexyl diisocyanate or hydrogenated MDI
IPDI:	Isophorone diisocyanate
ISOPA:	European trade association for producers of diisocyanates and polyols.
MDI:	Methylenediphenyl diisocyanate
REACH:	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMOa:	Risk management option analysis - helps decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.
SVHC:	Substance of very high concern
TDI:	Toluene diisocyanate



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