SUCCESSFULLY NAVIGATING REACH



A guide to the restriction process applying to diisocyanates

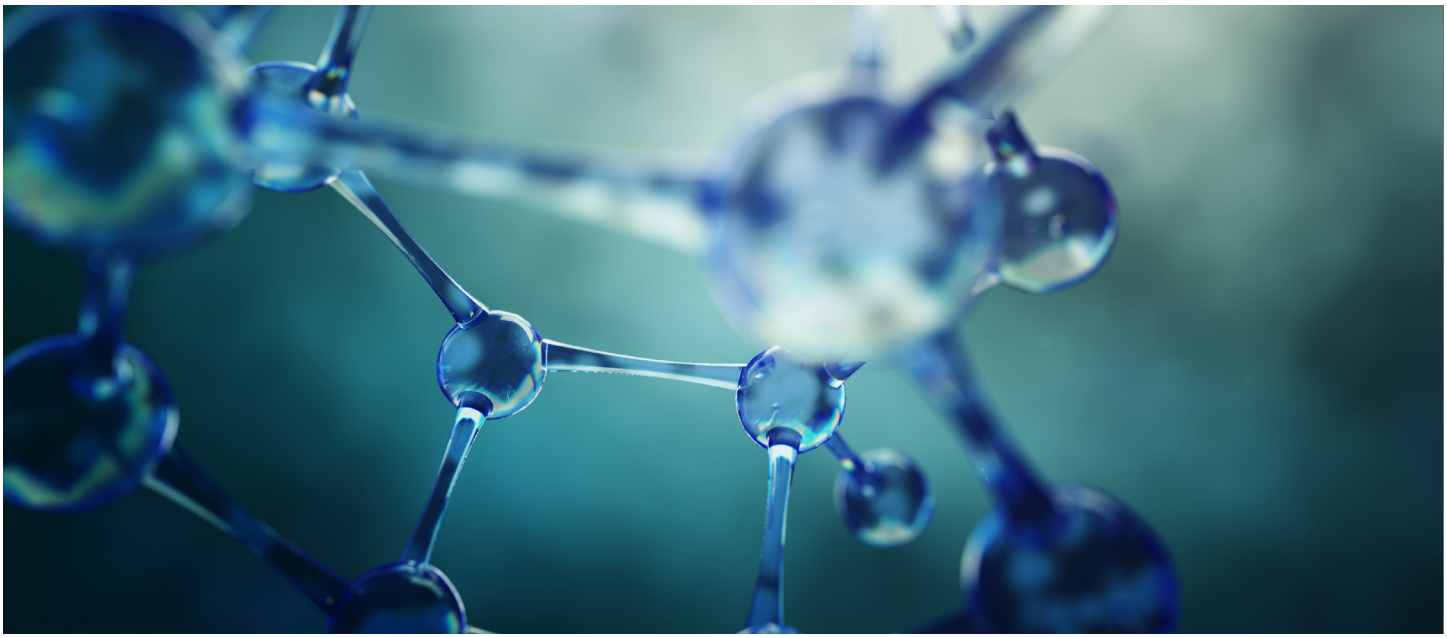
isopa EUROPEAN DIISOCYANATE & POLYOL PRODUCERS ASSOCIATION

ALIPA EUROPEAN ALIPHATIC ISOCYANATES PRODUCERS ASSOCIATION

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.



Polyurethane
A Product For The Future

Polyurethanes are versatile, modern and safe. They are used in a wide variety of applications to create all manner 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 huge variety of applications.

Thanks to its versatility and unique properties, the list of applications is long and getting longer with new innovative applications coming on to the market all of 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 wouldn't exist without diisocyanates and polyols. 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 react to a polymer and foam.

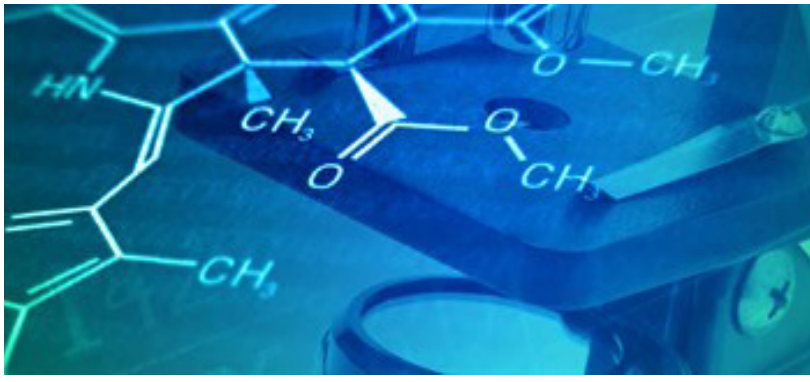
For polyurethane to live up to quality expectations and products' technical specifications, pigments and additives are added in order to ensure the exact formulation of the foam. The varieties in density are endless and all blocks of foam are tested for conformity in order to meet the EU's safety standards.

As the molecule is adapted to provide different properties, polyurethane foam can either be more rigid or more flexible. 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 use of end-of-use vehicle tyres in children's 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.



Who are ISOPA & 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 & Diisocyanates

What is REACH all about?

Adopted in 2006, REACH 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.

In order to deliver on such ambitious objectives, the Regulation has put in place a number of processes that have kept the chemical industry and its value chains quite busy 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; including an assessment of their hazards and potential risks.

Evaluation

ECHA and 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) 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 huge range of applications, authorities 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 & REACH

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

Evaluation led by Poland 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. On the other hand, MDI has been under evaluation in Estonia since 2013.

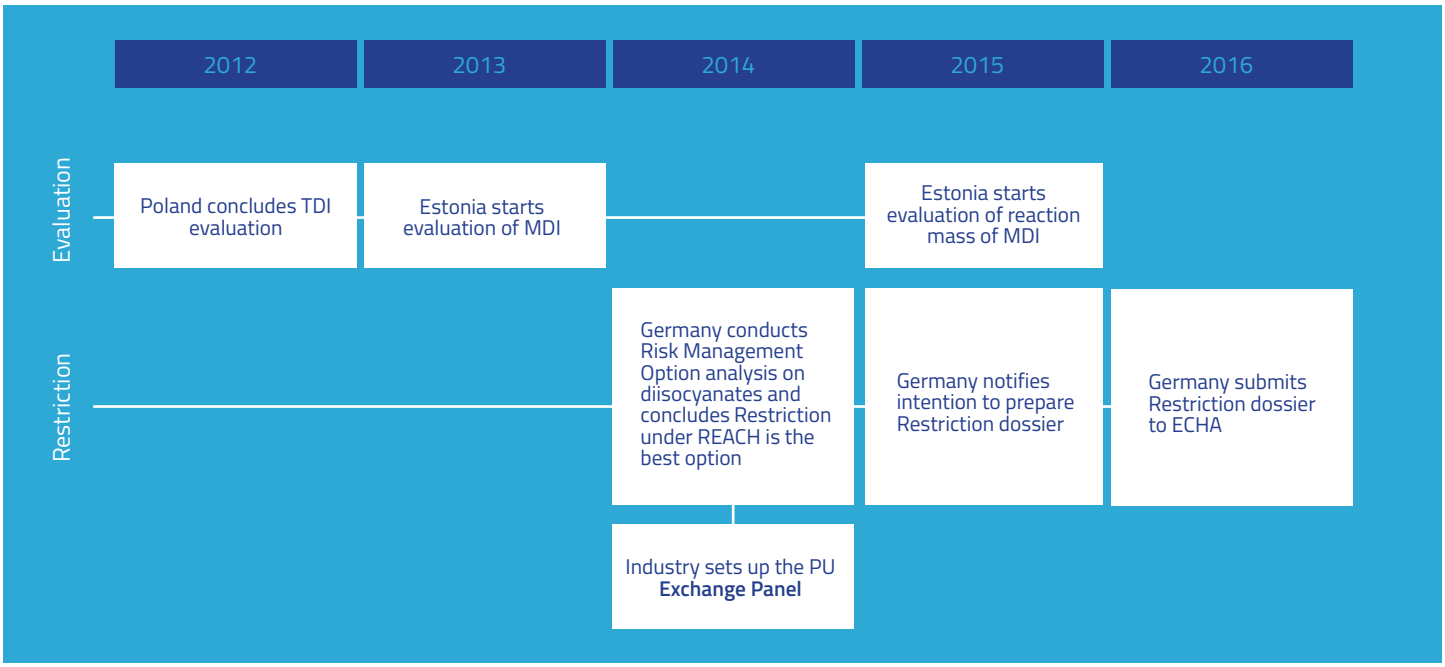
Restriction led by Germany

Meanwhile, BAuA, the German REACH Competent Authority (CA), took a particular interest in the respiratory sensitizing properties of diisocyanates at 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.

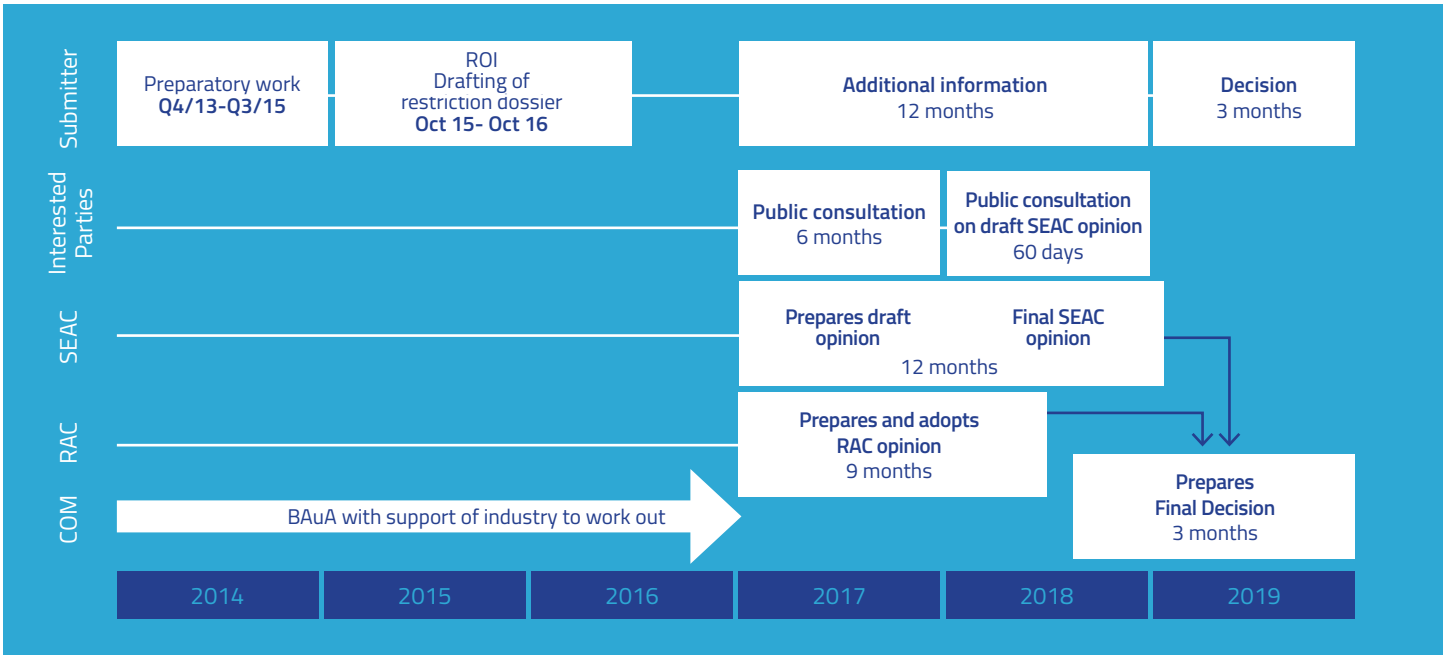
In October 2015, BAuA formally registered its intention to prepare a restriction dossier. The dossier was formally sent to ECHA in October 2016 and is currently undergoing compliance check. We expect the public consultation to start in March 2017.

You will find below a first description of what German authorities have proposed. The very final proposal will be made public when the stakeholder consultation starts in 2017.

REACH timeline



Restriction process



Training

We understand that the following elements should be part of the restriction proposal:

- The training material 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;
- Users of diisocyanates will have to keep a record of the training of their employees in case of enforcement by authorities;
- Each employee will have to be trained once every four years depending on the level of exposure;
- The transition period during which industry must get ready for the restriction will be the subject of political discussion at the end of the regulatory process; and
- Industry will recommend to authorities an implementation roadmap in the coming months.

Exemption- The restriction dossier will also contain a procedure allowing industry to demonstrate that workers are carrying out product-use combinations in ways that lead to no relevant exposure. In this case, such tasks will be exempted from the need for training.

Trainings will depend on levels of exposure:

Level 1 training (4 hours)*	Level 2 training (4+4 hours)*	Level 3 training (4+4+8 hours)*
▪ 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 ▪ Level 1 training can be e-learning	▪ Handling of mixtures at ambient temperature (incl. foam tunnels) ▪ Handling incompletely cured articles (e.g. freshly cured, still warm) ▪ 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 ▪ Maintenance and repair that needs access equipment ▪ Change management	▪ Open handling of warm of 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) * The list is indicative and not exhaustive. More tasks could be added.

Industry's commitment and dialogue with REACH regulations

Adopted in 2006, REACH 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.

In order to deliver on such ambitious objectives, the Regulation has put in place a number of processes that have kept the chemical industry and its value chains quite busy in recent years.

Associations Involved

List of panel members

EU	ALIPA CEC (Footwear) 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 at European and national level are strongly committed to the safe use of diisocyanates and safety at the workplace.

For ISOPA and 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. 2 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 which 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 (HMDI) or hydrogenated MDI and isophorone diisocyanate (IPDI). Aliphatic diisocyanates are specialty intermediate chemicals used primarily in the production of coatings, adhesives, sealants and elastomers. They are converted in polyisocyanates and are used in smaller quantities than the aromatic diisocyanates.

Where are they used?

Together with polyols, MDI, TDI, HDI and HMDI 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.

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 1 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-PU sectors of the EU-27 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, approximately 5 million tons of polyurethanes were produced in the EMEA region in 2012. In the same period, worldwide consumption of polyurethane raw materials amounted to approx. 15.3 million tons.

Safety

Are diisocyanates safe?

Like any substance, diisocyanates' use 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.

What is sensitisation?

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 high allergic reaction with respiratory impacts (e.g. asthma).

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

Furthermore, it is important to highlight that the majority of MDI's and TDI's uses are industrial or professional applications. Health complaints only occur if the person is in contact with the substance after high levels of exposure.

MDI and TDI are intermediates and cannot be found in finished consumer products. Therefore sensitisation is more likely to occur with workers rather than consumers.

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?

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.

According to the Risk Management Option Analysis conclusions, "the envisaged restriction would prohibit the use of substances which contain more than 0.1wt% of free diisocyanate (of whatever kind), unless a company can prove convincingly that they have an internal system in place that ensures the procedures to handle diisocyanates are strictly followed. This should also include conditions that cover health risks to bystanders (e.g. building occupants), especially from spray foam applications. Compliance to such a system should be shown by participation in a certification scheme that requires maintaining a minimum of certain use conditions."

Restrictions would therefore target products containing more than 0.1% by wt monomeric diisocyanates.

Are diisocyanates still available on the EU market and can I still legally use them?

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

What are the next steps?

BAuA has registered its intention to introduce a restriction dossier and we expect BAuA to submit it to ECHA in October 2016.

It is in this dossier that BAuA will detail the procedures and measures that industry will have to implement in order to guarantee the safe handling of diisocyanates at the work place.

The Risk Assessment and Socio-Economic committees of ECHA are then expected to give opinions on the dossier. Public consultations will take place during this process and all stakeholders will be invited to share their views with ECHA.

Once both opinions have been published, the European Commission has three months to prepare the final decision.

What shape is the restriction likely to take?

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

Detailed measures are currently under consideration.

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
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.
ROI:	ECHA Registry of Intentions
SVHC:	Substance of very high concern
TDI:	Toluene diisocyanate

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