A guide to the restriction process applying to diisocyanates

Fachverband Schaumkunststoffe und Polyurethane e.V.

Brüssel • Frankfurt • Stuttgart
Postal address: Stammheimer Straße 35 • D-70435 Stuttgart
Tel. +49 711 993 751-0 • **www.fsk-vsv.de** • fsk@fsk-vsv.de

Exclusion of liability

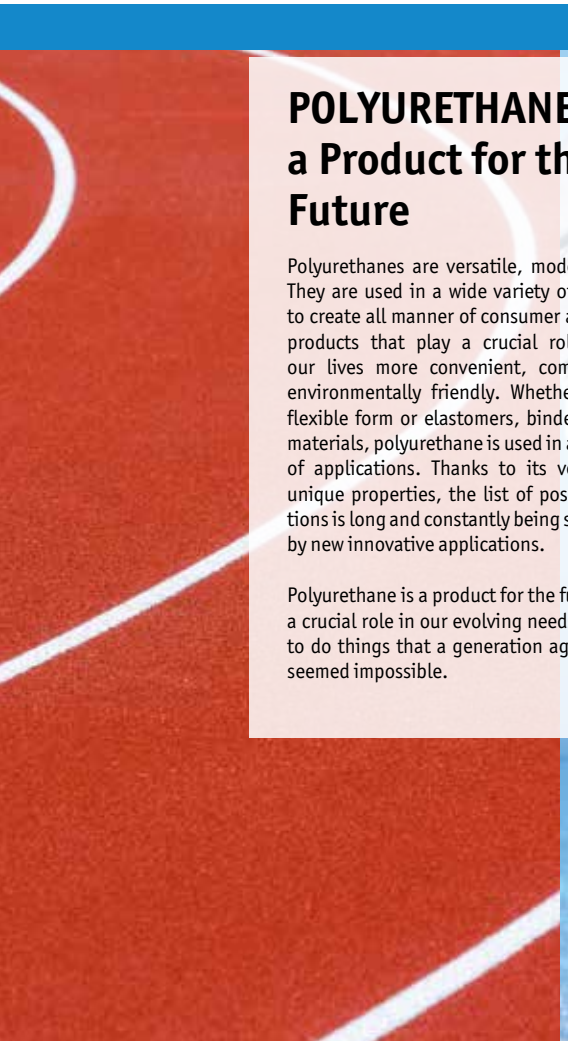
This document is for informational purposes only. All data and information contained in this document are taken from sources FSK considers reliable. In addition, the authors have taken the utmost care to ensure that the facts and opinions expressed are appropriate and accurate. However, no guarantee or liability can be assumed for correctness – neither expressly nor implicitly. Moreover all information may be incomplete or summarized. Neither the FSK nor the involved parties or cooperating companies assume any liability for damages resulting from the use of this document or its contents or otherwise in this context.

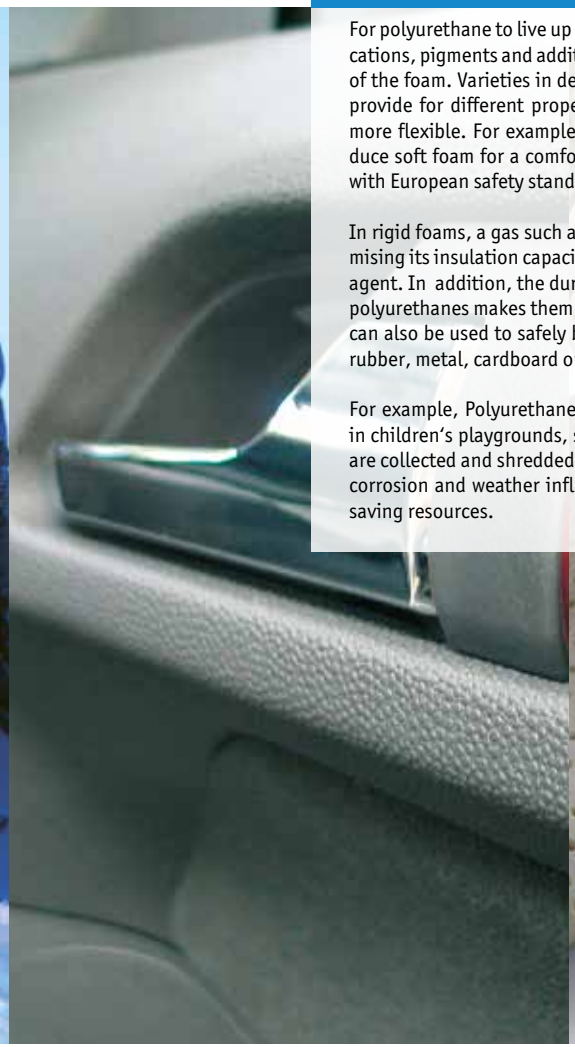
Welcome to the FSK guide on REACH processes applying to the treatment and handling of diisocyanates.
This document was created in cooperation with ISOPA/ALIPA and EUROPUR to examine possible questions concerning diisocyanates and their safe handling in the PUR value chains of our members. More specifically, 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 possible applications is long and constantly being supplemented by new innovative applications.

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. 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 and foam. By adding water, acid or the use of physical propellants, foam is produced.

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. Varieties in densities are almost endless, the molecule is adapted to provide for different properties, polyurethane foam can be made more rigid or more flexible. For example, carbon dioxide is used as the blowing agent to produce soft foam for a comfortable sofa. All foam blocks are tested for compliance with European safety standards.

In rigid foams, a gas such as pentane is "trapped" in the foam's closed cells, optimising its insulation capacity. As an alternative, water can also be used as blowing agent. 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, metal, 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 significantly increasing their durability and saving resources.

FSK –
Specialist Association Foamed Plastics and Polyurethanes

Successful industries need strong professional organizations as a platform for exchanges and contacts and the representation of interests. The FSK is one of the most important trade associations of its industry in Europe and, with its 50-year tradition, is the largest national association of the polyurethane and foamed plastics processing industry.

The Specialist Association Foamed Plastics and Polyurethanes e.V. (FSK) is an association of the plastics processing industry, representing a total volume of approx. 9 billion euros for the polyurethane and foamed plastics industry. The FSK is involved in a network of several associations, such as the ARGE (specialist associations for chemicals, plastics and textiles).

Members of the FSK from over 10 countries include raw material companies, machine manufacturers, system houses/formulators and above all processing companies from the material sectors polyurethane, polypropylene, polyethylene, rubber foams, melamine resin foam, PVC foam etc. OEMs such as Volkswagen and BMW are also members in the FSK.

Who are ISOPA/ALIPA and EUROPUR?

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.

EUROPUR is the European association of flexible polyurethane foam blocks manufacturers.
Polyurethane foams make our daily lives safer and more comfortable. They are vital to applications that we take for granted. Mattresses, furniture cushions and car seats are just some examples. As part of the global chemical industry, EUROPUR is committed to Responsible Care®. This notably means that we seek to continuously improve the environmental, health and safety knowledge and performance of our technologies, processes and products over their life cycles.

Registration

Evaluation *and*

Authorisation *of*

CHemicals

REACH & DIISOCYANATE

As important building blocks for polyurethane production diisocyanates are subject to the REACH ordinance.

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 the chemical industry and its value chains have implemented in recent years.

Registriation

Since 1, June 2007, 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...).

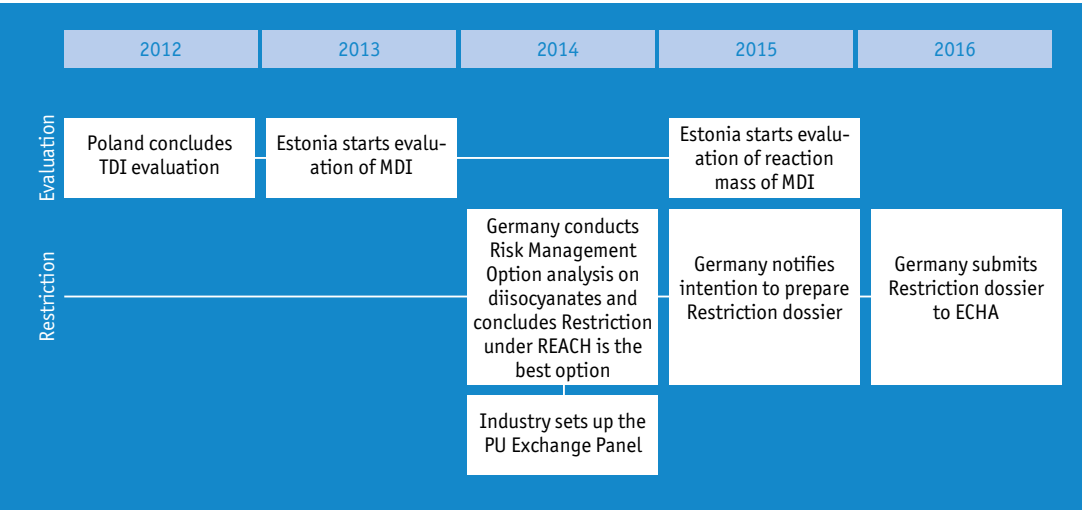
Restriction

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 are exposed to the substances are both informed and trained in order to manage any risks associated with handling the substances.

REACH & DIISOCYANATE (What has happened until now)

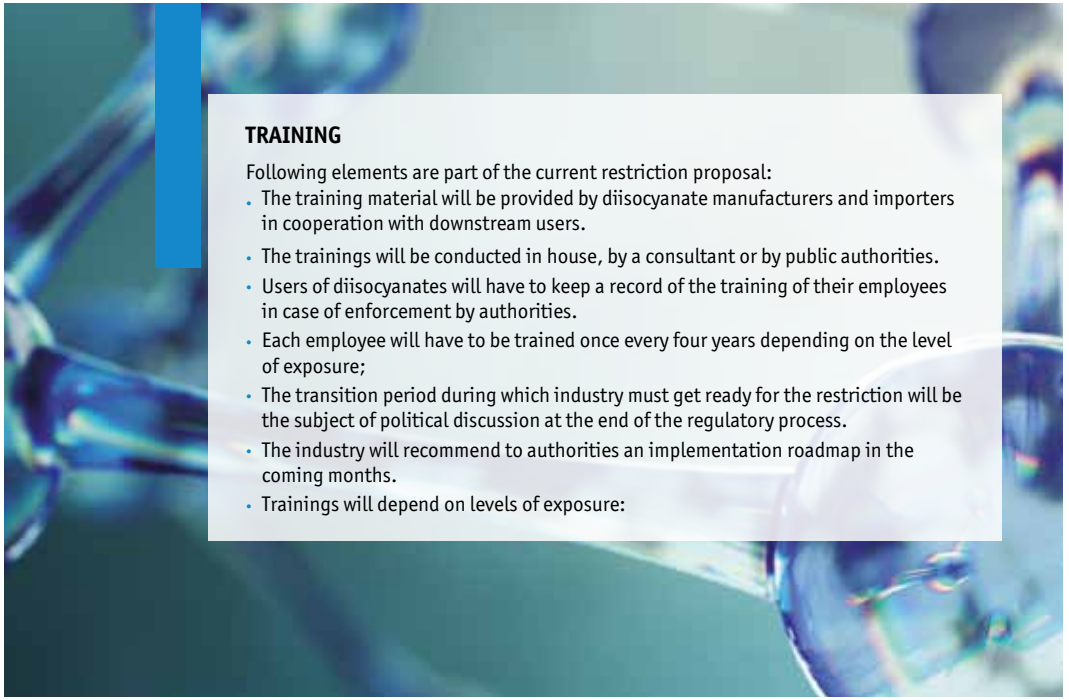
Diisocyanates have been subject to regulatory processes in Poland, Estonia and Germany since 2012.

REACH TIMELINE



Evaluation led by Poland and Estonia
Both TDI and MDI and aliphatic isocyanates 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 (Federal Agency for Occupational Safety and Health), 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/April 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.



TRAINING

Following elements are part of the current 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.
- The industry will recommend to authorities an implementation roadmap in the coming months.
- Trainings will depend on levels of exposure:

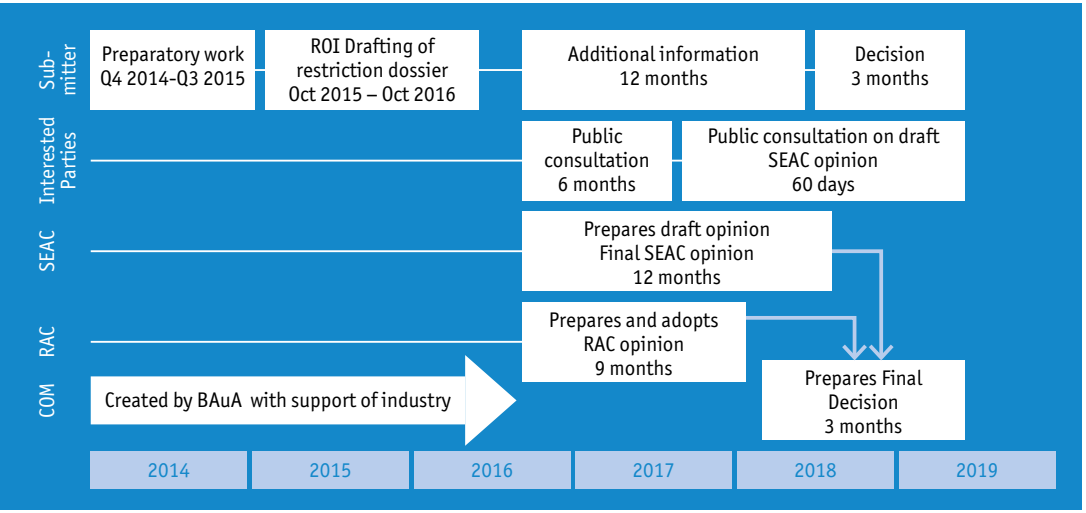
Level 1 training (4 hours)*	Level 2 training (4+4 hours)*	Level 3 training (4+4+8 hours)*
• Loading/Unloading Trucks • Pumping/loading using closed systems • Application of sealants and adhesives (including foam application from cans) • Handling of cold fibers and composite materials after manufacturing • Polyurethane processing 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 and hot formulations (45°C 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.*

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.

RESTRICTION PROCESS



COM: *European Commission*
SEAC: *Committee for Socio-Economic Analysis (the committee develops ECHA statements on the socio-economic impact of potential legislation on substances in the REACH process.)*
RAC: *Committee for Risk Assessment (the committee develops ECHA statements on the risks of substances to human health and the environment in the REACH process.)*

Industry's commitment and dialogue with REACH regulators

The diisocyanate industry (manufacturers), processors, formulators/system houses and machine manufacturers were integrated in the process right from the beginning in order to provide the authorities with the most reliable and uniform data and make information available to the REACH regulators which could apply to all enterprises, including small and medium-sized enterprises (SMEs).

Following the RMOA of diisocyanates, carried out by the BAuA in 2014, ISOPA and ALIPA decided to pursue a further cooperation with downstream associations on REACH-related issues and to actively involve authorities conducting research on diisocyanates with relevant information within the framework of a newly created platform, the PU Exchange Panel. The aim of this group is to enable the entire value added chain to be better involved in the process with BAuA and all other REACH authorities in Europe. It supports the BAuA in the development of appropriate and reliable measures. These measures, which are then mandatory, ensure highest possible product responsibility.

–NH–CO–O–

PARTICIPATING ASSOCIATIONS

ALIPA (European Aliphatic Isocyanates Producers Association)
CEC (European Confederation of the Footwear Industry)
CEPE (European Council of the Paint, Printing Ink and Artists' Colours Industry)
COTANCE (European Leather Industry)
Deutsche Bauchemie (Association for manufacturers of construction-chemical products)
EFCC (European Federation for Construction Chemicals)
EFIC (European Furniture Industries Confederation)
EPF (European Panel Federation)
EPDLA (European Polymer Dispersion and Latex Association)
Euratex (European Apparel and Textile Confederation)
Euromoulders (European Association of Manufacturers of Moulded Polyurethane Parts for the Automotive Industry)
Europur (European association of flexible polyurethane foam blocks manufacturers)
FECC (European Association of Chemical Distributors)
Fedustria (Federation of the Belgian textile, wood and furniture industry)
FEICA (Association of the European Adhesive and Sealant Industry)
FSK e.V. (Specialist Association Foamed Plastics and Polyurethanes)
ISOPA (European trade association for producers of diisocyanates and polyols)
IVK German Adhesives Association)
IVPU (German Industrial Association for Polyurethane Rigid Foam)
PPA (European Association for Panels and Profiles)
PU Europe (European Association for the polyurethane insulation industry)
VdL (Association for paint and printing ink)
ZVEI (Central Association of the Electrical Engineering and Electronics Industry)

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, 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.

alipasafeguard, 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 DIISOCYANATE

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 used primarily in the production of coatings, adhesives, sealants and elastomer. They are converted into polyisocyanates and used in smaller amounts than aromatic diisocyanates. Besides these important diisocyanates, there are a few other specialties.

Where are they used?

Together with polyols, aromatic and aliphatic diisocyanates 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.

** Source: ISOPA 2013*

SAFETY

Are diisocyanates safe?

Diisocyanates can be safely used in the workplace and in the production process if the chemicals are handled according to relevant risk management and safety measures. Since diisocyanates are exclusively reactive chemicals, the end products are also safe. After the chemical reaction, practically no free diisocyanates are present in the products, i.e. consumers are not exposed to these substances and do not come into contact with these substances.

Do MDI and TDI meet Substance of Very High Concern (SVHC) criteria?
Our industry firmly believes that diisocyanates are not SVHC according to the criteria outlined under REACH, for the three following reasons:

- The threshold for respiratory sensitisation is never met if 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 diisocyanates 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 recover.
- In the last decade, we have observed a ssignificant 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 diisocyanates uses are industrial or professional applications. Health complaints only occur if the person is in contact with the substance after high levels of exposure. These 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 restrictions on diisocyanates being considered?
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 is the current status of the procedure?
BAUA's proposal to limit the handling of diisocyanates over 0.1% by weight to certified trained persons is currently being examined by ECHA. The Committee on Risk Assessment (RAC) and the ECHA Committee on Socio-Economic Analysis (EAC) are currently drafting a statement on the dossier. BAuA is collecting additional information and continues to work closely with the industry. At ECHA, consultations are already taking place among the Member States, also involving the PU Exchange Panel and the FSK. The industry is significantly involved in the process and thus can incorporate their views and numerous proposals in the restriction proceedings.

What are the next steps?
Following the publication of the RAC and SEAC statements and the public consultation (expected to start in May 2017), the European Commission will decide on the proposed restriction within three months. If the European Commission adopts BAuA's proposal, a uniform and compulsory training and certification system will be introduced throughout Europe.

Who is affected?
Each company dealing with diisocyanates is obliged to train its employees in the safe handling and use of the substances and to provide proof of this (certification). All companies along the value chain are affected, from manufacturer / importer to system houses / formulators to downstream processors.

What will businesses be facing?
The training content will be uniformly developed across Europe. All companies must compulsorily train all employees according to these contents, whereby the scope is based on the type of possible exposure. This also applies to certification.

When will training and certification become obligatory?
Directly following the Commission's decision, the training and certification system will be implemented across Europe. The content and prerequisite for this are already in the development phase.

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.*
Diisocyanate:	*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*
FSK:	*Specialist Association for Foamed Plastics and Polyurethanes*
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*
NDI:	*Naphthalene 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.*
RTP:	*Resins Technical Platform*
SVHC:	*Substance of very high concern*
TDI:	*Toluene diisocyanate*