

# Topic Summary

Edition 1: February 2019

## Restriction of the use of diisocyanates in the European Union

### Executive Summary

The marine industry, as a downstream user of polyurethane, will be impacted by upcoming changes to the legislation regarding diisocyanates. This document contains details of the relevant legislation including recent and pending developments and a description of how it could affect the work of the marine industry. Annex 1 (page 5) answers frequently asked questions.

The two main EU legislations related to the restriction of diisocyanate are REACH & OSH. REACH is the EU chemicals regulation and OSH is the EU workplace health and safety regulation. These two regulations have an impact on the use of diisocyanates and the related polyurethanes supply chain, which is relevant to the marine industry because these substances are used for coating materials, foam (insulation materials and moulds), sealants, bonding and adhesive materials and a wide variety of other applications. The reason for restriction of the use of diisocyanates and diisocyanate containing materials is the risk of asthma associated with working with the substance.

REACH has impacts on materials and products/components and machinery and a series of applications will need to be monitored, as the recent updates will impact coating application processes & quality of paint products, foam (moulders and isolation materials), sealant application and bonding materials. OSH and REACH also have an effect on the application processes.

ICOMIA is a stakeholder the polyurethanes (PU) exchange panel along with other industries committed to the safe use of diisocyanates and safety at the workplace at a European level. A restriction dossier has been produced and by June 2019, the European Commission will prepare a draft amendment to the REACH regulation and implement the applicable rules of the OSH Directive, which then will be adopted if no objection is raised by the European Parliament or the Member States.

For all the downstream users of PU, which includes the marine industry, behaviour in the workplace is key to ensuring the safe use of diisocyanates. Under REACH it is necessary for targeted product stewardship initiatives to be developed for the control of diisocyanate. In this case, training is at the core of the proposed amendments to the restriction and all users of diisocyanate must be prepared to provide training for employees, as well as implement the procedures that reduce risk for their workers. Upcoming restriction measures mean that professional workers handling diisocyanates/PU will require training.

The marine industry should be aware that any workers handling these materials will require training, which is currently being developed with the support of ICOMIA. ICOMIA will work with other industries on the PU exchange panel to ensure that relevant training is developed, and related procedures are incorporated within the next framework.

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## Background

It was highlighted in the President of the European Commission Jean-Claude Juncker's recent State of the Union address that a priority initiative for delivery before the European Parliament elections protection of workers from the risks related to exposure to carcinogens or mutagens at work. Further, there is now a recognised connection between REACH (which is about regulation of chemicals) and health and safety in the workplace regulations.

Diisocyanate (a specific kind of isocyanate) is a substance which is considered a potential threat to both the environment & human health. Isocyanates are well-known dermal and inhalation sensitizers in the workplace and exposure can cause asthma, lung damage and, in severe cases, death.

ICOMIA has been engaged in the restriction process from the beginning, in order to provide authorities with the relevant information about our industry. This ensures that the REACH and OSH regulators have a pragmatic and harmonised approach, which is applicable to all companies within the recreational marine industry and the large yachts industry.

## Relevance for the marine industry

Diisocyanates and polyols are the two main components of polyurethane. Polyurethane is a polymer and used in the marine industry in coating materials, foam (insulation materials and moulds), sealants, bonding and adhesive materials and a wide variety of other applications (for example elastomers).

Polyurethane is derived from the chemical reaction between diisocyanates and polyols; when mixed together, they polymerise. There are many types of diisocyanates, the foremost of which are: methylene diphenyl diisocyanate (MDI) and Toluene diisocyanate (TDI)

## REACH

[REACH \(EC 1907/2006\)](#) is an EU Directive from 2006. It aims to improve the protection of both the environment and human health through the better and earlier identification of the properties of chemical substances. REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals. The regulation 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. Unlike previous legislation, REACH places the burden of proof on industry.

To comply with REACH, 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 these objectives, there are a number of processes in place:

- **Registration:** Companies (manufacturers, importers, downstream users) are obliged to collect information on the properties and the uses of the substances. This includes an assessment of their hazards and potential risks.
- **Authorisation:** The authorisation procedure aims to ensure 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 ECHA [SVHC List](#). The list includes Carcinogenic, Mutagenic or

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Reprotoxic (CMR) substances, Persistent Bio-accumulative Toxic (PBT) substances and substances of equivalent concern (endocrine disruptors, sensitisers, etc.)

- **Evaluation:** ECHA and EU Member States must 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.
- **Restriction:** The process of the current diisocyanate restriction and being 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, including diisocyanates, where the product is used in a large number 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 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 weight monomeric diisocyanates.

### OSH Framework Directive

The European Framework Directive on Safety and Health at Work ([Directive 89/391 EEC](#)) (also known as OSH Framework Directive) encourages measures which improve the safety and health of workers at work. It applies to all sectors of activity (including the marine industry), both public and private, except for specific public service activities, such as the armed forces, the police or certain civil protection services. The general principles of prevention under OSH include avoiding and evaluating risks, combating the risks at source, prioritising collective protective measures (over individual protective measures), giving appropriate instruction to workers and developing a coherent overall prevention policy.

Further information on OSH and REACH can be found in Annex 2.

### Current Status

Diisocyanates have been subject to regulatory processes in Poland, Slovenia, Estonia and Germany since 2012. The evaluation (under REACH) was led by Poland, Slovenia and Estonia. The restriction of use was led by Germany.

BAuA, the German REACH Competent Authority focused on 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 BAuA recommended mandatory training that would ensure safety in the workplace for workers handling diisocyanates. Integrating a training and certification scheme defining minimum conditions for the safe handling of the substances is at the core of this recommendation. Detailed measures need to be assessed and agreed at European level.

BAuA formally registered its intention to prepare a restriction dossier in 2015 and submitted the final BAuA restriction dossier to ECHA in 2016. ECHA's restriction dossier incorporates the comments from Committee for Risk Assessment (RAC) and Committee for Socio-

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Economic Analysis (SEAC) and comments received during the public consultations. Once ECHA's final restriction dossier has been published, the European Commission has three months to prepare (started with some delays in February 2019) the draft amendment to the REACH regulation and implementing the applicable rules of the OSH Directive which then will be adopted if no objection is raised by the European Parliament or the Member States.

The most recent decisions taken by the European Commission are:

- Restriction measures has to be reduced in its complexity for technical/legal reasons but also to ensure acceptance amongst Member States.
- Training for those handling diisocyanates at work will be at the core of the restriction measures of diisocyanates
- The result of the independent scientific evaluation by RAC/SCOEL (REACH) will be handed over to the Competent Authorities of OSH Directive
- Diisocyanates are a potential priority substance within OSH Directive
- The intention of the legislation is to improve the behaviour of employees at the workplace with the aim of reducing the risk of developing occupational asthma.

The main goals within the restriction are:

- Suitable risk assessment tool used to develop the right risk management measure
- Consistent training across the EU
- Workable for both diisocyanate and polyurethane users and downstream users
- Level playing field across the EU

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

- EU harmonised training materials will be provided by diisocyanate manufacturers and importers for the use of downstream users. These materials will be developed in cooperation with downstream users.
- The training 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 training will be conducted using a train-the-trainer principle
- Users of diisocyanates will have to document the completion of the training
- 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.
- 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
- Following European Commission recommendations to further cooperate with downstream associations in the context of REACH-OSH related issues, we will actively provide relevant information to authorities conducting research on diisocyanates in the Polyurethane (PU) Exchange Panel and MoU Group diisocyanates restriction.
- The PU Exchange 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

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downstream associations of the PU Exchange Panel are joining efforts to develop teaching materials.

For all the downstream users of PU, which includes the marine industry, behaviour in the workplace is key to ensuring the safe use of diisocyanates and training will be at the core of this regulation. The marine industry should be prepared to provide training for employees handling diisocyanates/PU, as well as implement the procedures that reduce risk. Upcoming restriction measures mean that professional workers handling diisocyanates/PU will require training. ICOMIA will work with other industries on the PU exchange panel to ensure that relevant training is developed, and related procedures are incorporated within the next framework.

### Further information

- [REACH \(EC 1907/2006\)](#)
- [OSH Framework Directive \(89/391 EEC\)](#)
- [Review of the REACH Regulation](#) from 2018

## Annex 1: Frequently asked questions

### What restrictions of diisocyanate are there outside EU?

EPA – USA announced in 2015 that it is taking action to protect consumers from new uses and imports of harmful diisocyanates in polyurethane. Diisocyanates as a category are subject to Toxics Release Inventory reporting. According to the EPA – USA, isocyanates used in the production of polyurethanes such as coatings, elastomers, adhesives, and sealants pose a risk through consumer and general population exposure, as PU can be found in consumer products used in and around homes or schools. Australia also wants to follow the US path to the restriction of use, focused on the protection of consumers, to stay in compliance with EPA - USA

Australia, Ireland and the United Kingdom have set long-term occupational exposure limits and short-term limits for workplace air.

More information:

- [The Control of Major Accident Hazards Regulations 2015](#) (UK legislation)
- [Regulating chemicals \(REACH\) if there is no Brexit deal](#)
- [Guide to handling isocyanates in Australia](#)
- [Isocyanate handling in Ireland](#)
- [EPA USA Guidance on managing diisocyanate](#)

### What are the different types of diisocyanates?

**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**).

### What are diisocyanates used for?

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Together with polyols, MDI and TDI are the essential building blocks for the manufacturing of polyurethane (PU). PU can be tailored to be either rigid or flexible, and it is the material of choice for a broad range of applications.

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.

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 chain are manufacturers of building insulation, white goods, automotive, marine Industry (including recreational craft), furniture and bedding, footwear, coatings and adhesives, etc.

### **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 and will become mandatory in the future once the restriction is adopted by the European Union.

### **Which companies produce diisocyanates?**

European manufacturers of aromatic diisocyanates and polyols are: Covestro, BorsodChem, Dow, BASF, Huntsman and Shell.

European Isocyanate producers are BASF, Covestro, Evonik and Vencorex.

### **How much diisocyanate 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.

### **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?**

The isocyanate industry claims that MDI and TDI are not SVHC according to the criteria outlined under REACH, for the following reasons:

- The threshold for respiratory sensitisation<sup>1</sup> is never met when risk management measures are applied correctly. Therefore, the isocyanate industry is convinced that the inclusion of diisocyanates as sensitisers under the SVHC process would not be justified or proportionate to the risk.

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<sup>1</sup> 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).

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- 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 total recovery.
- In the last decade, industry 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*.
- 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 products.

### **Are there alternatives to polyurethanes?**

Polyurethanes provide outstanding benefits in many applications and contribute significantly to sustainable development 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.

## **Annex 2: Further information on regulations**

### **REACH: Regulation (EC) No 1907/2006; Registration, Evaluation, Authorization and Restriction of Chemical Substances Regulation**

REACH is an EU regulation on 'Registration, Evaluation, Authorisation and Restriction of Chemicals'. It was adopted in 2007 to improve the protection of human health and the environment from the risks that can be posed by chemical whilst enhancing the competitiveness of the EU chemicals industry. The regulation has an impact on most companies not only within the EU but as well on Global bases. It improves the protection of human health, enhances industry competitiveness, promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals and, in principle, applies to all chemical substances – not only those used in industrial processes but also in our day-to-day lives (for example in cleaning products, paints, clothes, furniture and electrical appliances). The authorisation procedure aims to insure the risks from Substances of Very High Concern (SVHC) are properly controlled and are progressively replaced by suitable alternatives whilst ensuring the EU internal market functions well.

### **Directive 89/391/EEC - OSH "Framework Directive"**

Directive 1989/391/EEC is often referred to as the "framework directive" and the 'basic law' on occupational safety and health in the EU. It established the instrument of risk assessment

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in European occupational safety and health risk (OSH) legislation, which, when it was adopted in 1989, was a revolutionary principle for the legal systems and OSH management systems of many countries. Instead of merely complying with prescriptions and limit values, employers can decide on improvement measures that best meet the risk profile of the company. The Framework Directive can thus be considered a milestone for workplace prevention measures occupational safety and health risk assessment methodologies. The aims of the directive include:

- Establishing an equal level of safety and health for the benefit of all workers. However, domestic workers, certain public and military services, and self-employed are exempt.
- Ascribing responsibility to employers for preventing ill-health at work; obliging employers to take appropriate measures to make work safer and healthier.
- Defining role and key elements of risk assessment, such as hazard identification, workers participation, adopting adequate measures (with the priority of eliminating risk at source), documentation and periodical re-assessment.
- With the new obligation for prevention processes in the companies, the Directive implicitly raises the question for new forms of safety and health management as part of general management processes.