Commission Regulation (EU) 2020/1149 of 3 August 2020 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards diisocyanates (Text with EEA relevance)

COMMISSION REGULATION (EU) 2020/1149

of 3 August 2020

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards diisocyanates

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[(1)], and in particular Article 68(1) thereof,

Whereas:

(1) Diisocyanates have a harmonised classification as a respiratory sensitiser category 1 and as a skin sensitiser category 1 according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(2)]. Diisocyanates are used as chemical building blocks in a wide range of sectors and applications, in particular in foams, sealants and coatings, inter alia, throughout the Union.

(2) On 6 October 2016, Germany submitted to the European Chemicals Agency ('the Agency') a dossier[(3)] pursuant to Article 69(4) of Regulation (EC) No 1907/2006 ('the Annex XV dossier'), in order to initiate the restriction procedure set out in Articles 69 to 73 of that Regulation. The Annex XV dossier indicated that respiratory sensitisation, due to both dermal and inhalation exposure to diisocyanates, leads to occupational asthma in workers, which has been identified as a significant occupational health problem in the Union. The annual number of new occupational diseases caused by diisocyanates (estimated to be more than 5 000 cases) is considered unacceptably high. The Annex XV dossier demonstrated that action on a Union-wide basis is necessary and proposed to restrict the industrial and professional use, as well as the placing on the market, of diisocyanates on their own, and as constituent of other substances and in mixtures.

(3) The restriction proposed in the Annex XV dossier aims to limit the use of diisocyanates in industrial and professional applications to those cases where a combination of

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2020/1149. (See end of Document for details)*

technical and organisational measures are implemented, and a minimum standardised training course has been followed. Information on how to get access to the course should be communicated throughout the supply chain and it should be the responsibility of the operators placing these substances and mixtures on the market to ensure that training courses are available to the recipients of such substances or mixtures.

(4) On 5 December 2017, the Agency's Committee for Risk Assessment ('RAC') adopted its opinion[4] concluding that the proposed restriction, as modified by RAC, is the most appropriate Union-wide measure to address the identified risks arising from exposure to these substances in terms of effectiveness in reducing those risks. Moreover, it considered that the implementation of the modified proposed restriction would reduce as well the number of diisocyanate-related cases of dermatitis.

(5) RAC concluded that appropriate training is a basic necessity, and that every worker handling diisocyanates should have a sufficient knowledge of the hazards of these substances and an awareness of the risks related with their uses, as well as sufficient knowledge of good working practices and appropriate risk management measures (RMMs), including the correct use of appropriate personal protective equipment. RAC notes that particular training measures are needed to raise the awareness about the importance of health protection by means of appropriate RMMs and safe handling practices.

(6) RAC considered that the cut-off limit of 0,1 % by weight, set for diisocyanates in a substance or in a mixture, corresponds to the lowest concentration limit existing for specific diisocyanates classified as respiratory sensitisers category 1. RAC also agreed with the dossier submitter that the implementation of an indicative or binding occupational exposure limit would not be sufficient to reduce the number of occupational asthma cases to a level as low as possible, since currently, no threshold is known for the sensitising effect of diisocyanates.

(7) On 15 March 2018, the Agency's Committee for Socio-Economic Analysis ('SEAC') adopted its opinion[5], in which it confirmed RAC's conclusion that, in view of its socioeconomic benefits and costs, the proposed restriction is the most appropriate Union-wide measure to address the identified risks. Furthermore, SEAC concluded that the proposed restriction is affordable for the affected supply chains.

(8) SEAC recommended a 48 month deferral of application of the restriction in order to provide sufficient time to all actors for the full implementation of the restriction requirements.

(9) The Agency's Forum for Exchange of Information on Enforcement, referred to in Article 76(1)(f) of Regulation (EC) No 1907/2006, was consulted on the RAC and SEAC opinions concerning the proposed restriction and its recommendations have been taken into account.

(10) On 9 May 2018, the Agency submitted the opinions of RAC and SEAC to the Commission. Based on those opinions, the Commission concludes that an unacceptable risk to human health arises from the use or placing on the market of diisocyanates,

on their own, as a constituent of other substances and in mixtures. The Commission considers that those risks need to be addressed on a Union-wide basis.

(11) Taking into account the Annex XV dossier as well as the opinions of RAC and SEAC, the Commission considers that a minimum requirement for training should be provided to industrial and professional users without prejudice to stricter national obligations in the Member States. The Commission also considers that information of this requirement should be included in the packaging.

(12) For the purpose of possible future revisions of the current restriction, Member States should report to the Commission in accordance with Article 117(1) of Regulation (EC) No 1907/2006 any established training requirements, the number of reported cases on occupational asthma and occupational respiratory and dermal disease, any national occupational exposure levels and information on enforcement activities.

(13) Without prejudice to Union occupational safety and health legislation, in particular the Council Directive 98/24/EC on chemical agents[6], this restriction is intended to enhance the employers' capacity to achieve a higher level of risk control. Small and medium sized enterprises will benefit from this act, which will further enhance the implementation of the present occupational safety and health requirements by providing diisocyanates-specific training programmes throughout the supply chain.

(14) Economic operators should be granted a period of sufficient length to adapt to the new requirements. A transition period of 3 years is appropriate to allow the concerned workforce to perform the required training.

(15) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(16) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2020/1149. (See end of Document for details)*

Done at Brussels, 3 August 2020.

For the Commission

The President

Ursula VON DER LEYEN

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2020/1149. (See end of Document for details)*

ANNEX

In Annex XVII to Regulation (EC) No 1907/2006, the following entry is added:

74. Diisocyanates, O = C=N-R-N = C=O, with R an aliphatic or aromatic hydrocarbon unit of unspecified length	1.	Shall not be used as substances on their own, as a constituent in other substances or in mixtures for industrial and professional use(s) after 24 August 2023, unless: (a) the concentration of diisocyanates individually and in combination is less than 0,1 % by weight, or (b) the employer or self-employed ensures that industrial or professional user(s) have successfully completed training on the safe use of diisocyanates prior to the use of the substance(s) or mixture(s).
	2.	Shall not be placed on the market as substances on their own, as a constituent in other substances or in mixtures for industrial and professional use(s) after 24 February 2022, unless: (a) the concentration of diisocyanates individually and in combination is less than 0,1 % by weight, or (b) the supplier ensures that the recipient of the substance(s) or mixture(s) is provided with information on the requirements referred to in point (b) of paragraph 1 and the following statement is placed on the packaging, in a manner that is visibly distinct from the rest of the label information: “As from 24 August 2023 adequate training is required before industrial or professional use”.
	3.	For the purpose of this entry “industrial and professional user(s)” means any worker or self-employed worker handling diisocyanates