Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions

DIISOCYANATES

ECHA/RAC/RES-O-0000001412-86-174/F
ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

Agreed

30 November 2017

5 December 2017

ECHA/RAC/RES-O-0000001412-86-174/F

30 November 2017

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s):	**Diisocyanates**
EC No.:	**-**
CAS No.:	**-**

This document presents the opinion agreed by SEAC and the Committee's justification for its opinion. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitter's proposal, amended for further information obtained during the public consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

Germany has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at http://echa.europa.eu/web/guest/restrictions-under-consideration on **22 March 2017**. Interested parties were invited to submit comments and contributions by **22 September 2017**.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: *Veda Marija VARNAI*

Co-rapporteur, appointed by RAC: *Sonja KAPELARI*

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **5 December 2017.**

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The opinion of RAC was adopted **by a simple majority** of all members having the right to vote. The minority position including its grounds is made available in a separate document which has been published at the same time as the opinion.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: *Johanna KIISKI*

Co-rapporteur, appointed by SEAC: *Karmen KRAJNC*

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **30 November 2017*.***

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation.

The draft opinion takes into account the socio-economic analysis, or information which can contribute to one, received from the interested parties provided in accordance with Article 69(6)(b) of the REACH Regulation.

The draft opinion was published at http://echa.europa.eu/web/guest/restrictions-under-consideration on **20 December 2017.** Interested parties were invited to submit comments on the draft opinion by **20 February 2018.**

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on ***[date of adoption of the opinion]***. **[**The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by ***[number of days]*** by the ECHA decision ***[number and date]*****]**[1].

[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and][5] 71(1) of the REACH Regulation.**] [**No comments were received from interested parties during the public consultation in accordance with Article[s 69(6) and][3] 71(1)**]**[6].

The opinion of SEAC was adopted ***by*** **[*consensus*.][*a simple majority*]** of all members having the right to vote. [The minority position[s], including their grounds, are made available in a separate document which has been published at the same time as the opinion**.]**[6].

[1] Delete the unnecessary part(s)

Contents

OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Substance Identity (or group identity)	Conditions of the restriction
Diisocyanates	1. Shall not be used as substances on their own, as a constituent in other substances or in mixtures for industrial and professional uses, unless a) the cumulative concentration of diisocyanates in the substance or mixture is less than 0.1 % by weight, or b) the substance or mixture in the form in which it is supplied to the user, including the combination of such substance or mixture, its packaging and any application aid is placed on the market in accordance with paragraph 2b), or c) the employer or self-employed worker ensures that measures and training are taken prior to the use of the substances or mixtures in accordance with the provisions described in Appendix 13[2] (Trainings and Measures). Member States may implement or continue to apply own provisions for the use of these substances and mixtures as long as the minimum requirements of Appendix Trainings and Measures are met. The employer or self-employed worker shall document the compliance to the requirements of Appendix 13 (Trainings and Measures). Proof of successful completion of a training according to Appendix 13 (Trainings and Measures) shall be recognised in all other Member States. 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 uses, unless a) the cumulative concentration of

[2] According to the dossier submitter proposal, the texts of Appendix 12 (Exemptions) and Appendix 13 (Trainings and Measures) should become part of the final legal text. Elements proposed to be included in the final text are available in Appendix 7 and Appendix 8 of the Background document. Additional information can be found in Appendix 5.

	diisocyanates in the substance or mixture is less than 0.1 % by weight, or b) the substance or mixture in the form in which it is supplied to the user, including the combination of such substance or mixture, its packaging and any application aid is compliant with Appendix 12 (Exemptions), or c) the supplier ensures that the recipient of the substance or mixture is provided with information according to paragraph 3. 3. For the purpose of 2c) manufacturers and importers of diisocyanates on their own or as a constituent in other substances and importers of mixtures containing diisocyanates shall develop a set of teaching material in accordance with the provisions of Appendix 13 (Trainings and Measures) in an official language of the Member State where the substance or mixture is placed on the market before placing the substance or mixture on the market. They shall ensure that training courses based on the training material are available to the recipients of such substances or mixtures. They shall review and update the training material after a maximum of 8 years, or without delay if new information, which may affect the risk management measures, becomes available and inform the recipients accordingly. Natural or legal persons formulating mixtures containing diisocyanates within the EU shall provide necessary information for the development of the teaching material upon request of their substance suppliers. All downstream users may be consulted for the purpose of the development and update of the teaching material.

THE OPINION OF RAC

See the opinion of RAC.

THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the restriction proposed by the Dossier Submitter on ***Diisocyanates*** is the most appropriate Union wide measure to address the identified risks, as concluded by RAC, taking into account the proportionality of its socio-economic benefits to its socio-economic costs provided that the conditions are modified as stated in the RAC opinion as demonstrated in the justification supporting this opinion.

The conditions of the restriction proposed by RAC and SEAC are:

Substance Identity (or group identity)	Conditions of the restriction
Diisocyanates, O=C=N-R-N=C=O, with R an aliphatic or aromatic hydrocarbon unit of unspecified length	See Annex 1 for example conditions established by RAC and SEAC to show how they could be set out. The Commission will draft the final conditions and this is for their consideration.

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

Description of and justification for targeting of the information on hazard(s) and exposure/emissions) (scope)

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Description of the risk(s) addressed by the proposed restriction

Information on hazard(s)

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Information on emissions and exposures

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Characterisation of risk(s)

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Uncertaintees in the risk characterisation:

See the opinion of RAC.

Evidence if the risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Evidence if the existing regulatory risk management instruments are not sufficient

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of RAC and SEAC

Summary of proposal:

The Dossier Submitter considers that an unacceptable risk to workers arises from exposure to diisocyanates due to respiratory sensitisation. The analysis made indicates that handling diisocyanates leads to approximately 6500 new cases yearly, mainly occupational asthma (OA). Occupational diseases caused by diisocyanates are reported in all Member States.

It is explained in the proposal that diisocyanates are being used throughout the EU. The importance of extending the necessary training throughout the supply chain to ensure the effectiveness of the measure is highlighted in the Background Document.

It is further stated that since the measures proposed result in similar obligations throughout the EU, the restriction would not disturb the internal market, and would actually reduce any existing market distorting effects by providing more uniformity in the conditions of use across the EU.

RAC and SEAC conclusion(s):

Based on the key principles of ensuring a consistent level of protection across the Union, SEAC and RAC support the view that any necessary action to address the risks described in the Background Document should be implemented in all MS.

RAC agreed with the conclusion that the identified risk to the workers is not adequately controlled and needs to be addressed. Diisocyanates are being used throughout the EU. Therefore, action is required and it should be taken on a union wide basis.

Key elements underpinning the RAC and SEAC conclusion(s):

RAC concluded that the risks for workers due to the use of diisocyanates are not adequately controlled. SEAC recognises that a significant share of cases of OA could be avoided through the implementation of improved technical and organisational measures and work practices, including better usage of PPE, and a transition towards using products with less potential for exposure.

Diisocyanates are used throughout the Union. Currently, the level of protection and level of risk differs between different Member States and different companies. The proposed measure aims at developing equally high standards of health protection with regard to occupational exposure to diisocyanates throughout the Union.

Also, the free movement of workers and goods within the EU would be enhanced by common requirements at the EU level, as appropriate training would be arranged throughout the EU and possible exemptions applied regardless of the Member State where the use takes place. Workers, who will take relevant training in one Member State, should not need to repeat such training if they move to another Member State. SEAC notes that common requirements across the EU/EEA would also provide a common basis for competition between companies.

Workers possibly exposed to diisocyanates already must undergo training. Directives 89/391/EEC and 98/24/EC on occupational safety and health[3] define a generic obligation to provide the workers with adequate safety and health training for all possible workplace hazards. However, the requirements in the Directives are at a general level and do not for example specify the form, duration or frequency of the training; for instance, the form of the training can be oral communication or instructions given in written form. Directives 89/391/EEC and 98/24/EC do not foresee specific requirements for work with diisocyanates or even sensitisers more generally.

Certain Member States have additional national regulation which supports better implementation of the training requirements of Directives 89/391/EEC and 98/24/EC with regard to diisocyanates.[4] This is certainly an important reason why the level of implementation also appears to vary widely between the Member States and sectors.

Given the limited requirements (e.g. training requirements in Directives 89/391/EEC and 98/24/EC), stricter enforcement of the worker protection legislation alone would not be able to provide significant improvement in health protection of workers. It is also agreed that, as claimed by the Dossier Submitter, the quality level of training may have been difficult to enforce since quality requirements have not been implemented in the EU level legislation.

Training is already organised by industry organisations. For example, the member companies of European Diisocyanate and Polyol Producers Association (ISOPA) have launched a training program called "Walk-the-talk" as a part of a product stewardship program. The training programs provided by industry associations are much more focused to the specific issues encountered with diisocyanates. However, according to the Dossier Submitter, the capacity to reduce OA cases through the voluntary industry programme is not in the same order of magnitude as for the proposed restriction. As voluntary programs are not mandatory, it is difficult to affect the level of participation and thus effectiveness of the programs. The Dossier Submitter reports that the number of workers covered by the product stewardship programs is estimated to be 13 000 workers – that is only 0.9% of the potentially exposed workers in EU-28. Furthermore, in regard to voluntary programmes, it is noted that no guarantee of perpetuity can be given.

[3] Directive 89/391/EEC - OSH "Framework Directive"
Directive 98/24/EC - risks related to chemical agents at work
[4] For example, Sweden and Denmark, see chapter B.9.1.2. in the dossier for more information.

JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Justification for the opinion of RAC and SEAC

Scope including derogations

Justification for the opinion of RAC

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Justification for the opinion of SEAC

Summary of proposal:

The Background Document contains assessments of three restriction options (RO) under REACH: the proposed restriction entailing an implementation of a training program for workers exposed to diisocyanates along with a possibility of exemptions (RO1), one entailing the training requirement without a possibility of exemptions (RO2), and finally, a general ban of the use of diisocyanates (RO3). Additionally, a few other risk management options inside and outside of REACH have been considered however discarded.

RO1 (the proposed restriction - training with exemptions)

The proposal limits the use of diisocyanates in industrial and professional applications to cases where i) the concentration of diisocyanates in substances and mixtures is less than 0.1% by weight, ii) the substance or mixture in the form in which it is supplied is compliant with conditions of 'very low potential for exposure' as specified in Appendix 7 of the background document or iii) a minimum standardised training package has been implemented.

The concentration limit proposed is 0.1% by weight, which corresponds to the lowest specific concentration limit existing for specific diisocyanates.

Exemptions can be applied to substances and mixtures with very low potential for exposure, which are, according to the proposal by the Dossier Submitter, substances and mixtures where there is no relevant risk of occupational asthma. The substance or mixture fulfils the criterion of very low potential for exposure if the cumulative concentration of all diisocyanates is demonstrated to be below 0.001 ppm as time weighted 8 hours average, skin exposure is low and the biological concentrations are demonstrated to be below the values set down for each diisocyanate. Exemptions are not possible for applications where aerosols are sprayed, at temperatures above 45 °C or if personal protection equipment of Category III or technical ventilation is needed during the application, due to the high exposure.

Regarding possible exemptions, it is a requirement that the manufacturer, importer or formulator (M/I/F) performs an evaluation of whether the conditions of Appendix 7 (Exemptions) in the Dossier Submitter's proposal are fulfilled. The outcome of the analysis must be documented and the documentation provided to enforcement authorities on request. Information according to Appendix Exemptions must be communicated to downstream users in the safety data sheet. The downstream user must then choose to either use an exempted, possibly more expensive product, or ensure their workers participate in the training program.

Where the exemption procedure is not followed by the M/I/F or Downstream User, workers using substances or mixtures that contain diisocyanates in concentrations 0.1% or more by weight would have to participate in a training program set up according to Appendix 8 (Trainings and Measures) of the Background Document. There are six different training options considered in the Background Document:

a) courses at an established education centre,
b) training is part of a supplier's technical support,
c) external (off-site) course,
d) on-site training,
e) e-learning,
f) train the trainer practice with in-house instruction of the workers

It is expected that the training sessions would take three to eight hours per worker (depending on the training option chosen) and be repeated every four years.

The Dossier Submitter has originally assumed that exemptions will be applied to practically all substances and mixtures with very low potential for exposure, based on discussion with ISOPA/ALIPA over their plans for the implementation of this proposal. ISOPA and ALIPA members are reported to cover about 80% of diisocyanates placed on the EU market.

According to this scenario, 1.6 million workers out of 5.2 million of all workers exposed to diisocyanates will have to be trained.

RO2 (training for all workers using diisocyanates at 0.1% or above, no exemptions exist)

In this case, there would be training requirements for all workers using diisocyanates in concentrations of 0.1% by weight or above; no exemption would be possible for substances and mixtures with very low potential for exposure. The Dossier Submitter concludes that the measures under this option would require more resources (i.e. it is likely to be more expensive due to the need to train much more workers (5.2 million)) when compared to RO1 (1.6 million). However, the risk reduction outcomes would not increase in proportion as the overwhelming majority of cases of occupational asthma has been expected to occur in the sectors where the workers would need to be trained already under RO1.

RO3 (total ban of diisocyanates)

In addition to the above two ROs, the Dossier Submitter also considered a restriction on the placing on the market and use of all substances and mixtures containing diisocyanates. It was explained by the Dossier Submitter that the existence of suitable alternatives is very poor. Uses are diverse and universal alternatives do not exist. In the case of building products, alternatives have been identified for some uses. For most uses alternatives either do not exist or the implementation thereof would not lead to a decreased risk level (for example in the

case of epoxides). Historically diisocyanates were introduced as a less risky alternative to traditional solvent based products, the use of which easily led to accidents due to flammability.

Due to the unavailability of alternatives, this option would create major economic consequences, and is believed by the Dossier Submitter to be unacceptable also from a social perspective (unemployment). The analysis made in the dossier shows that the negative consequences to the vehicle refinish sector alone would by far outweigh the benefits expected from this risk management option.

Other risk management options than a restriction under REACH

- The authorisation route under REACH has been discussed but discarded, first, because it is considered impractical due to the high number of uses involved and the related high number of applications for authorisation expected, and second, because the possibilities for substitution are found to be very limited (almost non-existing). It is also highlighted that with a restriction, all diisocyanates (including diisocyanate residues in prepolymers) can be addressed in a single regulatory action.

- Addressing the identified risks via the tools provided in the Directives on occupational safety and health (OSH) (98/24/EC and 89/391/EEC) has been assessed to some extent. It is noted that occupational exposure limit values (OEL) (set for 9 different diisocyanates) have been implemented widely within the EU, however new cases of occupational asthma continue to develop in high numbers. The Dossier Submitter claims it is not clear to what extent the existing national OELs actually protect workers against the risk of sensitisation. It is explained that undetected peak exposures of short duration, or undetected situations of increased exposure - including situations of dermal exposure - contribute to the development of new cases of occupational asthma. The Dossier Submitter therefore concludes that lowering the OELs or the introduction of improved engineering controls will not be effective enough to reduce the number of occupational diseases. Namely, daily exposure levels are usually below OEL values, which leads to the conclusion that the main problem lies in improper use and handling of diisocyanates, including the improper use of personal protective equipment (PPE). So, awareness rising through training to ensure better handling of diisocyanates and correct use of PPE is considered by the Dossier Submitter to be the preferred way of achieving risk reduction. It is recognised in the dossier that the OSH legislation already requires the employer to ensure that workers receive adequate safety and health training. It is however explained that the frequency, duration and content of training have not been standardised under OSH, leaving room for variation in the level of implementation by the individual companies facing the requirement. It is concluded that since new OA cases still develop in unacceptable numbers, the OSH obligation needs to be supported by specialized measures. The proposed restriction would provide for better defined tools and content which the companies could use to improve the level of protection.

- As mentioned above, the Dossier Submitter lists also a voluntary "self-restriction" by industry as a possible measure, however, the Dossier Submitter expects this not to attract enough participation to improve the situation.

The merits of REACH in the management of the identified risks are highlighted in the Background Document. The Dossier Submitter claims that the possibility to include the entire

supply chain under one measure, enabling the resources and know-how at the top of the supply chain to be incorporated, and a top down flow of information is an important feature to improve the handling of isocyanates. The Dossier Submitter concludes that as a regulation for the placing on the market of substances, REACH is particularly well suited for this purpose. It is stated that the proposed restriction would build an EU wide mandatory basic framework that would be more specific than minimum requirements laid down under the OSH legislation.

SEAC conclusion(s):

SEAC agrees that among the ROs described, based on the analysis presented, the proposed restriction (RO1) appears to be the most appropriate option.

SEAC notes that the proposed measure could complement the existing, more general legislation and in so doing ensure that the training provided is correct in its content and available to all in the supply chain, thereby contributing in reducing risks to an acceptable level. SEAC agrees that the definition of specified, EU wide substance specific training requirements and extension of obligations through the supply chain would bring a clear distinction with the past and as such the proposed measure would make a difference compared to what has been achieved by the OSH instruments.

SEAC agrees that based on the analysis presented in the dossier the possibility of exempting substances and mixtures with very low potential for exposure would considerably reduce the burden foreseen for industry. According to RAC, the vast majority of OA cases takes place amongst the "high risk" workers (workers that will be automatically trained under both options, RO1 and RO2, and will therefore be equally protected under the two options). Therefore, based on benefits per a person trained ratio, RO1 appears superior to RO2. The SEAC conclusion on the relative order of RO1 and RO2 is however subject to uncertainties relating to enforcement costs for exemptions in RO1.

SEAC agrees that based on the analysis in the dossier alternatives do not generally appear to be available, and therefore a ban of (widespread) use of diisocyanates (RO3) is not a viable option.

Regarding authorisation and voluntary action, SEAC concurs with the analysis made by the Dossier Submitter and considers these options as not appropriate in the present case.

With regard to OSH legislation, based on the discussion in the background document, SEAC understands that REACH could be better suited to defining the necessary specific training requirements due to the possibility to make them mandatory throughout the EU.

SEAC notes that RAC has proposed a different way of setting out the conditions of the proposed restriction (see Annex 1) to incorporate the previous Annex 12 (Exemptions) and Annex 13 (Trainings and measures). Whilst SEAC supports this new way of setting out the conditions to increase the transparency of the requirements, SEAC has had only limited possibility to evaluate them further. However, this can be explored during the consultation on the SEAC draft opinion.

Key elements underpinning the SEAC conclusion(s):

RO1 (the proposed restriction - training with exemptions)

The possibility to achieve behavioural change through training has been demonstrated in the studies assessed by the Dossier Submitter and as such training appears to be an appropriate measure to be used. The literature reported in the dossier does not contain a case entirely corresponding to the measure proposed under the restriction proposal. Specifically, a key study used to assess the efficiency of training, reported by the UK HSE, also included follow-up inspections, which may have affected the perceived effectiveness. To account for the possibility that the effectiveness of the training measure proposed might be lower than what was estimated, the Dossier Submitter has performed sensitivity analysis by request from SEAC. The sensitivity analysis is further discussed in the evaluation of the assessment of the socio-economic impact.

SEAC notes that Directives 89/391/EEC and 98/24/EC already require proper training of workers along with the implementation of specific protection, prevention and monitoring measures.

SEAC, on the one hand, considers that it is in principle possible to manage the identified risks effectively on a Member State level under the present framework, as is demonstrated by outcomes of dedicated campaigns or national specific legislation. On the other hand SEAC sees that harmonised EU wide action would support unified level of risk management by companies in the different Member States. SEAC agrees that the training program included in the proposal is far more specific than the current requirements (e.g., the content of training has been specified; for details, see Appendix 8 (Training and measures) in the Background Document, and as such it would enhance more uniform and better focused training of workers across the EU.

SEAC agrees that the extension of the obligations through the supply chain would enhance the possibilities to achieve a more uniform level of awareness of the need of protection, and also contribute to keeping the level of awareness high, since the need of protection would be further advertised through the safety data sheets, and relevant training material along with information on how to access it would be readily available to all.

SEAC agrees that requiring training where there is no relevant risk would be unreasonable. Therefore, SEAC in principle supports the possibility to exempt substances and mixtures with very low potential for exposure (RO1). Issues relating to cost-effectiveness and practicality of exemptions are addressed in the respective parts of the opinion.

The opinion of RAC recommends that to ensure the quality and the credibility of the training programs, members states in which the training is to be implemented should be responsible for the approval of the training material and the development of the training system. While SEAC acknowledges that Member State approval could be expected to increase the credibility and effectiveness of training courses, SEAC regards this addition problematic in three ways.

First, it is inevitable that extra costs would be incurred to Member States due to the approval activity.

Secondly, SEAC has not been provided with any information on the possible magnitude of those costs and how this might affect the current balance of costs and benefits.

Thirdly, the requirement for Member State approval could harm the recognition of training throughout the EU. SEAC considers this unfortunate, taking into account that the recognition

of training throughout the EU was raised as an important factor by several parties in the public consultation of the Annex XV dossier. However, cooperation between Member States may be expected to maintain coherence between training materials and possibly alleviate the expected extra burden to Member States. RO2 (training for all workers using diisocyanates at 0.1% or above, no exemptions exist)

The Dossier Submitter argues that this option is not the most appropriate EU wide measure. SEAC agrees with the position, that there is no need for training where there is no relevant risk. It is noted, though, that RAC does not fully agree with the (simplifying) assumption that all the OA cases would take place among workers in the "high risk group".

Under RO2 workers in the "low-risk group" would also be covered by the training requirement and thereby be protected. Even though the Dossier Submitter for benefits quantification purposes presumed that all occupational asthma cases would occur due to exposure to substances and mixtures with high potential for exposure, it is clearly stated in the dossier that certain number of cases would also appear due to the exposure to substances and mixtures with very low potential for exposure. RAC is still considering the question how large this proportion is; initial, however, partial information is that up to 20% of OA cases might refer to low exposure. In any case RO2 would cover all workers that are at risk for OA and consequently provide for higher level of worker protection.

The Dossier Submitter claims that workers in the low risk group would actually be even better protected through an RO1-induced (voluntary) transition to substances and mixtures with low potential for exposure qualifying for exemptions. However, although seemingly convincing, the practical significance of this claim was not substantiated in the dossier.

Where the costs of implementing the Appendix Exemptions proposed by the Dossier Submitter are significantly lower than the corresponding costs of training of people using only substances and mixtures with "*very low potential for exposure'*, RO2 would be clearly more costly to the industry than the Dossier Submitter's proposal. This appears to be the situation according to the analysis made by the Dossier Submitter.

According to the cost-benefit analysis performed (see chapter on overall proportionality), the monetised benefits expected from RO2 outweigh the related costs in all scenarios. SEAC considers RO2 a good second option where the uncertainties relating to risk reduction, or exemption-related enforcement costs under RO1 are considered excessive.

RO3 (total ban of diisocyanates)

SEAC agrees with the Dossier Submitter's reasoning to discard this restriction option. The Dossier Submitter provided information on the (un)availability of alternatives. Diisocyanates are reported to be used in a wide variety of applications. Universal alternatives do not exist.

SEAC notes that specifically low molecular weight diisocyanates offer a specific set of properties that is not easy to find in other substances (fast reaction, adjustable properties, reduced necessity for the use of volatile solvents, etc). This makes finding alternatives very challenging also in the case of specific applications. In some cases, alternatives are available but have serious health hazards themselves. SEAC agrees that transition to alternatives of that kind would be regrettable and cannot be generally promoted.

Even though information is limited and not available for all uses, SEAC can agree with the conclusion that it seems very likely that suitable alternatives do not exist for most of the

applications. This means that the costs to industry due to substitution efforts would be very high, and in many cases the activities where diisocyanates are used would need to be stopped or relocated outside the Union. This would affect workers (unemployment, other social consequences) and the society as a whole.

SEAC finds the Dossier Submitter's discussion convincing, however, it has not been carefully substantiated. Due to the treatment being somewhat superficial, the assessment of RO3 contains uncertainties. However, taking into account the lack of public consultation comments promoting potential alternatives, SEAC concurs with the Dossier Submitter's conclusion that a complete ban of the use of diisocyanates and mixtures containing diisocyanates does not appear a proportionate option.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Socio-economic impact

Justification for the opinion of SEAC

Summary of proposal:

The Dossier Submitter has made a quantitative, monetised analysis of both costs and benefits expected due to the restriction. Present values of costs and benefits were calculated using the discount rate of 4 %.

The impact assessment in the proposal is limited to the EU-28 and for a time period of 20 years. According to the Dossier Submitter, the length of the analytical period was chosen to cover at least a full implementation period to reach full effectiveness and to account for health benefits accruing over several years due to avoidance of OA incidence. It is expected that OA will develop at some point during the respective worker's working life, with the main effects limited to the remaining working life time. Therefore, a 20–year time period was considered a suitable time period for performing a forecast.

The Dossier Submitter has provided a present value of the costs for the 20-year period, and the average cost per year (PV) to illustrate the yearly costs, however, no annualized values of the present value.

Baseline of training

It is explained in the Background Document that some health and safety training partly overlapping with the proposed training scheme is already taking place either based on OSH requirements, national regulation or voluntary action. This was however not taken into account in the quantitative analyses made. Instead, it is assumed that training of workers would be arranged from point zero, such that all costs would be a consequence of the proposed restriction, and no benefits from training had accrued yet.

The Dossier Submitter explained that the effect of training required by Directives 89/391/EEC and 98/24/EC in this regard is not expected to be relevant, because in the directives only a general requirement of ensuring that the workers receive adequate safety and health training is included, without specification of the frequency, duration and content of training. It is therefore expected that the current legislation does not ensure a proper content of training. A dedicated analysis into the contents of training under OSH was not done by the Dossier Submitter. According to the Dossier Submitter, training potentially corresponding to the proposed training scheme has been implemented in some Member States, however, representing only a minor share of the market (e.g., in Denmark and Sweden, covering 1-2% of diisocyanates use). Therefore, this would not have major impact on the average EU costs (or benefits).

As regards the voluntary product stewardship programs discussed earlier, contents of such training programs are expected to be comparable to the proposed training program, since they were largely created for the same purpose by the same parties. In cases where such a program already exists, the actual benefits of the proposed restriction would be expected to be lower than the generally estimated benefits since some workers would already be adequately trained. The Dossier Submitter has made an assessment of costs as regards the Walk-the-Talk program and concluded that the cost would be around €0.34 million per year, since the project covered only 13 000 workers (0.9% of all exposed EU workers) and the training was performed only once in 10 years. The effect of the non-inclusion of such costs (of existing voluntary measures) on the baseline is minor since the main training costs consist of opportunity costs of workers, which will occur more frequently than before. Anyhow, savings would be made only relating to the time period during which the enterprises would, in the absence of a restriction, continue following the voluntary program.

SEAC conclusion(s):

Some concerns were raised regarding the methods used as SEAC scrutinised the analysis, namely, some sectoral cost elements were reported as socio-economic costs (although just transfers from a sector to another), and some cost calculations lacked transparency. The sectoral vs. societal costs are further discussed in the costs section. Where the reporting of the assessment of costs and benefits was not entirely transparent in the Annex XV dossier, the Dossier Submitter, based on SEAC's request, provided further information during opinion making.

SEAC notes that the use of averages per year of present values instead of annualized values is not a standard practice, however, considers it acceptable as illustrating rough magnitude of annual costs.

In the derivation of the baseline situation the Dossier Submitter addressed the EU in general; the exact baseline on the Member State basis was not clarified. SEAC regards that while

providing a general union level viewpoint, the use of EU averages does not allow an assessment of specific situations in individual Member States. However, SEAC also understands that provision of a Member State level baseline would be significantly more laborious.

While the baseline of training was successfully described in a qualitative manner, the quantitative estimation of costs and benefits did not account for training already taking place due to current legislation and voluntary action. SEAC considers that this renders the analysis made imperfect in this respect, however, acknowledges that for the purpose of quantification certain simplifications are necessary. SEAC agrees that where individual companies and/or Member States already provide training corresponding to the proposed training program, the current restriction proposal would bring further costs mainly if it is more time consuming or more frequent. Similarly, benefits expected from the proposed restriction might already have been partly achieved through existing measures. However, significant additional benefits are expected due to consistent and improved training material as well as of more frequent training where applicable.

Costs

Summary of proposal:

The Dossier Submitter assessed the cost for all three ROs.

RO1 (the proposed restriction - training with exemptions)

The cost analysis presented for RO1 in the Annex XV dossier is based on costs of training and costs of identifying exemptions. The main driver of compliance costs is by far the costs of training while the effect of costs for exemptions is minor.

It was first assumed by the Dossier Submitter that all workers in sectors "Construction chemicals" and "Automotive repair (excluding vehicle refinish)" (the so called low risk group, including 3.6 million workers) would use substances and mixtures for which exemptions would be applied by the M/I/F and would therefore not need to undergo the training program. Workers in other sectors (the so called high risk group, including 1.6 million workers) would participate in the training program if continuing using the substance. During the opinion making process the Dossier Submitter reviewed the assumption regarding the low risk group and clarified that up to 30% of these workers might actually need to take part in the training program because suitable exempted products would not necessarily be available or preferred by the company. The calculations were amended accordingly.

The analysis of costs for training considers direct costs deriving from course fees and indirect costs relating to lost productivity due to lost working hours in activities directly related to production. The Dossier Submitter has estimated the expected annual costs relating to each of the six identified training options ranging from e-learning to three different kinds of course packages here discussed as "classroom training" (training options A, B and C). Course packages A, B and C differ from each other as regards the provider, location and practical organization of the course, affecting the course fee. Low bound and high bound estimates for costs over 20 years have been provided based on the annual costs of the least expensive (e-learning) and the most expensive (option C – external training course including training material and certificate) training option. A central estimate trying to include the varying situations and preferences of different enterprises and employees was not provided in the Annex XV dossier due to lack of information.

Training costs - Direct costs from course fees

The estimation of costs due to course fees is based on an estimate of course fee per participant (€425, in case of a training where workers would take part in training as an individual in training institution) and the number of workers to be trained, or the daily fee of a commissioned trainer (€870) and the number of groups of 20 workers to be trained, in case of a group training. Course fee per worker is based on information on actual course fees of comparable training from Germany and the United Kingdom, weighted and adjusted to the EU price level. The estimation of the daily fee for a commissioned trainer is carried out based on EUROSTAT statistics on turnover per person employed in the relevant sectors.

The size of a training group is mentioned in the dossier to be an important factor affecting training costs in training options where a commissioned trainer is used. Due to economies of scale, the higher the number of participants at the training course, the lower is the total cost of training. On the other hand, a relatively small size of the training group is reported to have a positive influence on behavioral change. The Dossier Submitter considers that a near-optimum benefit/cost ratio would be achieved when 20 workers take part in each course, and this number of workers per group was assumed in subsequent estimations.

As regards e-learning, the cost estimate for fixed costs has been derived based on assumptions on one-time costs for software development, annual maintenance costs (fixed expenditure) and costs for adjustments after 10 years. The cost figures used were based on the Dossier Submitter's own experience in the development of an earlier software. Software development costs and costs for adjustments were annualized (interest rate of 4% used). When summing up the cost factors gave an estimate of €39 000 per year for years 1-10 and €46 000 for years 11-20 (as updated in the Background Document).

Training costs - Indirect costs from lost productivity

Productivity loss per worker per hour has been calculated based on the number of hours expected to be spent in training (3 to 8 hours depending on the training method chosen) and productivity loss in an hour for the sector in question (23 €/h for construction and automotive repair sector and, 22 €/h for the other sectors). The estimates for productivity losses were derived based on EUROSTAT information on value added per worker assuming 230 working days a year.

The total training costs for RO1 were thereby estimated to be between €25.2 million and €164 million (annual average of the PV over the 20-year assessment period) for the least expensive and the most expensive training option respectively. It is stated in the dossier that about 10% of the workers to be trained (i.e. of the high-risk group workers) would be eligible for e-learning (the least-cost training option). However, this assumption was not included in the calculations made by the Dossier Submitter but in the calculations e-learning is assumed for everyone in the low bound estimate and for no-one in the high bound estimate.

Costs for exemptions

Costs for industry would be incurred from testing substances and mixtures and conditions of use (one-off costs) to assess whether the product qualifies for an exemption, and from data preparation and communication efforts (running costs). The expected number of product groups to be tested is 80-120, and the cost per product group is estimated to be €500 - €1

000. The resulting one-off cost estimate has been rounded to €5-10 million, or €0.4-0.74 million annually. Taking into account also the costs for data preparation and communication (€0.25-1 million annually, considering 500-1000 products a year) an estimate of €0.65-1.74 million per year is derived. Based on the discount rate of 4% it is calculated that the total cost over the investment period of 20 years would be from €9 million to €24 million.

RO2 (Training for all workers using diisocyanates at 0.1% and above, no exemptions exist)

In case of RO2, training costs are the only type of costs considered in the Annex XV dossier. Training costs were derived in a similar manner as for RO1, however considering that the number of workers to be trained would be higher (5.2 million, including 1.6 million workers in the high risk group and 3.6 million workers in the low risk group). Higher number of workers to be trained leads to considerably higher costs even though the additional training (for the low risk group) is expected to be done via the least expensive training option (e-learning).

The total training costs for RO2 are estimated at €79-218 million annually for the least expensive and the most expensive training method respectively.

RO3 (total ban of diisocyanates)

The dossier includes an estimation of costs expected from a complete ban of using diisocyanates for one sector, vehicle refinishing. It is explained in the dossier that the repair of a car body always requires the use of coatings based on diisocyanates; the performance of possible alternatives is lower and the substances have hazard properties themselves. It is estimated that one year of premature vehicle retiring results in a value loss of about €2 100 - €2 800. This figure was estimated based on the average price of a new car, the residual value of a damaged car and an average body repair investment. A straightforward calculation exploiting estimates on traffic incidence rate, the number of vehicles in use, the number of damaged vehicles per year and the fraction of vehicles requiring body refinishing implies that costs of about €5.3 billion per year as a low bound would result for this sector.

A comprehensive quantitative estimation has not been made by the Dossier Submitter due to lack of data and since it was considered too complex a task because of the wide variety of uses. The economic impacts of a complete ban to the entire EU market have been indicated on basis of statistics for economic value added, which is being directly created by the use diisocyanates for the production of goods in the EU-28. The estimate hereby derived is €18 billion per year and is claimed to be a lower bound estimate.

Summary of restriction costs

The risk management options considered and the related cost estimates are shown in Table 1. The low-end estimates assume e-learning for all workers to be trained; the high-end estimates assume e-learning for low-risk workers in RO2 (no training for low-risk workers due to exemptions in RO1) and training according to training option C for high-risk workers.

In addition to the original figures presented in the Annex XV dossier (Tables 7 and 10), new estimates have been provided by the Dossier Submitter and are included in Table 1 below. The new estimates differ from the original ones for two main reasons. First, the cost for classroom learning according to option A is used (instead of option C) as option A appears to

more properly reflect the societal costs. Secondly, the new estimate accounts for a need to train also some workers in the low risk group (30% of them according to the assumption used here). The respective estimations were provided during opinion making and will be used in the proportionality assessment later.

Table 1. *Results of the cost estimation of the ROs assessed.*

	RO1 (Training and exemptions)	**RO2 (training for all)**	**RO3**
Additional costs (PV, million € in average per year)	26 - 170	79 - 220	18 000
Additional costs (PV, million € over 20 years)	510 - 3300	1600 - 4400	360 000
Classroom training (option A) + Exemptions in RO1 + E-learning for 30% of "low-risk" workers **in RO1**	1550	2280*	
Remark	For training (high risk group) and exemption procedure (low risk group)	Only training, but for a larger collective (high and low risk group)	Option not supported by SEAC

* Training option A for the high risk group, e-learning for the low risk group

SEAC conclusion(s):

SEAC generally agrees with the methods used and assumptions made by the Dossier Submitter in deriving estimates on costs for industry. There are three notable points of divergence as follows:

- SEAC concludes that the key driver for the socio-economic costs is the choice of the training method. Contrary to what is presented in the dossier, SEAC considers that the classroom training options (A, B, C) are in principle equal as regards costs to the society. The cost differences between them as described by the Dossier Submitter are mainly due to assumed differences in prices and fees, not in the additional societal resources needed, and therefore they can be treated as transfers between sectors, not true societal costs.

  SEAC also expects that industry actors will usually choose a less expensive training format among the ones covering their needs. However, there could also be situations where a company uses the most expensive training option (option C). Therefore, SEAC considers that the estimates based on training option A as a middle estimate are representative values to be used in training cost calculations.

- SEAC finds that another important cost driver is the number of employees needing training in case of RO1; some of the workers in the low risk group might not be covered by exemptions and would therefore need to participate in the training program. This raises training costs for RO1 relative to what was originally reported in the dossier.

- SEAC also considers that the costs for e-learning might be overestimated. The original estimation in the dossier assumes a similar level of productivity loss for classroom training and for e-learning. SEAC considers that a part of productivity losses associated with classroom type training would be avoided in case of e-learning due to the flexibility of e-learning as regards time and place of training.

SEAC acknowledges that the higher flexibility of RO1 due to the possibility of defining exemptions could increase its relative cost effectiveness, however, costs due to enforcement of exemptions may increase social expenditure needed in RO1.

Key elements underpinning the SEAC conclusion(s):

SEAC highlights that it is important that only the opportunity costs, i.e. the additional resources needed for the preparation and arrangement of the course, are included. In case there are several course providers providing a similar course, the lowest fee could generally reflect the opportunity cost, i.e. cost for the additional resources needed. Other companies may have higher fees, however, those can be seen at least partly as transfers from sector to another and not as real societal costs. In this case, SEAC assumes course options A, B and C to be essentially similar classroom courses with very similar opportunity costs.

SEAC also expects that other things being equal, a company would generally choose the least expensive training option. However, SEAC acknowledges that in some cases a company may also need to use a more expensive option. Therefore, SEAC regards that the costs of training option A as a middle estimate provides the best proxy for the expected training costs.

SEAC reviewed the assumptions used and calculations performed and makes the following general observations applying to both RO1 and RO2:

Training costs

- Course fees

  SEAC agrees that course fees can be taken as a reflection of the resources used for preparing and arranging the course. SEAC appreciates the description of a wide variety of training options in the dossier; this reflects what the responsible companies will be faced with in practice. However, as highlighted above, SEAC considers that a difference between social costs and sectoral costs should have been made more clearly among the different classroom training options. The more expensive course fees may include e.g. payments to a certain brandname and/or other cost elements, which do not affect the true socio-economic cost. The upper estimates of training costs, (reported in Table 83 of the Background Document) therefore overestimate the expected costs.

  The estimation of course fee per worker is determined based on information from two Member States (Germany and the United Kingdom). Using information only from two Member States naturally brings about some uncertainty. After the necessary weighting and adjustment to EU price level the data from the two sources give practically the same result.

The calculations made assume that classroom training would be organised for groups of 20 workers. The Dossier Submitter states that a near-optimum benefit/cost ratio would be achieved with this group size. The Dossier Submitter justifies this statement with references to literature relating to the learning results of children at early grades and the ongoing practice in courses given to workers working with asbestos. The population covered by the literature referenced is not considered representative of the population in question here by SEAC. However, in the absence of further information or information contradicting the suitability of the group size of 20 workers, SEAC accepts the use of the number in the cost calculations. It is further acknowledged, that group size does not affect the costs of e-learning. Furthermore, the significance of group size it is overshadowed by the main cost element – productivity loss – which is independent of group size and simply depends on the total number of people being trained.

- Number of workers to be trained
  SEAC finds this to be another important cost driver. During SEAC opinion making it was recognized that also under RO1 some of the "low-risk" workers might need to participate the training program in practice. This would be the case where certain product(s) used would not be covered by exemptions for instance, because: i) the M/I/F would decide to forego exemption, or ii) the products would not qualify for exemptions, or iii) the employer would choose to use non-exempted products for some other, non-specified reason. The Dossier Submitter addressed this issue by updating their estimation of RO1 costs based on the assumption that 30% of the "low-risk" workers would in practice participate the training program. The related estimations are reflected in Table 1.

  It was brought up in the public consultation of the Annex XV dossier that the training of workers entering the business or workers who enter the workforce only temporarily (e.g. summer replacements) might give rise to some extra costs. SEAC considers this a possible issue since depending on sector, employee turnover may be high. As regards workers entering the business, SEAC considers the costs to be covered by the cost estimation made by the Dossier Submitter. As to temporary workers, the related training costs have not been included. SEAC expects that investment on training of workers who only might use the substance a couple of times would be considered disproportionate by the industry actors. SEAC considers that modification of work profiles where possible[5] (tasks involving handling of diisocyanates to be done by those workers trained) on the one hand, or the "train the trainers" system and/or e-learning on the other could help in such situations.

- Number of hours used in training per worker

  The estimate of 3 to 8 hours is an expert estimation by the Dossier Submitter. In the absence of specific information SEAC takes the numbers as given. Comparison to training relating to other subjects was not considered helpful by SEAC taking into account that the contents of training and amount of information to be absorbed would be different.

- Frequency of training
  The Dossier Submitter set the interval of repetition of training at 4 years using expert estimation. The length of the interval was not justified in the dossier with the effectiveness of the training in mind. However, further to a question by SEAC the Dossier Submitter explained that a cycle of 2 years would not be sustainable from the cost-benefit point of

[5] SEAC acknowledges, that a costly, regulation-induced safety training may cause rigidities at a work place - more specialization and/or outsourcing of work and potential more slack periods at work compared to the current situation. This concern is thought to have a relatively minor economic effect and is not further developed in the analysis.

view. A slightly longer cycle could, according to the Dossier Submitter, raise questions on the sustainability of use and handling improvements in the period between consecutive training sessions. SEAC notes that 4 years is broadly in line with the repetition intervals of some other existing training schemes (asbestos, 6 years; thermoset resins/SE, 5 yrs). Comments received during the public consultation do not provide clear and concordant information on whether the training should optimally be more or less frequent compared to what was proposed by the Dossier Submitter.

- Productivity loss per worker per hour

  SEAC agrees with the principle of using lost productivity to describe indirect costs of training. However, SEAC considers that productivity losses relating to e-learning can be expected to be lower than those relating to classroom training.

  The derivation of the values of €22 per hour and €23 per hour for productivity loss was further clarified to SEAC during opinion making. SEAC agrees that "value-added-per-worker" could be used to reflect the productivity cost of an employee. It is assumed that a worker needs to be trained for safety issues a certain time period (a few hours). For this time, the worker is not available for productive tasks, and no temporary labor can be expected to be used for such a short time. As a result, a certain percentage of the annual value-added-per-worker is lost, and this reflects a cost to the society. If a personnel cost is used instead, the productivity loss may be somewhat underestimated. For instance, looking at Table 76 in the Background Document, the value-added per worker appears to be about 30% higher than personnel costs.

- Costs for e-learning
  An e-learning course is inexpensive to prepare, scale-up, and distribute, and SEAC also expects that the related productivity losses will be considerably lower than those of classroom training. That is because in the case of e-learning a worker would have a lot more freedom to decide when and where the training would be taken.

Given the findings above, the costs proposed to be representative by the Dossier Submitter, however, both in case of e-learning and in case of classroom training, are found to be overestimated according to SEAC view. This in turn causes both the lower and upper ranges (reported in Table 83 of the Background Document) to be overestimated. Secondly, failing to account for the fact that certain employees potentially eligible for exemptions, may actually not be exempted in RO1 for one reason or other underestimated the number of employees to be trained within that option in the original calculation. This caused the relative cost-efficiency of RO1 to be clearly overestimated. The issue was taken into account and modified calculations were provided by the Dossier Submitter during the opinion making.

SEAC notes that using expert judgement introduces uncertainty in the estimation however, SEAC accepts the use of them since empirical data are scarce. No overall more suitable estimates/parameter values were made available in the public consultation comments.

Costs for exemptions

In practice, regarding exemptions, the M/I/F makes and documents the necessary analysis demonstrating low potential for exposure. Information to customers would be included in the safety data sheet. The costs of the process would be included in the price of the product where

possible. Downstream users would then decide whether to pay for the more expensive product or invest in training of their workers.

Several cost elements concerning exemption setting were recognised in the dossier: the number of product groups tested for possible exemptions, prices of testing per product group, and running costs related to data preparation and communication. The assumptions used are expert estimations by the Dossier Submitter. The estimation, especially the exact coverage of "one-off costs" and "recurring costs" is not considered completely transparent to the reader. However, considering that the industry has been closely involved in the development of the process, and supports the approach, the burden to industry is not expected to be excessive.

SEAC notes the RAC recommendation for 3rd party independent assessment of exemption dossiers. There has been no assessment of the costs and benefits related to such a provision and so SEAC cannot give an evaluation of this proposed requirement. However, in principal, costs from a third-party monitoring should not be any larger compared to monitoring done by authorities if there were no significant additional overhead and/or overlapping activities in the practical work.

In case exemption setting ends up being very expensive, a larger share of workers need to undertake the training, and the effects of RO1 will develop towards the effects of RO2.

Costs relating to enforcement are discussed below.

Enforcement costs

Costs relating to enforcement were not assessed in the Annex XV dossier. SEAC initially had specific concerns regarding costs of enforcement in RO1. In case of RO1, enforcement activities should cover both the exemption procedure as well as training, whereas in RO2 only enforcement of training is needed. No reliable estimate of enforcement costs related to exemptions is available.

During the opinion making the Dossier Submitter provided SEAC with further information and discussion on the expected enforcement costs (discussed below). SEAC also acknowledges the recent note on average observed enforcement costs by ECHA[6], where an indicative value of €55 600 for enforcement of a restriction was derived for an order of magnitude indication of administrative costs (in 2014 values). This value, however, does not include e.g. costs of testing or test method development.

The Dossier Submitter expects that enforcement of the proposed restriction would be carried out within the normal regular inspection checks addressing also other company relevant regulatory requirements, and states that therefore no additional enforcement costs would be expected. SEAC agrees that while some extra costs could incur (due to inspections taking more time for example), in cases where a simple check of documentation were sufficient the extra costs would not be expected to exceed the level indicated in the ECHA note significantly.

Documentation checks are expected to be sufficient with regard to training requirements and also mostly in case of exemptions. However, in some cases it would be necessary to examine whether the conditions for an exemption have been fulfilled. In those cases, testing would be required if a complete justification had not been provided in the exemption justification. The Dossier Submitter explained that in such situations the enforcement authorities would be

[6] A presentation given in SEAC in July 2017.

expected to order the necessary measurements from an (possibly) external laboratory. The Dossier Submitter expects that the related costs would be in the range assessed for the costs relating to qualifying for an exemption in the first place by the M/I/F. An analysis of those costs is included in the dossier. SEAC further notes that the total costs incurring to enforcement authorities would be dependent on the frequency of and requirements for inspections. SEAC highlights that cooperation between national enforcement authorities would be important to avoid challenging one exemption several times and thereby to help keep enforcement costs low.

Costs for implementing technical and organizational measures

SEAC notes that costs accruing to industry actors due to the implementation of technical and organisational measures listed in Appendix Trainings and measures have not been assessed in the dossier. As a response to a request from SEAC the Dossier Submitter explained that most of the measures mentioned are already covered by existing legal requirements under other frameworks and therefore further costs are not expected. No comprehensive analysis of the measures already covered was made. However, SEAC regards that some elements appear new (e.g., obligation to offer biomonitoring options; documentation of the risk for bystanders both during normal use and emergencies), and therefore additional costs might be expected in that regard. There is no information available as to the magnitude of such costs. SEAC again notes that the low number of critical comments from the industry during public consultation would seem to indicate that industry actors do not see a problem here. SEAC acknowledges potential familiarization costs and costs due to prepration of the training, but underlines, that the main training costs are due to work time lost by those people being trained.

Comparison of RO1 and RO2

The comparison of costs of RO1 with RO2 is predominantly based on the balance of additional costs of the training measures in RO2 vs. costs of justifying the exemptions (including enforcement of exemptions) according to the proposed Appendix Exemptions in RO1. The costs of RO2 as presented by the Dossier Submitter appear considerably higher, because of the higher number of participants.

The costs of setting the exemptions include testing and forming the information and related documentation such that a M/I/F can claim (and provide support on that claim) a specific product to be exempted. In case the cost of setting an exemption is low, industry may gain by exploiting the built-in flexibility of RO1. However, if the cost of setting exemptions is high, the industry may decide largely not to utilise the exemption option, and the effects under RO1 end up being similar as in case of RO2. Therefore, from the industry point of view, RO1 should always appear less expensive or at the most as expensive as RO2. Therefore, RO1 adds flexibility of the system and in principle should be a more cost-effective option. However, the need to enforce the exemption system and consequent avoidance of training causes additional costs to the regulator. In a case where such exemption enforcement costs are high, RO1 could end up producing higher social costs compared to RO2. In other words, RO2 can be a less costly option only in a case where the mechanism for lowering the number of people being trained in RO1 costs more than the savings due to less training done.

Based on this SEAC believes that added benefits due to the flexibility of the RO1 would

generally outweigh potential costs due to enforcement needed. Only in a case where the costs of enforcing exemptions requires high expenditure, it could end up that the RO1 would have higher social costs than RO2. However, SEAC has no information needed to calculate the cost of enforcement of the exemption system. This lack of information causes uncertainty to the comparison of RO1 and RO2.

RO3 (total ban of diisocyanates)

As regard to "Wider economic and health impacts" of RO3 the Dossier Submitter states that due to a complete ban there could be a loss of €24.3 billion based on value added contributed by the direct manufacturing and use of isocyanates in the EU market.

SEAC welcomes the Dossier Submitter's approach to describe RO3 effects via a sector-level partial costs. Looking at the partial analysis on car repair sector, SEAC questions the use of a "year-of-car-service-time-lost" as a measure of non-use of diisocyanates. Somewhat similar, but a more correct measure could be a cost of a pre-ponement of all the future car generations due to shortened service life of cars. If such a calculation was developed, it would also need to take into account potential benefits from replacing old cars with safer, more modern and potentially more environmentally friendly alternatives. Based on this, SEAC has a view, that the calculation may somewhat underestimate (or overestimate) the effect of the non-use, however, non-arguable figures are difficult to produce due to the complexity of the calculations.

All in all, SEAC agrees with the Dossier Submitter in that the overall costs and benefits for human health resulting from a complete ban of diisocyanates are difficult to estimate. SEAC, basing on the fact that diisocyanates have broad usage in several industries and generally have no suitable alternatives for most of the uses, concludes, that a general ban on diisocyanates would cause - besides any direct effects – potentially significant losses to several production sectors due to disruptions, delays and interdependencies of sectors. No information on potential alternatives was brought up in the public consultation of the Annex XV dossier. As a whole, RO3 does not appear to be a credible alternative.

Benefits

Summary of proposal:

The Dossier Submitter assesses possible human health effects, whilst environmental impacts are considered not to be relevant for this restriction scenario.

In the proposal positive human health impact is described as the result of the reduction of a number of new cases of occupational asthma (OA) and skin diseases (skin sensitisation) related to diisocyanates in the future, due to the improvement in the standards of handling diisocyanates.

The Dossier Submitter explains the reduction of occupational asthma and skin diseases to occur as a result of behavioural changes. The workers are assumed to adopt more appropriate working methods (proper and stricter use of personal protection equipment) due to training performed in accordance with Appendix Training requirements. While Dossier Submitter was able to quantitatively asses the existing diisocyanates related occupational asthma incidence and its presumed reduction due to the training proposed, this was not possible for cases of skin sensitisation due to the unavailability of suitable EU-wide data.

The Dossier Submitter stated that the proposed restriction (RO1) would also stimulate substitution. Some producers indicated in public consultation that where technically feasible, they would substitute some of their products with substances and mixtures with lower risk in order to avoid the training requirements. Possible additional benefits due to this element were believed to be considerable, however, not quantified in the proposal.

Effectiveness of training for the reduction of asthma cases

Effectiveness is expressed by the potential to avoid a certain fraction of asthma cases in the future relative to the baseline, where the baseline means an average amount of OA cases on the Union level. A quantitative estimation for the reduction of the incidence rate after implementation of the proposed training is based on existing studies on safety training effectiveness. In order to sustain the level of awareness and correct handling, it is necessary to repeat the training at regular intervals (four years is proposed).

The Dossier Submitter assumes that due to the proposed restriction, 50-70 % of cases of occupational asthma due to exposure to diisocyanates would be avoided. The Dossier Submitter bases the effectiveness figures on the results of existing training programs.

The relative effectiveness of different training options has not been quantified in the dossier, but it is mentioned that e-learning is generally not expected to be as effective as face to face training options. However, the Dossier Submitter, when quantifying benefits, assumed that in those cases where e-learning is appropriate (low risk group), it would be as effective (50-70%) as other alternatives (e.g. classroom learning).

Originally the Dossier Submitter also included slight synergy effects (3 % for "low bound" or 4% for "high bound") on the effectiveness (improvements on the basis of improved behaviour) which would occure due to iteration of the training. The Dossier Submitter explained that these originated from a seemingly plausible assumption, however, since there is no reference available for this, this element was removed from quantification of benefits.

Monetised benefits

A quantitative assessment of the benefits expected has been made on the basis of the number of new cases of occupational asthma. The number of future cases associated with exposure to diisocyanates has been estimated in three different ways: based on EU-wide statistics on occupational asthma, based on observations in occupational epidemiological studies, and by quantifying the fraction of adult-onset asthma in the population that is due to occupational exposure to isocyanates. The three approaches give comparable results, which gives the number of 6500 new asthma cases annually. This figure is in the same ballpark as current information from RAC: "a narrower range of 2350 to 7269 cases could be robust enough for impact assessment, despite the uncertainties identified in the risk characterisation".

Direct costs due to therapy and medication, indirect costs due to disability (sick leave days) and reduction in earning and value creation capacity, and intangible costs relating to pain and suffering have been considered in the monetisation of the social damage. The intangible costs (individual welfare losses) have been presented in terms of the willingness to pay (WTP) values estimated by Máca & Ščasný (2014) in connection of an ECHA study on economic value of benefits of avoiding selected adverse human health outcomes due to exposure to chemicals in the European Union. Present values of benefits were calculated using the discount rate of

4 %.

An overview of the cost components of the occupational asthma is presented in table 2.

Table 2. *Overview of the cost of illness for occupational asthma, revisions by the Dossier Submitter during opinion making are included*

Cost category	**Costs driver**	**Annual value [€] - EU average**
direct costs	Therapy/ medicine	1 764/person
indirect costs (including social costs)	Disability (costs for the employer) [5 disability days of 230 working days x sector specific gross value added]	881/person
	Reduction in earning and value creation capacity [32 % of the sector specific personal costs]	10 144/person
intangible costs	Pain & suffering/ Welfare loss	1 800/person
Total		**14 589/person**

According to the Dossier Submitter the number of workers potentially exposed every year is estimated to be 5.2 million, of which 3.6 million workers are assumed to be at low risk and 1.6 million at high risk. It is estimated that about 10 % of exposed workers have already become diseased and therefore are not part of the population in which the new cases develop. Thus, the Dossier Submitter presumes that number of workers potentially at high risk is 1.44 million.

The Dossier Submitter has chosen 20 years as a period for which benefits were assessed. It is presumed by the Dossier Submitter that all cases of OA happen in the population of workers using substances and mixtures with high potential for exposure (that should undergo training under both RO1 and RO2), and therefore the number of avoided cases would be identical under the two restriction options. In the case of RO3 it is assumed that there would be no further asthma cases. As a consequence, the following results for the three ROs are derived by the Dossier Submitter.

Table 3. *Results on human health impacts (based on 6500 cases of occupational asthma per year in the baseline), revisions by the Dossier Submitter during opinion making are included*

	RO1	RO2	RO3
Cumulative number of avoided cases over 20 years (based on best estimate)	62 465* – 87 295**	62 465* – 87 295**	130 000
Monetary values (PV, € million) incl. social costs, average/year	251* – 350**	251* – 350**	594***

* Lower bound (50% OA cases reduction)
** Upper bound (70% OA cases reduction)
*** For total restriction 100 % OA cases reduction is presumed.

Impacts relating to skin sensitisation

The impacts relating to skin sensitisation are briefly discussed in the Background Document. It is noted therein that 13 % of the reported numbers of all occupational diseases (not only those related to diisocyanates) relate to skin sensitisation. The Dossier Submitter decided not to quantify benefits for skin sensitisation because data on occupational skin disease are only available in a few Member States and large uncertainties extrapolating to the EU-28 were expected.

It is concluded by the Dossier Submitter that if the skin sensitisation cases were accounted for health benefits would be even higher than that calculated above accounting only for asthma reduction.

SEAC conclusion(s):

SEAC generally agrees with the analysis of the Dossier Submitter regarding the benefits; the approach taken is generally considered suitable.

SEAC considers that the presumption that no OA cases will result due to exposure to substances and mixtures with very low potential for exposure, the simplification used for calculation purposes (i.e., all cases of OA happen in the population of workers using substances and mixtures with high potential for exposure) may lead to some overestimation of RO1 benefits. Namely, it is not possible to exclude that some part of OA cases occur also at lower exposures. The significance of this effect (and the level of overestimation of RO1 benefits) could not be quantified due to lack of data of exposure and health effects in workers exposed to products that would be eligible for exemptions according to the restriction proposal.

SEAC also considers that the effectiveness of training (50-70%) may be overestimated due to the fact that these figures were based on a study which indeed did cover training of workers with diisocyanates but had a somewhat different program structure (follow-up visits of labour inspectors included). Still, having in mind the results of other behavioral impact driven training and the repetitive character of the proposed training program, SEAC is of the opinion that the **effectiveness of training could be very close to the lower bound (50%)**

envisaged by the Dossier Submitter. Also RAC in their assessment pointed out that "reduction in the range proposed is not impossible to achieve".

Nevertheless, for proportionality comparisons, 30% effectiveness was also considered (see table 4).

The approach and results of the monetised benefits calculation appear reliable and robust enough for the assessment of benefits.

SEAC points out that an additional positive effect from the training performed would also come from reduction of skin sensitisation. Positive behavioural change also improves behaviour in case of other chemicals used by the same worker leading to additional positive effects.

Key elements underpinning the SEAC conclusion(s):

Number of occupation asthma cases

The current disease burden was estimated by the Dossier Submitter via three approaches (EU wide OA statistics, occupational epidemiological studies, assessment of adult-onset asthma in the population and quantifying the fraction that is due to occupational exposure to isocyanates).

SEAC notes that the three different methods used for the estimation of the number of emerging OA cases lead to comparable results – around 6500 new OA cases/year - which gives some credibility to the result. SEAC also notes that RAC agrees to consider diisocyanate-related OA as an irreversible state for the purpose of SEA.

SEAC notes also the results by RAC on assessing the incidence rate; current information from RAC is that "narrower range of 2350 to 7269 cases could be robust enough for impact assessment, despite the uncertainties identified in the risk characterisation". Since the figure the Dossier Submitter has provided is in the same ballpark as current information from RAC, SEAC believes that figure 6500 is a good starting point for benefits calculations, with a notion that a certain underestimation or overestimation of benefits are possible.

The Dossier Sumbitter for benefits quantification reasons presumed that all OA cases would appear due to the use of substances and mixtures with high potential for exposure (workers in the high risk group).

SEAC notes that a certain share of the OA cases can also be due to the use of substances and mixtures with very low potential for exposure (low risk group). This was communicated by RAC and also agreed by the Dossier Submitter. This issue is not taken into account in the quantitative analysis in the dossier. Therefore, the benefits of RO1 appear similar to those of RO2. This overestimates the relative effectiveness of RO1 vs. RO2 as reported in the dossier. The Dossier Submitter provided additional information during the opinion making on recognized OA cases due to isocyanates in the high and low risk groups, however, only concerning Germany. The information indicates that in Germany up to 20% of cases might come from the low risk group.

Effectiveness of training for the reduction of OA cases

The Dossier Submitter made a "best guess" that the effectiveness of the proposed training would be between 50% (low bound) and 70% (high bound), pointing out that an exact quantitative prediction of the expected reduction rate of cases of occupational asthma is scientifically not possible.

Methodologically the Dossier Submitter bases the quantitative estimate for the reduction of the incidence rate on several studies on reported effectiveness of different awareness activities, where the range was varying in the range 10 - 80 %. The studies that the Dossier Submitter took into consideration include two meta-analyses covering 28 and 33 evaluation studies respectively. The studies cover a broad range of occupations, for example construction workers, carpenters, etc. Very often they combine classroom lessons with active teaching, e.g. practical exercises. All training showed statistically significant positive results regarding the effect of the training on the knowledge level. A positive effect on behavioural change could also be confirmed by most of the studies. One of the meta-analyses was explicitly focusing on behavioural change (e.g. usage of proper PPE), with effectiveness results up to 80%.

The Dossier Submitter identified the Motor Vehicle Refinish study by the UK HSE as the most relevant source of information to be considered in the estimation of training effectiveness in the present case. The campaign was connected to a national awareness training project for spray painters using diisocyanates. The reduction in the incidence rate of occupational asthma was in the range 50 - 70 %.

SEAC concurs with the Dossier Submitter that the UK HSE project is the most relevant source of information when accessing the training effectiveness. It is focused on the same type of uses as the proposal by the Dossier Submitter. Nevertheless, as also pointed out by the Dossier Submitter, there are major differences between the UK HSE project and the current proposal, which are:

- The UK HSE project also included follow-up visits of labour inspectors in body-shops.
- In the current proposal, participation in training is obligatory, while in the UK HSE project it was voluntary.
- In the proposal regular repetition (every four years) of training is envisaged.

For this reason, a high/low scenario (50-70%) was proposed by the Dossier Submitter in order to generate numbers in a certain bandwidth.

Having in mind the differences (especially the inclusion of a post-inspection) between the UK HSE method and the proposed training, SEAC believes the overall effectiveness of the proposed training might be lower than envisaged by the Dossier Submitter. Nevertheless, due to other relevant behavioural impact driven training studies, which showed reasonably high efficiency results, SEAC is of the opinion that **effectiveness could be very close to the lower bound (50%) envisaged by the Dossier Submitter**.

SEAC has also considered that the level of current awareness and behavioural culture can vary among the different Member States and among certain sectors (also due to additional national legislation and already existing voluntary training). Consequently, the level of effectiveness might vary among different Member States and/or sectors, but it is unlikely that this would change the effectiveness assessment at the Union level. Studies on which the Dossier Submitter assessed the potential effectiveness of the proposal are namely based on studies from different countries/sectors, so we can assume that they in principle represent

the EU wide average.

By request from SEAC the Dossier Submitter also provided an additional (sensitivity) calculation of benefits based on the assumption that effectiveness would be 30%. The derived estimates are shown in Table 4 together with the estimates relating to the initial 50% and 70% effectiveness estimates.

Table 4. *Benefits comparison for different effectiveness figures over 20 years*

	Benefits of RO1 = RO2		
	30 %	**50 %**	**70 %**
Monetary values (PV, € million) incl. social costs, 20 years	3010	5017	7009

Concerning variations in training effectiveness due to different training methods, the Dossier Submitter reports that training methods with larger engagement of the trainee (e.g. by including hands-on exercises, structured group discussions and feedback to the trainee) have an up to three times greater impact on learning success and finally on the effectiveness of the training. Further important variables that are reported to have a positive influence on behavioural change include the presence of an expert trainer, a longer length of the training session and a relatively small size of the training group. SEAC agrees with the Dossier Submitter that e-learning may not be expected to be at the same level of effectiveness as face-to-face training options, as interactiveness and face-to-face feedback is more difficult to arrange. However, SEAC also regards that e-learning may be an effective training alternative for workers in the low risk group as the behavioural change needed is expected to relate to simple measures (e.g., wearing gloves)..

SEAC finds the Dossier Submitter's approach to effectiveness assessment appropriate, even though additional attention could have been given to quantifying the effectiveness in case various training methods are used. The Dossier Submitter explained that a more detailed estimate of effectiveness (especially comparison of different training methods) is beyond their present possibilities. SEAC recognises that a lot of resources would be needed for it and that reliability of such additional survey is still questionable, due to the limited information available.

SEAC also wants to stress that effectiveness in practise will largely depend on the quality of the practical implementation. Initiative of producers and importers to prepare unified materials and take care of proper implementation down the supply chain is of essential importance, especially for SMEs, who might not have sufficient resources.

SEAC highlights that an additional positive effect from the training performed (not quantified by the Dossier Sumbmitter) would result from reduction of skin sensitisation. Positive behavioural change would also improve proper behaviour in case of other chemicals used by same worker, which would lead to an additional positive effect. RAC pointed out in their opinion that some Diisocyanates (e.g. MDI, TDI – which are used in large volumes in the EU) have a harmonised classification as Carc. Cat. 2, but the carcinogenic endpoint was not further

considered by the Dossier Submiter. Consequently, further risk reduction for workers could be expected due to this effect.

Monetised benefits

The Dossier Submitter monetised the following benefits of the reduction of OA:

- therapy/medicine costs,
- sick leave days costs (costs for the employer),
- reduction in earning (personal costs),
- welfare loss.

Other impacts (e.g. risk for dying while having an asthma attack, shorter life expectancy, etc.) were not considered by the Dossier Submitter.

Direct costs (therapy/medicine costs)

The Dossier Submitter based its calculation of medical treatment costs on the German Social Accident Insurance data: average annual direct costs of **€ 2 433** (for year 2013) per case of occupational allergic asthma. Extrapolation to the EU-28 was made by using the prices of a basket of health-related goods and services (health or medical specific Purchasing Power Parities (PPP)), and then a simple population-based average was calculated. For the EU-28 the direct costs per OA case were estimated to be € **1 764**/OA case/year**.**

The Dossier Submitter also took into account two other relevant studies, one from the UK (no distinction between occupational and non-occupational asthma was made here), and another from Spain (only occupational asthma cases). Since German results fell in the middle, the Dossier Submitter decided to take this figure as a starting point for EU- wide cost calculation.

SEAC agrees with the approach where the Dossier Submitter took into consideration direct costs from three Member States, and used the one with middle cost as a basis for EU-28 extrapolation. This seems to give the best possible approximation of direct costs, however, acknowledging the fact that the three aforementioned Member States may not offer an unbiased information, and having in mind that the Dossier Submitter has no data for direct costs from other EU Member States.

SEAC notes that the Dossier Submitter did not discuss the possibility that some of the EU health systems may have a degree of state provision. SEAC acknowledges that the level of societal costs are not affected by who bears the cost of treatment (individual or state budget) - the data taken into account are namely total costs of therapy/medicine. The Dossier Submitter was not able to provide additional information on this issue.

Indirect costs (including social costs)

- Disability (sick leave days - costs for the employer):

The Dossier Submitter stated in the dossier that due to the unavailability of EU wide data on duration of work disability (sick leave days) per worker suffering from isocyanates induced OA, the Dossier Submitter used German Public Health Insurance information to collect data on the average number of sick leave days per case of Asthma bronchiale (for 2013). An average value of about **10 days** of sick leave per year per case of asthma bronchiale is reported. This value was used for the estimation of the productivity loss per case of asthma bronchiale per year caused by disability at work (sick leave days) for EU-28, gross value added in relevant sectors (NACE codes) was used to calculate disability costs, which resulted in € **1 762** /OA case/year.

SEAC believes that the number of disability days (sick leave days) might significantly vary across the EU-28, and the estimate used was not necessarily representative of the whole EU. On SEAC's request the Dossier Submitter provided information on two additional studies; one of them carried out in France, and the other one covering 11 European countries (Belgium, Estonia, France, Germany, Iceland, Italy, Norway, Spain, Sweden, Switzerland, UK). The results from both studies indicated lower mean numbers of sick leave days/OA case/year, namely 3.5 to 4.7 in case of France and 5.6 days in case of study in 11 European countries.

Based on this SEAC regards that **5 days** is a more appropriate figure to be used for the estimation of the health benefits and proportionality of the proposed restriction, and would be less probable to overestimate the expected benefits. The Dossier Submitter provided SEAC with additional calculations to take this into account. The resulting estimate of disability costs is € **881**/OA case/year.

- Reduction in earning and value creation capacity (cost for the employee):

The Dossier Submitter states that a worker with OA would usually need to change jobs internally, look for employment in another company, or might become unemployed (at least temporarily), depending on availability of suitable jobs in the company. In case of total work disability, the worker can ultimately be forced to leave the labour market permanently decreasing the productive capacity. Degradation of work qualification level or job experiences and corresponding work capabilities or skills are included in health impact valuation as social costs due to occupational/work-related asthma.

The Dossier Submitter estimates, based on several studies covering income reduction/total loss of income of workers with OA in different EU Member States, that the average reduction in income is 32% per year for an individual OA case. The estimation was based on eight studies focusing on workers with OA and their income losses. The studies covered a couple of thousands of workers in several Member States (e.g., France, Italy, United Kingdom). The results on the reduction in working capacity ranged from 22% to 40%.

It was estimated by the Dossier Submitter that on avarage, 15% of workers with OA would become unemployed with a consequent 100% loss in income, while the remaning 85% of workers with OA would on average have 20% reduction of salary.

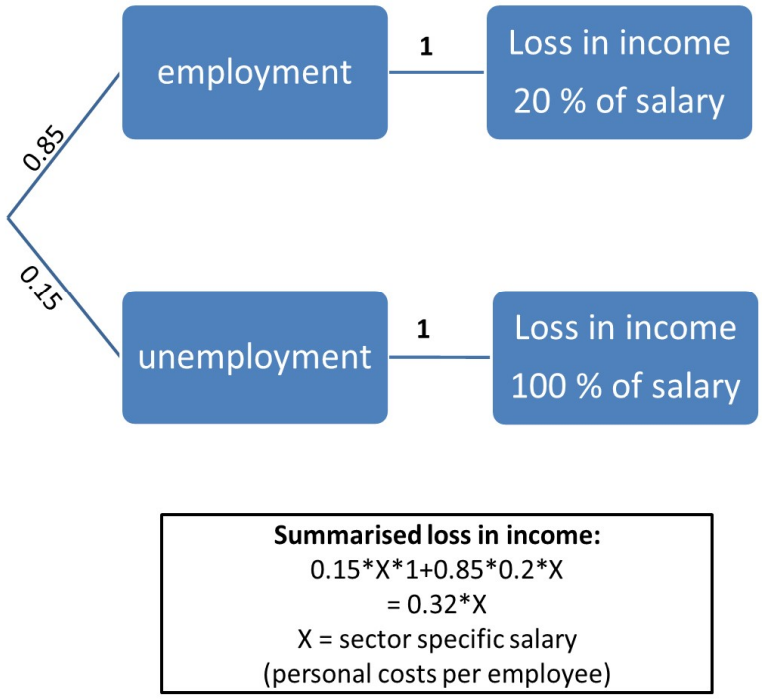

Figure 1. *Likelihood tree for income loss due to work related asthma*

Referring to personal costs per worker and assuming 230 working days per year the average value for annual loss in income in **all sectors** results in **€ 31 740.** The productivity loss is measured by gross value added in the relevant sectors (NACE codes). Based on 32% likelihood for total loss in income the average income loss would be **€ 10 144** /person/year.

SEAC in general finds the approach taken appropriate, and notes that the number of studies considered is reasonable and the studies cover large amount of workers in several Member States. SEAC finds the use of gross value added correct in cases where a worker needs to be temporarily away from work (and is not being replaced) and potentially in a case where she or he will exit from the workforce. However, in case a worker needs to and can move to a less productive work, the gross value added overestimates the cost.

Intangible costs (Pain & suffering/ Welfare loss)

Individual welfare losses (intangible costs) may arise if the quality of life is impaired due to pain and suffering caused by occupational asthma.

The Dossier Submitter took into account a recent ECHA study on economic value of benefits of avoiding selected adverse human health outcomes due to exposure to chemicals in the European Union which is the largest survey to date of individual willingness to pay for diseases associated with respiratory and skin sensitisation. In the project data was gathered comprising Czech Republic, France, Germany, Greece, Norway, Slovakia and United Kingdom. Sample sizes were approximately 1900 per country, and the responders were recruited based

on quota sampling: age, gender, education and size of residence and region. Connected to this research a WTP study for avoiding respiratory sensitisation outcomes was undertaken by Máca & Ščasný (2014).

SEAC agrees with the Dossier Submitter that the survey can be considered representative due to the sample and the approach taken. Having in mind that several Member States were covered, including countries of different size and economic situation, the study can also be considered representative of the EU.

In the study, asthma sufferers (ca. 4800) among the respondent group indicated that they had on average 9 asthma attacks during last 3 months; on average this would mean **36 asthma attacks per year.** The respondents also gave estimates on how much they are willing to pay to avoid one asthma attack. The figures varied from 26.6 to 87.9 EUR, the mean being ca. 50 EUR per avoided astma attack, which leads to an average value of asthma discomfort of **1800 EUR/OA case/year**.

It is explained in the dossier that a study from the USA also gave comparable results, even though the study was looking at the willingness to pay for a day of symptoms avoided, and not for an attack avoided as the study referred to here.

SEAC, although recognising challenges in setting a generic monetary value for respiratory problems based on a willingness-to-pay value from a specific valuation study, agrees with the approach taken. SEAC notes that the aforementioned robust study results are further supported with quotations of similar level WTP values from a few other studies (referenced in the Máca & Ščasný, 2014). SEAC therefore agrees that the study results can be used to assess the intangible costs for the restriction scenario although the study addressed asthma generally since corresponding information for OA specifically is not available.

Other impacts

Summary of proposal:

Social impacts: The Dossier Submitter claims that the social impacts of RO1 and RO2 can be expected in general to be positive. The avoidance of asthma disease has benefits regarding work ability with all consequences for employment and the individual income situation of workers. Social impacts (degradation of work qualification level or job experiences and corresponding work capabilities or skills) are included in the reduction in earning and value creation capacity calculation as part of human health impacts assesment.

Wider economic impacts: There are no estimates neither discussion in the dossier on "wider economic impacts" concerning RO1 and RO2. It is stated that in case of a total ban of isocyanates from the EU market (RO3) an extreme disturbance of the smooth-running processes within the supply chain which comprises 240 000 companies is to be expected, and that many jobs would be lost and potentailly replaced with less productive tasks (e.g. polyurethane producuts would no longer be produced in the EU).

Distributional impacts: The Dossier Submitter considered distributional impacts of the training costs on the basis of vehicle repair service. The Dossier Submitter presumed that 35% of training costs would be passed on to customers. The most expensive training option (external training course, option c) would in this case cause a price increase with up to 62 Eurocent per average service (e.g. a car repair job) and negatively impact the operating surplus with approximately 3 % per year if all workers need to be trained and not all costs can be passed

on to the customer. In case of a complete passing of the costs to the consumer the price of a service (car repair) would increase by ca. 2 € per service.

It is explained in the dossier that in some countries - Germany and Austria are mentioned - the expenditures for training are partly being refunded by taxes, because they will be accepted as business expenses. However, potential impacts of this on the costs or demand of training are not further discussed.

Other impacts on the market: A costly training requirement is expected to cause substitution of some products containing diisocyanates in higher concentrations by products with lower potential for exposure that can be exempted. The Dossier Submitter states that some industrial sectors are already considering this, however, they have not provided hard evidence (or quantification) of this claim.

In the beginning of implementation some aspects of the proposal will lead to uncertainty in the supply chain on how the new obligations can be fulfilled, potentially causing some negative economic impact. The Dossier Submitter however claims, that these effects are expected to be small and to be of a transient nature; with time the new processes and roles of the various partners in the supply chain will become better defined.

SEAC conclusion(s):

SEAC finds the discussion in the dossier on "other impacts" to be quite general, not offering much detailed information.

SEAC agrees that based on the information that has been provided the proposed restriction would have a positive social impact, and the negative distributional effects for consumers would not be excessive.

Key elements underpinning the SEAC conclusion(s):

Social impacts: SEAC agrees with the Dossier Submitter on the social effects of the proposed restriction in terms of positive consequences for employment (people will not lose jobs and the individual income will not decrease for people who would otherwise statistically get OA). Economic aspects of this impact are already taken into account in benefits monetization (reduction in earning and value creation capacity).

Wider economic impacts: Due to the unavailability of alternatives for a wide majority of uses, SEAC believes that RO3 (total ban) is also not acceptable from social perspective. Under those circumstances the businesses would be expected to largely either close down or translocate out of the EU, leaving their EU workers unemployed. It would then also be difficult to find the respective services within the EU, at least in comparative quality.

SEAC has a view, that besides direct effects, ceasing the use could cause important indirect effects to industries/sectors which rely on the usage. This could affect some seemingly unrelated industries as there may be technical and/or cost interdependencies which require different tasks in a production process to be undertaken in the same place/time and/or in a certain order. These interdependencies could cause some production processes to be ceased due to inability to use diisocyanates conveniently in the production process. However, no such indirect effects are articulated in the dossier.

Distributional impacts: The Dossier Submitter made an assessment of how the expected burden of training costs would be distributed. For that the Dossier Submitter assumed that 35% of costs for downstream users would be covered by a raise in product prices and 30% by tax refunds. The Dossier Submitter did not justify the presumption that 35% of all costs will be passed on to the customer. In case a M/I/F can pass the whole/most cost of training to customers (consumers), they may have less of an incentive to use an exemption route in RO1 (even if less costly), and due to this socially inoptimal ("too high") amount of training may result, and both the level and distribution of costs are affected. Such an effect is not discussed in the dossier.

Regarding tax refunds, SEAC notes that training costs can indeed largely be claimed however, the related practices vary between the Member States. As to the expected rise in the price of car service due to training costs, SEAC considers them to be significantly overestimated. As explained earlier, SEAC considers that training option C overestimates the actual training costs significantly. (If crudely estimated based on training costs relating to options A and C, the overestimation would seem to be about 170 %.)

Other impacts on the market: SEAC notes that costs for training will be borne by the downstream users and costs for exemptions initially by the M/I/F. As substitutes appear to be non-existent in many cases, there are no reasons to doubt the possibilities to add the (M/I/F) costs of exemptions to the product prices and therefore the costs would in the end be paid by the downstream users (or consumers) also in this case. Since exemptions overall appear far less expensive than training, it could be expected that using exempted products would indeed be generally preferred by the downstream users. However, depending on the volume of the product used by a company and the number of workers involved, different outcomes for different companies would be expected. For instance, small companies with occasional use of diisocyanates may forego training and outsource the diisocyanates-related tasks instead. This may impact the structure of the industry, however, monetary effects are difficult to forecast.

Overall proportionality

Summary of proposal:

The costs and benefits expected from the restriction options assessed by the Dossier Submitter are summarised in Table 5. Cost figures are presented as modified by the Dossier Submitter during the opinion making (training of additional 30% of low-risk workers in RO1 included) and use training costs related to training option A for classroom training (i.e., high-risk workers) as preferred by SEAC.

Table 5. *Summary and overview on results for possible ROs after 20 years, revisions by the Dossier Submitter during opinion making are included*

RO_n	Costs PV [€million]	Benefit PV [€million]	Net benefit [€million]
RO1: Appendix Training and Measures + Exemptions	1 550	3 010 (30% eff.) 5 020 (50% eff.) 7 010 (70% eff.)	1 460 **3 470** 5 460
RO2: Only Appendix Training and Measures	2 280	3 010 (30% eff.) 5 020 (50% eff.) 7 010 (70% eff.)	730 **2 740** 4 730

The comparison of RO1 with RO2 is predominantly based on the balance of costs of the training measures vs. costs of setting exemptions and including regulatory costs from enforcing such exemptions. The total costs of training measures in RO2 appear considerably higher because of the greater number of participants.

RAC and SEAC conclusion(s):

SEAC concludes that the proposed restriction is proportionate to the risk on the basis of an assessment of its cost and benefit comparison, and affordable to the affected supply chains.

SEAC also highlights that an additional positive effect from the training performed would come from reduction of skin sensitisation and due to improved behaviour in case of other chemicals used by the same worker.

Key elements underpinning the RAC and SEAC conclusion(s):

SEAC assessed the arguments and analysis presented by the Dossier Submitter and took note of RAC's conclusions and the risk reduction capacity of the restriction, and concluded that the overall argumentation supports that the proposed restriction is proportionate to the risk, for the following reasons:

(i) The proposed restriction is affordable to the diisocyanates industry within EU

Given the predominant industry support on proposal and overall positive response in the

public consultation, SEAC understands that the proposed restriction appears affordable to the industry as a whole. It is clear that there can be possible exceptions e.g. among small companies and/or companies only occasionally using diisocyanates products, for which the proposed regulation would be a burden. Comments received from industry during public consultation were predominantly supportive of the proposed restriction.

(ii) The proposed restriction is very likely to bring higher human health benefits than its costs. Those human health benefits could potentially be considerable.

Clear benefits are expected from the proposed restriction and these benefits have been demonstrated to outweigh the costsfor all three training effectiveness levels.SEAC also points out that both options (RO1 and RO2) would also be proportionate, even if training effectiveness would be lower (e.g. 30% as presented in the Dossier Submitter sensitivity analyses).

As shown in the above table, for each effectiveness level the net benefit of **RO1 is clearly higher than that of RO2**. SEAC notes that administrative burden and familiarisation costs accruing to users are most likely higher in RO1. This is a "price" to be paid for possibility to exempt from training. The net benefit comparison above is based on the assumption that the enforcement costs for exemptions and potential other administrative and familiarisation costs are reasonable, and that all OA cases occur in the high risk group.

SEAC agrees that RO3 is not an acceptable option. SEAC finds the quantitative evidence on RO3 provided by the Dossier Submitter not very informative, however agrees that due to widespread use of diisocyanates and unavailability of suitable, less harmful alternatives in most of the cases, the third option i.e, RO3 appears socially unacceptable.

SEAC overall concludes that given the comparison of costs and benefits, and the overall evidence of the significant social damage caused by the exposure to diisocyanates, it is from a socio-economic viewpoint sensible for society to invest in training to reduce exposure via improved use and handling of diisocyanates. Therefore, SEAC finds that the proposed restriction is proportionate from a socio-economic perspective.

Uncertainties in the proportionality section

The most important sources of uncertainties are listed in Table 6 below.

SEAC concludes that the main sources of uncertainties are the estimation of training effectiveness (50-70 %) and number of OA cases due to low exposure. Compared to the effectiveness, other sources of uncertainties in the costs and benefits estimation are considered to have a low impact on SEAC's conclusion on proportionality. Additional information can be found in the concluding sections of the SEAC evaluation of costs and benefits above.

Uncertainties in the cost-benefit calculations

SEAC considers that the assumptions used and the related uncertainties have been reported in the dossier clearly and transparently. The sources of uncertainty considered the most relevant by SEAC are further assessed in Table 6.

Table 6. *Uncertainties in the cost benefit assessment*

Description of uncertainty	Direction	Impact
Costs		
Possible need to train low-risk workers under RO1	(underestimation)	moderate; accounted for in new calculations
Number of hours spent in training per worker per year	suspected overestimation	low
Size of training groups - 20 persons assumed for each group, possible difficulties to always get full groups together not accounted for (larger groups not optimal). Since the training have to be performed before the worker starts to work with diisocyanets, the groups will probably often have to be smaller (for new worker).	unknown, suspected underestimation	low
Enforcement costs in RO1 - the number of inspections comprising measurements	underestimation	low
Number of workers - Assumed correlation between the diisocyanates market share and the number of workers	unknown	low (similar impact on costs and benefits)
E-learning might be a lot cheaper than estimated in the dossier. In that case costs for RO2 would be clearly lower (3.6 million workers might be taking e-learning) and net benefits for RO2 much more favourable than presented. The magnitude of the possible bias was not estimated due to lack of data on the appropriate opportunity costs on the relevant sectors.	overestimation	unknown
Benefits		
Incidence rate - 6500 OA cases/year	overestimation/ underestimation	
Effectiveness of training 50%-70%	overestimation	moderate; sensitivity to 30% has been analysed (RO1 and RO2 still B>C)
Presumption that no OA cases will happen due to exposure to substances and mixtures with low potential for exposure (low risk group), may lead to overestimation in RO1 benefit calculation	overestimation	moderate
Reduction in earning costs is expressed in gross value - it should be only cost for individual in case of unemployment	overestimation	low

Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The Dossier Submitter concludes on the practicality of the proposed restriction on the basis of its implementability and enforceability. However, they point out that not all of the aspects have yet been developed to the detail needed for a full implementation of the restriction as the development of some aspects (e.g. dissemination of the training content, elaboration of detailed training material) takes a lot of resources and depends therefore on the prerequisite that the restriction will be implemented.

Implementability

The Dossier Submitter concludes on the implementability on the basis of the following issues:

a) Responsibility for developing the necessary training material (content)

The practical implementation of the restriction proposal will be facilitated by the fact that the trade associations ISOPA and ALIPA have already established a system for customers at the top of the supply chain ("Walk the talk" and "Safeguard – We care that you care!"). Both associations organised the so called "PU exchange panel" where preliminary discussions on practical aspects of the implementation took place. Stakeholders of all users of diisocyanates were invited to participate. The final responsibility for the development of the training process and content will be transferred to a "training working group", a not-for-profit body representing industry and the other Stakeholders. The status of this body has not yet been determined.

b) Quality assurance of material (content) that is developed

The "training working group" will be responsible not only for the elaboration of qualitative training content but also for its further improvement. It should be open for all contributing parties to the training material. Further development of training content is being discussed in cooperation with an external consultant. An exchange with the institutes / instructors providing the actual training material (e.g. slides with a particular lay-out and sequence) and also training is considered by the Dossier Submitter.

Training material will take into account existing national regulations.

Industrial representatives have indicated their willingness to translate the training material in different EU languages.

In order to reach a level playing field in the EU, a mutual recognition system should be in place to recognise training and the qualification of trainers across the EU. The Dossier Submitter recommends establishing an advisory board where competent independent outsiders have the possibility to provide input.

c) Organising the training in practice (or training licenced trainers)

The developed training material (content) will be made available to downstream users as well as to existing (public and/or private) training institutes / education centers / competence academies (e.g. Shield group, TÜV, DEKRA) to use it. It is still under discussion how this should work in detail, but it is considered that the training institutes or the downstream user(s) should transform the training content into proper education material, train qualified instructors, which in turn would train the workforce. Several options of training formats are considered (e.g. courses on-site or off-site; integration of training into the product presentation, E-learning, train the trainer principle) but have not yet been decided.

In general, different training formats are expected (e.g. classroom training, video instructions, supervised work-assignments). However, details have not yet been elaborated.

d) The case of self-employed workers (one-man companies)

The Dossier Submitter considers that self-employed workers will be made aware of their training duties in the communication actions provided at a national level or when purchasing products in the scope of the restriction.

e) Roll-out planning

A time period of approximately 3 to 5 years will be needed for the implementation of the training system in all Member States for all use sectors.

For the communication of the requirements related to this restriction proposal several activities are foreseen which are listed in the Background document (e.g. referencing the existing restriction in an SDS; make it an obligation to meet restriction requirements with a provision in supply contracts). Some of these activities need to be set according to the REACH Regulation.

Evaluation of training

According to the Dossier Submitter, the trainer (any certification of the "commissioned expert" who performs the training for managers and qualified trainers is not specified) or the training center (if the training is established in a training center) is responsible for training evaluation and certifying training success whereas the "training working group" is responsible for the training process and the training content.

The testing of the attendees of the training (post-course testing) will be an integral part of the training course. Successful completing will be confirmed by a written document.

Enforcement

The restriction proposal intends primarily to enhance the safe working behaviour of users (workers / self-employed workers) who are exposed to diisocyanates by attending training in an interval of four years. The second objective is to improve the technical and organisational RMMs in place, according to the requirements listed in Appendix 8 Trainings and Measures of the Background Document. In Appendix 8, the Dossier Submitter describes a three tier system (measure group 1, 2 and 3) which is based on the frequency and duration of potential skin contact and on the likelihood of inhalation exposure due to vapour and / or vapour formation. The technical and organisational measures and the type and duration of the training are based

on these measure groups.

The training status of companies as well as the implementation of the necessary RMMs can be checked by enforcement as both have to be documented.

RAC and SEAC conclusion(s):

RAC and SEAC agree that to ensure the practicability of the restriction, the requirements of the restriction proposal need to be mandatory and standardised and effectively communicated throughout the supply chain.

RAC and SEAC consider it is essential that all downstream users (including those who are not members of industry associations) are aware of the existence of the (new) regulations related to diisocyanates as soon as they have been implemented.

RAC and SEAC agree with the Dossier Submitter that building measures upon an established system and sharing common measures and training will be very important for the practicality of the proposed restriction.

RAC and SEAC agree with the Dossier Submitter that initiatives from the top of the supply chain have to be transmitted to the (end) downstream user(s), in such a way that the same basic standards and competencies are reached for all persons handling diisocyanates (workers and self-employed workers) for uses not to be considered exempted.

According to RAC and SEAC, it is imperative that formulators of mixtures containing diisocyanates within the EU as well as downstream users should be consulted for the purpose of the development and update of the training material as it is necessary to know how the substances are used along the supply chain.

RAC and SEAC stress that the access to relevant training in various languages in all Member States is essential and that the manufacturers and importers etc. should be responsible not only for the elaboration and the quality of the training material but also for its translation.

RAC and SEAC agree with the Dossier Submitter that the training material should refer to National Regulations.

RAC and SEAC note that as the manufacturers, importers, etc. are responsible for the training content but the responsibility on the training format is on the trainers, the different responsibilities might be challenging with regards to the level of quality control of final training material.

RAC and SEAC point out that training may only be successful given that it is of good quality and that the training is adapted to the knowledge of the participants.

RAC and SEAC acknowledge that the achievement of behavioural changes needs special training as behaviour will not be easily changed.

RAC and SEAC acknowledge that the analytical methods regarding the content of (free) diisocyanates in a substance / mixture are adequately specified in the restriction proposal.

Although the Dossier Submitter only superficially considered the manageability of the proposal, RAC and SEAC would like to point out that for the manageability of this restriction it would be crucial that every aspect for implementation has been worked out in detail with a clear structure and with unambiguous responsibilities. In addition, all of the requirements

have to be very well communicated top down (the supply chain) as otherwise the level of administrative burden for the users but also for the Member States to find out the relevant information might be unbearably high.

RAC and SEAC conclude overall that as all aspects on the implementability and the enforceability have not been demonstrated, the practicality of the proposed restriction has not been completely justified, although in principle the restriction has a number of merits. This is in line with the Forum advice.

Key elements underpinning the RAC and SEAC conclusion(s):

Although ISOPA and ALIPA represent the major producers of diisocyanates and cover about 80% of the market (based on information from ISOPA / ALIPA), it will be a challenge to communicate the requirements by the restriction throughout the supply chain because a huge number of companies affected. According to ISOPA, in Western Europe about 200 companies are directly involved in the production of PU (ISOPA 2002), about 4600 companies are direct customers of these companies, and more than 18300 companies are producing PU-based final articles. The aliphatic diisocyanate raw material is supplied to about 1500 formulators, and further used by about 87000 companies to produce PU-based articles (ALIPA 2006).

In addition, the remaining 20% of the diisocyanate producers should also follow the communication requirements down the supply chain as otherwise one important prerequisite to reach all users of diisocyanates and inform them about the requirements of the restriction will not be fulfilled.

RAC and SEAC acknowledge that diisocyanates are used on the one hand in many large, medium and small scale industry, on the other hand they are used by professionals (including very small companies) and self-employed workers what makes the situation rather complex. Therefore RAC and SEAC are of the opinion that it has to be very clear from the beginning of the legal validity of the measure taken (e.g. restriction) who is responsible for:

a. the elaboration, translation and dissemination of the training material,
b. the implementation of the training in each of the Member States;
c. the review and update of the training material.

It is obvious that a clear structure for the implementation of the restriction have to be worked out and that someone has to take responsibility for the training process and content of training as well as for the distribution of the translated training material as otherwise the information and the requirements will get lost somewhere in the supply chain as the whole issue is quite complex. In addition, ideas / claims for improvement of training have also be managed in order to implement them in a structured way.

A good enough communication is a crucial issue. With regard to the training process it is particularly of importance that a structured way of communication between the "training working group" and the users of the training material will / can be elaborated as otherwise the success of the training and consequently the risk reduction will be highly questionable.

In REACH, downstream users have the right to make their own uses known to their suppliers by providing them with process details as well as information on the RMMs implemented to minimise the risk. This communication up the supply chain is essential (e.g. for the elaboration of the exposure scenarios) as uses that are not included in any registration dossier after the

legal deadline will not be permitted. However, in the present restriction proposal the communication up the supply chain is also necessary to provide the "training working group" with details which should be known to prepare adequate training content (as specific as possible for the uses but also for the companies). The transferability of training to actual jobsite demands among many other aspects affects the success of the training (Cohen and Colligan, 1998).

The appropriate implementation of the training and use of the implemented RMMs (including proper use of PPE) is the most important prerequisite to reduce exposure to hazardous substances used (e.g. diisocyanates). However, a prerequisite for the appropriate use of RMMs is the sufficient knowledge how to do so. This is why there is a strong demand for adequate training material particularly with regards to this restriction proposal. According to a statement by the United States Department of Labor *"Employers may find it challenging to institute and maintain effective hazard communication training, either because of a lack of understanding of what kind of training is required, or because of a lack of knowledge on how to conduct effective training"*, there might be a need of at least offering adequate training material to employers. So the efforts to work out training content by a "training working group" seems to be quite sensible.

Regarding training measures in general, it is stated in the Background Document that a conceptual model of OSH training might comprise a stepwise process of acquisition of new knowledge on hazards and safe behaviour, modification of attitudes / beliefs, and behavioural change. It is considered that a successful training measure reduces unsafe behaviour and accident risks or exposure to hazardous substances resulting in a lower accident rate or lower rate of occupational diseases. The Dossier Submitter describes different formats of training and their effects. Although these training are not comparable to the needs of the training in this restriction proposal, the information provided gives an incomplete overview on the aspects that should be considered in the elaboration of the training content and training formats.

RAC and SEAC consider that one of the reasons why training obligations in OSH might not have been that efficient in the past to prevent cases on occupational asthma is that the quality of the training was difficult to enforce as quality requirements had not been implemented in the legislation. Therefore RAC and SEAC consider enhanced enforcement due to the quality requirements set out in the proposal a crucial benefit in this restriction proposal. However, RAC and SEAC acknowledge that REACH enforcement officers might not be the adequate personnel doing this, or might not find themselves being the adequate personnel, at least at the beginning of restriction implementation. Besides, in some Member States REACH inspectors might be of a much smaller number than OSH inspectors (e. g. in Austria).

Some contributors to the public consultation pointed out that it might be difficult for a manufacturer to prepare training materials in which they appropriately take into account special use conditions, and stress that it might be better to leave it to the individual company, as is the case under directive 98/24/EC. SEAC agrees that training should be adjusted to the products used and conditions of use, and supports a centralised approach. The centralised approach appears more feasible as the burden to individual companies from preparing training might be overwhelming, and resources would be wasted due to overlapping work by many companies.

Monitorability

Justification for the opinion of RAC and SEAC

Summary of proposal:

According to the Dossier Submitter the following aspects (broken down in three different time frames, called by the Dossier Submitter "aspects") have to be considered regarding the monitoring of the effectiveness for the restriction proposal.

a) Short term aspects: National enforcement authorities can check if companies have fulfilled their training duties as defined in Appendix 8 of the Background Document.

b) Medium term aspects: Member States can organise audits to check if companies have implemented the RMMs as listed in Appendix 8 of the Background Document. This could be done in a coordinated union-wide action via SLIC (Senior Labour Inspectors Committee).

c) Long term aspects: The monitoring of the reduction of the number of new cases on occupational asthma which is assumed to be performed by surveys by the Dossier Submitter at regular intervals (e.g. every three years). However, a first conclusion will be drawn on a time scale of eight to ten years.

In addition, the Dossier Submitter calls upon industry to generate longitudinal epidemiological data that allow the evaluation of risks at current workplaces as well as the risk reduction due to this restriction.

RAC and SEAC conclusion(s):

RAC and SEAC agree that the restriction should be monitored in three different steps (i.e. aspects) as proposed by the Dossier Submitter.

RAC and SEAC concur with the Dossier Submitter that monitoring in the first instance can be performed by tracking the degree of implementation of training throughout the different Member States. In addition, RAC and SEAC acknowledge that any successful participation of workers in training sessions could be monitored by certificates. RAC and SEAC assume that a standardised template would facilitate the acceptation throughout the EU.

RAC and SEAC point out that the monitoring of the implementation of the RMMs listed in Appendix 8 (Training and Measures) (medium term aspect) of the background document might be much more difficult. RAC and SEAC consider that a SLIC campaign might be an adequate option for the checking the medium term aspects of the restriction proposal.

RAC and SEAC agree with the Dossier Submitter that monitoring the reduction of the number of new cases on occupational asthma (the main goal of this restriction proposal), should be performed on a long run.

RAC and SEAC note that the number of reported occupational asthma cases might increase in the first years due to the raised awareness of this issue.

RAC and SEAC concur with the Dossier Submitter that large changes with regards to training materials should only be undertaken after the completion of two cycles of training. Otherwise the monitored effectiveness could be too much influenced by the revisions of the training material, so that the data would underlie a bias.

RAC and SEAC appreciate the generation of epidemiological data evaluating a trend in

diisocyanate-related occupational asthma incidence.

Key elements underpinning the RAC and SEAC conclusion(s):

Short term aspects:

As the number of occupational asthma cases can only indicate on a longer run a certain trend, monitoring a short-term aspect (implementation of training) might be quite sensible.

Medium term aspects:

As the restriction proposal also includes the improvement of some RMMs according to Appendix 8 (Training and Measures) and as the implementation of these measures is considered to have a positive effect on the risk reduction capacity (as the exposure level would be reduced), these aspects should be monitored as proposed by the Dossier Submitter.

Although a certification attesting the implementation of the requested RMMs could be of help to monitor this aspect, there does not seem to be an adequate certification programme. A certification according to OSHAS 18001 (future: ISO 45001:2018) standard might not be specific enough. In addition, RAC and SEAC agree with the Dossier Submitter that transferring government enforcement responsibilities to outside organisations should be avoided.

Long term aspects:

The monitoring of the reduction of new cases on occupational asthma is the most important issue as the number of new cases on occupational asthma was the starting point of the restriction proposal. Monitoring is considered to be performed on the long term (10 to 15 years) on the basis of a regular survey by the Dossier Submitter.

Epidemiological data could be of valuable support to set further actions (e.g. the implementation of exemptions for training for some specific uses / tasks).

UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

RAC

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

SEAC

Summary of proposal:

The major uncertainties of importance for the socio-economic assessment identified by the Dossier Submitter are:

- The prevalence of asthma in the working population could be lower than the 10 % assumed; in that case the number of workers at risk and therefore the number of asthma cases could be higher than what is estimated.
- The assumed correlation of the isocyanates' market share with the number of workers might be incorrect because the degree of process automatisation in manufacturing could be essential for a number of workers.
- In the calculation of overall costs (for about 1.6 million workers) in RO1 a combination of each training concept with e-learning has not been considered. The listed uses (see Annex B.2 in the dossier) indicate that most of them would at least require the training for group 2 defined in Appendix 8 Trainings and Measures of the Background Document. It is assumed that only 10 % of uses or workers will be classified to stage 1 of that Appendix, where the training by e-learning could be a possible option. The costs of e-learning are definitely lower, so the effect for total costs will be very low due to the share of 10 %.
- The costs values and savings based on asthma cases cannot be infinitely cumulated. Due to findings on the average age of the asthma sufferers, the number of working years and statistical life expectancy, the resulting modelling over 20 years is just a snapshot, which would not continue indefinitely.
- The effects due to a reduction in skin sensitisation (13 % of reported numbers of occupational diseases) have not been quantitatively assessed.

SEAC conclusion(s):

SEAC considers that the most significant uncertainty underlying the analysis presented in the dossier relates to the effectiveness of training in reducing risks. Compared to the uncertainty of effectiveness, SEAC considers the other sources of uncertainty (notably, the number of workers to be trained under RO1, the cost of exemption enforcement in RO1, and those listed above) regarding the assessment to be low.

SEAC considers that, taking into account the sensitivity analysis made regarding the effectiveness of training and the number of workers to be trained, the proportionality assessment provides a robust conclusion, in the sense that SEAC is confident that in the event of additional information becoming available and of reduction of uncertainties, the conclusion by SEAC regarding the proposed restriction would not change.

Key elements underpinning the SEAC conclusion(s):

The key elements underpinning the SEAC conclusions are discussed in parts of the opinion where relevant.

REFERENCES

Máca & Ščasný (2014) An appendix: Willingness to pay for avoiding respiratory sensitisation outcomes in Maca, V., et al. (2014). Stated-preference study to examine the economic value of benefits of avoiding selected adverse human health outcomes due to exposure to chemicals in the European Union: Sensitization and Dose Toxicity. Report for ECHA.

ANNEX

Conditions of the restriction

[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 dd.mm.yyyy (date of entry into force plus 1 (or 2) year(s)), unless:
   a) the cumulative concentration of diisocyanates in the substance or mixture is less than 0.1% by weight, or
   b) measures are implemented according to paragraph 9 and
   c) adequate training is successfully completed according to paragraph 8 by the worker or self-employed worker handling substances according to paragraph 1.

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 uses after dd.mm.yyyy (date of entry into force plus 1 (or 2) year(s)), unless the:
   a) cumulative concentration of diisocyanates in the substance or mixture 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 of paragraph 1 b and c.

3. Paragraphs 1 and 2 shall not apply to those use(s) where the supplier (manufacturer, importer or formulator) ensures that the specific use of a ready-to-use product[7] containing ≥ 0.1% diisocyanates in the substance or mixture leads to very low risk of exposure for the dermal and inhalation route. The relevant section of the Safety Data Sheet shall be updated accordingly.

   In this context very low risk of exposure means that:

   i. aerosols are not generated, and
   ii. warming or heating the substance or mixture above 45 °C is not required, and
   iii. the sum of the concentrations for all diisocyanates measured during air monitoring shall be < 1 ppb as a time-weighted average of 8 hours, and
   iv. very low dermal exposure is demonstrated by a recognised dermal assessment tool.

[7] A ready-to-use product includes the diisocyanate(s) as a substance or mixture in the ready-to-use form, with other auxiliary substances, packaging and application devices.

4. Manufacturers and importers of diisocyanates which are not exempted according to paragraph 2a or paragraph 3 shall co-operate to:

   a) develop a minimum set of training material in accordance with paragraph 8, supported by information provided by downstream user;

   b) ensure that adequate training material is available to the recipients of the substance(s) or mixture(s) in an official language of the Members State(s) where the substance(s) or mixture(s) is placed on the market;

   c) review and update the training material after a maximum of 8 years, or without delay if new information, which may affect the risk management measures, becomes available and inform the recipients accordingly..

5. Users[8] of diisocyanates which are not exempted according to paragraph 1a or paragraph 3 and their employer shall keep documentary evidence to demonstrate successful completion of a training according to paragraph 8.

6. Proof of successful completion of any training according to paragraph 8 taken in one Member State shall be recognised in all other Member States.

7. The training according to paragraph 8 should be provided by trainers who have undergone specific training covering at least the aspects set out in part 1 of Appendix X.

8. The content of the training according to paragraph 1c should cover:

   a) at least the aspects set out in part 2 of Appendix X;

   b) at least the additional aspects set out in part 3 of appendix X for the following uses: Handling open mixtures at ambient temp. (incl. foam tunnels); spraying in a ventilated booth; application by roller; application by brush; application by dipping and pouring; mechanical post treatment (e.g. cutting) of not fully cured articles which are not warm anymore; cleaning and waste; and any other uses with similar risk of exposure for the dermal and inhalation route.

   c) At least the additional aspects set out in part 4 of appendix X for the following uses: Handling incompletely cured articles (e.g. freshly cured, still warm); foundry applications; maintenance and repair that needs access to equipment; open handling of warm or hot formulations (> 45 °C); spraying in open air, with limited or only natural ventilation (includes large industry working halls) and spraying with high energy (e.g. foams, elastomers); and any other uses with similar risk of exposure for the dermal and inhalation route.

[8] For the purposes of this entry users means workers and self-employed workers undertaking tasks and/or subtasks with diisocyanates on their own, as a constituent in other substances or in mixtures for industrial and professional use(s) or supervising these tasks and/or subtasks.

Users performing various tasks shall complete the training for the highest requirements for his working tasks according to paragraph 8.

The training should be carried out at least every 4 years.

9. For any use of diisocyanates which is not exempted according to paragraph 1a or paragraph 3, the user shall ensure that exposure is minimised[9]. Minimisation in this context means at least that the conditions should include:

   a) the additional measures set out in part 2 of Appendix Y for the following uses: Handling open mixtures at ambient temp. (incl. foam tunnels); spraying in a ventilated booth; application by roller; application by brush; application by dipping and pouring; mechanical post treatment (e.g. cutting) of not fully cured articles which are not warm anymore; cleaning and waste; any other uses with similar risk of exposure for the dermal and inhalation route.

   b) the additional measures set out in part 3 of Appendix Y for the following uses: Handling incompletely cured articles (e.g. freshly cured, still warm); foundry applications; maintenance and repair that needs access to equipment; open handling of warm or hot formulations (> 45 °C); spraying in open air, with limited or only natural ventilation (includes large industry working halls) and spraying with high energy (e.g. foams, elastomers); and any other uses with similar risk of exposure for the dermal and inhalation route.

10. This restriction should apply without prejudice to other Community legislation on workers protection.

[9] In this restriction minimised means compliance with at least the conditions set out in part 1 of Appendix Y.

Appendix X

Part 1: Trainers' training

a) Basic information on restriction, training requirements and implementation.

b) Measuring devices and their limitations

c) Deposition and distribution

d) Protection of bystanders

e) PPE needed and its limitations

f) Storage requirements

g) Behaviour-based safety management

h) Emergency plans

i) Management of Change

j) Certification requirements for attendees.

Part 2: Basic training of workers (employed and self employed)

a) Chemistry

b) How can you be exposed

c) Signs of sensitisation

d) Odour of hazard

e) Importance volatility /…something missing??

f) Viscosity/ Temperature / Mol. Wt

g) Personal Hygiene

h) PPE needed and its limitations

i) Clothing

j) Risk of dermal contact

k) Risk of exposure to not fully cured polyurethane

l) Skin protection scheme

m) Ventilation

n) Cleaning , leakages, maintenance

o) Discarding empty packaging

p) Protection of bystanders

q) Identification of critical handling stages

r) Specific national code systems (if applicable)

s) Behaviour-based safety

t) Certification requirements for attendees.

Part 3: Intermediate training of workers (employed and self employed) (classroom training)

a) PPE needed and its limitations

b) Behaviour-based aspects

c) Maintenance

d) Management of change

e) Evaluation of safety instructions

f) Risk in relation to application process used

g) Certification requirements of attendees.

Part 4: Advanced training of workers (employed and self employed) (classroom training)

a) Feedback

b) Additional certification

c) Spraying in open air

d) Open handling of hot or warm formulations (>45°C)

e) Certification requirements for attendees.

In the context of part 3 and part 4, classroom training could mean on the job training or training in a work related environment. The classroom training should have a minimum duration of four hours.

Appendix Y

Part 1: General conditions of use to ensure minimisation of exposure

- RMMs as defined in the supporting documents (e.g. in exposure scenarios in eSDS for substances, or measures prescribed in SDSs for mixtures) are in place.
- Application equipment is regularly maintained at least once per year.
- Equipment critical for safety protection (e.g. temperature indicators, overheating safety switches, ventilation systems) is working according to specification and has been checked according to predefined schedules. This shall be proven by relevant documentation.
- If heated application systems are used, these are equipped with an overheating switch off protection that will bring the equipment temperature to a safe level.
- If exhaust equipment is used (either fixed or mobile) this is constructed in such a way that fresh air replaces exhaust air and that nobody is exposed to exhaust air.
- Facilities, machines and tanks shall be constructed and arranged in such a way that also when an equipment part fails, uncontrolled release of isocyanate at the workplace is prevented.
- Where required (e.g. in (e) SDS) exhaust equipment is available.
- Emergency kits (cleaning small spills, splashes) are available.
- Cleaning solutions, cured waste and residual diisocyanate shall only be stored in dedicated areas, in separate containers outside the normal working area.
- Organisational measures are implemented to ensure engineering controls are used and maintained.
- Companies have documented proof that their workers have been trained according to the requirements of this restriction.
- Workers are offered to undergo a medical consultation when taking up work and offered follow-up consultations after that yearly. The offer for such a consultation and the decision of the worker shall be documented.
- Companies have documented the risk for neighbouring workplaces and bystanders both during normal use and during emergencies.
- Companies have tools or implement systems that prevent non-workers from entering the work area when in use and during specified time of restricted access, unless accompanied by a person trained according to the specifications of this Appendix. Access shall only be permitted with PPE specified for the ongoing work stage.
- Companies have a check and maintenance schedule for their ventilation equipment.

- Written instructions are available for the performed tasks.
- Personal protective measures.
- Protective equipment has been defined and has been made available dependent on product properties and use.
- Sufficient skin cleaning and conditioning materials are made available.

Part 2: Additional technical measures

- Qualitative detection tools (e.g. wiping tissues) for detection of deposited isocyanate are available.
- Companies provide evidence that technical equipment is sufficient for risk management.
- Organisational measures.
- Effectiveness of protection measures should be regularly checked and documented.
- If open systems are used, reasons for not using closed systems have been documented. This includes steps such as maintenance and repair.

Part 3: Additional organisational measures

- Quantities available during use and quantities stored are limited to the amount necessary to allow a smooth workflow.
- The emergency planning is appropriate for release of large amounts of isocyanate. Appropriate protection equipment for first aiders and/or technical personnel is available.
- Documented work procedures exist for the task carried out. These list specific precautions needed (e.g. installation of LEV, the sealing of rooms to prevent uncontrolled emissions).
- Define and communicate a minimum time to re-entry of the working area to avoid exposure of other workers, and a minimum time to re-occupation of rooms by persons from the general population, according to information in SDS.
- Tools, including written instructions, are made available to those concerned in order to communicate and control blocking of workspaces for bystander access.
- Companies have introduced a behavioural based management system for performance improvement. For professionals a Behaviour Based Performance Program (BBP) is part of training.
- Biomonitoring options are offered.