**Response to comments on the SEAC draft opinion**

**on the Annex XV dossier proposing**

**restriction on**

**DIISOCYANATES**

**EC number:** - **CAS number:** -

**15 March 2018**

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| **Substance: Diisocyanates**  **EC number:** -  **CAS number:** - | Comments and response to comments on SEAC draft opinion on Annex XV restriction report  submitted by **Germany** on **07/10/2016**  Public consultation on SEAC draft opinion started on **20/12/2017** |

Comments on the SEAC draft opinion and specific information requests

## Specific information requests

1. A derogation to the restriction has been requested for diisocyanate-based medical device synthetic casting products regulated under the Medical Device Directive 93/42/EC (MDD) (to be repealed by the Medical Device Regulation 2017/745/EU (MDR)). The products intended to be covered by this derogation is used in the construction of orthopedic casts, as well as specialised prosthetics and orthotic devices. They can also be used for other applications where support and/or immobilisation of body parts as a medical treatment is required. Use is in hospitals and medical practice. With regard to the economic feasibility of this potential derogation, please identify potential additional costs in case the derogation is not granted.
2. In relation to the technical and organisational measures proposed in Appendix Y of the example condition in Annex I to the SEAC draft opinion, please identify potential costs due to (the introduction of) such measures that are **additional** to those already borne due to compliance with Occupational Safety and Health laws.
3. Related to the affordability of the measure, SEAC is interested in:
   1. the general affordability of the proposed measure taking into account costs of preparation of training as well as company level costs due to participation in training. This should be suitably justified and where possible quantified.
   2. the affordability of the proposed measure related to any potential issues specifically encountered from the SME point of view? This should be suitably justified and where possible quantified.
4. In the SEAC draft opinion Annex – Conditions of the restriction – it is proposed that there would be a 1 or 2 year transitional period after the date of entry into force of the proposed restriction. Please, explain whether such a transitional period would be adequate and to give a justification for your opinion.

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| **Ref.** | **Date/Name/Org.** | **Comments** |
| 323 | **Date/Time:** 2018/01/31 13:28  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Germany  **Company name confidential: Yes** | **Comments on the SEAC draft opinion:**  It is our opinion, that the training courses contain too many non essential details and should be limited to a maximum of 2 hours. It is common knowledge, that the attention of humans in training situations drastically drops after 2 hours. Therefore training courses of 4 hours are not effective. The content should be cut to really essential parts like the personal protection measures. |
| **Specific information 4:**  A transition period of only 1 to 2 years is not sufficient to prepare the extensive training program, as this work load needs to be managed ON TOP of the day to day business. For SMEs the day to day business is essential for economic survival and SMEs do not have special employees (or whole departments) managing this extra work load. Therefore, a transition period of at least 5 to 6 years is required. It is our opinion that ECHA grossly underestimates the severity of problems SMEs are confronted with. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  As to drops in the attention level after a certain period of time, according to our understanding, there does not seem to be anything hindering the employer from dividing the training content to be distributed in several sessions. A 4-hour training could thereby be distributed in two 2-hour sessions for example.  SEAC agrees that a transition period of several years will be necessary before full implementation can be expected. The transition period should account for setting up the training programs (up to 2 years) and training of the workers (within 4 years). SEAC regards that a transition period of 4 years in total for carrying out the training required would be reasonable. |
| 324 | **Date/Time:** 2018/01/31 16:04  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  British Coatings Federation  **Org. country:**  United Kingdom | **Comments on the SEAC draft opinion:**  The British Coatings Federation is the sole UK Trade Association representing the interests of the decorative, industrial and powder coatings, printing inks and wallcovering manufacturers. Coatings are critical to UK industry, with 300,000 workers relying on our members' products every day, and the UK is a net exporter of coatings and inks. BCF's members represent 95% of the UK sales of coatings, inks and wallcoverings.  We would like to thank the authorities for providing us with an opportunity to comment on the proposed restriction on the use of di-isocyanates, as detailed in the Annex XV dossier prepared by the German authorities. The paints, coatings and inks sectors use di-isocyanates primarily in ‘2-pack / 2K’ systems consisting of two components which are combined just prior to application, to form a reactive mixture that hardens within a few hours. This technology is used to protect and decorate metal, wood and other substrates, for example transparent, high gloss, durable, weather-resistant exterior coatings for all vehicles (cars, aeroplanes, ships and trains) and infrastructure (bridges). Some of our members’ products fall within the scope of the current proposal, due to the free di-isocyanate content of the hardener component.  We support the objective to reduce the number of work-place related asthma cases caused by di-isocyanate use, and we always encourage downstream users to use the appropriate measures available to ensure the continued safe use of our members’ products, as recommended in safety data sheets and literature. However, we would question whether implementing the proposed REACH restriction would be more effective than focusing on improving and enforcing the correct risk management activities through existing national and European workplace occupational safety and health legislation and controls (e.g. Chemical Agents Directive) , enforced by the local MS authorities, which we believe should take precedence over REACH.  Pursuing an OSH-approach, with the support of national authorities and trade associations, can lead to a significant reduction in cases. This has been proven in the UK over the last 10-15 years, with the HSE and BCF campaigns on the safe use of isocyanates in the Vehicle Refinish sector leading to a four-fold reduction in asthma cases in this sector during the period 2004-2014. This is a direct result of the increased awareness and focus placed by the bodyshops on the issue, thanks to the excellent comprehensive literature, well-attended Safety and Health Awareness Days (SHAD) provided by the HSE and enforcement. The use of proper formal risk assessment procedures, relevant worker training and awareness, and the correct use of measures to mitigate the risks (both PPE and operational measures) is already standard practice across UK industry. A mandatory training programme in accordance with the proposed REACH restriction would be costly (to both industry and regulators), difficult to enforce, and will require significant resource and several years to implement.  If, however, the decision after this consultation is to continue to proceed with a REACH-based approach to di-isocyanates then we accept that the German proposal is the best way to do this, with a Restriction on use and appropriate mandatory training. We have therefore provided answers below to the specific questions posed within the public consultation on this presumption. The key focus should be on providing this training in the most efficient and least bureaucratically burdensome format. Isocyanate / polyurethane technology is an essential part of our formulating toolbox – there are many key applications for which there are no alternatives to isocyanates available. Also, please note that we endorse the arguments provided in page 23 (A2.2.2) of the Restriction report regarding the reasoning for not pursuing an Authorization approach for these substances.  BCF Responses to the specific questions raised during the previous public consultation  Question 1  What transition period do you consider to be appropriate to implement the measures specified in the restriction proposal and why? Please mention potential priorities in terms of application area or geographic regions.  Answer 1  A minimum of five years will be required as a transition period, in order to implement the measures across all EU Member States, once the training provision is in place. We would suggest that those countries where occupational asthma is known to be an issue should be prioritized. Within the paints, coatings and inks, we would recognize the vehicle refinishing sector as a major user of di-isocyanate-based products, in terms of number of workers and ensuring safe spray application of 2-pack topcoats onto car bodies.  Question 2  What approaches (in addition to those already mentioned in the dossier) would you propose to communicate the requirements of the restriction through the supply chain, to effectively inform all levels of downstream users about their duties (including SMEs and self-employed practitioners)?  Answer 2  European and national trade associations can provide a vital link between the authorities and industries that will be using di-isocyanate products. We have a very extensive network with downstream user trade associations, to ensure that the appropriate action is taken by the right organizations, whether they be multinational companies or SMEs. Also, a national publicity campaign (through social media and trade press) should be planned, to ensure companies who are not members of trade associations are aware of the requirements.  Question 3  Could you give examples of training methods in the area of occupational health and safety which have proven to be particularly effective? Could you provide information on how the effectiveness of these methods has been assessed?  Answer 3  We would strongly encourage active engagement with the UK HSE to understand the successful initiative that has been running over the past 10 years with regard to safe spraying of isocyanate-based coatings in the vehicle refinish sector. There are several documents available from the HSE website, including HSG 276 and INDG388 Rev 2, 2014). The SHAD training and awareness days run by the HSE were also extremely useful and effective. This initiative has led to a four-fold reduction in occupational asthma cases in workers in this sector over the period 2004 – 2014. Effective enforcement by authorities is also an essential component.  Question 4  Do you have an information on a case(s) where respiratory or skin isocyanate-related symptoms were observed with a product containing less than 0.1% diisocyanates? Please provide as detailed case information as possible.  Answer 4  We have no such knowledge or information  Question 5  How would the proposed training program affect your company (we are particularly interested in how this affects SMEs or self-employed persons)?  Answer 5  Our members already train their workers to safely use all raw materials used in coatings and inks under the UK’s Control Of Substances Hazardous to Health Regulations (COSHH), so we would not expect any major additional direct training to be needed to meet the restriction requirements. Our members are ready to support the proposal by providing the appropriate training content for our customer sectors, as would be expected under the proper principles of product stewardship. |
| **Specific information 4:**  A minimum of five years will be required as a transition period, in order to implement the measures across all EU Member States, once the training provision is in place. We would suggest that those countries where occupational asthma is known to be an issue should be prioritized. 1-2 years will be insufficient for relevant parties to carry out the required training to comply with the restriction |
| **SEAC Rapporteurs response:**  Thank you for your comments. Please note that the consultation of the restriction proposal ended in September 2017 and the present public consultation (and its related questions) refers to the SEAC draft opinion.  With regard to OSH legislation being more suitable to reduce the risk from isocyanates, 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.  We agree that a transition period of several years will be necessary before full implementation can be expected. The transition period should account for setting up the training programs (up to 2 years) and training of the workers (within 4 years). We regard that a transition period of 4 years in total for carrying out the training required would be reasonable.  We agree that close cooperation with industry associations and Member State health organisations is vital setting up a fruitful and efficient training program. |
| 326 | **Date/Time:** 2018/02/14 11:34  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  3M Belgium bvba/sprl  **Org. country:**  Belgium  **Country:**  Germany  **Attachment:** | **Comments on the SEAC draft opinion:**  3M provides comments to question 1 of the specific information requests. |
| **Specific information 1:**  Please find the information in the attached document. |
| **SEAC Rapporteurs response:**  Thank you very much for the information submitted relating to medical devices.  We understand your concern and have considered carefully the comments submitted by you and other parties.  We note that the Medical Devices Regulation requires medical device manufacturers to train professional users of their products and that it is common practice in the sector to give training to users. We see that the proposed training would probably be more detailed in some respects than the existing ones, but it appears that some of the time needed is already allocated (and a part of the content required is already covered). Therefore the extra time consumed would be less than what is stated in the dossier and extra costs might be lower than expected. In case of low-risk products the possibility of exemptions can be utilized.  Justification presented for the claim that healthcare providers would return to using older cast materials despite their disadvantages appears quite superficial. Having no information on performance levels, transition to more expensive prefabricated braces seems in principle a viable opportunity in cases where the related costs are lower than the costs of training. Information available on the magnitude of expected costs and benefits in the sector due to the proposed restriction is very limited and does not allow SEAC to conclude on a derogation being justified. |
| 327 | **Date/Time:** 2018/02/15 14:11  **Type:** BehalfOfAnOrganisation  **Org. type:**  National Authority  **Org. name:**  Health and Safety Executive  **Org. country:**  United Kingdom  **Attachment:** | **Comments on the SEAC draft opinion:**  1. The UK Health and Safety Executive’s (HSE’s) overarching view  i. The HSE remains of the opinion that the current regulatory Occupational Safety and Health (OSH) framework already in place across the EU is robust and sufficient to prevent and control occupational exposure to diisocyanates if applied correctly and enforced by the relevant authorities.  ii. Tackling occupational ill-health is an important part of the UK health and safety system and reducing the number of cases of lung disease including occupational asthma from exposure to hazardous substances is a priority.  iii. HSE’s success in achieving improved workplace risk management measures for diisocyanates, and the consequent reductions in cases of occupational asthma, have been achieved by working within the framework of our national legislation implementing EU OSH legislation, and without introducing new law.    iv. HSE is also of the opinion that REACH authorisation of diisocyanates is not an appropriate risk management measure to prevent and control exposure of these substances.  v. The HSE does not support the proposal to introduce any additional EU wide regulation, compulsory training or compulsory biological monitoring to help to control occupational exposure to diisocyanates in member states.  vi. It is also the HSE’s view that this issue is not a uniform problem across the EU and each member state should be able to decide on the most appropriate measures for them and that this issue does not require a single market resolution.  vii. HSE considers that currently the proposed restriction is neither enforceable nor practical with many gaps existing in the assessment.  In addition, HSE continues to have a number of issues regarding the proposed restriction as outline below, with further details provided in the attached Appendix.  2. Overlap with OSH legislation  In GB, diisocyanates are regulated under the Control of Substances Hazardous to Health Regulations 2002 (COSHH) which covers all hazardous substances/processes under one regulatory umbrella (excluding Asbestos and lead). There are similar arrangements in Northern Ireland. COSHH:  • places duties on employers to put measures in place to protect workers from being exposed to hazardous substances at work  • implements EU OSH legislation such as the Carcinogens and Mutagens Directive (89/39/EC) and the Chemicals Agents Directive (98/24/EC), amongst other EU OSH legislation.  • applies to a wide range of substances with the potential to cause harm if inhaled, ingested or absorbed through the skin and covers carcinogens, mutagens, biological agents, substances toxic to reproduction, sensitisers, and asthmagens, including isocyanates.  The HSE is of the opinion that the current EU OSH legislative framework is robust and sufficient to prevent and control occupational exposure to diisocyanates if it is applied correctly and enforced by the relevant authorities.    The key focus of COSHH for controlling occupational exposure to hazardous substances is effective risk management with the emphasis on prevention of exposure and the application of good control practice.  COSHH also requires employers to provide information, instruction and training for all employees who use hazardous substances in their work. This includes the appropriate precautions and actions an employee must take to safeguard both themselves and others in the workplace. The employer must:  • find out what the health hazards related to a substance or process are  • identify and decide how to prevent harm to health by conducting a risk assessment  • provide control measures to reduce harm to health and make sure they are used  • keep all control measures in good working order  • provide information, instruction and training for employees  • provide monitoring and health surveillance in appropriate cases  • plan for emergencies.  3. Implementability & enforceability  HSE remains of the view that the proposed restriction is neither enforceable nor practical; a view which is supported by the RAC and SEAC conclusions that all aspects on the implementability and the enforceability have not been demonstrated and that the practicality of the proposed restriction has not been completely justified.  4. Consistency of training standards  HSE continues to have concerns regarding how i) consistency of training standards of the proposed training programme, and ii) a consistent level competence of the participants will be attained on completion of the training courses, will be achieved and monitored both within MSs and across the EU.  5. Costs to Member State (MS) Regulators  There would be additional significant costs to MS Regulators that have not been properly assessed in the restriction proposal  • HSE agrees with SEAC that there would be (potentially significant) additional costs incurred by MSs if there was a requirement under the restriction to make MSs responsible for the approval of the training material and the development of the training scheme. No information has been provided of the magnitude of such costs or how they would affect the presented cost/benefit balance.  • Further, even without such an obligation on MSs, there would still be significant costs incurred and resource implications for MS regulators:  o to assist industry in establishing the proposed training programme to ensure that it meets the required standards  o for the subsequent on-going evaluation/monitoring required to ensure the effectiveness and standards are met and  o in managing stakeholders, i.e. responding to regular enquiries regarding the programme.  • See regulator costs provided in HSE response to Question 2 of the public consultation on the SEAC draft opinion.  Given that diisocyanates have a much wider range of uses and sectors than either rodenticides or DCM, establishing a diisocyanates training programme to a consistent standard that met the requirements of the proposed restriction, would be considerably more complex, costly and resource intensive not only for industry but also the regulators.  Therefore, it is the HSE’s view that the full costs for implementing the proposed restriction have not been properly quantified or considered and must be properly addressed.  6. Key Economic assessment and Statistical concerns  • HSE continues to have reservations regarding the economic assessment and statistical analysis provided in the dossier as detailed in the attached Appendix. |
| **Specific information 2:**  There would be additional significant costs to Member State (MS) Regulators to assist with the establishment, evaluation and monitoring of the industry training stewardship programme for diisocyanates which has not been properly assessed  • Although the RAC opinion recommended that MSs should be responsible for the approval of the training material and the development of the training scheme, HSE agrees with SEAC’s view that i) there would be (potentially significant) additional costs incurred by MSs if this was made a requirement under the restriction; and ii) that no information has been provided of the magnitude of such costs or how they would affect the presented cost/benefit balance.  • Further, and as HSE previously raised, even without such an obligation on MSs, there would still be significant costs incurred and resource required by the MS regulators, the impact of which needs to be properly addressed. Regulator resource will be required:  - to assist industry in establishing the proposed training programme so as to ensure that it meets the required standards  - in the subsequent on-going evaluation/monitoring that the regulator will need to do to ensure the effectiveness and that the required standards of the programme are met; and  - in managing stakeholders, such as responding to regular enquiries from industry regarding the programme.  • The UK Rodenticide Industry Stewardship programme – required a considerable amount of regulator (HSE) resource to assist/guide/evaluate/monitor the programme. It took about 2-3 years (2014-2016) to overcome significant issues and establish a fit for purpose programme within the UK, with on-going work continuing. HSE resource 2014-2017: Hours = 4300; Cost = €350,000.  • Implementation in the UK of the REACH restriction derogation for dichloromethane (DCM)-based paint strippers for non-industrial uses by professional users. An Industry led training scheme requiring mandatory training of professionals according to the DCM training course syllabus established by HSE. Trainees must complete the syllabus and pass an on-line assessment of competence set up by the HSE before they can legally use DCM paint-strippers.  - HSE regulator costs to set up the on-line competency test and certification web-platform: €205,000; with annual costs of: €19,300  - These figures exclude Industry costs and on-going management of stakeholders, such as responding to regular enquiries (expected to reduce over time).  - It took considerable time, effort and resources to put in place even what was intended to be a relatively, simple online scheme. Developing an online scheme is difficult, expensive and time-consuming - it took a full 3 years (2013- 2016) to implement.  Given that diisocyanates have a much wider range of uses and sectors than either rodenticides or DCM, establishing a diisocyanates training programme to a consistent standard that met the requirements of the proposed restriction, would be considerably more complex, costly and resource intensive not only for industry but also the regulators. |
| **Specific information 4:**  It is unclear on what basis the proposed 1-2 year transition period as stated in the SEAC draft Opinion Annex is derived as no justification has been provided.  • Sub-paragraph e) ‘Roll-out period’ (page 45) under the heading ‘Implementability’, states that ‘A time period of 3-5 years will be needed for the implementation of the training system in all Member States for all use sectors.’  HSE remains of the view that if the proposed restriction is adopted, a transitional period of around 5-6 years would be required. This estimate is based on the 2-3 years it took both the UK Rodenticide Stewardship programme and the DCM industry led training scheme to become established.  Given that diisocyanates are more widely used in a number of different sectors, the Diisocyanates training programme is likely to be much more complex to achieve and hence will take longer to be implemented. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  Thank you for the interesting information relating to setting up training programs relating to rodenticides and dichloromethane.  Thank you also for your views relating to Member States regulatory costs. While we agree that these costs have not been fully elucidated in the dossier, we have no information that Member States would indeed systematically assist industry in establishing the proposed training programme and we are therefore not able to evaluate such costs.  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.  Thank you for the opinion on the transition period. We agree that a transition period of several years will be necessary before full implementation can be expected. The transition period should account for setting up the training programs (up to 2 years) and training of the workers (within 4 years). We regard that a transition period of 4 years in total for carrying out the training required would be reasonable. |
| 328 | **Date/Time:** 2018/02/19 10:04  **Type:** MemberState  **MS name:**  Germany  **Country:**  Germany  **Attachment:** | **Comments on the SEAC draft opinion:**  See attached document with comments on the draft SEAC opinion as well as some considerations on the role of MS |
| **SEAC Rapporteurs response:**  Thank you for your comments.  We have made the following text modifications:   |  | | --- | | p.11: Thanks for the remark, the text in the opinion has been updated.  p.12: We do not see why these two sentences have been tied together. The sentences are in different subparagraphs in the DO. The ISOPA/ALIPA coverage was stated here to allow an assessment of the weight of their claim that exemptions will be applied to practically all low-exposure products. The information on the number of workers is not related to this but is included to allow comparison to the number of workers trained under RO2. We do not see changes necessary here.  p16: In order to align the text with p.32 sentence "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." has been replaced by:  "Information received from the Dossier Submitter indicates that based on German data alone up to 20% of cases might come from the low-risk group.  p.25: The basic idea is that classroom costs are considered to be overestimated because they are based on option C (Table 7), and e-learning costs are considered to be overestimated because it has not been taken into account that e-learning allows the workers to do the training when it is the least disruptive to their main tasks. We do not see edition necessary.  p.26: (It is not the intention to claim it very likely, it is just to explain the situation.)  p. 27/1: The referenced text fragment will be deleted from the opinion.  p.27/2: In principle we agree that a more descriptive wording could have been used. However, the training will have to be enforced anyway, because high-risk workers will not be covered by exemptions. Setting up a separate system would most likely require more resources than having a few more objects of supervision in the training enforcement system. We see this more general wording to be more suitable and do not see changes necessary.  p.28: No addition needed, more on skin sensitisation data is on page 32. p.29: No addition needed on e-learning, more on effectiveness of e-learning is on p.34.  p.29: No addition needed on WTP, more on this is on pages 37-38.  p.31: No addition needed, it is clear that the number of workers was small; still we cannot agree that a similar fraction of workers will change their awareness due to the already explained reasons.  p.57/58: We do note the comment, but prefer to leave it to the Commission to find the appropriate wording. | |
| 329 | **Date/Time:** 2018/02/19 13:41  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  ISOPA Aisbl  **Org. country:**  Belgium | **Comments on the SEAC draft opinion:**  ISOPA supports the restriction on diisocyanates under REACH with the objective of sustainable and safe use of the diisocyanates.  Diisocyanates can be handled safely  Product stewardship at ISOPA (Walk the Talk) and ALIPA (We care that you care) has been advocated for many years and is still one of the key activities today.  The aim of these programmes is to engage the polyurethane value chain around safe handling of diisocyanates with proven success.  Industry communicated and explained that, with appropriate risk management measures in place, diisocyanates can be handled safely. Nevertheless Industry is committed to do even more.  Estimation of occupational asthma (OA) cases  The relative high number of new OA cases referred to in the background document is based on assumptions and not on actual health case reporting. It is based on the assumption of a factor 10 under reporting and the fact that of all OA cases in Europe 10% is due to working with diisocyanates. Taken the most valued reporting systems with financial incentive in Europe (table 12 of restriction dossier for Germany and UK, Germany has approx. 40-60 new confirmed cases/year and UK has approx.20 new confirmed cases/year), extrapolating to Europe leads to approx.250 – 350 new cases/year.  The RAC opinion as well as the SEAC third opinion arrives at 2,350 up to 10,150 new health cases/year. The difference between the actual national numbers and the range of uncertainty is that high that such calculations leads to questions.  However, industry is committed to further reduce the number of possible cases via trainings.  We like to point out that without a sound basis and a European uniform reporting system on the number of actual health cases, assumptions can not be interpreted and have to be avoided.  Exemptions  ISOPA believe that there are product/use combinations which have a very low potential for exposure and should be therefore exempted for restriction.  Industry is working intensively on developing a broadly accepted scientific tool such as the dermal assessment tool which would proof if a product/use combination could be exempted. Additionally the road of Human Bio Monitoring should be also further investigated and potentially being another tool to demonstrate low potential for exposure.  Training  ISOPA is committed to make the training a success.  Key prerequisite to achieve this goal is the adaptability to the needs of industrial and professional users, including self-employed persons.  The training has to be mutually accepted by all stakeholders across Europe and clear roles and responsibilities have to be defined of the different stakeholders. The inclusion of Downstream sectors in the process of developing teaching material is inevitable to make it a success.  ISOPA think, that industry is capable of developing the teaching material which then will be finally approved by central board of defined stakeholders.  ISOPA believes that the current proposal by the dossier submitter on training frequency is appropriate.  Original BAuA proposal  For several years the industry has cooperated with BAuA to develop a training scheme including two Annexes, which have been supported by industry.  For unknown reasons substantial parts of the original BAuA proposal have been changed by BAuA. These changes are not supported by the industry.  These changes create more confusion and unclarity than the original BAuA proposal. |
| **Specific information 1:**  ISOPA/ALIPA is not representing manufacturers of medical devices. Therefore, we have not the expertise/knowledge to answer this question. |
| **Specific information 2:**  Occupational safety and health is organized on a national level within EU. Therefore no harmonization is in place. As a result the additional cost for the proposed training measures is not easily predictable. ISOPA/ALIPA believes that the measures described in Appendix Y should be standard in all industries handling chemical products. It may be possible that in some industrial companies and professional enterprises some of these technical and organizational measures might not be fully implemented. |
| **Specific information 3:**  Regarding a.  The costs for the training measures will depend strongly on the availability of trainers, training sessions and the length of the transition period. Especially inhouse trainings held by an qualified internal trainer can minimize the costs for a company. Therefore, we think it is essential that inhouse training is allowed and that sufficient train-the-trainer courses are provided in each member state in an EU-wide harmonized format. To guarantee this, a sufficient transition period is needed. |
| **Specific information 4:**  ISOPA/ALIPA do believe that a transition period of at least 6 years as from the date of entry into force of the restriction will be required.  This duration is needed set up the training infrastructure in all member states and build up certified trainers and conduct all worker trainings as the key deliverables.  The transition period should apply uniformly to all EU member states to ensure a level playing field throughout EU.  Trainings conducted during the transition period should be renewed within 4 years after the transition period. This will give an incentive to early trainings and avoid that most trainings are conducted at the end of the transition period.  ISOPA/ALIPA supports also the idea of running within this 6 years of transition a pilot project. This pilot might be a specific application in one or more specific country(s) to allow all stakeholders to be prepared and learn from first experiences. A pilot will allow the testing of the didacts and content prior to translating the trainings to 25 European languages.  Additional comments (free text area):  It is the responsibility of industry to develop the training content and materials. ISOPA/ALIPA will set-up an advisory board for the training materials. This advisory board is open for national authorities to contribute and supervise the activities. Industry is looking for a EU-wide harmonized training program which would ensure the same level of training for all EU employees.  Therefore we oppose the idea of national approvals of finalized training materials by individual member states requiring individual national changes. Neverthess, national input is highly welcome via the advisory board.  Mutual acceptance of trained employees in all member states is needed for multi-national companies and professionals working cross-boarder. |
| **SEAC Rapporteurs response:**  Thank you for your comments. Some of them seem to relate to the proposal itself. At this stage the comments were invited for the SEAC draft opinion, and we will concentrate responding to those comments.  Thank you especially for the information relating to our specific information requests and for confirming that measures described in Annex Y should already be implemented in the industry.  We agree that a transition period of several years will be necessary before full implementation can be expected. The transition period should account for setting up the training programs (up to 2 years) and training of the workers (within 4 years). We regard that a transition period of 4 years in total for carrying out the training required would be reasonable. |
| 330 | **Date/Time:** 2018/02/19 13:46  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  ALIPA Aisbl  **Org. country:**  Belgium | **Comments on the SEAC draft opinion:**  ALIPA supports the restriction on diisocyanates under REACH with the objective of sustainable and safe use of the diisocyanates.  Diisocyanates can be handled safely  Product stewardship at ALIPA (We care that you care) has been advocated for many years and is still one of the key activities today.  The aim of these programmes is to engage the polyurethane value chain around safe handling of diisocyanates with proven success.  Industry communicated and explained that, with appropriate risk management measures in place, diisocyanates can be handled safely. Nevertheless Industry is committed to do even more.  Estimation of occupational asthma (OA) cases  The relative high number of new OA cases referred to in the background document is based on assumptions and not on actual health case reporting. It is based on the assumption of a factor 10 under reporting and the fact that of all OA cases in Europe 10% is due to working with diisocyanates. Taken the most valued reporting systems with financial incentive in Europe (table 12 of restriction dossier for Germany and UK, Germany has approx. 40-60 new confirmed cases/year and UK has approx.20 new confirmed cases/year), extrapolating to Europe leads to approx.250 – 350 new cases/year.  The RAC opinion as well as the SEAC third opinion arrives at 2,350 up to 10,150 new health cases/year. The difference between the actual national numbers and the range of uncertainty is that high that such calculations leads to questions.  However, industry is committed to further reduce the number of possible cases via trainings.  We like to point out that without a sound basis and a European uniform reporting system on the number of actual health cases, assumptions can not be interpreted and have to be avoided.  Exemptions  ALIPA believes that there are product/use combinations which have a very low potential for exposure and should be therefore exempted for restriction.  Industry is working intensively on developing a broadly accepted scientific tool such as the dermal assessment tool which would proof if a product/use combination could be exempted. Additionally the road of Human Bio Monitoring should be also further investigated and potentially being another tool to demonstrate low potential for exposure.  Training  ALIPA is committed to make the training a success.  Key prerequisite to achieve this goal is the adaptability to the needs of industrial and professional users, including self-employed persons.  The training has to be mutually accepted by all stakeholders across Europe and clear roles and responsibilities have to be defined of the different stakeholders. The inclusion of Downstream sectors in the process of developing teaching material is inevitable to make it a success.  ALIPA thinks, that industry is capable of developing the teaching material which then will be finally approved by central board of defined stakeholders.  ALIPA believes that the current proposal by the dossier submitter on training frequency is appropriate.  Original BAuA proposal  For several years the industry has cooperated with BAuA to develop a training scheme including two Annexes, which have been supported by industry.  For unknown reasons substantial parts of the original BAuA proposal have been changed by BAuA. These changes are not supported by the industry.  These changes create more confusion and unclarity than the original BAuA proposal. |
| **Specific information 1:**  ALIPA is not representing manufacturers of medical devices. Therefore, we have not the expertise/knowledge to answer this question. |
| **Specific information 2:**  Occupational safety and health is organized on a national level within EU. Therefore no harmonization is in place. As a result the additional cost for the proposed training measures is not easily predictable. ISOPA/ALIPA believes that the measures described in Appendix Y should be standard in all industries handling chemical products. It may be possible that in some industrial companies and professional enterprises some of these technical and organizational measures might not be fully implemented. |
| **Specific information 3:**  Regarding a.  The costs for the training measures will depend strongly on the availability of trainers, training sessions and the length of the transition period. Especially inhouse trainings held by an qualified internal trainer can minimize the costs for a company. Therefore, we think it is essential that inhouse training is allowed and that sufficient train-the-trainer courses are provided in each member state in an EU-wide harmonized format. To guarantee this, a sufficient transition period is needed. |
| **Specific information 4:**  ALIPA do believe that a transition period of at least 6 years as from the date of entry into force of the restriction will be required.  This duration is needed set up the training infrastructure in all member states and build up certified trainers and conduct all worker trainings as the key deliverables.  The transition period should apply uniformly to all EU member states to ensure a level playing field throughout EU.  Trainings conducted during the transition period should be renewed within 4 years after the transition period. This will give an incentive to early trainings and avoid that most trainings are conducted at the end of the transition period.  ALIPA supports also the idea of running within this 6 years of transition a pilot project. This pilot might be a specific application in one or more specific country(s) to allow all stakeholders to be prepared and learn from first experiences. A pilot will allow the testing of the didacts and content prior to translating the trainings to 25 European languages.  It is the responsibility of industry to develop the training content and materials. ALIPA will set-up an advisory board for the training materials. This advisory board is open for national authorities to contribute and supervise the activities. Industry is looking for a EU-wide harmonized training program which would ensure the same level of training for all EU employees.  Therefore we oppose the idea of national approvals of finalized training materials by individual member states requiring individual national changes. Neverthess, national input is highly welcome via the advisory board.  Mutual acceptance of trained employees in all member states is needed for multi-national companies and professionals working cross-boarder. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  Please see reply to Comment 329. |
| 332 | **Date/Time:** 2018/02/19 19:27  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  FEICA - The association of the european adhesives and sealants industry  **Org. country:**  Belgium  **Privacy comment:**  As with the case of exemptions, mutual recognition of trained employees across the EU is needed for companies and professionals operating cross-border. | **Comments on the SEAC draft opinion:**  FEICA, the Association of the European Adhesive and Sealant Industry, is a multinational association representing the European adhesive and sealant Industry.  FEICA and its members have always been working together with all actors in the PU (Polyurethane) value chain to improve the safe use of PU products and support this Restriction as a harmonised solution across Europe.  Exemptions    FEICA members would like to reiterate their strong support for the current set of criteria to grant exemptions, as already indicated in the input to the public consultation carried out last year on this issue.  To reduce the huge number (roughly 1 million people) of potential users to be trained, it is essential for the adhesives and sealants industry to be able to offer exempted PU products which have been proven to be used with a very low risk of exposure for the dermal and inhalation route, thus making additional training of their users unnecessary.  Our members are working on further developing recognised scientific-based dermal exposure assessment methods. This would allow to identify a product/use combination as a candidate for exemption.  In addition, it is vital that an Exemption will be accepted in all EU member states.  Training implementation  FEICA together with the manufacturers of diisocyanates organised at ISOPA and ALIPA is committed to develop and implement the training modules foreseen under the proposed restriction. However, a transition period of 1 or 2 years as currently mentioned in the SEAC comments would not be sufficient at all to prepare and implement the training obligations all over Europe.  Specifically, the rollout of the training to the many widespread uses of adhesives and sealants following the development of the training modules will require adequate timeframes. Likewise, collection of supporting evidence for exemption dossiers will require more than 2 years. FEICA members are supportive of a transition period of 6 years to ensure the effective implementation of training and exemptions.  FEICA members understand that the main goal of the training is for workers to improve their understanding of hazards, risks and how they can effectively mitigate such risks. Therefore, we believe measuring the effectiveness of a training module in hours is rather restrictive and may not necessarily fully reflect the achievements sought in the training.  As with exemptions, common recognition across all EU countries for the training modules and training certifications is vital. |
| **Specific information 1:**  FEICA does not represent manufacturers of medical devices and therefore, we have not the expertise/knowledge to answer this question. |
| **Specific information 2:**  Measures in Appendix Y are mainly targeted at industrial sites and FEICA members estimate that these are in place already or can be applied there without major cost implications. In professional applications by SMEs with comparably low risk levels, where an exemption cannot be applied such companies may find some of these measures unjustifiable. |
| **Specific information 3:**  While difficult to anticipate in exact terms, FEICA members believe that the estimated cost of implementation of the training measures will have a significant economic impact, particularly on smaller companies who use PU products only as a minor part of their operations.  Recognising that there are over a million workers that use these products intermittently, a training scheme may not be affordable to many customers of the FEICA members.  We take this opportunity to further highlight our support for the acceptance of adequate exemption criteria in the dossier, as it would ease the burden on the industry, while ensuring the health and safety of workers. |
| **Specific information 4:**  FEICA members strongly support a transition period of 6 years as from the date of entry into force of the restriction to ensure the adequacy of the implementation of the training.  This time frame is needed set up the training modules and the infrastructure in all member states and build up certified trainers and conduct all worker trainings as the key deliverables. For exemption dossiers the required evidence needs to be collected per product / use combination. Based on preliminary experience by FEICA members this also cannot be accomplished within a 2-year period. (see above)  A transition period of six years would allow all concerned actors to start working on the implementation of the measures foreseen in the restriction, ensuring full compliance with requirements at the end of the transition period. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  Thank you especially for the information relating to our specific information requests.  We do note the possible situations with SMEs with comparably low risk levels, where an exemption cannot be applied. However, with low risk levels, e-learning (associated with the lower costs) is expected to be applicable and also, with time, exempted products and alternatives not based on diisocyanates are expected to be more and more available.  We agree that a transition period of several years will be necessary before full implementation can be expected. The transition period should account for setting up the training programs (up to 2 years) and training of the workers (within 4 years). We regard that a transition period of 4 years in total for carrying out the training required would be reasonable. |
| 333 | **Date/Time:** 2018/02/20 10:03  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Maler und Lackierer Innungsverband Nordrhein  **Org. country:**  Germany | **Comments on the SEAC draft opinion:**  The proposed restriction of diisocyanates needs specifications for the different sectors of industry where these products are used. The training program will only make sense if it is adapted to the different requirements of these industrial sectors. Users of PU-foam will need totally different training program than painters using brush or spray gun. The repeat frequency of 4 years is estimated to be too high. As it assumed that in the painting sector app. 250.000 people have to be trained under the requirements of this restriction, a repetition after 5-6 years should be acceptable. Also the duration of the training has to be reduced for the repetition of the training program. If a basic training of 4 hours is considered, for the repetition half of the time should be sufficient for refreshment of the learning contents.  As the three-year education of painters in Germany include the use of hazardous materials as well as the use PPE, the extent of the training courses should be reduced for these well-educated painters. Generally it should be distinguished between educated painters and unskilled workers. If the mentioned training extent is calculated for these unskilled workers, the well-educated painters would only need a reduced (may be by half) training. |
| **Specific information 3:**  a) The painting companies in Germany employ on average 5-6 painters, who will all need the training program. As typically the whole stuff will need the training program of group 2 or group 3, i.e. in total 8 to 12 hours of training, this will lead to an outage time of in sum 9 working days where no customers´ orders can be accepted. Assuming hourly wage rates of 70 € (netto) this will lead to deficiency in receipts of 5040 € for an average painting company.  b) About 90% of the painting companies in Germany are SMEs. Assuming a typical turnover for the companies with an average of 5-6 painters of about 500.000€ per year, it can be calculated that the a.m. outage time will lead to minimum costs of 1% of the turnover for a typical SME painting company in Germany. More than this, such a company with 5-6 employees can´t afford to send all employees at the same time to such a training course, because no one would be left in these small companies for urgent work to be done. Thus, the employees have to be trained in different courses, which increase the outage time of the management, if they will train their own employees. |
| **Specific information 4:**  A transition period of at least 5 years should be appropriate. As in Germany app. 250.000 employees are possibly working as painters with materials containing diisocyanates, this time and the corresponding facilities are needed for the recommended training. Extrapolating these numbers to other affected industry sectors it can be assumed that only in Germany a few million employees need to be trained. Also the trainers (i.e. commissioned experts, safety or occupational health specialists) themselves may need training for the special field of diisocyanates. |
| **SEAC Rapporteurs response:**  Thank you for your comments, especially for the information relating to our specific information requests.  We agree that a transition period of several years will be necessary before full implementation can be expected. The transition period should account for setting up the training programs (up to 2 years) and training of the workers (within 4 years). We regard that a transition period of 4 years in total for carrying out the training required would be reasonable. |
| 334 | **Date/Time:** 2018/02/20 10:07  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Bundesverband Korrosionsschutz e.V.  **Org. country:**  Germany | **Comments on the SEAC draft opinion:**  The proposed restriction of diisocyanates needs specifications for the different sectors of industry where these products are used. The training program will only make sense if it is adapted to the different requirements of these industrial sectors. Users of PU-foam will need totally different training program than painters using brush or spray gun. The repeat frequency of 4 years is estimated to be too high. As it assumed that in the painting sector app. 250.000 people have to be trained under the requirements of this restriction, a repetition after 5-6 years should be acceptable. Also the duration of the training has to be reduced for the repetition of the training program. If a basic training of 4 hours is considered, for the repetition half of the time should be sufficient for refreshment of the learning contents.  As the three-year education of painters in Germany include the use of hazardous materials as well as the use PPE, the extent of the training courses should be reduced for these well-educated painters. Generally it should be distinguished between educated painters and unskilled workers. If the mentioned training extent is calculated for these unskilled workers, the well-educated painters would only need a reduced (may be by half) training. |
| **Specific information 3:**  a) The painting companies in Germany employ on average 5-6 painters, who will all need the training program. As typically the whole stuff will need the training program of group 2 or group 3, i.e. in total 8 to 12 hours of training, this will lead to an outage time of in sum 9 working days where no customers´ orders can be accepted. Assuming hourly wage rates of 70 € (netto) this will lead to deficiency in receipts of 5040 € for an average painting company. |
| **Specific information 4:**  b) About 90% of the painting companies in Germany are SMEs. Assuming a typical turnover for the companies with an average of 5-6 painters of about 500.000€ per year, it can be calculated that the a.m. outage time will lead to minimum costs of 1% of the turnover for a typical SME painting company in Germany. More than this, such a company with 5-6 employees can´t afford to send all employees at the same time to such a training course, because no one would be left in these small companies for urgent work to be done. Thus, the employees have to be trained in different courses, which increase the outage time of the management, if they will train their own employees. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  Please see reply to Comment 334. |
| 335 | **Date/Time:** 2018/02/20 11:20  **Type:** MemberState  **MS name:**  Netherlands  **Country:**  Netherlands | **Comments on the SEAC draft opinion:**  The Netherlands welcomes the proposal to take steps to prevent exposure to di-isocyanates, a serious health risk for workers which indeed is not adequately controlled. We have, however, the following concerns:  • The current proposal does not safeguard adequate protection. The core of the restriction is the listing of obligatory elements of a training programme combined with measures taken during application. This approach would, however, require a more concrete elaboration of those measures as well as requirements on the examination to be effective. We therefore suggest another approach based on the expected qualifications of examinees rather than requirements of training materials.  • We have doubts about the role of national governments in the organisation and controlling of the training system, which is in the proposal based on approval of training material, and corresponding enforcement. In a system based on qualifications of examinees, there is less need for such a role of Member States.  Finally we refer to the Forum advice on enforceability of the proposal. |
| **SEAC Rapporteurs response:**  Thank you for your comment.  We would like to point out that it is not in the SEAC remit to assess options on which a full analysis has not been submitted in the Annex XV dossier or in the public consultation and therefore possibilities to address your proposal in the opinion are limited.  We do share your doubts regarding Member States’ obligations relating to the approval of training materials. This is reflected in the opinion. |
| 336 | **Date/Time:** 2018/02/20 14:21  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  MedTech Europe  **Org. country:**  Belgium  **Attachment:** | **Comments on the SEAC draft opinion:**  As outlined in our statement on the restriction report in September 2017 (see attachment), the definition of OHS requirements to control risks related to the use of diisocyanates is in general appreciated. Nevertheless, the proportionality and cost-benefit ratio of the proposed restriction are impaired by the very detailed and inflexible training provisions. The efforts and inconsistencies described in our first statement are still valid and these constraints would not increase safety and risk control. Thus training provisions in the restriction entry still need to be more flexible.  We would like to highlight once more that the medical devices industry already fulfils its duty to ensure safe application of diisocyanates in existing manufacturing operations (by means of OHS legislation) and training healthcare professionals (in the context of our information duty under the medical devices legislation).  1. Manufacturers of medical devices using diisocyanates:  In view of our own manufacturing operations, we have the following comments on SEAC’s draft opinion and its restriction proposal:  Training effort/duties – new uncertainties to be resolved  Regarding frequency and duration, SEAC's proposal now says "should" instead of "shall".  It’s unclear whether this should gain more flexibility, as requested in our first statement. This could also be over-interpreting because SEAC names the unspecified form, duration or frequency of training as weakness of current OHS legislation (see e.g. p. 10) and votes for a more specific regulation under REACH.  So the constraints and inconsistencies mentioned in our first statement remain valid and it is still needed to have a more flexible, fit for purpose provision for the training requirements.  Appendix X says "In the context of part 3 and part 4, [...] the classroom training should have a minimum duration of four hours." and the overall training effort is estimated by SEAC to be 3 to 8 hours (per worker, every 4 years).  It is unclear whether this intends to reduce the duration for workers in group 3 from 12 to 8 hours, because such reduction seems to be conflicting with the proposed paragraph 8 ("Users performing various tasks shall complete the training for the highest requirements for his working tasks according to paragraph 8").  In any case, the new provisions for part 3 and 4 are not consistent with the proposed conditions of the restriction: paragraph 8c assigns maintenance work to part 4 (high risk/exposure) but the topic is listed under part 3 for medium risk/exposure.  Beneficial but not efficient  The SEAC draft opinion clearly outlines that the socio-economic benefits are higher than the related costs. But this does not prove the efficiency of the proposed measures and does not explain why a more flexible approach (that e.g. allows more synergies with existing OHS training) is not possible. E.g. the frequency and duration of training is discussed (p. 24/25) without providing any rationale why exactly "3-8 hours every 4 years" must be fixed as a legally binding requirement.  Stricter classification into risk/measure groups  According to the new SEAC proposal, three additional uses are now classified as "3" instead of "2" (3 = highest risks and highest effort for training etc.): Handling incompletely cured articles (e.g. freshly cured, still warm); foundry applications; maintenance and repair that need access to equipment.  Reasoning for this is missing in the SEAC document.  2. Professional use of medical devices containing diisocyanates:  The restriction proposal also affects the use of medical devices containing diisocyanates by healthcare professionals, e.g. in hospitals. As these uses are already strictly regulated under the sectoral legislation on medical devices, we believe that they should be exempted from the proposed REACH restriction.  The Medical Devices Regulation (previously Medical Devices Directive) requires medical device manufacturers to train professional users of their products as part of the risk control measures for the design and manufacture of the devices:  Annex I, Chapter I, point 4 reads as follows:  “Manufacturers shall […] provide information for safety (warnings/ precautions/contra-indications) and, where appropriate, training to users.”  “Manufacturers shall inform users of any residual risks.”  Even if this was not a legal requirement yet under the Medical Devices Directive, it is common practice in the sector to give training to users. For medical devices containing diisocyanates, the concerned manufacturers organise training workshops to new and existing customers per country/region on how to safely use the product to protect both users and patients. For polyurethane applications, adhesives and sealants (e.g. synthetic cast tapes and splints), this includes an explanation and demonstration of the resin composition, room/table/protection requirements and precautions, appropriate use of gloves during handling and setting time, water exposure techniques, and application techniques.  Furthermore, Material Safety Data Sheets and available studies on the Environmental, Health and Safety aspects of diisocyanates are shared with the end users and/or the hospital laboratory and safety personnel. These precautions have been in place since the introduction of synthetic cast tapes and splints in 1979. These tapes and splints have been used in millions of patients. |
| **Specific information 1:**  What should be considered are the costs due to additional trainings at healthcare facilities required by the planned restriction:  The planned restriction would require healthcare providers to organise additional training for employees. Trainings need to be planned, prepared, executed, repeated, documented, etc. which is connected with additional resources and costs. As emergency personnel needs to be kept ready it will often not be possible to train all employees at once requiring more than one training to be scheduled. This will affect literally thousands of healthcare providers from large hospitals to small practices and their employees. In order to avoid this, it is very likely that healthcare providers will return to PoP-casts, despite their disadvantages (including clinical ones), negatively affecting patients or use more expensive prefabricated braces. All this would impose additional costs on healthcare insurance etc. and in sum lead to higher general expenses for healthcare systems in the EU Member States despite the fact that a medical device per the MDD and MDR already needs to be safe for users, patients and third persons, is subject to risk management and required to be accompanied by information for its safe use (labelling and instructions for use leaflet). |
| **Specific information 2:**  Currently the costs of technical and organisational measures cannot be estimated. Given the existing high safety standard, the costs, constraints and lost production volume due to the (inflexible) training requirements are expected to be more significant. |
| **Specific information 3:**  1. Impact on medical device manufacturers:  Currently the affordability for individual users (medical device manufacturers) cannot be predicted. But even if the measures might be expected to be affordable for some users, they are not efficient as outlined above: Average OHS training costs in manufacturing are expected to double due to the inflexible requirements. Every 4 years, an additional shut-down of production of at least two days would be required, both without improving health and safety of concerned workers.  2. Impact on professional users of medical devices:  The planned restriction would require healthcare providers to organise additional training for employees. Trainings need to be planned, prepared, executed, repeated, documented etc. which is connected with additional resources and costs. As emergency personnel needs to be kept ready it will often not be possible to train all employees at once requiring more than one training to be scheduled. This will affect literally thousands of healthcare providers from large hospitals to small practices and their employees. In order to avoid this, it is very likely that healthcare providers will return to PoP-casts despite their disadvantages (including clinical ones), negatively affecting patients or use more expensive prefabricated braces. All this would impose additional costs on healthcare insurance etc. and in sum lead to higher general expenses for healthcare systems in the EU Member States despite the fact that a medical device per the MDD and MDR already needs to be safe for users, patients and third persons, is subject to risk management and required to be accompanied with information for its safe use (labelling and instructions for use leaflet). |
| **Specific information 4:**  Time-relevant measures for implementation are e.g. gap analysis (including the assessment of all formal requirements) after publication of the binding conditions, preparation of further training measures required (e.g. formal qualification of trainers), roll-out of training for all concerned employees. In case of continuous shift operations, the 3-12 hours training sessions for all employees have to be coordinated with production downtime, which could be limited to a single summer and a winter break per year. Thus transitional periods of less than 2 years would significantly increase the risk of incomplete implementation (legal non-compliance) or an elevated (inefficient) implementation effort, i.e. extraordinary production downtime. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  The conditions of the restriction have been reformulated in such a way that those affected by the restriction can clearly understand their duties. For example a minimum duration of 4 hours has been proposed for the “intermediate” and ”advanced” training (measures group 2 and 3 respectively in the initial restriction proposal) to account for the more extensive content proposed in the training program. This reformulation of the conditions do not undermine the SEAC assessment which e.g. initially considered a training duration of 3 to 8 hours depending on the training options. Some additional text has been included in the SEAC opinion to clarify the above.  Additionally, the requirements to ensure the minimisation of risks for some activities were changed from those described in Part 2 to those described in Part 3 of Appendix Y (measure group 2 and 3 respectively in the initial restriction proposal) during the development of the RAC opinion and after taking into consideration the comments received in the public consultation of the Annex XV dossier (Comment 1654). We point out that the impact according to several comments received in this public consultation should not be significant since it is understood that these measures are already implemented by industry to minimise the risks.  Please see also reply to Comment 326. |
| 337 | **Date/Time:** 2018/02/20 15:59  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Verband der Automobilindustrie e. V. (VDA) / German Association of the Automotive Industry  **Org. country:**  Germany  **Attachment:** | **Comments on the SEAC draft opinion:**  Diisocyanates are used for the production of modern vehicles in a large variety of applications. The use of diisocyanates is necessary and widespread along the entire supply chain of the automotive industry, from the development via the production to the car workshop.  The unique properties of diisocyanates make this substance group indispensable for many areas of the automotive industry. Any restriction of the use of diisocyanates will therefore have an impact on the development, the production and the repair of cars in Europe.  Different diisocyanates with concentrations of monomers higher than 0.1 % by weight are processed in various applications.  The following applications are widely used in the automotive industry:  • Adhesives and primers on the basis of MDI for bonding windshields in automatic and manual processes  • Adhesives and sealing compounds on the basis of MDI and IPDI in the body shop and the assembly  • Adhesives on the basis of MDI for the production of plastic parts  • Casting resins on the basis of MDI in the tool shop  • Hardener for clear coats on the basis of HDI for the series painting of vehicles  • Hardener for clear coats on the basis of HDI for the manual painting of vehicles  • Hardeners for fillers on the basis of HDI for the manual painting of vehicles  • Polyurethane foam on the basis of MDI for acoustic insulation in the assembly  Diisocyanates are applied as well in automatic and encapsulated units as in manual operations by using appropriate technical and/or personal protective equipment.  Diisocyanates have sensitizing properties and can cause allergic reactions of the skin and the respiratory tract. The highest risk is the inhalation of isocyanates in vapor or aerosol form.  Based on this knowledge the German automotive industry has been using diisocyanates for a long time only by applying and observing high technical and personal protective equipment. The critical monomer content was continuously reduced and diisocyanates with an extremely low vapor pressure like e.g. MDI, were selected.  In principle, a potential inhalation hazard, with the exception of the painting of vehicles, could be excluded in the automotive production.  The serial painting of vehicles is highly automated in cabins with targeted air flow. An inhalation hazard to employees is thereby prevented.  Manual paint processes which are necessary for example for the repair of vehicles and for the production of small series or special paints, are carried out in cabins with targeted air flow and the use of mostly self-contained breathing apparatus.  Dermal hazard occur only briefly (e.g. risk of splashes on the skin) and can be avoided by the use of suitable protective equipment and supplementary organizational measure (e.g. work instructions).  The relevant national labor protection laws such as the German Ordinance on Hazardous Substances (Gefahrstoffverordnung) and the “Technical Rules for Hazardous Substances” (Technische Regeln für Gefahrstoffe) are decisive for the protection of employees against diisocyanates for the German automotive industry. The limits and the requirements for personal protection equipment as well as the training of the employees as defined in these regulations are successfully implemented by the German automotive industry not only for diisocyanates but also for all hazardous substances and offer a good protection of employees from diseases caused by activities involving hazardous substances.  For activities with diisocyanates the Technical Rule 430 „Isocyanate” is relevant. When implementing the protective measures described there as well as appropriate information and training of the employees, an adequate protection can be ensured. This is obviously also the opinion of the ministry responsible for occupational health and safety, the BMAS, and the Committee on Hazardous Substances (AGS, Ausschuss für Gefahrstoffe) since we are not aware of any planned or even ongoing regulatory activities to change the requirements for activities with diisocyanates.  The statement that asthmatic diseases often occur when using diisocyanates does not coincide with the findings in the automotive industry. The industrial use of diisocyanates can safely be carried out when the current German labor protection laws are followed and does not need further restriction in the automotive industry.  The high numbers of occupational diseases caused by diisocyanates cited in the Annex XV Dossier can therefore not be comprehended for the industrial use in the automotive industry. Further requirements and restrictions therefore cause only bureaucracy and costs.  Downstream user (DU) of diisocyanates containing products should also be enabled to identify safe uses, for which - in accordance with point 2b of the proposed restriction - exemptions could be claimed. Every DU is well aware of the activities of its employees with diisocyanates and the occurring exposure. Proof and documentation of compliance with the required limits for dermal and inhaled exposure to diisocyanates could be done in the context of the risk assessment of the employer.  It should be allowed to do the required training for measure group 2 via e-learning. In larger companies e-learning training sessions provide a better uniformity and control of realized trainings. Standardized training sessions and tests via e-learning ensure a high level of transparency and a good documentation. A lot of other web based trainings (WBT) - like instructions for handling with technical equipment (e.g. crane), trainings for fire protection or the enforcement of compliance tests - are demonstrating this.  Web-based trainings may use film sequences or pictures, in order to transfer the training content in a comprehensible and sustainable way. Afterwards the level of knowledge can be checked and, if necessary, deepened with sample solutions.  The duration of the training should depend on the content, which has to be communicated. The definition of a fixed duration is from our perspective not effective.  If an employee works with diisocyanates, occupational safety requires an instruction, which contains already many points of the proposed training content. The remaining points of the proposed training content could be integrated without any problems into the annual occupational health & safety instruction. Thereby no further organizational measures such as additional trainings or workshops are required.  Existing instruments of occupational safety should be used for the implementation of the required measures. In order to reduce the administrative burden the measures, which were already defined and described in the risk assessment or in the operating instructions, should also be mentioned in the annexes as adequate protective measures. There are also references to national regulations in other places of the documents, so that this should be possible without any problems.  Not only external specialists also internal specialists should be allowed to train the employees and act as a commissioned expert. The DU should be able to decide on his own, whether he qualifies one of his own employees (internal multiplier) as an commissioned expert - who will then organize the training course in the company -, or if he mandates an external specialist.  The training documents should be made available to the companies either directly by the manufacturers or by their associations.    Safety precautions of hazardous substances like diisocyanates have a high priority and are already part of the daily practice of safety at work in the German automotive industry. There is a sophisticated system to protect employees at the highest level by the Ordinance on Hazardous Substances and extensive technical regulations.  Should additional problems with the handling of diisocyanates arise, governmental agencies should work with the established safety at work committee. The additional regulations should be completely compatible with the existing work protection law at least for countries like Germany.  It is extremely questionable that REACH regulates safety at work parallel with the existing national occupational safety regulation over and over again like here in this discussed restriction for diisocyanates. Hereby arises double regulations which generate costs without increasing the safety. Aside, there is the risk of employers losing overview based on the multitude of regulations and that regulations with contradictory statements were generated for one and the same facts.  Therefore, it is incomprehensible that RMOA ended in the suggestion for a restriction. Because it is a difficulty in safety at work, it would have been also possible to manage it with the already existing occupational safety regulations. |
| **Specific information 1:**  VDA is not representing manufacturers of medical devices. Therefore, we have not the expertise/knowledge to answer this question. |
| **Specific information 2:**  In our opinion, the occupational safety measures existing in the user groups 1 and 2 are sufficient to ensure a safe level of protection for the handling of diisocyanates.  Additional extensive training methods cause additional avoidable costs. Corresponding to occupational safety Guidelines, every employee working with diisocyanates already has to be trained annually. Furthermore, every two years a preventive occupational medical care is offered to the employees.  All additional trainings and employment medical examinations cause additional costs and lead to redundant work since the laws are not harmonized.  Consequential costs result from obligatory documentation requirements because synchronization with documentation requirements corresponding to labor protection laws is intended. |
| **Specific information 3:**  We expect an additional effort for trainings for about 60.000 to 65.000 employees, who are handling with diisocyanates at the facilities of German automobile manufacturers.  For big industrial companies, which care for Occupational Safety as an important part of their corporate structure and implemented initial and annual instructions the additional effort for another training program will be out of scale. An instruction for the workers takes place in the framework of the common instruction for hazardous substances according to the on-site hazard assessment, which considers also all specific conditions for this working place in a concrete way. If something wasn’t communicated during the instructions it could be integrated in the existing training systematic.  Furthermore the employees are provided advice for preventive occupational medical care on a regular basis.  The additional benefit of another training does not correspond with the additional costs. In big industrial companies around hundreds to thousands employees will have to go through such an additional training and as a matter of fact everything has to be documented by a central site.  We also want to indicate, that monitoring the training programs by all SMEs means an extensive additional effort for the supervisory authorities. We plead for appropriate training requirements especially for craft producers and garages. We think that even for the intermediate training of workers e-learning would be the most workable and cost-effective instrument.  The SEAC-Opinion still considers a minimum duration of four hours for the classroom training which has to be repeated every four years. The duration of the training should depend on the content, which has to be communicated. The definition of a fixed duration is from our perspective not effective. At least a flexibilisation of the actual situation should be granted. For example: instead of four hours every four years it should be possible to train one hour annually.  Even the downstream user (DU) of diisocyanate containing products should have the opportunity to identify and explain an exemption for safe use according to 2b of the restriction proposal. The DU knows best the activities of his employees with diisocyanates and the occuring exposure. The proof and the documentation for compliance with workplace exposure limits of dermal and inhalative exposure with diisocyanates could be recorded with the hazard assessment of the employer. |
| **Specific information 4:**  The proposed 1 or 2 year transitional period seems to be too short.  For big industrial companies it is an enormous effort to install another training program and to integrate this in the existing occupational health programs (as is in question 2 already described).  Furthermore it makes sense to run a pilot project. The training material should be tested in some selected companies, before rolling out in all member states.  Stakeholders/producers need time to prepare training programs, to qualify trainers and multipliers and to educate employees. Therefore in our opinion a realistic transitional period seems to be 5-6 years. |
| **SEAC Rapporteurs response:**  Thank you for your comments. Some of them seem to relate to the proposal itself. At this stage the comments were invited for the SEAC draft opinion, and we will concentrate responding to those comments.  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.  We agree that training that is already carried out should not need to be duplicated due to the proposed restriction but developed to cover also any new requirements.  As to practical arrangement of training, according to our understanding, there does not seem to be anything hindering the employer from dividing the training content to be distributed in several sessions. 4-hour training could thereby be distributed in two 2-hour sessions for example.  We agree that a transition period of several years will be necessary before full implementation can be expected. The transition period should account for setting up the training programs (up to 2 years) and training of the workers (within 4 years). We regard that a transition period of 4 years in total for carrying out the training required would be reasonable. |
| 338 | **Date/Time:** 2018/02/20 16:19  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  EUROPUR aisbl  **Org. country:**  Belgium  **Attachment:** | **Comments on the SEAC draft opinion:**  EUROPUR is the European Association of Manufacturers of flexible polyurethane foam blocks and EURO-MOULDERS is the European Association of Manufacturers of Moulded Polyurethane Parts for the Automotive Industry. The companies in the membership of both associations produce flexible polyurethane foam (flexible foam) and the associations cooperate on the safe handling of diisocyanates on a permanent basis via a joint working group dedicated to health and safety issues. Both associations are therefore herewith answering to the public consultation jointly.  EUROPUR and EURO-MOULDERS are supporting the objectives and principles of the proposed restriction for diisocyanates, which we believe will contribute to a level playing field in Europe to address the risk related to the usage of the substances and further improve the protection of workers.  However, we herewith also wish to provide a number of critical comments on how the proposed legal text outlined in the annex to the opinions of RAC and SEAC amends the original proposal by Germany. The amendments made would render the implementation of the proposed restriction very difficult if not impossible in the flexible polyurethane foam industry. Our comments are detailed in the attached detailed contribution. |
| **Specific information 2:**  Most of the technical and organization measures proposed in Appendix Y of the example condition in Annex I to the SEAC opinion are already implemented in the flexible foam industry today. As highlighted in the attachment outlining our general comments, we do not believe that offering biomonitoring should be implemented since this would not add additional benefits compared to the air monitoring systems and personal protective equipment already in use in the industry today. |
| **Specific information 3:**  EUROPUR and EURO-MOULDERS have asked their members for information on how workers are trained with regards to safe handling of diisocyanates today already. We believe that the proposed measures are affordable. Training material already exists in individual companies for most of the heading envisaged under the restriction. This training material will have to be aligned and additional training material will need to be developed for some headings that are not always fully covered in all companies’ current training material (e.g. on change management for example). The aligned training will then need to be translated in all the official languages of the European Union. It is not possible to exactly calculate the cost of developing training material in line with all the headings of the restriction but we believe that this amount will be in the range of 200 to 300 KEUR for our industry. This is considered by our member companies to be an acceptable cost. EUROPUR and EURO-MOULDERS will play a leading role in the development of aligned training material for our industry.  We had discussed estimates of the cost of the training with the German authorities in the wake of preparation of their restriction dossier and believe that the cost of participation in trainings was well calculated by them in the restriction dossier.  High availability of trainers will minimize costs. A long transition period is needed to train enough trainers. |
| **Specific information 4:**  EUROPUR and EURO-MOULDERS believe that a transition period of about 6 years as from the date of adoption of the restriction will be required rather than the 1 to 2 years proposed.  A 6-year transition period may seem to be long. But it is justified because of the tasks that need to be carried out before the restriction can enter into force. Indeed, during the transition period, a training infrastructure and network of qualified trainers will need to be established throughout the European Union. Once such trainers and training infrastructure become available, several million workers will need to undergo their first training in compliance with the terms of the restriction. This will take time.  Another reason for such a transition period is that, for this restriction to become effective, Member State competent authorities will need to take decisions on a number of issues before industry can comply with the terms of the restriction. For example: How are qualified trainers educated and their competences verified? How is the comprehension of the training evaluated? Will there be training requirements imposed by national authorities beyond those foreseen by the restriction? What records should be kept by companies to show that they comply with the terms of the restriction? It is expected that these and other questions will need to be discussed with the competent authorities of each Member State during the transition period, which should therefore be long enough.  For all companies, but especially for SMEs, we would like to highlight that a pragmatic solution needs to be found to avoid a too frequent repeat of training sessions for new hires, especially where face to face training is required. In the case of workers starting a new job falling under Measure Group 2 / Part 3, we would advise that a pragmatic solution is found for such people. The first level of training (Measure Group 1 / Part 2) could be given at the time of start of their job as part of the normal safety instructions since it can be performed via e-learning. The second part of the training (face-to-face) according to the terms of the restriction could be given within a reasonable period of time thereafter (e.g. within one month or two) to ensure that a “critical mass” of workers is available for the training. This would ensure that companies do not need to organize a full training session each time one new worker arrives and would help mitigating the cost of the restriction. |
| **SEAC Rapporteurs response:**  Thank you very much for the information relating to our specific information requests. We understand from your comments that the technical and organisational measure proposed in Appendix Y are already implemented in your industry sector but the possibility of biomonitoring. Biomonitoring was proposed by the Dossier Submitter and supported by RAC as a requirement to ensure that potential peak exposures could also be monitored for activities which present a higher potential risk.  We agree that training that is already carried out should not need to be duplicated due to the proposed restriction but developed to cover also any new requirements.  We agree that a transition period of several years will be necessary before full implementation can be expected. The transition period should account for setting up the training programs (up to 2 years) and training of the workers (within 4 years). We regard that a transition period of 4 years in total for carrying out the training required would be reasonable.  We are aware of the specificities of trainees and new workers especially in sectors where a high turnover of workers takes place but points out that the same requirements should apply to ensure the safe handling of diisocyanates to all workers and especially to those without any previous experience. |
| 339 | **Date/Time:** 2018/02/20 16:43  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  European Committee of Domestic Equipment Manufacturers (CECED)  **Org. country:**  Belgium | **Comments on the SEAC draft opinion:**  Draft Contribution from CECED to the Public Consultation on the Draft Opinion of the Committee of Socio-economic Analysis (SEAC) on Diisocyanates restriction. |
| **Specific information 1:**  CECED is representing manufacturers of home appliances (white goods) and not of medical devices. |
| **Specific information 2:**  Existing Occupational Safety and Health requirements and provisions exist on EU Member States level and are applied by all CECED Member companies.    CECED estimates that the technical and organisational measures, which are described in the Appendix Training, are already implemented due to Occupational Safety and Health requirements and measures, which have to be continued independently of the proposed restriction. Therefore, with regard to the proposed restriction of Diisocyanates, additional costs for technical and organisational measures are insignificant. |
| **Specific information 3:**  CECED represents industrial downstream users of Diisocyanates.    The main applications of Diisocyanates are the manufacturing of rigid PU isolation foam in cooling appliances and hot water tanks. Accordingly, our contribution is related to bullet point "a".  The installations and production procedures of PU foam allow the classification of our affected workers in Measures Group 1 of the training requirements. That means, basic trainings with 4 hours length have to be organized.  The following cost calculations are based on a 4h basic training in the industrial sector.  Case studies-training:  1.) Training via e-learning:  It would be the preferred method, because of the individual time planning possibility.  Training course: e-learning module with external content, but company internal produced: costs estimated by 300.000 € in first language. Additional costs of 50.000 € for translation costs per language.  Case study e-learning: 300 workers/managers trained in 3 languages for 2 time periods (12 years: (i) direct costs: 450€ per worker, (ii) indirect costs: 100€ per worker per 4h training.  2.) Classroom training by internal Work Safety responsible person:  It is the training method with lowest costs (15-30 workers/training), however, not suitable if individual workers have to be trained.  Only indirect costs have to be calculated.  Additional preparation costs for a 3 to 4 hours training presentation: 20.000€ per language.  3.) Trainings via training institutes or in-house trainings by external trainers:  These training methods should be avoided in industry, because of highest costs per worker.  To summarize all points, CECED estimation:  The training costs for industrial downstream users are additional costs for training measures, which are additional to the existing Occupational Safety and Health provisions. The effectiveness of the trainings to reduce risks related to the health of workers is not evident. |
| **Specific information 4:**  CECED member companies are industrial downstream users of Diisocyanates.    Due to the implemented occupational safety management in our industry and activities allocated mostly in Measures Group 1, adequate training measures could be established within due time.    Therefore, the transitional period is not essential for industrial downstream users, but the availability of representative training materials from the Diisocyanates manufacturers in due time is essential. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  Thank you especially for the information relating to our specific information requests and for confirming that measures described in Annex Y should already be implemented in the industry. |
| 340 | **Date/Time:** 2018/02/20 16:44  **Type:** MemberState  **MS name:**  Sweden  **Country:**  Sweden | **Comments on the SEAC draft opinion:**  The Swedish Chemicals Agency support the main conclusions made by SEAC in the draft opinion. As stated by SEAC, the aim of the restriction proposal is to develop equally high standards of health protection with regard to occupational exposure to diisocyanates throughout the EU. These harmonized requirements will also enhance the free movement of worker and goods and provide common basis for competition between companies.  As regards the proposal that member states should approve the training material at a national level, as proposed by RAC in the RAC opinion, we agree with SEAC that this may counteract the benefits of a harmonisation. We are therefore at this point hesitant to this proposal. As pointed out by SEAC in the draft opinion, any costs for the extra administrative burden for the member states are also not included in the cost/benefit analysis of the restriction proposal.    Experiences from the current national regulation on requirement of education for persons that handle diisocyanates in Sweden shows that it is important that the education is adapted to the conditions at the workplace. We find it doubtful that an authority will have this knowledge. For more information on experiences, please see comment no 1558 in RCOM, which was submitted by the Swedish Work Environment Authority in the first public consultation on the dossier of this restriction proposal. |
| **SEAC Rapporteurs response:**  Thank you for your support.  We agree that it is important that the training is adapted to the conditions at the workplace, and that authorities might not be in the best position to know what the optimal solution is in each and every case. |
| 342 | **Date/Time:** 2018/02/20 16:51  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  ZVEI Domestic Electrical Appliances Division  **Org. country:**  Germany  **Attachment:** | **Comments on the SEAC draft opinion:**  In our discussions with the German dossier submitter and in public consultation on the proposal for diisocyanate restriction under REACH, we have already expressed our concerns regarding the restrictions proposed at present.  Herein, we would like to clarify again our point of view – namely, that of downstream industrial users –, since we still harbor considerable misgivings and believe that our needs have not been adequately addressed in the SEAC Draft Opinion which is now pending consultation, either.  We see and understand the efforts of the authorities in cooperation with industry to reach a workable solution for commercial enterprises or one-man businesses, which would take into consideration the particular hazards that the employees of these companies are subjected to. We welcome and support every measure that leads to an effective improvement in the safety of our employees at work.  In principle, however, we see no justification for introducing procedures within the scope of the REACH regulations for banning chemicals that were originally intended for occupational safety. We doubt that it is expedient to apply an instrument of restricting chemicals with the explicit intent to continue permitting all applications to date by way of exemption clauses. Should lawmakers see the need for subsequent improvements in training measures, such remedies should be implemented primarily within the existing legislative framework of occupational safety and health.  In the electronics industry, diisocyanates are employed in a wide variety of ways, including bonding agents and insulating compounds for electronic components, as well as varnishes and coatings.  The most significant application, in terms of quantity, is the production of insulating polyurethane hard foams with MDI preparations for cooling appliances (interior walls of body and door) or in heating technology.  In the overwhelming number of application scenarios, there is no direct contact of the employee with the substance mix that contains the diisocyanate (cf. attachment: PU Foaming Process in the Manufacture of Cooling Appliances). Only during repair or maintenance, a contact between workers and chemicals cannot be ruled out entirely. For this reason, in the home-appliance industry, such operations are only performed under the use of adequate technical exhaust systems and/or personal safety equipment. Employees working in these areas are being briefed within the scope of the usual hazardous materials training courses, according to their workplace profile, by the in-house safety engineer, who will also point out the specific requirements in handling diisocyanates. Moreover, workers are under regular medical surveillance by their company physicians.  Up to now, this approach – in Germany based on the Gefahrstoffverordnung (GefStoffV, Ordinance on Hazardous Substances) and the Technische Regeln für Gefahrstoffe (TRGS, Technical Guidelines on Hazardous Substances), for diisocyanates specifically TRGS 430, “Isocyanates – Hazard Assessment and Safeguards” ¬ has proven very effective in the home-appliance industry. Not least due to the continuous improvement of safety standards (through the introduction of management systems such as e.g. OHSAS 18001 [ISO 45001 in the future] or through participation in walk-the-talk trainings by the PU industry [ISOPA]), the precautionary measures are so efficient that not a single case of respiratory ailments as a result of the diisocyanate use is known in our industry.  We therefore regard the existing strategy in handling diisocyanates within the German and European home-appliance industry, along with the safety precautions in place for a safe industrial application, as absolutely adequate. For this reason, we see no need for toughening statutory requirements for our industrial sector. To the contrary, we believe that the legal instruments already in effect are quite sufficient to ensure a safe handling of diisocyanates in the industrial environment, not only in the home-appliance industry.  Contrary to previous restrictions in REACH Appendix XVII, compliance with the proposed restriction for diisocyanates cannot be verified in the product itself. We would therefore want to point out that the monitoring of the training measures – especially in view of the vast number of small and medium-sized companies – would require a significant extra effort on the part of the supervisory authorities.  We seriously doubt that the assumption of the dossier submitter will prove true that in the future, training measures could be reduced considerably by introducing safer products (attachment Exemptions), especially since the very absence of these safe products was a decisive motivation for proposing the comprehensive training concept in the first place. Nevertheless, the ZVEI Domestic Electrical Appliances Division sees an urgent need for the chemical industry to provide small-business users with intrinsically safe products, so that no additional training would be required, given the large number of users (approx. 5 million throughout the E.U.).  Moreover, we doubt that the strict guidelines on the content, duration, and frequency of training courses in the industry will actually lead to improvements in handling diisocyanates. For didactical reasons, we regard a training requirement of, say, four or eight hours once every four years as non-productive. Experience has shown that regular shorter briefings in smaller intervals are far more suitable in maintaining awareness of the risks inherent in hazardous substances.  In addition to these remarks, we would like to emphasize that our members are open to new and improved training materials that include new experiences, identify potential risks and precautionary measures, or provide evidence of improved emergency response. Such information can be immediately integrated into ongoing training activities.    Concerning the in-house safety experts in our industry, we are absolutely confident that they are fully capable of …  a) … training relevant employees in the safe handling of diisocyanates. In order to qualify them in the subject, the chemical industry should offer an external advanced training for safety engineers (“training the trainer”).  b) … developing adequate training measures for the employees based on training material which has to be supplied by the chemicals manufacturers. It is essential that companies receive the training material in time and will not have to wait for ready-made training programs, which, in addition, are licensed by the manufacturers and subject to fees.  c) … communicating new insights into the risks and handling of diisocyanates to the employees, depending on their workplace, at any time.  From our point of view, the subject of training has been inflated in the course of the discussion to an enormous construct that does not correspond to the needs and the actual hazards of downstream industrial users. One reason for this could be that, in our perception, both the restriction dossier and the discussion in the industrial coalition of the so-called "PU Exchange Panel" focus primarily on the manufacturers of diisocyanates and the professional technical users. |
| **Specific information 1:**  ZVEI Domestic Electrical Appliances Division is representing manufacturers of home appliances (white goods) and not of medical devices. |
| **Specific information 2:**  Existing Occupational Safety and Health requirements and provisions exist on EU Member States level and are applied by all ZVEI Domestic Electrical Appliances Division´s member companies.  ZVEI Domestic Electrical Appliances Division estimates that the technical and organisational measures, which are described in the Appendix Y, are already implemented due to Occupational Safety and Health requirements and measures, which have to be continued independently of the proposed restriction. Therefore with regard to the proposed restriction of Diisocyanates, additional costs for technical and organisational measures are insignificant. |
| **Specific information 3:**  ZVEI Electrical Appliances Division represents industrial Diisocyanate DU.  The main applications of Diisocyanates are the manufacturing of rigid PU isolation foam in cooling appliances and hot water tanks.  Accordingly our contribution is related to bullet point a.  The installations and production procedures of PU foam allow the classification of our affected workers in Measures Group 1 of the training requirements. That means, basic trainings with 4 hours length have to be organized.  The following cost calculation is based on a 4 h basic training in the industrial sector.  Case study training:  1. Training via e-learning  It would be the preferred method – especially for new employees, who have to be trained individually, because of the individual time planning possibility.  Training course: e-learning modul with external content, but company internal produced:  costs estimated by 300.000 € in first language. Additional costs of 50.000 € for translation costs per language.  Case study e-learning:  300 workers / managers trained in 3 languages for 2 time periods (12 years):  direct costs: 450 € per worker  indirect costs per worker: 100 € per 4 h training  2. Classroom training by internal Work Safety responsible person  It is the training method with lowest costs (15 - 30 workers/training), not suitable, if individual workers have to be trained.  Only indirect costs have to be calculated.  Additional preparation costs for a 3 to 4 hours training presentation: 20.000 € per language.  3. Trainings via training instituts or in house trainings by external trainers  These training methods cause the highest costs per employee.  A large number of trainers are required to carry out these training courses. In the opinion of our member companies, these external trainers do not necessarily have the same in-depth knowledge and experience of possible risks etc. in the respective working environment as their own internal experts. Our member companies therefore are convinced that if the PU industry provides the necessary information/training materials, they will be able to conduct these training courses themselves with the same or greater success, less effort and at a lower cost. |
| **Specific information 4:**  ZVEI Domestic Electrical Appliances Division´s member companies are industrial downstream users (DU) of Diisocyanates.  Due to the implemented occupational safety management in our industry and activities allocated mostly in Measures Group 1 adequate training measures could be established within due time.  Therefore the transitional period is not essential for industrial dowmstream users, but the availability of representative training materials from the Diisocyanate manufacturers in due time. |
| **SEAC Rapporteurs response:**  Thank you for your comments, especially for the information relating to our specific information requests.  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.  We agree that the enforcement of the training requirements is costly to the national authorities. However, we expect that the enforcement will mainly be based on documentation checks and as such would not require resources that would significantly differ from those spent in the enforcement of other restrictions.  Regarding the expected reduction in the utilisation of the training measures due to increasing availability of low-risk products, we share the optimism of the Dossier Submitter, and welcomes the related initiative for developing low-risk alternatives.  We agree that industry should take advantage of different training methods available and choose the ones that fit to their needs the best. |
| 343 | **Date/Time:** 2018/02/20 17:18  **Type:** MemberState  **MS name:**  Belgium  **Country:**  Belgium | **Comments on the SEAC draft opinion:**  Point 10 of the restriction ‘This restriction should apply without prejudice to other Community legislation on workers protection’ is really needed, as in certain cases the training obligations in this restriction are less protective than the OSH requirements.  For example the exemption of training for the so called ‘very low risk of exposure’ jobs is in violation with OSH training requirements. Very low risk doesn’t mean no risk: In Directive 98/24/EC (chemical agents) art 8 (Information and training for workers)"the employer shall ensure that workers and/or their representatives are (among others) provided with the data obtained pursuant to the risk analysis (…)".  Also, incidents can increase the risks: art 7.5 "The employer shall ensure that information on emergency arrangements involving hazardous chemical agents is available (…)".  Also, a very essential point is missing from the list of subjects for training: The correct practical use of the Personal Protective Equipments needed: in the practice, inspectors notice that this is a very weak point, with serious health consequences.  Training of workers should be specific to the individual workplace. Providing a generalized training generates the risk that workplace particularities are missing, making the training much less effective. In this respect point 4c is insufficient: according to Directive 98/24/EC workers’ training and information should also be updated to take account of changing circumstances at the workplace.  Point 5 of the restriction proposal: it is the responsibility of the employer to keep records, not the responsibility of the worker.  The question of the public resources needed for the accreditation process is key in the implementation of such a Restriction. An additional point on the certification (costs to the industry actors) is mentioned below. |
| **Specific information 2:**  OSH also imposes exposure minimization, minimization of the number of exposed workers, emergency measures, appropriate health surveillance, … . Based on this proposal, the costs will be 'outsourced' (based on an certification scheme provided by accredited bodies) so some limited extra costs (only) could apply to the enterprise.  However, the ‘Behaviour based performance program’ point seems unfamiliar to us: that might constitute an extra cost. |
| **Specific information 3:**  Quoting Directive 89/391/EEC, art 12.4: training of workers may not be at the workers' expense and must take place during working hours. The obligation is already there. It is the same for SME’s, because every worker is entitled to have equal protection. So there will not be significant extra costs, especially because the training obligations in the restriction are (maybe apart from the ‘Behaviour based performance program’) not more severe than what OSH requires (see also reply under point 2). |
| **SEAC Rapporteurs response:**  Thank you for your comments.  We agree that the correct practical use of PPE is essential content of the training. We regard that it is included in the topic “PPE and their limitations” and it will be further developed within the training material.  We agree that the content of training should be adapted to the specific use in question. |
| 344 | **Date/Time:** 2018/02/20 17:36  **Type:** MemberState  **MS name:**  Sweden  **Country:**  Sweden | **Comments on the SEAC draft opinion:**  The socio-economic analysis is focused on the manufacturers and cost of training for them. Since diisocyanates are widely used restrictions will have consequences for many types of products. Some of those products, for example medical devices have beneficial effects for human health. We are concerned that a strong restriction with consequences for medical devices may have impact on public health. The socio-economic effects of such a restriction therefore has to be analysed, especially with focus on downstream users (health professionals, patients, as well as manufacturers using a small part that contains diisocyantes). If one presume that diisocyanates can be replaced the toxicological profile of the replacement compounds has to be compared to the one for diisocyanates to be able to scientifically discuss which compound that has the best profile. Overall, there has to be a risk-benefit discussion. |
| **Specific information 1:**  We welcome the specific information requested by Germany, but would like the scope to include all types of medical devices since it is not clear to us why it was restricted to orthopedic casts, specialized prosthetics and orthotic devices. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  We note your concern about the potential impacts on human health that a restriction on the use of diisocyanates in medical devices may present. SEAC has received some limited information on impacts expected to the sector. Based on the information received SEAC does not have enough information to support a derogation on medical devices. Please see also the reply to the Comment 326. |
| 347 | **Date/Time:** 2018/02/20 23:33  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  PU Europe  **Org. country:**  Belgium | **Comments on the SEAC draft opinion:**  PU Europe is the European voice of the polyurethane (PUR / PIR) insulation industry. It has been set up as the European federation of national PU associations in 1981, and gathers today manufacturers of insulation articles represented through eleven of those associations as well as leading raw material suppliers.  Polyurethane insulation is one of the most effective insulation materials commonly available today. It is lightweight, easy to handle and install, and its very low thermal conductivity means that a much thinner layer than most other insulation materials is needed to get the same level of energy efficiency. Furthermore, PU insulation has a high compressive strength, is unaffected by air infiltration and is resistant to the passage of moisture. All of these attributes make it an extremely durable material that retains its thermal properties over time. It is also extremely versatile and can be used just about anywhere.  Because it is so versatile, PU insulation is commonly used in a number of different ways:  • Insulation boards and blocks  • Spray insulation  • Composite/sandwich panels  • Pipe insulation  Based on a recent internal survey, we estimate around 110-150 sites with a total workforce of 20,000-25,000 employes producing boards and block foam in Europe. Of interest, older estimates revealed that circa 6,000 companies are involved in the production (from suppliers, manufacturers to servicing) and up to 61,800 when counting the installers/applicators. It is important to note that the number of applicators of spray foam is difficult to estimate.  As significant down stream users of MDI, over 50% of the formulation relies on MDI, PIR/PUR manufacturers and suppliers of spray foam components are following closely the proposal for a MDI use restriction (PU Europe has been involved since day one in the so-called “PU Exchange Panel” mentioned on page 39 of the background document dated 5 Dec. 2017). Together with other trade associations, we provided information and input to BAuA -German REACH competent authorities- during the drafting process of their restriction proposal.  Due to our previous work in 2017 on the BAuA proposal, and because of the way the public consultation has been drafted (focused on 4 specific questions), we were confident that the RAC and SEAC opinion would simply take forward BAuA proposal. Unfortunately, we discovered few days before the end of the consultation that RAC & SEAC opinion introduced significant changes to BAuA proposal that would move most of the workforce in production sites from measure group 2 to measure group 3 (or now called part 3 and 4 respectively in annex X of the opinion dated 30 nov 2017). This change had not been properly communicated to the PU insulation industry and simply fails to recognize the measures put in place on our members sites to already ensure the highest health and safety standards. Moving the “handling of incompletely cured articles” and “maintenance and repair that needs access to equipment” to the highest mesures group would lead to signicant additional efforts and costs (direct and indirect like loss of working time) due to the unnecessary additional training. As indicated earlier, manufacturers are implementing a wealth of technical and organizational measures to reduce or avoid exposure to MDI .  PU Europe strongly calls for a proper dialogue with the industry to be established on this key issue of which workforce should be covered by the intermediate or advanced trainings (part 3 and part 4 of annex X), and we look forward to contribute to the next steps of this exchange. |
| **Specific information 2:**  It is paramount to note that Occupational Safety and Health laws are a national competence, therefore each country has its own provisions, which makes a simple answer to this question not possible for PU Europe (European Federation of rigid PU foam insulation manufacturers). While our members have implemented on a voluntary basis the walk the talk programme (developed by ISOPA, the European MDI/TDI suppliers trade association), the proposed use restriction will most probably cover more workers than it is today the case. Furthermore, the introduction of national prescriptive requirements in place of voluntary schemes will for sure add new costs to the industry (notably in relation to the paper work and maintenance of updated dossiers in each company on a yearly basis). As indicated earlier, additional costs incurred by the introduction of the MDI use restriction measures cannot be estimated by PU Europe. |
| **Specific information 3:**  While PU Europe understands the principles underpinning the use restriction proposal, we believe that a less dogmatic approach should be taken when it comes to the length of the training (4 + 4 + 4) and the way to train the workers. A more objective oriented and flexible approach of the proposal would benefit workers health.  As for the preparation of the training, PU Europe holds the view that a uniform set of training materials for all over Europe should be prepared to a) minimize costs for industry (mutualisation of resources), b) make for a seamless implementation (due to acceptance by all stakeholders/wuld also make sure that industries in “small” countries can implement in a straight forward way the legislation), and c) in order to ensure level playing field (avoiding different “standards” in Europe). With regard to the training of workers, PU Europe believes that each measure group could receive the training in a different form than a class room training (via e-learning for instance), and the training should be allowed to be split (not mandatory to have the 4 hours in one go). Furthermore, the distribution of the duration over MG 1-2-3 currently proposed would need to be checked once the content of each training modules become more clear.  As for the costs companies would bear for training their workers, in-house training and some blended learning (e-learning and class room training) would held minimise costs, but it is important to highlight that loss of working time for trainees will be the more important costs (travel to the training center needs to be factored). PU Europe believes that the lower range of SME definition will not be able to have an in-house training, and will therefore rely on third party trainers who usually are expensive.  Specific point on new workers falling under MG 1 and MG2: they should not be prevented from working if their certificates have not yet been granted. This is especially true for new staff, temporary workers or third party intervening at the company premises. A kind of “light” version, or “basics”, of the training should be given at the time of joining of these new workers, and after a few days the rest of the training course must be followed by those workers. “The "light" or "basic" version should be trained in-house by a trained employee of the company itself. The method train the trainer multiplies and spreads the knowledge and leads to a higher working flexibility. When a new worker joins the company (or any of the other worker above described), it will be very expensive to imagine setting up immediately a training course for him/her.  Finally, PU Europe would like to emphasize that considering the advancement of social science and technologies, training methods should be fit for the 2020+ horizon (media tools but also the habits of the work force at that time). |
| **Specific information 4:**  As indicated above, PU Europe favors a European approach to the use restriction proposal, which means the creation of harmonized (and translated in most European Languages) training modules as well as the establishment of an architecture to maintain those modules over time. The task ahead is very significant and we cannot imagine coping which such a tight timeframe (developing the training modules would probably take 2 years). Furthermore, not to create bottleneck on the training markets (all workers obliged to follow a training in a given year), it is advisable to extend this period to at least 6 years. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  The conditions of the restriction have been reformulated in such a way that those affected by the restriction can clearly understand their duties. For example a minimum duration of 4 hours has been proposed for the “intermediate” and ”advanced” training (measures group 2 and 3 respectively in the initial restriction proposal) to account for the more extensive content proposed in the training program. This reformulation of the conditions does not undermine the SEAC assessment which e.g. initially considered a training duration of 3 to 8 hours depending on the training options. Some additional text has been included in the SEAC opinion to clarify the above.  Additionally the requirements to ensure the minimisation of risks for some activities were changed from those described in Part 2 to those described in Part 3 of Appendix Y (measure group 2 and 3 respectively in the initial restriction proposal) during the development of the RAC opinion and after taking into consideration the comments received in the public consultation of the Annex XV dossier (Comment 1654). We would like to point out that the impact according to several comments received in the public consultation should not be significant since it is understood that these measures are already implemented by industry to minimise the risks.  Regarding the organisation of the trainings, according to our understanding, there does not seem to be anything hindering the employer from dividing the training content to be distributed in several sessions. 4-hour training could thereby be distributed in two 2-hour sessions for example.  We are aware of the specificities of trainees and new workers especially in sectors where a high turnover of workers takes place but we would like to point out that the same requirements should apply to ensure the safe handling of diisocyanates to all workers and especially to those without any previous experience.  We agree that a transition period of several years will be necessary before full implementation can be expected. The transition period should account for setting up the training programs (up to 2 years) and training of the workers (within 4 years). We consider that a transition period of 4 years in total for carrying out the training required would be reasonable. |