**Response to comments document (RCOM)**

on the Annex XV dossier

proposing restriction on

**Diisocyanates**

**Non-confidential**

**ECHA/RAC/RES-O-0000001412-86-176/F**

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

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| **Substance name** | **EC number** | **CAS number** |
| Diisocyanates | - | - |

5 December 2017

General Comments and answers to specific information requests

## Specific information requests:

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.
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)?
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?
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.
5. How would the proposed training program affect your company (we are particularly interested in how this affects SMEs or self-employed persons)?
   1. what would be the most important cost to your company from the proposed training program – the €-cost of training, loss of employee time, else?
   2. would the training program benefit your company in other ways besides potential improvements in worker health, such as improved productivity/working methods?

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| **Ref.** | **Date/type/Org.** | **Comments** |
| **1511** | **Date:** 2017/04/20 15:20  **Content:**  Environmental emissions;  Description of analytical methods;  Information on costs;  Transitional period;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** United Kingdom  **Company name confidential:** Yes  **Privacy comment:** IP.  Do not have access to personal health records. | **Comment:**  The proposed restrictions require improved definition |
| **Answer to specific info request 1:**  >5 years to allow for increased training and process improvements, significant requalification and assessment of alternatives (ie multi million). |
| **Answer to specific info request 2:**  Accompanying and manufacturing documentation and labelling would need to be updated. |
| **Answer to specific info request 3:**  Air monitoring.  Correct use of PPE.  Independent regular occupational health checks. |
| **Answer to specific info request 5:**  Clarification of the 0.1% weight restriction is required.  Cost implications to prove compliance.  Increased product costs from requalification and additional risk from using a new material. |
| **Dossier submitter response:**  Thank you very much for your comments.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 5)  The rationale for the 0.1wt% limit is now explained in the (revised) Background document (Section A.2.2.3)  Regarding the costs of compliance under the restriction, in Annex 8 of the BD (Appendix 13 – Trainings and Measures) different options for the training format were defined depending on the measure group. This offers the opportunity to choose the training format which fits best to the conditions of your company to reduce work time losses and the administrative burden of the restriction as far as possible. |
| **RAC Rapporteurs comments:**  Thank you for your comments and for the advice to improve the “definition” of the restriction. RAC has proposed a revision of the conditions which is included in the opinion.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  To 2) RAC agrees that accompanying and manufacturing documentation (e.g. safety data sheets) have to be updated and if there is any new information regarding classification and labelling, the registrant will also be responsible for updating their registration without any delay.  To 5) The limit value of 0.1% w/w was chosen by the Dossier Submitter as it represents the lowest Specific Concentration Limit (SCL) established for diisocyanates (as shown in the Background Document (Table 7, Annex B): for some diisocyanates SCL of 0.1% or 0.5% has been derived, while for others there is yet no harmonised classification available). |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  RAC has streamlined the conditions of the restriction; the new proposal of another description has been made and it is included in the committees’ opinion.  SEAC agrees that certain transitional period will be needed in order to prepare all what it is needed for proper implementation. How long this period is going to be, will be decided on the political level. |
| **1514** | **Date:** 2017/05/19 13:30  **Content:**  Other socio economic analysis (SEA) issues;  Transitional period  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** EUROPUR aisbl  **Org. country:** Belgium  **Attachment:**    **Privacy comment:** No comment | **Answer to specific info request 1:**  EUROPUR believes that a transition period of about 5 years as from the date of adoption of the restriction will be required.  Such a 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 the restriction to enter into force, Member State competent authorities will need to take decision on a number of issues before industry can comply. 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.  As regards timing, the transition period (and the entry into force of the restriction) should be applied in the same way across the European Union for a given measure group, to provide for a level playing field.  One issue that EUROPUR would like to raise with regards to the transition period is the risk of “bottleneck” in training demands just before the restriction enters into force. As with any new requirement, there is indeed a risk that a large number of companies wait until the last moment to train their workforce in accordance with the terms of the restriction. We would call on competent authorities in EU Member States to foresee mechanisms on their territories to avoid such bottlenecks.  While it may seem tempting to have a pilot project run in a specific country to “test” the restriction, it seems difficult in practice to carry out unless the authorities of a Member State decide by themselves that their country should be a volunteer for such a project. A more interesting approach, that may help avoiding bottlenecks in training too and ensure a level playing field within a given application, may be to phase the entry into force of the restriction according to measure groups, proceeding first with applications with a higher potential exposure to isocyanates (the so-called measure group 3). |
| **Answer to specific info request 2:**  EUROPUR believes this question is addressed primarily to the manufacturers and importers of diisocyanates and mixtures. As they place the diisocyanates and mixtures on the market, they should inform their customers of the requirements of the restriction. However, as a trade association of downstream users, we will play our role in communicating on the restriction and the duties of downstream users to our part of the supply chain (flexible polyurethane foam production). This will for example take place via our newsletters or via member briefings, presentations and other documents as we see fit. |
| **Answer to specific info request 3:**  The flexible polyurethane foam industry has for years made use of documents created by the European Association of Diisocyanates and Polyols Producers (ISOPA) on the safe handling of diisocyanates. These include their product stewardship programme ‘Walk the Talk’, but also different documents and checklists for the safe handling of chemicals. As a trade association of downstream users, EUROPUR has in 2016 published “Guidelines for the establishment of a safety management system in a polyurethane foam plant”, a large part of which focuses on the safe handling of chemicals used in PU foam production. These and other documents are used by individual PU foam producers to create their own training materials.  Both the trainings and documents created by ISOPA and EUROPUR are put at the disposal of the industry. Companies are free to use them or to create their own training resources themselves or with the support of specialized companies. It is therefore not possible to state that one or the other method/material is better.  One tool to assess the efficiency of training in the industry is monitoring / data gathering. EUROPUR has been collecting information on cases of occupational asthma from its members since 2014. The feedback from our members shows that the number of cases of occupational asthma is flexible PU foam production is very limited but also sheds some light on the possible causes of identified cases. One of these causes is bad habits or practices that can develop in the workforce over time. We therefore believe that the approach taken in the proposed restriction to repeat training at regular intervals is a good tool to keep awareness and knowledge on a high level. Also the fact that the restriction foresees thorough training of team leaders and other staff in supervision roles is seen as positive. |
| **Answer to specific info request 5:**  A large number of flexible polyurethane foam producers are SMEs. Irrelevant of whether companies are SMEs or not, we consider that worker protection has to be to the highest standard in all companies. Our industry operates according to the risk management measures highlighted in safety data sheets and their exposure scenarios. In addition, several pieces of EU legislation applicable across all EU Member States do cover the risk of accidental exposure (for example the Seveso Directive for companies using TDI), helping to implement a culture of safety where risks are reduced to the minimum acceptable level. Workers in our industry are already well trained today on the safe handling of diisocyanates.  The being said, as regards this restriction, we find it positive that the requirements of the restriction as proportional to the risk of exposure and that uniform minimum training requirements are set across the European Union. It is expected that the restriction will impose to review training materials, a task in which EUROPUR as a trade association will seek to assist companies in, and to document that workers have followed the training and successfully completed the end-of-training evaluation. In an industrial setting like PU foam production, we believe the latter can be achieved by keeping a registry of training according to the restriction in the plant.  For the restriction to work in our industry, it will be paramount that the qualification of trainers is recognized from one Member State to another. Indeed, in smaller Member States, the number of flexible PU foam plants is limited. It is unlikely that all countries will appoint local training institutes or specify procedures to validate the qualification of trainers for small panels of trainees. Trainers will therefore have to obtain their proof of qualification from other Member States in order to train the workforce locally.  Similarly, the staff turnover between companies can be relatively high in our industry, especially for manual tasks. If a worker has proof from his previous employer in the same sector that he has successfully passed the training requirements set by the restriction, his current employer should be able to recognize this training. |
| **Dossier submitter response:**  Thank you very much for your comments, and for your support of the restriction proposal.  Thank you for the idea about a staged introduction of obligations for the various measure groups (with obligations for the highest risk group being introduced first). This needs to be considered in a future discussion on implementation options.  To 5) Regarding your concerns about the validity of training certificates and trainer qualifications across borders in the EU. Of course, the proposed concept assumes that the training and trainer certificates will be transferable over borders. But, it has to be taken into account that the certificates which validate the competencies for safe work are valid for a specific measure group. In case of a job change which implies a higher measure group, some further training is needed to qualify for this type of activities. |
| **RAC Rapporteurs comments:**  Thank you for your comments.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end. To keep the restriction proposal rather simple, RAC prefers a single date for the restriction to enter into force and not a staged introduction for the implementation of measures. However, this topic is also a political one and will therefore be discussed in another Committee.  RAC considers that the Competent Authorities in the Member States are aware of the risk of “bottleneck” regarding the training demands.  To 2) RAC agrees with your comment that the communication of the requirements of the restriction has to start at the top of the supply chain (e.g. at the level of manufacturers / importers). However, your assistance as a trade association in the communication of the requirements of the restriction is highly appreciated.  To 3) This information is noted. It supports, as you pointed out, the need for regular high-level training of workers and self-employed persons.  To 5) RAC agrees that worker protection has to be at the highest standard in all companies (irrelevant of the size of the company). As you point out, a culture of safety is needed to minimise the risks due to the use of diisocyanates as far as possible to reach this aim.  RAC agrees that it is reasonable to match the requirements of the restriction with the risk of exposure / risk of sensitisation.  The other topics are addressed by the Dossier Submitter´s reply to your comments. |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  1) We agree that several years will be needed for the full implementation of the proposed restriction, but the final decision on this will be taken on political level.  5) We agree that uniform minimum training requirements are set across the European Union and that the training taken should be mutually accepted by the MS. |
| **1515** | **Date:** 2017/05/22 15:04  **Content:**  Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  <redacted>  **Org. country:** Germany  **Company name confidential:** YES | **Comment:**  We would like to voice our support for this restriction proposal. The scope of the proposal (in particular the option of measures and trainings) seems to be very sensible approach with model character for future cases. We would welcome it if this type of restriction concept is applied also for future restriction cases as a “best practice model” as it seems to adequately balance and satisfy both the needs for effective risk management and for industries’ continued use of specific substances. |
| **Dossier submitter response:**  Thank you very much for your comments, and for your support of the restriction proposal. |
| **RAC Rapporteurs comments:**  Thank you for your comments and for your support. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. |
| **1516** | **Date:** 2017/05/22 17:13  **Content:**  Scope or restriction option analysis;  Baseline;  Information on costs;  Information on benefits;  Transitional period;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** ISOPA AISBL  **Org. country:** Belgium | **Comment:**  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) has been for many years and is still today one of the key activities.  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.  Restriction is the preferred option  ISOPA believes that the restriction, implementing mandatory training for using diisocyanates as well as the possibility of exempting ‘products’, is an appropriate option to guarantee safe occupational handling of diisocyanates. The restriction is an efficient complementary measure to national occupational safety and health measures.. It addresses behaviour that is not in line with safe handling requirements. Even more important the restriction will create a harmonized legislation the European Union .  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.  ISOPA is also convinced that the restriction will require an appropriate transition period including a pilot phase. The training has to be mutually accepted by all stakeholders across Europe and clear roles and responsibilities of the different stakeholders involved have to be defined.ISOPA supports shared responsibilities along the value chain as defined in the current proposal.  ISOPA supports the idea of easy access to the training material.  Implementation  ISOPA isready to invest significant resources in improving workers’ safety. Therefore we have started to develop a holistic concept on the implementation of the restriction.  Exemptions  ISOPA believes that there are product/use combinations which have a very low potential for exposure.  Industry provided mechanisms to identify such product/use combinations and exempt them  Enforcement  ISOPA will support the value chain by providing appropriate information about the new requirements via various channels. However, manufacturers will not be able to ensure the enforcement of the restriction as the value chain of polyurethanes is by far to complex.  Enforcement is a governmental task and thus this role should be assigned to the authorities.  Socio-Economic impact  ISOPA realizes that the restriction will have an economic impact on the polyurethane value chain. This effect should not lead to a loss of the dynamics in this industry. Diisocyanates and polyurethanes are key materials contributing to strategic sectors in Europe and are a strong backbone of the industrial sector in the EU.  Polyurethanes are playing already a significant role in providing answers to the challenges of today`s societies e.g. climate change or mobility. |
| **Answer to specific info request 1:**  ISOPA believes 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 to collect the training materials, align and harmonize the materials, 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 need to 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 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. |
| **Answer to specific info request 2:**  ISOPA is calling for a concerted approach between industry and authorities.  ISOPA member companies will fulfil the legal requirements by documentation in the safety data sheet  ISOPA proposes to use the European and national associations to reach out to the value chain including different media channels, e.g. dedicated websites, conferences or webinars.  ISOPA asks for equivalent support by authorities on European and member state level. |
| **Answer to specific info request 3:**  ISOPA has launched several years ago their product stewardship programmes “Walk the Talk” and “ISOPA Driver Training program including certification. This schemes had to be voluntary as competition law would not have allowed for mandatory schemes. These programmes were and are communicated in classroom trainings to downstream users.  Some diisocyanate manufacturers conduct e-learning schemes to train their employees since many years in a successful manner.  In general the number of diisocyanate related health complaints decreased significantly whereas the use of diisocyanates has grown over the last decades above GDP,  Experience of the chemical industry supports the approach of the dossier to repeat training in regular intervals in order to keep awareness and knowledge on a high level. |
| **Answer to specific info request 4:**  This question is mainly directed to downstream user of diisocyanates with very low concentrations of diisocyanates. ISOPA has no information that such health cases occured. |
| **Answer to specific info request 5:**  ISOPA made their best effort to ensure during the exchange with BAuA that the burden for SME`s and self-employed persons will be manageable. Therefore we strongly support the implementation of an e-learning module or web based training in combination with class-room training (blended learning). |
| **Dossier submitter response:**  Thank you very much for your comments, and for the support of the restriction proposal.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 5) In Appendix 13 – “Trainings and Measures”, different options for the training format were defined depending on the measure group. We consider e-learning as suitable for the lowest risk groups (“measure group 1”), but at this point in time less suited for the other groups, because it lacks a personal interaction that is important for promoting behavioural changes. However, a combination of e—learning and face-to-face training may be envisaged. We are aware of progress in hardware and software development that has already increased and may still significantly increase the performance of e-learning tools further, but we do not think that practical instructions can be substituted completely by e-learning. |
| **RAC Rapporteurs comments:**  Thank you for your comments and your support for the restriction proposal.  RAC agrees that safe handling of diisocyanates should be achieved not only through training measures but also through the implementation of appropriate technical risk management measures. This is reflected in the opinion.  ISOPA´s commitment to make the training a success is highly appreciated. RAC concurs that the key prerequisite to achieve this goal is the adaptability to the needs of industrial and professional uses, including self-employed persons.  RAC also agrees with your statement that clear roles and responsibilities of the different partners who are involved in the process to make the training a success have to be defined and that easy access to the training material is essential.  RAC agrees with the proposal to exempt from the restriction requirements those product-use-combinations with a low potential for exposure both via the inhalation and the dermal route. Nevertheless RAC has streamlined the criteria to demonstrate the low potential for exposure for exempted products to facilitate the implementability of the restriction. This is reflected in the opinion.  RAC notes that enforcement is a governmental task and will remain in the hands of national authorities.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  RAC welcomes the idea on the incentive to early training and the idea of a pilot project. However, it might not be easy to find a structured way to implement these ideas.  To 2) RAC points out that improvements regarding the documentation in safety data sheets are important as not all companies have fulfilled the requirements in the past (e.g. detailed information on the appropriate PPE (if needed) is sometimes lacking).  RAC notes that a well-functioning communication along the supply chain of the requirements of the restriction is needed to achieve its goals (safe handling of diisocyanates, reduction of cases of occupational asthma).  To 3 and 4) Noted.  To 5) In the revised conditions the concepts of the Dossier Submitter have been retained and their reply is relevant. |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  We agree that the training taken should be mutually accepted by the MS.  Thank you for giving your view on the effect of the expected economic impacts on the dynamics in the industry.  We agree that several years will be needed for the full implementation of the proposed restriction. The final decision on the length of the period will be taken on the political level. |
| **1517** | **Date:** 2017/05/24 10:26  **Content:**  Scope or restriction option analysis;  Baseline;  Information on costs;  Information on benefits;  Transitional period;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** ALIPA Aisbl  **Org. country:** Belgium | **Comment:**  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 for many years and is still today one of the key activities.  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.  Restriction is the preferred option  ALIPA believes that the restriction, implementing mandatory training for using diisocyanates as well as the possibility of exempting ‘products’, is an appropriate option to guarantee safe occupational handling of diisocyanates. The restriction is an efficient complementary measure to national occupational safety and health measures.. It addresses behaviour that is not in line with safe handling requirements. Even more important the restriction will create a harmonized legislation the European Union .  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.  ALIPA is also convinced that the restriction will require an appropriate transition period including a pilot phase. The training has to be mutually accepted by all stakeholders across Europe and clear roles and responsibilities of the different stakeholders involved have to be defined. ALIPA supports shared responsibilities along the value chain as defined in the current proposal.  ALIPA also supports the idea of easy access to the training material.  Implementation  ALIPA is ready to invest significant resources in improving workers’ safety. Therefore we have started to develop a holistic concept on the implementation of the restriction.  Exemptions  ALIPA believes that there are product/use combinations which have a very low potential for exposure.  Industry provided mechanisms to identify such product/use combinations and exempt them  Enforcement  ALIPA will support the value chain by providing appropriate information about the new requirements via various channels. However, manufacturers will not be able to ensure the enforcement of the restriction as the value chain of polyurethanes is by far to complex.  Enforcement is a governmental task and thus this role should be assigned to the authorities.  Socio-Economic impact  ALIPA realizes that the restriction will have an economic impact on the polyurethane value chain. This effect should not lead to a loss of the dynamics in this industry. Diisocyanates and polyurethanes are key materials contributing to strategic sectors in Europe and are a strong backbone of the industrial sector in the EU.  Polyurethanes are playing already a significant role in providing answers to the challenges of today`s societies e.g. climate change or mobility. |
| **Answer to specific info request 1:**  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 to collect the training materials, align and harmonize the materials, 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 need to 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. |
| **Answer to specific info request 2:**  ALIPA is calling for a concerted approach between industry and authorities.  ALIPA member companies will fulfil the legal requirements by documentation in the safety data sheet  ALIPA proposes to use the European and national associations to reach out to the value chain including different media channels, e.g. dedicated websites, conferences or webinars.  ALIPA asks for equivalent support by authorities on European and member state level. |
| **Answer to specific info request 3:**  ALIPA has launched several years ago their product stewardship programme “We care that you care”. This scheme had to be voluntary as competition law would not have allowed for mandatory schemes. This programme was and is communicated in classroom trainings to downstream users.  Some diisocyanate manufacturers conduct e-learning schemes to train their employees since many years in a successful manner.  In general the number of diisocyanate related health complaints decreased significantly whereas the use of diisocyanates has grown over the last decades above GDP,  Experience of the chemical industry supports the approach of the dossier to repeat training in regular intervals in order to keep awareness and knowledge on a high level. |
| **Answer to specific info request 4:**  This question is mainly directed to downstream user of diisocyanates with very low concentrations of diisocyanates. ALIPA has no information that such health cases occured. |
| **Answer to specific info request 5:**  ALIPA made their best effort to ensure during the exchange with BAuA that the burden for SME`s and self-employed persons will be manageable. Therefore we strongly support the implementation of an e-learning module or web based training in combination with class-room training (blended learning). |
| **Dossier submitter response:**  Thank you very much for your comments, and for the support of the restriction proposal.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 5) In Appendix 13 – “Trainings and Measures”, different options for the training format were defined depending for the measure group. We consider e-learning as suitable for the lowest risk groups (“measure group 1”), but at this point in time less suited for the other groups, because it lacks a personal interaction that is important for promoting behavioural changes. However, a combination of e—learning and face-to-face training may be envisaged. We are aware of progress in hardware and software development that has already increased and may still significantly increase the performance of e-learning tools further, but we do not think that practical instructions can be substituted completely by e-learning. |
| **RAC Rapporteurs comments:**  Thank you for your comments and your support for the restriction proposal.  RAC agrees that safe handling of diisocyanates should be achieved not only through training measures but also through the implementation of appropriate technical risk management measures. This is reflected in the opinion.  ALIPA´s commitment to make the training a success is highly appreciated. RAC concurs that the key prerequisite to achieve this goal is the adaptability to the needs of industrial and professional uses, including self-employed persons.  RAC also agrees with your statement that clear roles and responsibilities of the different partners who are involved in the process to make the training a success have to be defined and that easy access to the training material is essential.  RAC agrees with the proposal to exempt from the restriction requirements those product-use-combinations with a low potential for exposure both via the inhalation and the dermal route. Nevertheless RAC has streamlined the criteria to demonstrate the low potential for exposure for exempted products to facilitate the implementability of the restriction. This is reflected in the opinion.  RAC notes that enforcement is a governmental task and will remain in the hands of national authorities.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  RAC welcomes the idea on the incentive to early training and the idea of a pilot project. However, it might not be easy to find a structured way to implement these ideas.  To 2) RAC points out that improvements regarding the documentation in safety data sheets are important as not all companies have fulfilled the requirements in the past (e.g. detailed information on the appropriate PPE (if needed) is sometimes lacking).  RAC notes that a well-functioning communication along the supply chain on the requirements of the restriction is needed to achieve its goals (safe handling of diisocyanates, reduction of cases of occupational asthma).  To 3 and 4) Noted.  To 5) In the revised conditions the concepts of the Dossier Submitter have been retained and their reply is relevant. |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  We agree that training taken should be mutually accepted by the MS.  Thank you for giving your view on the effect of the expected economic impacts on the dynamics in the industry.  We agree that several years will be needed for the full implementation of the proposed restriction. The final decision on the length of the period will be taken on the political level. |
| **1519** | **Date:** 2017/05/29 14:31  **Content:**  Scope or restriction option analysis;  Baseline  **Type:** MemberState  **Country:**  Cyprus | **Comment:**  Having gone through the proposed restriction we definitely share the opinion of the dossier submitter that a restriction for the use of Diisocyanates is a necessity in the European Union. The annual numbers of occupational asthma and diseases in workplaces are indeed unacceptably high. We are also aware of the challenges: due to the extreme complexity of the supply chain and the variety of uses it is very difficult to broadly substitute and achieve a simple restriction in the whole European area.  However, given the nature and the target group of the proposed restriction (professional and industrial users for which training according to the use is suggested) the Department of Labour Inspection of Cyprus is of the opinion that the appropriate legal instrument for this future restriction is the existing EU workplace safety legislation rather than REACH/Annex XVII. It does not seem practical and efficient to have this restriction in the context of REACH enforcement given the complex labour safety specific requirements. The exemptions described in the future Appendix 12 and 13 are tailored for assessment by experts in workplace safety. In either case the exemptions and the requirements of paragraphs 2 and 3 of the restriction text need to be further aligned with the appendices 7 and 8. It is also important for Appendixes 12 and 13 (Appendix 7 and 8 of the dossier) to be made part of the legal text of the restriction, in order to be enforceable.  Finally, in terms of harmonization of the content of all products containing diisocyanates in the European market, we would like to have the restriction extended to products intended to be used by the general public.  Specific questions to MSCA and Forum  6. Could you please identify which regulations regarding diisocyanates exist in your country? Is there any overlap between any of these regulations and the present restriction proposal on diisocyanates?  We have a national limit for Toluene diisocyanate (TDI) of 0.014 mg/m3 or 0.002 ppm under the Control of Factory Atmosphere and Dangerous Substances in Factories (Amendment) Regulations of 2012 (P.I. 69/2012)  There is no overlap with the proposed restriction because the national regulations are posing an air limit instead of a content limit. However it is not clear to us if there will be an overlap with the proposed exemptions.  7. 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 a reference or copy of the case study.  We do not have such information  8. Please provide comments to the generic uses and the corresponding “measures groups” in Appendix 8 of the restriction proposal (Restriction report appendix, page 465). Do you think the assignment is correct? What kind of measures would you propose as the most relevant ones for the different measures groups?  We would appreciate in the final restriction a more clear and direct relation of the duty holders and the obligations of Paragraph 3 and the future Appendix 13. The suggested restriction text, which makes a reference to the annexes, is very complex and not easy to understand.  9. In terms of enforcement, do you anticipate any specific issue for a harmonised implementation of the proposed restriction in the EU? Could you please elaborate on the answer?  9. Would better implementation of worker protection legislation give the same results? Please tell us why you have this opinion, if possible justified with any analysis performed.  We are of the opinion that the appropriate legal instrument for this future restriction is the existing EU workplace safety legislation. The wording and obligations of the proposed restriction is also closer to that legislation.  We do not agree with the statement under A1.3.2 «Long term experience with the application of the Chemical Agents Directive (CAD, Directive 98/24/EC) has shown that occupational safety and health measures are not efficient enough to reduce sensitisation by diisocyanates to an acceptable level» simply because there is no harmonized limit for diisocyanates in the CAD. For other substances for which a harmonized limit is in place a gradual reduction of the workers exposure has been achieved. |
| **Dossier submitter response:**  Thank you for your comments to our proposal and for the data provided.  The issue whether REACH or OSH is the better framework to regulate diisocyanates has been discussed vividly. Our positon on this issue was reformulated and expressed in Section A2.2.1 of the background document. In the end a political decision needs to be taken if REACH should address this issue as proposed.  The information presented in the Annex 8 and 9 is to be made part of the final legal text. Appendices 12 and 13 only serve as summary of what information should be part of a final version.  To 8) The assignment of uses to the different measure groups was reached after extensive discussion in an expert group, with representatives of the DS, the major manufacturers of diisocyanate and relevant industry associations. As is indicated in the dossier, assignments of typical task to measure groups are to be considered as generic, if further indications are not available, based on the judgement in the expert group. If data are available that may necessitate choosing a higher group this has to be communicated to the users. |
| **RAC Rapporteurs comments:**  Thank you for your comments as well as for your answers to the specific information requests and your general support for the restriction proposal.  RAC agrees with your statement that the appropriate legal instrument for the regulation of occupational health and safety is the EU workplace safety legislation. However, the reasons why the REACH legislation might be of benefit in this case have been elaborated in the Background document and in RAC´s opinion. In addition, RAC points out that a huge effort has been made by the Dossier Submitter to find a way to reduce the number of cases on occupational asthma which still occur (despite the OSH regulation(s)).  RAC agrees that the conditions of the restriction proposal (including the Appendices) need to be revised to be enforceable and has consequently updated them. Thank you for the advice.  RAC notes your thoughts with regard to the harmonisation of the legal requirements for workers and the general public. RAC would like to mention that there is already an existing entry in REACH/Annex XVII (entry 56) which addresses the use of Methylenediphenyl diisocyanate (MDI) for consumers. According to the Dossier Submitter´s researches on ECHA´s dissemination site, there are no registered consumer uses of diisocyanates that would not be covered by the existing Annex XVII restriction for MDI. However, the Dossier Submitter found out that spray paints containing a HDI-homopolymer are sold via Internet Marketing, and could pose a risk for consumers. Nevertheless, to be able to include consumers/the general public in the current restriction proposal, information on the risk characterisation and on the social economic issues would be needed for consumer use, which have not yet been elaborated. There is no available information on health risk of application of diisocyanates-containing products by consumers, and no new information on exposure and health risks related to consumer uses of diisocyanates was provided during the Public Consultation. This issue is elaborated in the Background document (A.1.2). |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  The original proposal has been revised and is included in the committees’ opinion. |
| **1520** | **Date:** 2017/05/29 14:30  **Content:**  Hazard or exposure;  Transitional period  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** The Federation of Norwegian Industries & the PUR-Group  **Org. country:** Norway | **Comment:**  PUR-gruppen comprises member companies manufacturing flexible polyurethane foam for mainly furniture and bedding, manufacturers of rigid polyurethane products mainly for thermal insulation purposes, thermal insulation spray applications, application of polyurea coatings for numerous applications and member companies supplying raw materials and processing equipment and PU consultants.  PUR-gruppen is a part of The Federation of Norwegian Industries.  The federation represents more than 2,400 member companies with approx. 126,500 employees. Member companies' interests are the Federation's main focus. The Federation of Norwegian Industries engages in the most important industrial and business policy issues of the day.  PUR-gruppen and The Federation of Norwegian Industries support the restriction on diisocyanates with the aim of safe use of diisocyanates.  We believe that restriction is the preferred option. Implementing mandatory training for using diisocyanates is a suitable way to ensure safe occupational handling of diisocyanates. We believe that the restriction will require an appropriate transition period and that the development of training modules for Measure Group 3, such as spray operations in open air with limited or only natural ventilation, should be given the highest priority in the transition period. It should then be followed by development of training modules for Measure Group 2, such as handling open mixtures at ambient temperature and finally, modules for Measure Group 1.  For the restriction to be manageable it needs to be applied as uniformly as possible across Europe and qualifications of trainers and trainees mutually accepted.  PUR-gruppen and The Federation of Norwegian Industries provide input on the 5 specific questions raised below in the ECHA public consultation on the restriction dossier for diisocyanates |
| **Answer to specific info request 1:**  PUR-gruppen and The Federation of Norwegian Industries believe that a transition period of 5-6 years will be required to design and establish structures and training modules required for all involved work forces.  We would suggest to start with the development of training modules for Measure Group 3, particularly involving spray operations in open air with limited or only natural ventilation, followed by the development of training modules for Measure Group 2, such as handling open mixtures at ambient temperature. |
| **Answer to specific info request 2:**  A close dialogue between PUR-gruppen, The Federation of Norwegian Industries, our members and national health authorities is important. We will continue to keep our members informed about the process on our web site, in media and during our technical meetings and conferences. |
| **Answer to specific info request 3:**  Many of our member companies have developed internal training programmes for their employees, which have worked well for many years. For our smaller member companies and self-employed persons, PUR-gruppen has developed a 4 hours long training programme based mainly on the ISOPA1 product stewardship programme ‘Walk the Talk’. This training course has been given to both our SME member companies and self-employed persons as well as non-member companies once a year during the last couple of years. The training course has been very much appreciated. |
| **Answer to specific info request 4:**  We are not aware of any such cases. |
| **Answer to specific info request 5:**  We believe that the burden for our member companies will be manageable. However, we support ‘blended’ training, i.e. a combination of e-learning, web based training, class room training and ‘on the job’ training to reduce the burden for our smaller member companies. |
| **Dossier submitter response:**  Thank you for your support.  Thank you for the idea about a staged introduction of obligations for the various measure groups (with obligations for the highest risk group being introduced first). This needs to be considered in a future discussion on implementation options.  The proposed concept foresees mutual recognition of trainers and trainees between member states.  The proposed concept offers a range of options to implement the trainings. The idea of “blended training” is possible. |
| **RAC Rapporteurs comments:**  Thank you for your comments and for the support for the restriction proposal.  RAC concurs with the request of an uniform application of the restriction proposal in the EU and points out that the Dossier Submitter has foreseen mutual recognition of trainers and trainees among Member States.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end. To keep the restriction proposal rather simple, RAC prefers a single date for the restriction to enter into force and not a staged introduction for the implementation of measures. However, this topic is also a political one and will therefore be discussed in another Committee.  To 2) Thank you for informing your members about the process. Your efforts will help to raise the awareness of the sensitising effect of diisocyanates and that measures have to be taken to protect workers / self-employed persons appropriately.  To 3 and 4) Noted.  To 5) RAC refers to the Dossier Submitter´s answer to your comments. |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  The original wording of the proposal has been revised and a possible formulation is included in the committees’ opinion.  We agree that the training taken should be mutually accepted by the MS. |
| **1522** | **Date:** 2017/05/30 16:40  **Content:**  Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. name:** Swedish Work Environment Authority  **Org. country:** Sweden | **Comment:**  We welcome stricter rules on products containing diisocyanates. However, the requirements in Appendix 8 (13) need an additional review before decision. The requirements need so be limited, precise and justified. E.g. air monitoring once a year is advised. Are all details in the training necessary? Why is there a reference to GISCODE or similar? Shouldn´t the recommendations from the supplier, for this kind of products, be more precisely adapted to the product than these are?  It needs to be clarified if, when and how monitoring is required by the employer. Also depending on the results when additional measures are required. Biological monitoring may offer better possibilities than air monitoring to check the exposure.  It is proper that manufacturers and importers shall develop the training material. The proposal for a restriction should also contain requirements on the supplier to provide a safety data sheet with detailed requirements for the use of their product. Based on the safety data sheets provided today the employer will not be able to verify if their use meets the requirements in appendix 8 (13). For example, RMM are often not precisely described, which and when. How shall the ventilation be tested?  The measures for each product that follows from appendix 8 (13) on page 466-467 should be outlined in the safety data sheet. This will help the employer to offer a safe working environment. |
| **Answer to specific info request 2:**  The measures for each product that follows from appendix 8 (13) on page 466-467 should be outlined in the safety data sheet. This will help the employer to offer a safe working environment. |
| **Dossier submitter response:**  Thank you very much for your comments, and for the support of the restriction proposal.  The DS agrees that some aspects regarding the requirements in Appendix 13 still need more elaboration and will submit ideas in order to convert this to a final proposal. We agree that biomonitoring can be an additional tool to air monitoring for assessment of the exposure at the workplace. However, to our knowledge it is not possible to establish limit values indicating a truly safe level of exposure for biomonitoring. For this reason this method seems not viable for ascertaining the appropriate measure group for a given workplace.  References to GISCODE (or similar) are included to make it possible to use results of existing assessment schemes without each time having to start from scratch. |
| **RAC Rapporteurs comments:**  Thank you for your comments and for the advice to revise the conditions of the restriction proposal (including the Appendices) to be enforceable. The initial conditions have been revised and are included in the opinion.  With regard to biomonitoring, RAC points out that biomonitoring is considered a useful tool to assess workers’ exposure to diisocyanates. However, it has to be noted that biomonitoring reflects total exposure to diisocyanates (via inhalation and dermal exposure routes). It cannot differentiate relative contributions of particular sources of exposure (inhalation and/or dermal), even if workplace personal air measurements are available. One further limitation of biological monitoring is that it reflects average daily exposures as peak exposures are not accessible by these methods since (urine) metabolites have a poor correlation to short-term peak exposures.  To 2) RAC agrees that the safety data sheet should include detailed requirements for the safe use of an exempted product. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. The original wording of the proposal has been revised and a possible formulation is included in the committees’ opinion. |
| **1523** | **Date:** 2017/05/30 18:23  **Content:**  Hazard or exposure;  Transitional period  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Deutsche Bauchemie e.V.  **Org. country:** Germany  **Attachment:** | **Answer to specific info request 1:**  Deutsche Bauchemie is of the opinion that a transition period of at least 6 years is needed after entry into force.  This period of time is urgently required to prepare the training materials and to organize the implementation in the different member states. Especially in the construction sector a huge number of SMEs at the end of the supply chain (professional end users of di-isocyanate containing mixtures) will be affected by the restriction proposal. Especially for that part of the supply chain appropriate training concepts and tools have to be developed. |
| **Answer to specific info request 2:**  To inform all relevant DU in the relevant supply chains joint efforts of competent authorities and industry is needed.  The member companies of Deutsche Bauchemie will fulfil the legal requirements by documentation in the safety data sheet. Additionally Deutsche Bauchemie is ready to inform customers of member companies (professional end users) on a voluntary basis via their associations and directly with brochures, workshops and similar media. |
| **Answer to specific info request 3:**  In the construction sector training courses are in place which combine technical and occupational health and safety aspects. This is an efficient approach to limit the effort and time for professional end-users of construction products. If in certain member states related training courses already are in place the pre-defined training content should be combined into a training concept which then covers the training requirements resulting from the restriction with other topics.  To cover the huge number of professional end-users in the construction sector (mainly SMEs) training concepts like e-learning and the train-the-trainer concept should be considered. It will not be feasible that all relevant workers in the construction sector will join external class room trainings. |
| **Answer to specific info request 4:**  Deutsche Bauchemie has no information that such health cases occured. |
| **Answer to specific info request 5:**  Deutsche Bauchemie is an association of formulators of diisocyanat-containing mixtures. Within our member companies the training requirements will create moderate additional effort but the companies are familiar with these kind of requirements and they will be able to deal with it in their industrial surroundings.  For the customers of our member companies (professional end users of mixtures) it will be more difficult the implement the restriction. To make the restriction manageable for this group of affected DU the following approaches are helpful  E-learning  Train-the-trainer concept  Exemptions for product-use-combinations with very low potential for exposure  Combination of the diisocyanate training with technical or educational/vocational training |
| **Dossier submitter response:**  Thank you very much for your comments.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 3 and 5)  The restriction as proposed allows for a range of training options, suiting work schedule and economic considerations also for small firms. For “Measures Group 1” (identified as uses which require “basic training” in the revised conditions of the restriction) this includes e-learning as well. The proposed concept does not prevent to combine the necessary trainings with other vocational or technical trainings. A “train the trainer” concept is possible.  An option to identify products with a very low potential for exposure is part of the proposal. |
| **RAC Rapporteurs comments:**  Thank you for your comments and your information about the result of the evaluation of work-related diseases by the BG-Bau.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  RAC agrees that particularly for SMEs appropriate training concepts and tools have to be developed.  To 2) Your promise to provide adequate information and documentation in the safety data sheets is appreciated.  To 4) Noted.  To 3 and 5). In the revised conditions the concepts of the Dossier Submitter have been retained and their reply is relevant. Additionally, it is to be noted that trainers are required to follow a specific training covering at least the aspects set out in the conditions of the restriction. |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  We agree that several years will be needed for the full implementation of the proposed restriction, but the final decision on this will be taken on political level. |
| **1525** | **Date:** 2017/05/31 11:58  **Content:**  Scope or restriction option analysis;  Hazard or exposure;  Information on benefits;  Transitional period;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** FEICA - The association of the European adhesive & sealant industry  **Org. country:** Belgium | **Comment:**  FEICA, the Association of the European Adhesive and Sealant Industry, is a multinational association representing the European adhesive and sealant Industry. With the support of its national associations and several direct and affiliated members, FEICA coordinates, represents and advocates the common interests of our industry throughout Europe. In this regard FEICA aims at establishing a constructive dialogue with legislators in order to act as a reliable partner and create a mutually beneficial economic and legislative environment.  FEICA and its members have always been working together with all actors in the PU value chain to improve the safe use of PU products, and support this Restriction as a harmonised solution across Europe.    1. Impact of the proposed restriction on FEICA members  What are diisocyanates used for?  Uses of diisocyanates in adhesives & sealants cover a very diverse set of markets and uses as can be shown below due to the performance advantages of using diisocyanates in the products.  Diisocyanate containing products are in many of the above examples the only, or the preferred, products for their applications and FEICA supports the Restriction condition to ensure that their usage can continue to benefit industry in Europe.  Are PU products containing diisocyanates safe?  Based on the long-term commitment to product safety, the adhesives & sealants industry is convinced that PU products can be handled safely in industrial and professional applications if the recommendations in the safety data sheets are followed.  Due to the close relationship with our customers, we advise and support end-users of polyurethane products in implementing appropriate protective measures for the safe handling of diisocyanates. In addition, the polyurethane industry continuously makes efforts to supply the market with environmentally friendly, lower-emission products using state of the art technology.  The decline in the number of sensitization cases in relation to the increasing high number of users is the result of these ongoing endeavors of the adhesives and sealants industry.  Are there any alternatives to diisocyanates?  Polyurethanes cannot be produced without aromatic or aliphatic diisocyanates. Therefore, there is currently no commercially viable alternative to MDI, TDI, HDI, IPDI or H12MDI and others. Competitive technologies have not been found to be able to replace polyurethane properties in most of the respective articles.  2. Key messages on the proposed restriction  Responsibilities  FEICA acknowledges that diisocyanate producers (M/I), representing the industry at the start of the chain, should bear the main legal responsibilities and guidance role for the entire process. FEICA members support a fair sharing of responsibilities and a strong collaboration between all actors of the value chain for the preparation of training content.  Supply Chain  Adhesives and sealants are used by a large number of very small to very large companies throughout Europe, which are active in a wide variety of industries. Therefore, practicability of implementing the restriction is of utmost importance. This includes the necessity to utilize existing training schedules and to have the possibility to integrate the training on diisocyanate use with other topics. Such training schedules also vary from country to country and this organizational variation has to be taken into account.  FEICA would seek a situation where a trained person from one European country would be able to work with PU products in another country, provided he or she is in possession of relevant documentation.  Exemptions    To reduce the huge number (roughly 1 million people) of potential users to be trained, it is also essential for the adhesives and sealants industry to be able to offer exempted PU products which have been proven to be used without the risk of sensitization by diisocyanates by design, thus making additional training of their users unnecessary.  FEICA members would like to express their strong support for the current set of criteria to grant exemptions as foreseen in the Annex Exemptions.  In addition, an Exemption should also be recognized in all EU countries. |
| **Answer to specific info request 1:**  FEICA members would support a minimum 6 years from the date of the final adoption of the Restriction. The Adhesives & Sealants industry has a very significant number of users that will likely need to be trained across a large variety of sectors in many different languages. In this context, industry will need to prioritise sector specific training needs and develop the pan-European training content where needed, including distributors in a very diverse value chain.  Regarding the foreseen Exemptions, FEICA members expects a high number of adhesive & sealants applications to fulfil the conditions for Exemptions which will reduce the number of workers needing Training – these actions toward defining exempted applications are likely to take place in the first years after the adoption of the Restriction. |
| **Answer to specific info request 2:**  For FEICA members, the Safety Data Sheet (SDS) is the key method to communicate where an Exemption exists or where Training will be required. Therefore, FEICA members support that the SDS should contain all the relevant information.  As part of a communication strategy initiated by FEICA, FEICA plans to continue running education/communication sessions to our members on the actions required for compliance to the Restriction conditions e.g. Seminars at the FEICA Conference. |
| **Answer to specific info request 5:**  Granting of Exemptions will play a significant part in the ability of the diverse Adhesives & Sealants industry to reduce the total number of people to be trained.  Training in Adhesives & Sealants will have an effect across the entire supply chain; we anticipate that many SMEs and self-employed persons will require Training to use products that are not exempt from the Restriction.  To allow for most effective training implementation it should be integrated with existing training schemes, e.g. during education, technical trainings, OSH trainings, etc. |
| **Dossier submitter response:**  Thank you very much for your comments.  Our concept foresees mutual recognition of trainers and trainees between member states.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  We appreciate your support for the possibility to develop and market exempted products. The details of such an exemption have our full attention.  To 3 and 5)  The restriction as proposed allows for a range of training options, suiting work schedule and economic considerations also for small firms. For “Measure Group 1” this also includes e-learning. The proposed concept does not prevent to combine the necessary trainings with other vocational or technical trainings. |
| **RAC Rapporteurs comments:**  Thank you for your comments and the detailed information on the use of diisocyanates in the adhesive and sealant industry.  RAC agrees that the responsibilities with regard to the restriction proposal have to be clear.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  To 2) Your support that adequate information and documentation has to be provided in the safety data sheets is appreciated as well as your commitment regarding the communication of the requirements of the restriction among your members.  To 3) and 5) RAC refers to the Dossier Submitter´s answer to your comment. |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  We agree that training taken should be mutually accepted by the MS. |
| **1526** | **Date:** 2017/05/31 12:50  **Content:**  Scope or restriction option analysis;  Information on costs;  Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** <redacted>  **Org. country:** Belgium  **Company name confidential:** YES  **Attachment:**  <redacted>  **Privacy comment:** see remarks specific question 5 | **Answer to specific info request 5:**  1. It is important that the training program can be implemented in existing training sessions to minimize cost.  2. Adaption to the differences in education level of the different employees must be considered.  3. In order to reduce costs it is important that the training program can be organised per country.  4. Because the processing of isocyanates (sector/industry) is so different, the need for sector-specific training is obvious.  For example : the large difference in processing and application between : footwear-,furniture-, foam-, textile, adhesives-, moulded parts for automotive-, insulation-, electrical and painting industry. |
| To 5.1)  We agree that the combination of the mandatory trainings with other existing trainings would increase the practicability of the restriction for your industry. As long as the stated obejctives are reached and no negative effects on the effectiveness of the different single trainings are expected, a combination of trainings would, of course, be possible.  To 5.3) The standard approach will indeed be to organise the proposed trainings per country/language.  To 5.2), 5.3) and 5.4)  In principle, manufacturers and importers as well as the trade associations of relevant downstream users will be responsible for providing the content for the training material. The involvement of the different trade associations shall assure that the training material is adequately designed to the special needs of the workforce. |
| **RAC Rapporteurs comments:**  Thank you for your comment.  RAC refers to the Dossier Submitter´s answer. |
| **SEAC Rapporteurs comments:**  Thank you for your comment.  4) Manufacturers and importers should in cooperation with downstream users should, according to the proposal, prepare different training materials for different types of uses (de facto: sector-specific training). |
| **1527** | **Date:** 2017/05/31 13:06  **Content:**  Scope or restriction option analysis;  Information on costs;  Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** <redacted>  **Org. country:** Belgium  **Company name confidential:** YES  **Attachment:**  <redacted> | **Answer to specific info request 5:**  1. It is important that the training program can be implemented in existing training sessions to minimize cost.  2. the training can be reduced from 4 hours to 2 hours  3. As these training session certificates have a validity of 5 years it is advisable to use also 5 years instead of 4 years for the certificate.  4. we find that niv2 for spray painting applicator is more advisable than not niv3 as foreseen now. |
| **Dossier submitter response:**  Thank you very much for your comments.  To 5.1)  We agree that the combination of the mandatory trainings with other existing trainings would increase the practicability of the restriction for your industry. If considered as having no negative effects on the effectiveness of the different single trainings a combination of trainings would, of course, be possible.  To 5.2)  The training length provided for the different training modules gives an estimate for the time needed to cover all topics and to conduct the exercises. The estimated training length of the different training modules is based on discussions with experts from industry and trade association of professional users. We do not think that the learning goals can be reached in half the time. In case you decide to run the trainings at the workplace, and for Measure Group 1 implement e-learning for some of the modules there would be, of course, more flexibility. However, training units less than 1 hr should be avoided. However, the individual training parts should be taken in a reasonable time frame. Moreover, documentation should be provided that shows that the total time will sum up to the required training length and cover the required topics.  To 5.3)  As it stands now, the training repeat cycle (and the validity of any certificates) uses a four year cycle. In our consideraions this seemed as a good compromise between stustainability and economic feasibility of the trainings.  To 5.4) Thank you for your comment. We will use that in a final consideration of our grouping approach. |
| **RAC Rapporteurs comments:**  Thank you for your comment.  RAC refers to the Dossier Submitter´s answer. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. The proposal for the length and the frequency of training was mostly based on already existing training programs. Shorter training and less frequent training might be less costly, but it would also reduce the positive health benefits effect. |
| **1528** | **Date:** 2017/05/31 13:20  **Content:**  Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Confederation of Danish Employers  **Org. country:** Denmark | **Comment:**  The restriction proposal - regarding user obligations - is not fit for purpose neither legally nor practically.  We recognise that exposure to diisocyanates at the workplace can pose a serious risk to employees health. However, the proposed obligations in section 1.b) and 1.c) that is meant to set obligations for users are clearly unfit for adaptation in REACH Annex XVII, and the restriction proposal section 1 should therefore be let out. For the following reasons:  1. The user obligations of the proposal aims to regulate occupational health and safety at the workplace, which is out of the scope of REACH, practically as well as legally, with regard to the Treaty.  2. The proposal has the "top down" approach of REACH as its raison d'être, but setting user obligations for the organisation of work at every workplace, is the exact opposite. Complex workplace issues are best addressed in the OSH directives with the involvement of social partners.  3. Risk assessment and planning of the handling of diisocyanates at the workplace is a national issue with respect to the minimum obligations in the OSH-directives. The responsibility for organising the OSH at the workplace is placed on the employer. However, the proposal as it stands will contribute to an entanglement of legal complicity for the national authorities.  4. The inclusion of an obligation for the manager to pass the training program is not in line with the general obligation for the employers to give instruction. The employer shall be able to plan the OSH and to give general instruction – not to do the work himself.  5. Diisocyanates are only one group of problematic hazardous substances at the workplace. The OSH legislation represent a broad approach to risk assessment and planning of the total number of substances in a process. The proposed restriction is taken out of a context by focusing only at one group of substances.  6. An alternative wording of the proposal could be similar to the present restriction on Dichloro Methane (REACH Annex XVII, no. 59), where a binding frame for the obligations for Member States, is described. This will allow Member States to adapt user restrictions and training in the use of diisocyanates in the structure of national OSH regulation, where the OSH Directives have been implemented.  Ad 1: Section 1.b) and 1.c)are both clearly provisions for regulating occupational health and safety (OSH) at the workplace, which is outside the scope of REACH (article 2,4 a), and which REACH is not suited for.  There is even a substantial question of the legality of user obligations in the proposal.  The proposal states - as the reason for forwarding the proposal for regulation of diisocyanates in section A.2.2.1 in the restriction report - that REACH is considered the more efficient alternative. The Confederation of Danish Employers stresses, that the EU's access to regulating health and safety at the workplace in the member states - by restricting the organisation of work, at the individual workplaces - is not a matter of "pick and choose" which legal instrument is more attractive.  In this respect, it reads very clearly from REACH, that it is issued with regard to the functioning of the single market (art. 114, former 95 in the treaty), and though this article states, that regulation must take into consideration the public health, it does not mandate, that regulation under this article regulates clear cut OSH-issues, such as the organisation of work and technical layout of individual workplaces.  On the contrary, it is clear from article 151 and 153 in the treaty, that mandate for the EU to regulate OSH is solely by way of minimum directives. Regulating OSH by way of REACH annexes - only motivated by efficiency considerations - does not make a legally sustainable case for setting aside the workings of the treaty.  There is a reason for this distinction: OSH regulation in the EU is based on tripartite cooperation, and has a large body of social partner involvement, with consultation as an integrated part of the legal process. This is a well-functioning system, approved by the member states will be by-passed altogether, if OSH provisions for chemical agents are to be set in REACH annexes in the future.  Ad 2: The argument for setting user restrictions in the proposal is misguided.  The restriction proposal - regarding user obligations has as its principal argument, that regulating di-isocyanates from the top-down is more efficient than OSH directives. While this holds true for obligations put on the manufactures and formulators, top-down it is clearly not the case, when setting highly detailed, complex provisions and obligations for thousands of employers and workers at individual enterprises, throughout the EU. Quite the contrary.  At a the more practical level, the proposed user obligations in section 1.b) and 1.c) constitutes almost a complete set of mirroring OSH-regulation, that will function as a semi-parallel legislative body to the OSH regulation that is by way of the OSH-directives, already in place for all hazardous chemical agents, and which works in a legislative structure that differs in a substantial way from the structure of the diisocyanate restriction proposal.  There is no question, that on the majority of SME's it will be almost impossible for an employer to work out what must be done to comply with the proposed specific diisocyanate provisions and the with the obligations in general, that follow from the OSH regulation.  In conclusion; the proposal is against the ambition of the Commission to lower administrative burdens, on European enterprises.  Ad 3: The proposal will contribute to an entanglement of legal complicity for the national authorities, and will collide with the entire structure of the OSH-regulation that is already in place:  National legislation in the member states will have to be sorted out in meticulous detail, to figure out exactly how much of the provisions of the annex on diisocyantes is already covered by the OSH-directives, and therefore does not apply, and what in the national regulation goes beyond the minimum provisions of the annexes, and what then is new obligations for the employers that needs to be enforced - like the presence of "Qualitative detection tools (e.g. wiping tissues) for detection of deposited isocyanate are available."  In the bigger picture, the workings of the OSH-directives are based general integrated risk assessment and preventive measures, in the entire production chain, and in cooperation between employers and employees. Imposing separate legislative obligations on the end users, regarding risk assessment, use, training, ventilation, documentation on one singled out substance, will short circuit the whole structure of the OSH regulation.  In conclusion: Section 1.b and 1.c should be entirely left out of any further advancement of the proposal.  Ad 4: The proposed inclusion of obligations on managers - who are never to work with the substance or mixtures - to take the proposed trainings prior to the use of the substances or mixtures, is quite misplaced.  It follows already very clearly from the legislative body of the OSH-directives, that employers at enterprises that use hazardous chemical agents - or where there is a risk of exposure from hazardous dusts, fumes etc. - are already obliged to have in place risk assessments, preventive measures, training, ventilation, and personal protective equipment in place, in a hierarchy of prevention. It is up to the employer - in corporation with the employees - to organise this in the most efficient way, at the particular workplace. How this is done, in the most efficient way, varies a lot from one enterprise to another. Training of the managers may be fit for purpose at one company, while quite irrelevant at the other.  Therefore, the idea, as put forward in this restriction proposal for isocyanates, to oblige managers to attend training on one specific substance out of dozens that a company may very well have to include in its preventive strategy, is quite out of place, and in contradiction with the structure of the OSH-legislation. The risk is that attention will be taken away from other much more relevant risks at the workplace.  In Denmark, there is already a training programme in the national OSH legislation for isocyanates, which the employer must provide to the workers prior to working which this substance. This requirement does not encompass managers, and is a one-time-only course, which does not entail repetition. The experience is, that this regulation is sufficient, as there has been only a dozen cases of reported occupational diseases annually, over the last 12 years, related to isocyanates, though it is widely used in industry and construction.  Ad 5: REACH is regulating substance by substance, while OSH legislation is taking a broad approach by requiring enterprises to make a general risk assessment at the workplace involving all hazardous substances. Setting up a supplier based training program for only one group of substances is therefore taking away focus from the total potential exposure to hazardous chemicals.  Ad 6; As we recognise the need for extra focus for the handling of diisocyanates at the workplace, we propose an alternative text inspired by the present restriction on Dichloro Methane in REACH Annex XVII, no. 59. This alternative will allow Member States to adapt user restrictions and training programmes in the use of diisocyanates into the structure of national OSH regulation where the OSH Directives have been implemented. This will also take into account national traditions for setting up training programs:  Diisocyanates  “Member States shall define appropriate provisions for the protection of the health and safety of those professionals using diisocyanates. Those provisions shall include a requirement that a professional shall hold a certificate that is accepted by the Member State in which that professional operates, or provide other documentary evidence to that effect, or be otherwise approved by that Member State, so as to demonstrate proper training and competence to safely use diisocyanates.” |
| **Dossier submitter response:**  Thank you for your contribution to the ongoing discussion.  The issue whether REACH or OSH is the better framework to regulate diisocyanates has been discussed vividly during the development of the opinion by the RAC and SEAC Committees. Our position on this issue was reformulated and expressed in Section A2.2.1 of the background document. In the end a political decision needs to be taken if REACH should address this issue as proposed. |
| **RAC Rapporteurs comments:**  Thank you for your comments and for the advice to revise the conditions of the restriction proposal to be enforceable and for your information on the obligations related to isocyanates in Denmark.  To 1 to 5) RAC agrees with your statement that in general the appropriate legal instrument for the regulation of occupational health and safety is the EU workplace safety legislation. However, RAC stresses that this restriction proposal is not a replacement for OSH but builds on the requirements of the OSH legislation to identify a specific set of technical and organisational measures that will result in safer handling practices for diisocyanates across the Member States. The reasons why the REACH legislation might be of benefit in this case have been elaborated in the Background document and in RAC´s opinion.  In addition, RAC points out that a huge effort has been made by the Dossier Submitter to find a way to reduce the number of cases of occupational asthma which still occur (despite the OSH regulation(s)). RAC considers that the aim to reduce the number of cases of work-related occupational asthma can be effectively achieved through this restriction proposal.  Furthermore, as industry provides support with regard to information and training material, the supply chain is the most appropriate way for communication (top-down). However, that does not mean that REACH legislation is in general more efficient to regulate OSH issues.  Some Member States have taken the initiative to implement national OSH regulations for isocyanates (e.g. Germany, Denmark, Sweden). To harmonise these efforts and to establish the same protection level for all workers and also self-employed workers throughout the EU, action on an Union wide basis is needed.  RAC does not agree with your concern that the employers of small enterprises have the burden to work out the needs for compliance with the requirements of the restriction. On the contrary, especially smaller companies will benefit from the restriction, since its structure is expected to cover the gaps in OSH implementation particularly in SMEs, providing diisocyanate-specific training programmes.  The idea of training managers is highly appreciated by RAC as they should be informed about work-related risks and how to prevent them at least with regard to one group of substances. RAC considers that training measures as proposed might also raise the awareness for workers´safety and health in general.  To 6) Thank you for proposing an alternative text for the handling of diisocyanates at the workplace. However, as explained above, RAC considers that the REACH legislation would be a better option for the implementation of specific requirements for the safe use of diisocyanates than the OSH legislation. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. We agree with the response as written by RAC. We would like to point out that still remaining number of occupational asthma cases shows that further risk management is needed. The current OSH legislation (directives) does not seem to support the prescription of the obligatory EU unified requirements regarding training preferred by the Dossier Submitter, and it seems that REACH would be the best option to do so. Proposed top-down approach requires cooperation of downstream users and at the same time gives them a knowledge/mechanisms which they might not have at the moment, which might benefit especially SMEs with smaller resources available. |
| **1529** | **Date:** 2017/05/31 13:26  **Content:**  Scope or restriction option analysis;  Information on costs;  Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Bundesverband Korrosionsschutz  **Org. country:** Germany  **Attachment:**  <redacted>  **Privacy comment:** because the document is not originally produced by our organisation, we have not the permission to make the documents official. | **Answer to specific info request 1:**  Because other re education periods are 5 years, we think this will be a good time frame to implement this restriction |
| **Answer to specific info request 3:**  revolving training for employees in nuclear power plants |
| **Answer to specific info request 5:**  a: cost because of loss of employee time  b: we al ready run health trainings |
| **Dossier submitter response:**  Thank you very much for your comments, and for the support of the restriction proposal.  To 1)  In our considerations 4 years seemed an optimal duration for a repeat cycle.  We appreciate your readiness to support the development of the training material by providing information and expertise. In principle, the training material is developed and distributed by a non-profit company, and will be made available for free. But, training centres which will use the material commercially and companies not part of a trade association involved in the development, may be asked by the developing consortium to pay a moderate fee to contribute to the development costs. For development of the training program the avaliable training programs from industry (ISOPA / ALIPA: “Walk the talk” / “We care that you care”) and the national programs in DK, SE, and UK shall be taken into account.  To 5)  Regarding the costs of compliance under the restriction, in Annex 8 (Appendix 13 – Trainings and Measures) different options for the training format were defined depending on the measure group. This offers the opportunity to choose the training format which fits best to the conditions of your company to reduce work time losses and the administrative burden of the restriction as far as possible.  You have commented on advantages of e-learning and training at work to reduce the burden of the mandatory trainings. In case you decide to run the trainings at the workplace, and for Measure Group 1 implement e-learning for some of the modules there would be, of course, more flexibility. However, training units less than 1 hr should be avoided. However, the individual training parts should be taken in a reasonable time frame. Moreover, documentation should be provided that shows that the total time will sum up to the required training length and cover the required topics.  You have commented on the accessibilty of the training material. In principle, manufacturers and importers as well as the trade associations of relevant downstream users will be responsible for providing the content for the training material. But, the development and distribution of the material will be organized by a central platform which will be run by the manufacturers/ importers. It is planned that the manufacturers/ importers will integrate the training requirements together with links for further information into the Safety Data Sheet to get the downstream users informed. |
| **RAC Rapporteurs comments:**  Thank you for your comments and for the support for the restriction proposal.  RAC refers to the Dossier Submitter´s answer. |
| **SEAC Rapporteurs comments:**  Thank you for your comments and the information provided. |
| **1530** | **Date:** 2017/05/31 14:01  **Content:**  Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. name:** Danish Working Environment Authority  **Org. country:** Denmark | **Comment:**  The Danish Working Environment Authority (DWEA) will refer to the EU treaty on Functioning of the European Union – OJ C 202 (2016) article 153. In the treaty it is stated that the OSH-regulation in the EU-directives are minimum requirements. This means that the member states can demand further requirements than stated in the OSH-directives. DWEA finds that the restriction proposal is in conflict with the treaty with respect with the fact that OSH-regulation is minimum requirements whereas the REACH regulation are binding requirements where it is not possible for the member states to demand higher requirements.  DWEA will also refer to the frame directive 89/391/EEC article 12 on improvements in the safety and health of workers where it is stated that the employer must instruct his employees before the work is started and repeatedly. The employer must also take measures necessary for the safety and health protection of workers according to article 6 in the frame directive. DWEA finds that the restriction proposal is in conflict with these two articles in the frame directive.  It is stated in REACH article 2, section 4a, that REACH shall apply without prejudice to the community OSH-regulation including the frame directive 89/391/EEC. This means that REACH cannot overrule the OSH-regulation and DWEA finds that this restriction proposal will overrule the OSH regulation and the demands for the employer and the possibility for the member states to demand higher requirements than stated in the OSH-directives.  DWEA finds that demands or regulation of occupational education must be placed in the regime of training and instruction according to the OSH-regulation. This will ensure that each member state can regulate demands for education or training in their own national legislation as it suits best for their current situation.  DWEA sets national requirements of a specific educations for all employees and self-employed who work with monomers and pre-polymers of isocyanates or with products containing more than 0.5% isocyanates. This is possible since the OSH-regulation is minimum directives and the Danish Authority can set a higher level of protection than stated in the OSH-directives.    DWEA finds also that it is inappropriate that the suppliers are demanded to work out material for education. DWEA fear that the material not will be sufficient and will not ensure a sufficient level of protection for the workers.  DWEA finds that the existing system with the safety data sheet is sufficient for the information from the supplier due to the strict demands for the content in the safety data sheet.  DWEA finds that an approach towards only one single substance is difficult for the employers to handle. DWEA prefer a broad approach towards safe use and handling of dangerous chemical substances and materials at work places stated in the OSH-regulation. |
| **Answer to specific info request 3:**  The Danish Working Environment Authority demands in the executive order of work with substances and materials that workers and self-employed who work with monomers and pre-polymers of isocyanates or products containing more than 0.5% isocyanates must be educated and in possession of a diploma of the specific education of work med isocyanates. The education is performed by certified educators at technical schools.  The Danish social partners have together with the Danish Working Environment Authority decided the aim, the duration and the content of the educations.  There are three different educations for work with isocyanates:  • Work with isocyanates  • Work with isocyanate artificial plaster bandages  • Joining of building elements |
| **Answer to specific info request 5:**  As stated above it is a demand in the Danish OSH-regulation that workers working with isocyanates must have a specific education before they work with isocyanates.  This means that the companies must pay an education for their employees but this cost is little compared with the possible costs if an employee gets a disease due to exposure to isocyanates at work. The education will ensure that the employee know the risks of work with isocyanates and what safety measures they must take in order to avoid exposure to isocyanates. |
| **Dossier submitter response:**  Thank you for your contribution to the ongoing discussion.  The issue whether REACH or OSH is the better framework to regulate diisocyanates has been discussed vividly. Our positon to this issue was reformulated and expressed in Section A2.2.1 of the background document. In the end a political decision needs to be taken if REACH should address this issue as proposed.  Please note that the present proposal is not about one substance, but covers a group of substances with similar health problems.  An obligation for manufacturers/importers instead of individual employers/companies to develop training material allows for a dissemination of best available methods and materials. |
| **RAC Rapporteurs comments:**  Thank you for your comments and for your information on the obligations related to isocyanates in Denmark.  RAC is aware of Article 153 of the Treaty on Functioning of the European Union. If the restriction is in conflict with the Treaty, that will have to be clarified by the corresponding bodies of the European Commission.  RAC acknowledges that the appropriate legal instrument for the regulation of occupational health and safety is the EU workplace safety legislation. However, the reasons why the REACH legislation might be of benefit in this case have been elaborated in the Background document and in the RAC´s opinion. In addition, RAC points out that a huge effort has been made by the Dossier Submitter to find a way to reduce the number of cases of occupational asthma which still occur (despite the OSH directives(s)).  RAC stresses that this restriction is not a replacement for OSH but is expected to enhance the employers’ capacity to achieve a higher level of risk control, primarily through improved safety-at-work training. This is especially significant for smaller companies, particularly SMEs, where the proposed restriction is expected to cover the gaps in OSH implementation, providing diisocyanate-specific training programmes all the way down the supply chain.  RAC agrees with the Dossier Submitter that the actors at the top of the supply chain (manufacturers/importers) can define best practices for the safe handling of diisocyanates more effectively than individual companies down the supply chain, especially SMEs. However, while the development and evaluation of the training content is foreseen to be centralised (as a responsibility of a “training working group”), transforming the training content into proper education material and training of qualified instructors are proposed to be performed by the training institutes or by the downstream user(s). These separated responsibilities will on the one hand allow to take specific site requirements into account but may on the other hand decrease the quality of the final training imparted and the harmonisation of training across the EU. RAC agrees, nevertheless, that, in spite of these uncertainties, the implementation of the training will be effective in reducing the number of occupational diisocyanate-induced asthma cases in the EU. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. We refer to the response of RAC above. We would like to point out that still remaining number of occupational asthma cases shows that further risk management is needed. The current OSH legislation (directives) does not seem to support the prescription of the obligatory EU unified requirements regarding training preferred by the Dossier Submitter, and it seems that REACH would be the best option to do so. Proposed top-down approach requires cooperation of downstream users and at the same time gives them a knowledge/mechanisms which they might not have at the moment. Is seems that such downstream users, mostly SMEs, might benefit the most from this measure. |
| **1531** | **Date:** 2017/05/31 14:29  **Content:**  Baseline;  Information on alternatives;  Information on costs;  Information on benefits  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** IVPU - Industrieverband Polyurethan-Hartschaum e.V.  **Org. country:** Germany | **Comment:**  If you have any questions or you want a courtesy translation in English of our below german comments, pleast come back to us an write your request to the e-mail address: <redacted> |
| **Answer to specific info request 1:**  Für den Aufbau des Schulungssystems sind mindestens 5 Jahren erforderlich.  Nach dem Aufbau eines funktionsfähigen Schulungssystems ist eine Übergangsphase von mindestens 2 Jahren notwendig, um alle betroffenen Beschäftigten des Unternehmens sukzessive zu schulen. Die Schulungskapazität der Unternehmen orientiert sich daran, dass die Beschäftigten bei Aufnahme der Tätigkeit und dann wiederkehrend alle 4 Jahre geschult werden müssen. Sollen innerhalb von 2 Jahren alle Beschäftigten eines Unternehmens trainiert werden, sind zweimal höhere Schulungskapazitäten als diejenigen, die im „Normalbetrieb“ erforderlich wären. Die Bereitstellung dieser Kapazitäten beinhaltet eine Herausforderung; eine weitere Verkürzung der Übergangsphase können von den Unternehmen aufgrund der begrenzten personellen und organisatorischen Ressourcen nicht bewältigt werden. |
| **Answer to specific info request 2:**  Die industriellen Hersteller von PU Dämmplatten sind in Verbänden organisiert, die sie bei der Umsetzung der Trainingsmaßnahmen unterstützen können. In Branchen, die von kleineren und handwerklichen Betrieben geprägt sind, ist die Unterstützung durch staatliche Stellen, Berufsgenossenschaften, Handwerkskammern usw. erforderlich. |
| **Answer to specific info request 3:**  Die Schulungsmaßnahmen sollten bevorzugt am Arbeitsplatz selbst erfolgen. Kürzere und häufigere Unterweisungen sind insbesondere bei Beschäftigten, die einfache Tätigkeiten ausführen, effektiver als mehrstündige Klassenraumschulungen. Kürzere, wiederholte Unterweisungen direkt am Arbeitsplatz sind effektiver, solange die Konzentrationsfähigkeit der Unterwiesenen noch nicht nachgelassen hat. Schulungen von mehr als einer Stunde sind nach unserer Erfahrung ineffektiv.  Der Trainer sollte die Trainingsinhalte individuell auf den Arbeitsplatz zuschneiden und nicht relevante Inhalte weglassen dürfen. Im Fokus steht das eigene Arbeitsumfeld. Die Schulungsinhalte sollten so komprimiert werden, dass sie in insgesamt 2 Stunden (Maßnahmen 1) oder 4 Stunden (Maßnahmenpaket 2) vermittelt werden können.  Gute Erfahrungen wurden mit einer etwa einstündigen „Basisunterweisung“ gemacht, die vor Aufnahme der Beschäftigung durchgeführt wird. Nach einiger Zeit folgen weitere, arbeitsplatzbezogene Unterweisungen („training on the job“).  Das Web basierte Training ist eine sehr effektive Option, da es interaktiv ist und eine unmittelbare Lernkontrolle ermöglicht. |
| **Answer to specific info request 4:**  Nein, derartige Fälle sind nicht bekannt. |
| **Answer to specific info request 5:**  Das Trainingsprogramm bedingt geringere Flexibilität bei temporären Stellenbesetzungen oder Umbesetzungen. Zeitarbeiter oder Urlaubsvertretungen, die naturgemäß kurzfristig eingestellt werden, müssen zunächst geschult werden und stehen erst nach einiger Zeit für den Arbeitseinsatz zur Verfügung. Basiseinweisungen, die von unternehmenseigenen Trainern gegeben werden („Train the trainer“-Konzept) und durch spätere, kurze Trainingseinheiten ergänzt werden können, sind gerade für Zeitarbeitskräfte oder Vertretungen die einzig praktikable Form der Schulung. Externe Schulungen kommen für Vertretungen oder nur zeitweilig Beschäftige nicht in Frage.  Schulungen und Prüfungen sollten in jedem Falle unternehmensintern durchgeführt werden. Nur so ist sichergestellt, dass die betriebsspezifischen Gegebenheiten berücksichtigt werden können.  Der Trainer hat dabei die Aufgabe zu überwachen, dass der Geschulte die Prüfung selbständig ablegt. Der Trainierte hat durch Unterschrift zu bestätigen, dass er die Prüfung selbständig entsprechend der Prüfungsbedingungen abgelegt hat. Ein vergleichbares Verfahren wird z. B. bei Masterarbeiten als ausreichend angesehen.  a) Für die Schulungen entstehen Kosten (Arbeitszeitausfall und Trainerkosten) von etwa 950 € pro Mitarbeiter und Jahr.  Weit höhere Kosten entstehen durch den Stillstand der Anlagen, da die Produktion während der Schulung unterbrochen werden muss. Der Ausfall einer oder ggf. mehrerer Schichten führt zu Kapazitätseinschränkungen und Umsatzverlusten.  Bei 3-Schichtbetrieb müssen 3 Bedienermannschaften geschult werden. Während der Schulung muss die Anlage abgeschaltet werden, so dass nicht produziert werden kann. Wegen Urlaub und Krankheit ist es erfahrungsgemäß nicht möglich, die gesamte Bedienermannschaft an einem Termin zu schulen, es sind also 2 Schulungstermine erforderlich. Daraus ergibt sich, dass die Anlage aufgrund der Schulungen während 6 Schichten still steht. Bei ca. 600 Schichten im Jahr bedeutet das einen Umsatzausfall von 1 %. Bei einem Branchenumsatz von 1 Mrd. gehen 10 Mio. Umsatz jährlich verloren.  b) Die vorgesehenen Schulungsmaßnahmen bringen keinen Zusatznutzen, da die schon heute durchgeführten Trainingsmaßnahmen ihren Zweck vollkommen erfüllen. In Unternehmen, die Dämmplatten oder Blockschaum unter industriellen Bedingungen kontinuierlich herstellen, sind keine Erkrankungen durch MDI bekannt geworden. |
| **Dossier submitter response:**  Thank you very much for your comments.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 3)  The training length provided for the different training modules gives an estimate for the time needed to cover all topics and to conduct the exercises. The estimated training length of the different training modules is based on discussions with experts from industry and trade association of professional users. We do not think that the learning goals can be reached in half the time. In case you decide to run the trainings at the workplace, and for Measure Group 1 implement e-learning for some of the modules there would be, of course, more flexibility. However, the individual training parts should be taken in a reasonable time frame. However, documentation should be provided that shows that the total time will sum up to the required training length and cover the required topics.  To 5)  In our opinion the proposed options to implement trainings are sufficiently flexible to adopt a scheme spread over time that optimally fits a company, without a need for total production stops.  We do not see the need to make any difference between temporary and permanent workers as far a training needs are concerned. Such needs should be considered in the assignment of tasks to such employees. |
| **RAC Rapporteurs comments:**  Thank you for your comments as well as for your answers to the specific information requests.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  To 2) Thank you for the offer to support users in implementing training programmes. RAC is aware of the fact that SMEs will need specific support by governmental agencies, chambers, trade associations, etc.  To 3) RAC agrees with your proposal regarding trainings (e.g. the training should preferably be conducted at the workplace itself). However, RAC is aware of the fact that this might not be possible in all cases.  To 4) Noted.  To 5) RAC refers to the Dossier Submitter´s answer to your comment. |
| **SEAC Rapporteurs comments:**  Please see reply to comment number 1568. |
| **1532** | **Date:** 2017/05/31 16:05  **Content:**  Transitional period  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** PU Europe  **Org. country:** Belgium  **Attachment:** | **Answer to specific info request 1:**  PU Europe holds the view that a minimum of 6 years is needed to allow the sector, mainly the suppliers and importers of diisocyanates with the support of the rigid polyurethane foam manufacturers, to design and establish the structures and training modules required for all work forces in the EU.  Our industry believes that the development of the training modules for Measure Group 3 materials associated with strategies for their roll-outs should be given the highest priority in the transition period.  It is also our understanding that a transition phase at national level for actually implementing the training for all employees, which is time & resource consuming, will be added to this transition period. We would also favour prioritization in that context with the emphasis being put to MG3 and MG2. |
| **Answer to specific info request 2:**  A constructive dialogue is needed between industries and national authorities. Whenever national associations exist, the best effort should be made to rely on those to develop and implement communication strategies towards the downstream users and SMEs in particular.  At European level, PU Europe will commit to play its part in communicating the requirements of the restriction to its membership (14 national association and 20+ EU based companies) via different communication channels like briefings to members, speeches during conferences/members’ meetings, detailed information on our extranet… |
| **Answer to specific info request 3:**  Within our membership, many of our members’ companies have developed and trained, i.e. using in-house trainings, their employees for the proper handling of diisocyanates for numerous years.  In the last few years, PU Europe has developed a training module dedicated to spray foam PU rigid insulation applicators (Measure Group 3). This spray foam stewardship scheme has been supported at national level by several national trade associations with a great success.  With regard to the question proper on training methods, we can report that applying the “train the trainer” principle in companies (supplying MDI or performing a foaming process in a factory) has proven very effective. Concerning the way to give the proposed training duration, we advocate for a flexible approach notably for MG1 and MG2- on how the 4 hours, or 4 +4, are given to the trainees. From a company perspective but also from a target audience one, it is suggested to have trainees following part of the training course, go to the workplace, then finish off their training course and be evaluated. Such approach also allows for the trainer to tune/adapt the training to the trainees and should ideally have an “on the work” training. In addition, our industry calls for “blended learning” method to be allowed above MG1. Indeed, e-learning should also be possible for part of the MG2 and MG3 trainings. Furthermore, considering the advancement of social science and technologies, training methods should not be seen as static, notably since the actual training of the proposed restriction will be performed in the 2020-2030s period.  As a side comment to the training methods, workers falling under MG1 and MG2 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 this new worker to ensure basic safe working practice, and after a few days the rest of the training course must be followed by those workers. When a new worker joins the company (or any of the other type of workers above described), it will be very expensive to imagine setting up immediately a training course for him/her. Hence our call to allow e-learning or a more flexible approach for providing modular training within the MG itself.  Furthermore, to get the certificate (passing the exam but also receiving the proof of the evaluation), it should not be mandatory to go to an evaluation centre, and we recommend that the trainer is given the competences to carry out this task. |
| **Answer to specific info request 4:**  PU Europe has not received any evidence or information suggesting that isocyanate-related symptoms were observed with a product containing less than 0.1% diisocyanates. |
| **Answer to specific info request 5:**  As stated in our answer to question 4, PU Europe believes that blended learning, a mix of e-learning and “on the work” learning, has a key role to play in reducing the burden of self-employed persons and SMEs in taking a training course. For that reason, MG2 and MG3 should permit this type of learning method. |
| **Dossier submitter response:**  Thank you very much for your comments.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 5)  In our opinion the proposed options to implement trainings are sufficiently flexible to adopt a scheme spread over time that optimally fits a company.  The issueing of a certificate/conformation that the course has been succesfully passed is planned to be an integral part of the training session.  We do not see the need to make a difference between temporary and permanent workers as far a training needs are concerned. Such needs should be considered in the assignment of tasks to such employees. |
| **RAC Rapporteurs comments:**  Thank you for your comments and for the support for the restriction proposal.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is as pointed out by the Dossier Submitter a political decision in the end. To keep the restriction proposal simple, RAC prefers a single date for the restriction to enter into force and not a staged introduction for the implementation of measures. However, this topic is also a political one and will therefore be discussed in another Committee.  To 2) RAC agrees that the responsibilities with regard to the restriction proposal have to be clear. RAC welcomes your commitment regarding the communication of the requirements of the restriction among your members.  To 3) RAC appreciates the information about the training module dedicated to spray foam PU rigid insulation applicators.  RAC stresses that workers have to be trained before handling diisocyanates according to the OSH legislation. So, for the implementation of this restriction proposal (if it would be implemented in the way it is foreseen according to the restriction proposal) it would make sense to interlink the obligations according to OSH legislations with the ones according to REACH.  If certificates or any other documentary evidence are needed to comply with the restriction, workers and self-employed persons will only be allowed to handle diisocyanates after passing the required test.  Thank you for your proposal for the evaluation of the training.  To 4) Thank you for the information which is noted.  To 5) RAC refers to the Dossier Submitter´s answer to your comments. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Thank you for the information on ongoing training.  SEAC agrees that several years will be needed for the full implementation of the proposed restriction. The final decision on the length of the period will be taken on the political level. |
| **1533** | **Date:** 2017/06/01 01:26  **Content:**  Scope or restriction option analysis;  Transitional period  **Type:** Individual  **Country:**  Italy  **Company name confidential:** YES | **Comment:**  None |
| **Answer to specific info request 1:**  not less 18-24 months |
| **Answer to specific info request 2:**  We can inform using the normal communication tool (customer information, technical data sheet), the institutional communication could be different but in this case there are the employer organization that can help the information trough the supply chain |
| **Answer to specific info request 3:**  The diisocyanates are used since many decades, the correct ouse of them is part of current legislation in Italy for which is mandatory a periodical training in chemical management |
| **Answer to specific info request 5:**  The training program proposed is part of current responsability of employer and the loss of employee time with other hidden costs will probable part of the industrial cost of the products |
| **Dossier submitter response:**  Thank you very much for your comments.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 3) You mentioned the training obligation which is already part of the OSH regulation in your country based on the Directive 89/391/EC (Art. 12: Training of workers) and Directive 98/24/EC (Art. 8: Information and training for workers). The risk assessment done in the dossier has shown that although the employer is responsible for safety and health training of workers specific to the job or workstation, an unacceptable number of occupational asthma cases arise every year. Therefore, a specific training programme was developed for this restriction (see Annex 8).  To 5) In our socio-economic analysis lost production time can be seen as the most significant contribution to total costs of the measure. |
| **RAC Rapporteurs comments:**  Thank you for your comments.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  To 2 and 3) Noted. |
| **SEAC Rapporteurs comments:**  Thank you for your comment.  The loss of employees’ time was addressed by the Dossier Submitter in their socio-economic analysis. The transfer of costs to product prices was also considered. |
| **1534** | **Date:** 2017/06/01 10:01  **Content:**  Scope or restriction option analysis;  Hazard or exposure;  Information on benefits;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Other contributor  **Org. name:** <redacted>  **Org. country:** Finland  **Company name confidential:** YES | **Comment:**  We agree that there are high concerns in relation to the sensitising potential of diisocyanates at workplaces, as these are among the most common chemicals causing occupational diseases.  The restriction proposal covers only products intended for professional use. The consumer products containing > 0.1% diisocyanates are thus not covered by the restriction. This needs to be re-evaluated.  The proposal for a restriction is in line with the approach of sharing information throughout the supply chain. The manufacturer/importer would, through the requirements on providing training material, have to address all safety aspects thoroughly when preparing the trainings. In addition to the preparation of the training material, this could also result in improved SDSs and exposure scenarios. The training requirements and training material are likely to support the employer in fulfilling his/her obligations related to the OSH legislation (e.g. 89/391/EEC).  We agree that the restriction and training requirements must not apply to those conditions, where exposure is low or minimal. However, the conditions fulfilling the criteria for exemption are vaguely described in the proposal, and must be specified. It can be assumed that the exemption options may result in the development of more appropriate and safer packages and applicators, minimizing the potential for exposure, as manufacturers may want to avoid the requirements on providing training material etc.  Although we basically agree that the training requirement would most likely improve the working conditions and decrease exposure, we do have concerns related to the implementation of the requirements in the member states. It is highly important that the training is arranged in the official language(s) of the countries where the products are placed on the market. As it is the manufacturer/importer who should prepare the training material, we are worried about the translations. A similar problem has been seen in relation to SDSs, which are often provided only in English. Our second concern is related to the relevance of the contents of the training material, with respect to the real applications at the workplaces. Taking into account the wide field of applications, fulfilling the manufacturer’s (/importer’s) requirements is demanding. If the training material is prepared at a very general level, and not specifically addressing all different uses, the effectiveness on improving the working condition might be doubtful. Also the quality of training may vary a lot. The manufacturers/importers should be encouraged to consult national experts on occupational hygiene and safety to get assistance in the preparation of the training material. |
| **Dossier submitter response:**  We thank you for the positive approach to our proposal.  Products with use by professionals (including self-employed persons) shall be covered by the present restriction. We agree that the risk management for products sold exclusively to consumers is not covered and should be re-evaluated in a separate process. The present restriction proposal is regarded as a first step in order to reduce health risks from diisocyanates.  The standard approach will indeed be to organise the proposed trainings per country/language.  Manufacturers and importers as well as the trade associations of relevant downstream users will be responsible for providing the content for the training material in order to make sure it covers real life working conditions. National authorities will get an opportunity to take part in the preparation as a participant in an advisory board. |
| **RAC Rapporteurs comments:**  Thank you for your comments and your support.  RAC notes your thoughts with regard to harmonisation of the legal requirements for workers and the general public. RAC would like to mention that there is already an existing entry in REACH/Annex XVII (entry 56) which addresses the use of Methylenediphenyl diisocyanate (MDI) for consumers. According to the Dossier Submitter´s researches on ECHA´s dissemination site, there are no registered consumer uses of diisocyanates that would not be covered by the existing Annex XVII restriction for MDI. However, the Dossier Submitter found out that spray paints containing a HDI-homopolymer are sold via Internet Marketing, and could pose a risk for consumers. Nevertheless, to be able to include consumers/the general public in the current restriction proposal, information on the risk characterisation and on the social economic issues would be needed for consumer use, which have not yet been elaborated. There is no available information on health risk of application of diisocyanates-containing products by consumers, and no new information on exposure and health risks related to consumer use of diisocyanates was provided during the Public Consultation. This issue is elaborated in the Background document (A.1.2).  RAC agrees that not all of the current available safety data sheets (incl. the exposure scenarios) are of a good enough quality. Industry has guaranteed to update their documentation.  RAC also supports your comments regarding exemptions and the requirements regarding trainings. |
| **SEAC Rapporteurs comments:**  Thank you for your comment.  We agree that the wording of the entry would merit from elaboration. The original proposal has been revised accordingly and is included in the committees’ opinion. |
| **1536** | **Date:** 2017/06/01 15:51  **Content:**  Scope or restriction option analysis;  Hazard or exposure;  Environmental emissions;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** European Federation for Construction Chemicals (EFCC)  **Org. country:** Belgium  **Attachment:** | **Comment:**  I uploaded the "EFCC Position on the Restriction proposal for the use of Di-isocyanates" in the below section IV |
| **Answer to specific info request 1:**  EFCC would correspondingly suggest a transition period of at least six (6) years with the earliest possible starting date as of the entry into force of the legislation. This reasonable time period is crucial to draft and optimize training materials with practical and harmonized concepts, then to develop appropriate IT-tools easy to be used by the concerned actors along the supply chain, thereafter to build up certified trainers and set up the institutional training infrastructure for a smooth implementation in all Member States , and lastly to make all workers fully aware of the training materials consistently and periodically according to experience won during the proposed time period. A big challenge remains mostly by the unprepared SMEs for the professional end use of di-isocyanates containing mixtures. |
| **Answer to specific info request 2:**  Efficient lines of communication between industry and competent authorities are required. EFCC Member Companies and Associations will fulfill the legal requirements and documents this in the safety data sheets. Furthermore, EFCC strives to keep informed the customers of the Member Companies / Associations (for the professional end application), using different communication media such as dedicated websites or events (conferences, workshops or webinars) at national and European level, as well as via Guidance and brochures, on a voluntary basis |
| **Answer to specific info request 3:**  Efficient ways to spare efforts and time by professional end-users of construction chemicals/products containing di-isocyanates remain the availability of training courses combining technical and occupational health and safety aspects. If in some Member States the similar training courses are already in place, the pre-defined training content should be adapted and adjusted into a training concept covering also the training requirements resulting from the restriction of other substances or mixtures with similar impacts.  To cover most of the professional end-users in the construction sector (mainly SMEs), training concepts such as “e-learning” and “train-the-trainer” should be considered and improved. It won’t be easy that all concerned workers in the construction sector join external training classroom in commensurate time. |
| **Answer to specific info request 4:**  EFCC has no information that such health cases occurred in the construction sector. |
| **Answer to specific info request 5:**  EFCC represents Member Companies/Association as registrants and formulators of di-isocyanates substances and mixtures. The training requirements could create moderate additional efforts by the companies already familiar with this kind of requirements, but they will be able to manage all upcoming deals in the industrial surroundings.  For the customers of our member companies (professional end users of mixtures), the implementation of the restriction-legislation remains a big challenge. Therefore, the following approaches are helpful, in order to make the restriction-legislation manageable by the affected SMEs or self-employed persons:  • E-learning  • Train-the-trainer concept  • Exemptions for product-use-combinations with very low potential for exposure  • Combination of the di-isocyanate training with technical or educational/vocational training |
| **Dossier submitter response:**  Thank you very much for your comments.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 3 and 5)  The restriction as proposed allows for a range of training options, suiting work schedule and economic considerations also for small firms. For “Measure Group 1” this also includes e-learning. The proposed concept does not prevent to combine the necessary trainings with other vocational or technical trainings.  Use of a “train the trainer” concept is possible.  We appreciate your support for defining a concept for “exempted products”. |
| **RAC Rapporteurs comments:**  Thank you for your comments.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  RAC considers that especially smaller companies will benefit from the restriction, since its structure is expected to cover the gaps in OSH implementation particularly in SMEs, providing diisocyanate-specific training programmes. However, it will be important that SMEs inform industry about their needs with regard to the training content as the training should address the use(s) of diisocyanates at the workplace as specifically as possible.  To 2) RAC points out that improvements regarding the documentation in safety data sheets are important as not all companies have fulfilled the requirements in the past (e.g. detailed information on the appropriate PPE (if needed) is sometimes lacking).  To 4) Noted.  To 3 and 5) In the revised conditions the concepts of the Dossier Submitter have been retained and their reply is relevant. Additionally, it is to be noted that trainers are required to follow a specific training covering at least the aspects set out in the conditions of the restriction. |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  We agree that several years will be needed for the full implementation of the proposed restriction. The final decision on the length of the period will be taken on the political level. |
| **1537** | **Date:** 2017/06/01 16:02  **Content:**  **Type:** MemberState  **Country:**  Slovenia | **Comment:**  Answers to specific questions to MSCA:  6. Council Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work is transposed into a national legislation and implemented (including amendments). There is already an obligation for a training (workers to get adequate instruction) in an Article 6d.  8. This is a matter of workers protection legislation. Generel Chemicals inspectors are not even qualified in relation to an enforcement in the area of a workplace. 9. We agree that better implementation of worker protection legislation would give the same results. The reason is that article 6d of Concil Directive 89/391/EEC is already a legal obligation. At our opinion additional measure in a different legislation can not be more effective. We believe that existing provision in a legislation (article 6d) should be implemented in way to be effective. At our opinion the proposed restriction isn't enforceable and practical. |
| **Dossier submitter response:**  You have commented that a training obligation is already in place based on the Directive 89/391/EC (Art. 12: Training of workers) and Directive 98/24/EC (Art. 8: Information and training for workers). We like to emphasize that the risk assessment done in the dossier has demonstrated that although the employer is responsible for safety and health training of workers specific to the job or workstation an unacceptable number of new occupational asthma cases have arisen every year. Therefore, with this restriction we propose a specific mandatory training programme (see Appendix 13: Trainings and Measures). The responsibility for development and supply of the training concept and material would be on the side of the manufacturers / importers, and the associations of downstream users will support the development of the material by providing input. Of course, the employer remains to be responsible for executing the trainings (or allowing his workers to attend such trainings), but he will receive support from the supply chain. |
| **RAC Rapporteurs comments:**  Thank you for your comments and for your answers to the specific information requests.  RAC agrees with your statement that the appropriate legal instrument for the regulation of occupational health and safety is the EU workplace safety legislation. However, the reasons why the REACH legislation might be of benefit in this case have been elaborated in the Background document and in the RAC´s opinion. In addition, RAC points out that a huge effort has been made by the Dossier Submitter to find a way to reduce the number of cases of occupational asthma which still occur (despite the OSH regulation(s)).  RAC has revised the conditions of the restriction proposal (including the appendices) - the revised conditions are included in the opinion. Thank you for the advice. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. We would like to point out that still remaining number of occupational asthma cases shows that further risk management is needed. The current OSH legislation (directives) does not seem to support the prescription of the obligatory EU unified requirements regarding training preferred by the Dossier Submitter, and it seems that REACH would be the best option to do so. Proposed top-down approach requires cooperation of downstream users and at the same time gives them a knowledge/mechanisms which they might not have at the moment, which might benefit especially SMEs with smaller resources available. |
| **1538** | **Date:** 2017/06/01 17:22  **Content:**  Hazard or exposure  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** MC-Bauchemie Müller GmbH & Co. KG  **Org. country:** Germany  **Attachment:**  <redacted> | **Comment:**  Threshold values and criterion of very low potential for exposure |
| **Answer to specific info request 3:**  See our comment. |
| **Answer to specific info request 5:**  a) Loss of employee time  b) We have implemented training programs concerning health isues |
| **Dossier submitter response:**  Please realise that the 0.001 ppm value mentioned in the proposal is not meant as new OEL. It is meant as a value to identify products that are to be considered exempted from the restriction because they fulfil a set of criteria that would put them in a special extra low risk category. Therefore, an extra low limit for inhalation was chosen, so as to leave no doubt about the fact that the inhalation exposure is very low indeed. If it can be shown that the probability of dermal exposure as very low as well, extra measures as defined in the restriction are not necessary.  To 5)  Regarding the costs of compliance under the restriction, in Annex 8 (Appendix 13 – Trainings and Measures) different options for the training format were defined depending on the measure group. This offers the opportunity to choose the training format which fits best to the conditions of your company to reduce work time losses and the administrative burden of the restriction as far as possible. |
| **RAC Rapporteurs comments:**  Thank you for your comments and replies to ECHA’s information requests.  Regarding your comment on the upper limit for the cumulative air concentration of all free diisocyanate substances (0.001 ppm) as one of the criteria for exempting the products with very low risk of exposure, we support the Dossier Submitter’s reply. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. |
| **1540** | **Date:** 2017/06/01 17:57  **Content:**  Other socio economic analysis (SEA) issues;  Transitional period  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** European Committee of Domestic Equipment Manufacturers - CECED  **Org. country:** Belgium  **Attachment:** | **Answer to specific info request 1:**  CECED/ZVEI member companies have a proven record of no incidence to the health of workers resulting from the use of diisocyanates in their manufacturing facilities, in particular for the main application of insulation polyurethane foam (e.g. in cooling appliances, water heaters and other household appliances). Owing to the existing safety measures, work place trainings and work safety trainings, that are already established, working and integrated into the management system of our member companies, manufacturers can explain this good track record of absence of incidences. The continuous optimisation of safety requirements within industrial environments is part of the overall vision and strategy of CECED companies.  As explained in the accompanying position paper, CECED member companies conduct regularly safety training with their employees, who are in contact with chemical hazards. We therefore think, that 3 years to complete the trainings should be approppriate: 1 year for developing the new and improved training materials and 2 years for the implementation of the new training scheme and the training of workers.  Based on the experiences of the existing trainings (such as the walk the talk from Isopa) and the observed effects on the health of the employees as well as on new findings on the hazards of diisocyanates the training materials and training scheme should be updated and improved regularly. |
| **Answer to specific info request 2:**  CECED/ZVEI suggests a coordinated approach between industry and authorities. The distribution of information could be done via the network of European and national industry, retailers and trade union associations. Different media chanels should be used, e.g. dedicated websites (authorities and sectorial associations), conferences and webinars.  ZVEI/CECED think that a proactive involvement of European and Member state authorities in the communication activities is crucial to ensure an effective and efficient reach out of all agents in the supply chain. |
| **Answer to specific info request 3:**  CECED/ZVEI members have significant experience in the use of hazardous substances in industrial environments and training of workers in occupational health and safety. Diisocyanates have been a critical substance for our industry since long time ago, mainly for the intrinsic risk of explosion but also for the consequences to health. CECED members have been involved in many voluntary training initiatives on the safe use of diisocyanates, ruled by the “walk-the-talk” principle, such as the commonly used training scheme developed by the diisocyanates and PU manufacturers. These trainings and additional voluntary measures such as obligatory use of personal protective equipment and technical risk prevention measures are a consequence of the strict health policies of CECED members, which have resulted in zero incidences to workers health due to the use of diisocyanates in manufacturing facilities in Europe. |
| **Answer to specific info request 5:**  CECED is not in a position yet to estimate figures of costs, however, we believe that unnecessary extra costs could be prevented:  Effective trainings - In order to keep the awareness of the health risk arising from diisocyanates among the employees high, ZVEI/CECED considers frequent and shorter training sessions to be more effective than only one longer training session within a period of several years. CECED members would prefer 1h training each year than 4h every 4 years. We ask to leave it to employers’ decision how best to distribute the traning time in accordance to their needs and situation. CECED thinks that it would be more efficient to set minimum requirements in terms of the duration of training and, at the same time, leave the employer the freedom to structure the individual units as it best fits to the individual situation.  Loss of employees time – minor in comparison with the cost of the training since the time-loss can be optimised if the training is done under the umbrella of a wider occupational and health training. That is if the assumption that companies would have some flexibility to distribute the training times in accordance with their already established training programmes.  Administrative costs - CECED/ZVEI members already have in place different management systems (quality or health and safety) and they keep records of trainings performed, accordingly to the principles of these systems. To prevent the generation of different extra-documentation and in order to minimize the administrative costs and burdens, we consider that DU should be free to decide and generate the documentation that will show evidence of compliance with the training. |
| **Dossier submitter response:**  Thank you very much for your comments.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 5)  Different options for the training format were defined depending on the measure group. This offers the opportunity to choose the training format which fits best to the conditions of your company to reduce work time losses and the administrative burden of the restriction as far as possible. A “Train-the-trainer concept is considered as a possible option to implement the mandatory trainings”. |
| **RAC Rapporteurs comments:**  Thank you for your comments.  To 1) Your detailed information about the existing safety measures and the fact that in your member companies no occupational asthma cases due to diisocyanates occur is welcomed.  RAC notes that the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  RAC agrees that a regular repetition of the training is required to maintain its effectiveness. According to the RAC’s opinion, the training should be conducted as a minimum every 4 years. It will be therefore up to each company to decide the frequency of the training as long as the minimum frequency of 4 years is complied with. .  To 2) RAC notes that a well-functioning communication along the supply chain on the requirements of the restriction is needed for the restriction to achieve its goals (safe handling of diisocyanates, reduction of cases of occupational asthma).  To 3) This information is noted. It supports, as you pointed out, the need for regular high-level training of workers and self-employed persons. |
| **SEAC Rapporteurs comments:**  Thank you for your comment and the information provided. SEAC agrees with the opinion presented, that it should be cost-effective to have diisocyanate training combined with other training activities. The training requirement should be worded in the manner which ensures flexibility in the training provision. |
| **1541** | **Date:** 2017/06/01 18:02  **Content:**  Information on costs;  Information on benefits;  Transitional period  **Type:** BehalfOfAnOrganisation  **Org. type:** National NGO  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential:** YES  **Attachment:**  <redacted>  **Privacy comment:** As the uploaded file was not evaluated by myself, I don´t have the publishing rights. | **Comment:**  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. |
| **Answer to specific info request 1:**  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. Also the trainers (i.e. commissioned experts, safety or occupational health specialists) themselves may need training for the special field of diisocyanates. |
| **Answer to specific info request 2:**  The national authorities have to make sure that these requirements are communicated through the supply chain. Additionally, all technical data sheets for products containing diisocyanates have to inform the applier about the obligatory training. |
| **Answer to specific info request 3:**  Use of PPE;  training of first aiders; |
| **Answer to specific info request 5:**  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. No, as the three-year education of painters in Germany include the use of hazardous materials as well as the use PPE, the benefit for the painting companies is considered to be negligible. |
| **Dossier submitter response:**  Thank you for your comments  The four year repeat cycle was chosen to reach an optimum between the need to repeat instructions to reach sustainable results and the practicality of setting up a training system and related infrastructure. Taking into account experiences from existing OSH training schemes e.g. on asbestos (6 years) and thermoset resins (SE, 5 years) and yearly instructions on hazardous goods (in DE) we decided to take 4 years as a reasonable compromise. Please note that this is a minimum requirement.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 5)  Different options for the training format were defined depending on the measure group. This offers the opportunity to choose the training format which fits best to the conditions of your company to reduce work time losses and the administrative burden of the restriction as far as possible. |
| **RAC Rapporteurs comments:**  Thank you for your comments.  RAC agrees with your comments that the training should be adapted to the different requirements of different (industrial or professional) sectors.  It will be important that SMEs inform industry about their needs with regard to the training content, as the training should address the use(s) of diisocyanates at the workplace as specifically as possible. In this regard, the conditions of the restriction agreed by RAC include the requirement that the training material will be developed by the manufacturer/importers supported by information provided by the downstream users.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  To 2) RAC notes that a well-functioning communication along the supply chain is needed for the restriction to achieve its goals (i.e. the safe handling of diisocyanates and the reduction of cases of occupational asthma).  To 3) Noted. |
| **SEAC Rapporteurs comments:**  Thank you for your comment.  We agree that the training content should match the use in the sector.  1) We agree that several years will be needed for the full implementation of the proposed restriction. The final decision on the length of the period will be taken on the political level.  5) Thank you for your information concerning training costs for your company. The opportunity to choose a suitable training method is expected to help keep costs manageable. We note that cases of occupational asthma still develop in substantial high numbers and a regulatory action needs to be taken to address that risk. The proposed training scheme (with possible exemptions) appears to cause less disruption and costs to industry than a ban of use of diisocyanates. The analysis made implies that overall the expected costs are proportional to the benefits envisaged. |
| **1542** | **Date:** 2017/06/01 18:28  **Content:**  Scope or restriction option analysis  **Type:** MemberState  **Country:**  Finland | **Comment:**  We thank the dossier submitter for the restriction proposal and agree that diisocyanates are still causing occupational asthma cases and posing unaccepta-ble risk for workers. Respiratory sensitisers are one priority group of substances to be covered under chemicals legislation.  We consider that the clarity of the proposal needs to be improved. The re-striction proposal introduces different obligations to many different actors. The obligations should be clearly defined for each actor. Many actors are new and not defined in the REACH regulation such as self-employed worker and em-ployer.  Another aspect to be further considered is how e-commerce trade can comply with the proposed restriction requirements.  The Appendix 13 (Trainings and Measures) is quite complex and ambitious. The implementation as well as enforcement of Appendix 13 raises concern. In Fin-land most of the qualifications related to working conditions that are compara-ble with this proposal eg. fire work license card or plant protection certification are valid for 5 years. Hence, we propose to extend the repeat frequency of the training to 5 years.  Finally, advice from authorities enforcing the compliance with the proposed re-striction is important to make sure that enforcement of the restriction is feasi-ble. Good cooperation between REACH and OSH enforcement authorities is es-sential to achieve effective risk reduction. |
| **Dossier submitter response:**  Thank you very much for your comments.  Your objection on insufficient clarity of the restriction proposal which would make its enforcement difficult, has been noted. Regarding e-commerce trade: Because e-commerce involves formal ordering and (electronic) contracts we do not see this as much different from normal orders. But, in this case the customer has the duty to inform the supplier that he has fulfilled his duties under the conditions of the restriction. Such a communication can be made a prerequisite to conclude on the contract. Specific conditions on the obligations of the restriction and the reference to training offerings can be added.  You have proposed less frequent training repetitions. Sustaining behavioural changes will need a regular repetition of the training. It becomes unpractical and unmanageable to do this too often. On the other hand, waiting too long may lose some of the gains made. Taking into account experiences from existing OSH training schemes e.g. on asbestos (6 years) and thermoset resins (SE, 5 years) and yearly instructions on hazardous goods (in DE) we decided to take 4 years as a reasonable compromise. |
| **RAC Rapporteurs comments:**  Thank you for your comments and for your support.  RAC has revised the conditions of the restriction proposal (including the appendices) - the revised conditions are included in the opinion. Thank you for the advice.  With regard to your further comments, RAC refers to the Dossier Submitter´s answer. |
| **SEAC Rapporteurs comments:**  Thank you for your comment.  We agree that the wording of the entry would merit from elaboration. The original proposal has been revised accordingly and is included in the committees’ opinion. |
| **1543** | **Date:** 2017/06/01 19:02  **Content:**  Scope or restriction option analysis;  Hazard or exposure;  Environmental emissions;  Description of analytical methods;  Information on alternatives;  Information on costs  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Europacable  **Org. country:** United Kingdom  **Attachment:** | **Comment:**  Europacable comments concern clarifying scope, applied methodologies, way of providing information that depends on others. Our comments on the Main report and appendix are attached. |
| **Answer to specific info request 1:**  Europacable will investigate in advance of 2nd public consultation. |
| **Answer to specific info request 2:**  Europacable will investigate in advance of 2nd public consultation. |
| **Answer to specific info request 3:**  Europacable will consult its members for the 2nd public consultation. |
| **Answer to specific info request 4:**  Europacable will investigate in advance of 2nd public consultation. |
| **Answer to specific info request 5:**  Europacable will investigate in advance of 2nd public consultation. |
| **Dossier submitter response:**  The DS welcomes the comments and recommendations to clarify any unclear issues mentioned. We will take them into account for the review and update of the background document. |
| **RAC Rapporteurs comments:**  Thank you for your comments and for the detailed advice to improve the “definition” of the restriction as well as its conditions (incl. the Appendices). RAC has revised the conditions of the restriction proposal (including the appendices) - the revised conditions are included in the opinion. |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  Please note that there will not be another public consultation regarding the restriction proposal itself. There will be another Public consultation after agreement of the SEAC draft opinion. However, that is designed only for commenting the SEAC draft opinion and SEAC has no possibility to consider comments of other types at that point of time. |
| **1545** | **Date:** 2017/06/01 20:09  **Content:**  Information on benefits;  Other socio economic analysis (SEA) issues;  Transitional period  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** ZVEI - Domestic Electrical Appliances Division  **Org. country:** Germany  **Attachment:** | **Comment:**  ZVEI(Domestic Electrical Appliances Division) would like to use this consultation to inform ECHA and the REACH Competent Authorities about the view of the German and European domestic appliances industry on the intended restriction of diisocyanate substances under REACH Annex XVII. Our general comments can be found in the enclosed position paper developed under the umbrella of CECED, the European Association for the household appliance industry. |
| **Answer to specific info request 1:**  ZVEI(Domestic Electrical Appliances Division)/CECED member companies have a proven record of no incidence to the health of workers resulting from the use of diisocyanates in their manufacturing facilities, in particular for the main application of insulation polyurethane foam (e.g. in cooling appliances, water heaters and other household appliances). Owing to the existing safety measures, work place trainings and work safety trainings, that are already established, working and integrated into the management system of our member companies, manufacturers can explain this good track record of absence of incidences. The continuous optimisation of safety requirements within industrial environments is part of the overall vision and strategy of ZVEI(Domestic Electrical Appliances Division)/CECED companies.  As explained in the accompanying position paper, ZVEI (Domestic Electrical Appliances Division)/CECED member companies conduct regularly safety training with their employees, who are in contact with chemical hazards. We therefore think, that 3 years to complete the trainings should be approppriate: 1 year for developing the new and improved training materials and 2 years for the implementation of the new training scheme and the training of workers.  Based on the experiences of the existing trainings (such as the walk the talk from Isopa) and the observed effects on the health of the employees as well as on new findings on the hazards of diisocyanates the training materials and training scheme should be updated and improved regularly. |
| **Answer to specific info request 2:**  ZVEI(Domestic Electrical Appliances Division)/CECED suggests a coordinated approach between industry and authorities. The distribution of information could be done via the network of European and national industry, retailers and trade union associations. Different media chanels should be used, e.g. dedicated websites (authorities and sectorial associations), conferences and webinars.  ZVEI(Domestic Electrical Appliances Division)/CECED think that a proactive involvement of European and Member state authorities in the communication activities is crucial to ensure an effective and efficient reach out of all agents in the supply chain. |
| **Answer to specific info request 3:**  ZVEI(Domestic Electrical Appliances Division)/CECED members have significant experience in the use of hazardous substances in industrial environments and training of workers in occupational health and safety. Diisocyanates have been a critical substance for our industry since long time ago, mainly for the intrinsic risk of explosion but also for the consequences to health. ZVEI(Domestic Electrical Appliances Division)/CECED members have been involved in many voluntary training initiatives on the safe use of diisocyanates, ruled by the “walk-the-talk” principle, such as the commonly used training scheme developed by the diisocyanates and PU manufacturers. These trainings and additional voluntary measures such as obligatory use of personal protective equipment and technical risk prevention measures are a consequence of the strict health policies of ZVEI/CECED members, which have resulted in zero incidences to workers health due to the use of diisocyanates in manufacturing facilities in Europe. |
| **Answer to specific info request 5:**  ZVEI(Domestic Electrical Appliances Division)/CECED is not in a position yet to estimate figures of costs, however, we believe that unnecessary extra costs could be prevented:  Effective trainings - In order to keep the awareness of the health risk arising from diisocyanates among the employees high, ZVEI/CECED considers frequent and shorter training sessions to be more effective than only one longer training session within a period of several years. ZVEI(Domestic Electrical Appliances Division)/CECED members would prefer 1h training each year than 4h every 4 years. We ask to leave it to employers’ decision how best to distribute the training time in accordance to their needs and situation. ZVEI(Domestic Electrical Appliances Division)/CECED thinks, that it would be more efficient to set minimum requirements in terms of the duration of training and, at the same time, leave the employer the freedom to structure the individual units as it best fits to the individual situation.  Loss of employees time – minor in comparison with the cost of the training since the time-loss can be optimised if the training is done under the umbrella of a wider occupational and health training. That is if the assumption that companies would have some flexibility to distribute the training times in accordance with their already established training programmes.  Administrative costs – ZVEI (Domestic Electrical Appliances Division)/CECED members already have in place different management systems (quality or health and safety) and they keep records of trainings performed, accordingly to the principles of these systems. To prevent the generation of different extra-documentation and in order to minimize the administrative costs and burdens, we consider that DU should be free to decide and generate the documentation that will show evidence of compliance with the training. |
| **Dossier submitter response:**  Thank you very much for your comments.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 5)  Different options for the training format were defined depending on the measure group. This offers the opportunity to choose the training format which fits best to the conditions of your company to reduce work time losses and the administrative burden of the restriction as far as possible.  Furthermore, the combination of the mandatory trainings with already existing technical / vocational and other OSH trainings can be considered as a possible option, to reduce working time losses and to increase the practicability of the restriction. |
| **RAC Rapporteurs comments:**  Thank you for your comments.  To 1) Your detailed information about the existing safety measures and the fact that in your member companies no occupational asthma cases due to diisocyanates occur is welcomed.  RAC notes that the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  RAC agrees that a regular repetition of the training is required to maintain its effectiveness. According to the RAC’s opinion, the training should be conducted as a minimum every 4 years. It will be therefore up to each company to decide the frequency of the training as far as the minimum frequency of 4 years is complied with.  To 2) RAC notes that a well-functioning communication along the supply chain is needed for the restriction to achieve its goals (i.e. the safe handling of diisocyanates and the reduction of cases of occupational asthma).  To 3) This information is noted. It supports as you pointed out the need for regular high-level training of workers and self-employed persons. |
| **SEAC Rapporteurs comments:**  Thank you for your comment and the information provided. SEAC takes note on the information and comments presented. |
| **1551** | **Date:** 2017/06/07 19:37  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Belgium  **Company name confidential:** Yes | **Comment:**  As industrial users of diisocyanates, our manufacturing sites are well aware of the risks related to those substances. The use of closed systems is maximized and where manual operations cannot be avoided, the use of full-protection suits, gloves and respiratory protection is mandatory. We are also measuring exposure to disocyanates to ensure we comply with applicable exposure limits. Our workers get regular safety and occupational health trainings explaining the personal protection and first aid measures required for handling chemicals and highlighting the most hazardous substances, including diisocyanates. More information is provided in the responses to the specific questions. |
| **Answer to specific info request 1:**  We believe that a transitions of 3 to 5 years is needed to enable manufacturers of resins for paint/coating/ink to measure the residual isocyanate content in their product and adapt their production process to ensure residuals are below 0.1%. In case the residual isocyanate cannot be reduced below 0.1%, formulators of paints/coating/ink will have to change their formulations and re-qualify the new ones which takes an additional 1-2 years (sometimes more in specific application like automobile or aeronautic). In addition, several companies will have to invest in exposure control equipment, which can also take several years. |
| **Answer to specific info request 2:**  Current strategies, based on the SDS and additional communication from diisocyanate manufacturers via letter, are efficient for industrial users as we are already well informed since many years of the risk associated with the use of diisocyanates in our plants. As a result our sites have already implemented very severe exposure control equipment and personal protective equipments for these substances. |
| **Answer to specific info request 3:**  Our sites use a combination of  • Classroom training followed by a short exam  • on-the-job trainings per work station (specific to the installation and operations needed)  • lessons learnt from the past and from incidents or near-misses  • management audit and attention  As our sites handle several hazardous chemicals, we give general safety and occupational health trainings to the workers, highlighting the personal protection and first aid measures required for the most hazardous substances, including diisocyanates. We cannot give extensive training on each specific hazardous substance as this would become overwhelming and counter-productive. |
| **Answer to specific info request 4:**  We did not experience any sensitization case with product containing less than 0.1% diisocyanates, in all our European plants. The cases we had in the past were rare and with pure diisocyanates. For instance, our German sites did not experienced any incident from the toxic or sensitizing properties of isocyanates since it started to use diisocyanates in the early 1990s. |
| **Answer to specific info request 5:**  a) We would like to include this training in the existing training program on hazardous chemicals which already covers isocyanates. We can adapt the training package to include the latest recommendations. In that case, the cost would be very limited as it would take a couple of hours for the trainer to check the latest recommendations on isocyanates and update the presentation for our workers.  If the training has to be taken outside of the company (e.g. at an official training provider), the cost would be significant in terms of loss of employee time.  b) In companies dealing with many different chemicals, it is important that the training on isocyanate is part of the mandatory general hazard communication training and that it does not take precedence over this training otherwise the workers may have the false feeling that isocyanates are the only dangerous chemicals they use and may underestimate the risk of other substances. |
| **Dossier submitter response:**  Thank you very much for your comments.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 5)  Different options for the training format were defined depending on the measure group. This offers the opportunity to choose the training format which fits best to the conditions of your company to reduce work time losses and the administrative burden of the restriction as far as possible. Furthermore, the combination of the mandatory trainings with already existing technical / vocational and other OSH trainings can be considered as a possible option, to reduce working time losses and to increase the practicability of the restriction. |
| **RAC Rapporteurs comments:**  Thank you for your comments.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  To 2 and to 3) Thank you for the interesting information.  To 4) Noted.  To 5) RAC refers to the Dossier Submitter´s answer to your comments. |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  1) We agree that several years will be needed for the full implementation of the proposed restriction. The final decision on the length of the period will be taken on the political level.  5) Costs expected due to the training scheme have been assessed by the Dossier Submitter and are considered by SEAC in the assessment of the proportionality of the proposed restriction. |
| **1552** | **Date:** 2017/06/12 15:16  **Content:**  Hazard or exposure;  Other socio economic analysis (SEA) issues;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** 3M Belgium bvba/sprl  **Org. country:** Belgium | **Comment:**  3M is a manufacturer of diisocyanate-based medical device synthetic casting products. These products are regulated under the Medical Device Directive 93/42/EC (MDD), respectively in future even more strictly under the new Medical Device Regulation 2017/745/EU (MDR). Intended use is in the construction of most common orthopedic casts, as well as specialized 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. Usage is in hospitals and medical practice.  We believe the planned restriction…  • does not consider health care product specifics  • is in conflict with other legislation (e.g. the CLP- and REACH-Regulation which both have certain exemptions for Medical Devices)  The MDD and MDR require a risk/benefit-assessment for using a hazardous substance in a Medical Device. This assessment already needs to consider the risks for patients, users and other persons. An EHS study done with diisocyanate-based medical casting products under realistic use conditions shows they are safe to use. Under usual use conditions air levels were below detection limits making respiratory problems extremely unlikely. Specific Instructions for Use are packaged to each unit as required by the MDD/R.  An alternative diisocyanate-free medical device product may overall not be the better product to treat a patient. Being diisocyanate-free is not the only aspect to be considered here. Traditional cast applications made from plaster are known for leading to more shadow on the x-ray, making it more difficult for the expert to monitor fracture healing through the cast. Synthetic cast applications are known for their more radio friendliness (less kilovolts needed) and by far less shadow on the x-rays. Traditional plaster cast applications are, evidence based, leading to more undesired immobilization, and as such leading to more atrophies, osteoporosis, loss of strength and volume in muscles than synthetic cast applications, which are known for their functional stabilization levels. Traditional plaster casts cause undesired dirt and slurry in the operating room, leading to longer cleaning time. In contrast, synthetic cast tapes and splints are easy to use and clean to use, and more effective than traditional plaster (evidence based, more than 120 publications with 3M synthetic cast tapes and splints). In many hospitals in developed countries diisocyanate-based synthetic cast applications completely replaced traditional plaster.  Required training to be organized and conducted by healthcare facilities would add additional burden where a constant need to cost reduction is eminent. Healthcare facilities may decide to avoid this which may lead to the use of traditional plaster casting materials not always providing the best, state-of-the-art treatment for the patient. Patients could be blocked from better treatment at the risk of deterioration of their status of health leading to reduced life quality, and higher overall costs for health care systems (socio-economic impact).  In our view the planned diisocyanate restriction should clearly exempt Medical Devices, especially those which are invasive or come into direct contact with the human body, because they are already highly regulated by the Medical Device Directive 93/42/EC, respectively in future by the new Medical Device Regulation 2017/745/EU. There are already several exemptions for Medical Devices from regulations in place (e.g. in CLP 1272/2008/EC and REACH 1907/2008/EC) because the Medical Device legislation is regarded as THE legal instrument to ensure the safety of Medical Device products also regarding chemical substances involved. The planned restriction would lead to double (over) regulation and would also be in contradiction to other legislation. E.g.: Paragraph 6 of Appendix 12 to the future Annex XVII entry requires that if the evaluation of a substance or mixture containing diisocyanates leads to the conclusion that the substance fulfils the requirements for an exemption this and other information ensuring the safe use is to be communicated in the safety data sheet (SDS). However, according to REACH Article 2 (6) medical devices which are invasive or used in direct physical contact with the human body and preparations in the finished state, intended for the final user are exempt from the provisions of Title IV (need to provide an SDS). Thus, there is no SDS where to add the information required. In case of a Medical Device the MDD and MDR already require that safe use information is being provided in the Instructions for Use accompanying the product.  We welcome the planned diisocyanate restriction for an industrial setting and will respect the requirements in our production facilities. However, we believe it is not suitable for medical devices when used in their finished state at a health care facility. |
| **Dossier submitter response:**  Thank you for your comment and pointing out the potential overlap between regulations.  Indeed REACH Art 2.6(c) states that provisions of Title IV shall not apply to medical devices which are invasive or used in direct contact with the human body. By itself this does not include Title VIII (restrictions).  In this respect it is important to clarify first if medical devices containing diisocyanates are “articles” in terms of REACH, which would place them outside the scope of this restriction altogether.  If these are not to be considered as articles, the case for a general exemption under the MDR may be supported if it can be shown that the trainings as are already foreseen in the MDR cover similar topics as e.g. defined for Measure Group 1 of the restriction. Only in this case it can be expected to lead to comparable reduction of the occupational health risk. |
| **RAC Rapporteurs comments:**  Thank you for your comments and your detailed answers to ECHA´s request to provide specific information with regard to your claim for exemptions.  RAC points out that medical devices are not exempted from Title VIII of REACH and therefore the same requirements as for other uses apply in connection with this restriction proposal. RAC acknowledges that the Medical Device Regulation requires a risk/benefit-assessment for the use of hazardous substances in medical devices; however this assessment is focused on the patients and their need for treatment and not on the health protection of workers.  RAC does not see a significant difference from the medical facilities where the use of diisocyanates-containing casting products takes place to other workplaces handling diisocyanates (apart from the fact that safety data sheets might not be at the disposal of health workers but user instructions). Therefore RAC does not find any justification to exempt a priori the use of diisocyanate-containing casting products from the restriction requirements. RAC notes however, that according to the restriction, the manufacturer/importer/formulator of a diisocyanate-containing casting product can claim an exemption from the restriction requirements if they can demonstrate that the use of the product leads to very low risk of exposure for the dermal and inhalation route (see the condition of the restriction, as agreed by RAC, included in the opinion). |
| **SEAC Rapporteurs comments:**  Thank you for your comment and the information provided on the use of diisocyanates in medical devices. SEAC refers to RAC the response concerning the claim for an exemption. |
| **1554** | **Date:** 2017/06/15 15:47  **Content:**  Scope or restriction option analysis;  Baseline;  Description of analytical methods;  Information on alternatives;  Information on costs;  Information on benefits;  Other socio economic analysis (SEA) issues;  Transitional period  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. name:** UK Health and Safety Executive  **Org. country:** United Kingdom  **Attachment:** | **Comment:**  HSE’s overarching view:  i. The HSE is of the opinion that the current regulatory Occupational Safety and Health framework already in place across the EU is robust, and is 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 for the UK.  iii. HSE’s success in achieving improved workplace risk management measures for diisocyanates, and the consequent reductions in cases of occupational asthma in the UK, have been achieved by working within the framework of our national legislation implementing EU OSH legislation, and without introducing new law.    iv. In agreement with the Dossier Submitter, 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 for the reasons provided on page 23 of the restriction proposals summary report.  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 Isocyanates 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. In addition, HSE considers that currently the proposed restriction is neither enforceable nor practical with many gaps existing in the assessment in the impact assessment and the training methods and measures.  In addition to HSE’s overarching view that the proposed EU wide restriction is not necessary, we have a number of key concerns regarding the assessment and information provided in the diisocyanates restriction proposal dossier as follows:  - Estimation of the number of annual OA cases caused by diisocyanates  - Risk reduction capacity  - Sensitivity analysis  - Social impacts of work disability and individual costs for employee  - Assessment of alternatives  - Growth in the labour force  - Training length, frequency and format  - Consistency of training standards  - Regulators costs in the establishment, evaluation and monitoring of the industry stewardship programme for diisocyanates  - Biological monitoring |
| **Answer to specific info request 1:**  If the proposed restriction was adopted, a transitional period of around 5-6 years would be required on the basis of 2-3 years it took the UK Rodenticide Stewardship programme and the 2-3 years for the DCM industry led training scheme to each become established and given that isocyanates are more widely used in a number of different sectors the Diisocyanates Stewardship programme is likely to be much more complex to achieve and hence will take much longer to put in place. |
| **Answer to specific info request 3:**  The UK Control of Substances Hazardous to Health Regulations 2002 (COSHH) 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 HSE MVR SHADS:  - these were awareness raising days rather than formal training days;  - following the SHADs, enforcement inspections were used to support the SHADs and improve the effectiveness the awareness raising campaign;  - the evaluation reports of have been used as references within the DS report  - Voluntary Biological Monitoring (BM) offered as part of the HSE MVR SHADs was also effective and we were able to show significant reductions in exposures.  - Since then promotion of BM has been taken up widely (considering the diversity of the industry) through "best practice" and guidance value drivers rather than compulsion.  Other HSE awareness-raising campaigns for asbestos (targeting tradespeople) and for dermatitis in hairdressers. |
| **Answer to specific info request 4:**  If the question means total DIs < 0.1% then there probably aren't any cases because it probably unlikely that DIs identified in the MSDS as they do not have to list substances <0.1%.  However, if the question relates to monomers/non-monomers then there are lots of examples  o There are lots of MVR sprayers for example that are using spray paints with <0.1% monomer whereas foam manufacturing is mostly monomer-based.  In addition, if the isocyanate is volatile/sprayed then there is always the potential for higher levels of exposure, whereas if it is applied by a non-energetic process then exposure is low if it’s non-volatile. For example, we’ve never been able to measure exposures to MDI provided it was applied by roller and not sprayed; so the control options chosen in the past have always depended on these particular criteria.  o In summary, the focus has usually been on volatility and method of application – low volatility and applied with a roller = unlikely to be a problem, though there may be a potential for uptake if skin exposure occurs. |
| **Answer to specific info request 5:**  As stated in our attached response, based on our experience with DCM and Rodenticide industry stewardship/training schemes to become established (2-3 years each) to the required standards, there will be significant associated costs to MS regulators to assist in the establishment, evaluation and monitoring of the industry led isocyanates training scheme which will be far more complex will be considerably more resources intensive and costly. |
| **Dossier submitter response:**  Thank you for your extensive and critical comments to our proposal.  Regarding “Overarching view”:   1. The issue if REACH or OSH is the better framework to regulate diisocyanates has been discussed vividly. Our position to this issue was reformulated and expressed in Section A2.2.1 of the background document. In the end a political decision needs to be taken if REACH should address this issue as proposed. 2. The DS is a bit puzzled by the indication that the proposal would call for mandatory biomonitoring. Biomonitoring is mentioned at several occasions, but always as support to other measurements or as an offer made. In the meantime the conditions for defining exempted products have been rewritten and no longer include biomonitoring as an option. 3. In the preparation of the dossier the dossier submitter collected literature information and made a survey among EU-MS, described in the dossier. Though incomplete, indications are that the problem of OA because of the use is recognised in all countries. It is beyond our possibilities to differentiate to the level of detail you suggest.   Regarding “2. Economic and Statistical assessment concerns”:  The DS agrees with HSE that there are uncertainties in the estimations of the number of asthma cases. However, the DS cannot see how these uncertainties could be reduced. For example, underreporting is a known substantial issue; however the range of the overall underreporting factor applied in method 1 can only be a pragmatic assumption based on several published considerations. The DS has used three different approaches to estimate the number of cases/the incidence rate and described them transparently in the dossier. Thus it is possible for the ECHA committees to comprehend and discuss the approaches and to adjust values for other calculations if needed. The DS also carried out a sensitivity analysis and presented different scenarios in the SEA part of the dossier, covering the parameters on incidence rates and effectiveness.  In the meantime, additional data were submitted to SEAC that were performed to show the outcome of the analysis with less than the assumed 50 or 70% effectiveness (i.e. reduction in new OA cases). In terms of break-even after max 20 years the proposed model is quite robust, even at a lower % of effectiveness.  Regarding the difference in disability days in various MS: This subject was brought up in the discussions with SEAC as well. A re-assessment of the data showed that the number we have in the dossier is probably on the high side of the range for all EU-MS. However, it could be shown that this only leads to a small overestimation of benefits for avoided OA cases.  The summary of the assessment of alternatives was included in the dossier. The full report was made available to SEAC. It shows that in general industry experts do not consider alternatives that are offered as technically feasible, other than in some niches. Moreover, HH issues are not necessarily reduced (e.g. for epoxy resins). Therefore, it seems of little use to discuss substitution that will not materialise.  Regarding the fact that the workforce was taken as essentially constant over the 20 years period of analysis, this was based on an extrapolation of the figures from the recent past. Workforce was essentially stable, despite an increase in the volume used and increased automation.  Regarding “3. Training duration, frequency, format and associated costs”  Your data on enforcement costs of similar initiatives were read with interest. However, it should be realised that, although significant, these numbers are still small, compared to the other costs we project (which are mainly determined by productivity losses of employees being trained). Moreover, it is not clear if these are true extra costs, or costs because of re-assigning resources.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 3): Thank you for summarising the SHAD initiative in the UK. As the dossier shows, we read the related literature with great interest. We are aware of substantial differences between the HSE campaign and the restriction proposal. However, this was still considered as the closest example available.  To 4)  We would be interested in more data on this subject, because HSE is the only one specifically reporting a risk here.  To 5)  Regarding the costs of compliance under the restriction, in Annex 8 (Appendix 13 – Trainings and Measures) different options for the training format were defined depending on the measure group. This offers the opportunity to choose the training format which fits best to the conditions of a company to reduce work time losses and the administrative burden of the restriction as far as possible. |
| **RAC Rapporteurs comments:**  Thank you for your response to specific questions requested by ECHA and thoroughly elaborated comments.  Following your comments, RAC reconsidered the estimated incidence of diisocyanate-related occupational asthma cases in the EU.  To the RAC opinion, HSE correctly pointed out that the estimate of diisocyanates-related occupational asthma incidence is unlikely to apply only to occupational asthma defined in a narrow sense (i.e. as a disease due to causes and conditions attributable to a particular working environment and not to stimuli encountered outside the workplace), but applies to a wider definition of work-related asthma, encompassing work-aggravated asthma as well. Namely, the Dossier Submitter points out in the Background Document that in the EU context “a case of occupational disease is defined as a case recognised by the national authorities responsible for recognition of occupational diseases”, and uses the term „occupational disease” in “a broader sense to encompass the diseases reported to the different recording and compensation systems of the Member States”. According to EODS Report (European Occupational Diseases Statistics (EODS) Phase 1 Methodology, European Commission 2000), a majority of EU countries stated that the cases with a previously diagnosed non-occupational disease (e.g. asthma) which is later exacerbated by occupational factors are recognised as an occupational disease in their national system, and in none of these countries was possible to differentiate these cases (i.e. work-aggravated disease) from occupational disease in a narrow sense.  RAC recognises that the range of estimates of diisocyanate-related occupational asthma incidence presented by the Dossier Submitter is related to high uncertainties, and is rather wide (from 470 to 10150).  In the first approach, the main uncertainty is a factor of under-reporting of occupational diseases, including asthma, in the EU. Quantitative data on this issue are very limited and are not specifically focused on occupational asthma (European Commission 2013a, reference from the Background Document). Relevant data for only six EU countries were presented in the European Commission (2013a) document (for Hungary, Latvia, Norway, Slovenia, Sweden and UK), showing a range between 40% (UK) to almost 100% (Norway and Slovenia). Also, out of 28 EU countries, 16 countries (57%) provided information on diisocyanate-related asthma incidence. While it could be hypothesised that asthma incidences for the countries that did not provide data are similar to the ones that did, some uncertainty remains, especially due to high variation in incidences between countries (one order of magnitude).  Regarding the other two approaches, several limitations are pointed out by the Dossier Submitter in the Background Document. RAC also agrees with the uncertainties related to these two approaches raised by UK HSE. Nevertheless, RAC points out that due to deficiencies in the reporting system of occupational diseases and uncertainties related to available epidemiological studies, any approach would be just a rough, overall estimate of the real incidence. For example, the range of diisocyanate-related occupational asthma incidence estimated by the Dossier Submitter is supported by a rough estimate performed by the RAC, based on:  • total occupational asthma incidence (of any cause) of 2 to 5 cases per 100 000 workers (data from European Lung White Book, Occupational lung diseases. Gibson JG, Loddenkemper R, Sibille Y, Lundbäck B (eds.) The European Respiratory Society (ERS), 2013);  • 10% percent of occupational asthma related to diisocyanates among total occupational asthma incidence, as an approximate mean value from the data presented in Table 66 of the Background Document;  • range of under-reporting of 50% and 90% (from the available quantitative data for 6 EU Member States; EC Report); and  • employed population in the EU of 220 100 000 (Eurostat 2016).  Calculated values range between 880 and 11 000 cases of diisocyanate-related occupational asthma per year in the EU, with a mean value of approximately 6 000 cases.  Regarding your comment on the risk reduction capacity, RAC is aware of the stated uncertainties, but is also aware that due to the lack of data on training effectiveness in sectors other than MVR (motor vehicle refinish) and countries other than UK, a more precise estimate is hard to achieve. Nevertheless, although data for other health risks and industries show a wide range of effectiveness (from less than 10% to more than 80%, according to the Background Document), several studies with respiratory and skin sensitisers and irritants (showing from 45% to above 60% reduction of skin and respiratory symptoms) indicate that an effectiveness in the range proposed for this restriction is not impossible to achieve. In conclusion, uncertainties regarding the training effectiveness remain but are not likely to be quantified or reduced before the implementation of the proposed restriction.  Other issues raised by HSE:  Regarding other points (in “overarching view”), RAC is in line with the Dossier Submitter’s response. In addition, RAC considers that the UK HSE’s success in implementing improved workplace risk management measures for diisocyanates within the framework of the UK national legislation provides a good example of the efforts undertaken by the UK to reduce the diisocyanate-related occupational asthma incidence. However, similar efforts have been undertaken by only few other European countries (e.g. Denmark and Sweden), calling for a harmonised system, obligatory throughout the EU, to be implemented.  RAC is of the opinion that the issue of work-related diisocyanate asthma is relevant for all EU countries due to the widespread industrial and professional use of diisocyanates and the fact that occupational asthma cases related to exposure to diisocyanates are up to the present day recognised in a majority of EU countries for which data are available (13 out of 16 countries in response to the Dossier Submitter’s request for data). Even for those countries which did not report any case of diisocyanate-related occupational asthma, the incidence might be greater than zero due to the well-recognised fact of under-reporting of occupational diseases.  Regarding the comment on the practicality and enforceability of the proposed restriction, the issues related to these aspects are recognised by different parties and several recommendations, including the participation of the Member States in the approval of the training material developed by industry, are included in the RAC’s opinion. |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  1) We agree that several years will be needed for the full implementation of the proposed restriction. The final decision on the length of the period will be taken on the political level.  3) Thank you very much for the additional information on HSE MVR SHADS.  5) We agree that there would be costs relating to the establishment, evaluation and monitoring of the training scheme that have not been fully assessed in the dossier. However, we note that industry associations support the proposal and have taken responsibility of putting up the training program, therefore the costs to the member states authorities in this regard are expected to be limited.  (ii) We have assessed the suitability of the 50-70% effectiveness estimate carefully. We agree that especially 70% seems high, while 50% seems not to be too overestimated. The Dossier Submitter also made sensitivity analysis assuming effectiveness of 30% during opinion making to support the proportionality assessment. The assumption of a synergistic effect after two training rounds was withdrawn during opinion making.  (iv) As regards the number of days off work, we agree that the information included in the dossier was not representative of the EU wide situation. During opinion making the DS provided more information in this regard and the estimate used was reduced, in order not to overestimate the benefits of the restriction, from 10 to 5 working days a year.  (V) We appreciate your view; however, taking into account the low availability of alternatives overall and that the alternatives available largely have serious health hazards themselves, we found the amount of information provided sufficient to be able to conclude that a full ban of diisocyanates is not a viable option.  (viii) In the absence of information of the expected extent and direction of growth in the labour force in the relevant sectors the assumption of 0 growth provided by the Dossier Submitter was considered the best available estimate. We agree that 20 years is quite a long period. However, a change in the size of the workforce will affect costs and benefits in the same manner (less people to train, smaller population under risk). |
| **1555** | **Date:** 2017/06/20 18:09  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential:** Yes | **Comment:**  We have a note on the trainings planned for the handling of isocyanates.  It is currently planned to carry out the trainings by specialist consultants or authorities. We would prefer it generally if a member of staff can qualify for a course.  This would lead to two important advantages for companies:  1.) Training can be much more flexible and can be started immediately. This offers advantages in terms of possible growth and the training and introduction of new employees.  2.) A constantly present employee who is well trained in the handling of diisocyanates can constantly influence mistakes. Due to the presence in the daily working, he has the opportunity to actively assess the handling of diisocyanates, to identify mistakes and to especially train these aspects. |
| **Dossier submitter response:**  Thank you very much for your comments.  You have commented that a ”train-the-trainer” concept would make the restriction more practical. We agree, in case the trainings are held by a trained worker (Train-the-Trainer concept) immediate feedback can be given to unsafe behaviour. The options defined for implementation of the restriction foresee this option. A further advantage of this option is that the specifics of the workplaces and work processes may be can be taken much better into account than class-room learning. |
| **RAC Rapporteurs comments:**  Thank you for your comments.  RAC refers to the Dossier Submitter´s answer to your comments. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. |
| **1557** | **Date:** 2017/07/04 16:14  **Content:**  Scope or restriction option analysis;  Hazard or exposure;  Information on alternatives;  Other socio economic analysis (SEA) issues;  Transitional period  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** British Coatings Federation  **Org. country:** United Kingdom  **Attachment:** | **Comment:**  Please review the attached document from the BCF |
| **Answer to specific info request 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. |
| **Answer to specific info request 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. |
| **Answer to specific info request 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. |
| **Answer to specific info request 4:**  We have no such knowledge or information |
| **Answer to specific info request 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. |
| **Dossier submitter response:**  Thank you very much for your comments and the willingness to support a possible future introduction.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 3)  As becomes clear from our dossier (Chapters A2 and A3) in the preparation of our dossier and concepts described therein, we have extensively studied the material of HSE. |
| **RAC Rapporteurs comments:**  Thank you for your comments.  RAC agrees with your statement that the appropriate legal instrument for the regulation of occupational health and safety is the EU workplace safety legislation. However, RAC stresses that this restriction proposal builds on the requirements of the OSH legislation to identify a specific set of technical and organisational measures that will result in safer handling practices for diisocyanates across the Member States. The reasons why the REACH legislation might be of benefit in this case have been elaborated in the Background document and in RAC´s opinion.  In addition, RAC points out that a huge effort has been made by the Dossier Submitter to find a way to reduce the number of cases of occupational asthma which still occur (despite the OSH regulation(s)). RAC considers that the aim to reduce the number of cases of work-related occupational asthma can be effectively achieved through this restriction proposal.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  To 2) RAC welcomes your assistance as a trade association in the communication of the requirements of the restriction.  To 3) RAC refers to the Dossier Submitter´s answer to your comment.  To 4 and 5) Noted. |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  We agree that several years will be needed for the full implementation of the proposed restriction. The final decision on the length of the period will be taken on the political level.  We agree that proper enforcement is vital for the effective implementation of this proposal. |
| **1558** | **Date:** 2017/07/05 16:26  **Content:**  Scope or restriction option analysis;  Information on alternatives  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. name:** Swedish Work Environment Authority  **Org. country:** Sweden | **Comment:**  The Swedish Work Environment Authority (SWEA) thinks that it is positive with Germany's proposal for limiting the exposure of diisocyanates through training requirements. Sweden already has similar regulations that are legislated by SWEA, see answer on specific question 3 for more details. SWEA think that the German proposal in one way is too detailed and in another way too general when it comes to what should be included in the education. Based on our experience it is important that the education is adapted to the conditions at the workplace. In Sweden we have requirements that workers learn to handle diisocyanates safely, see answer on specific question 3. The education must be different depending on which industry is covered. The risks are different when you, for example, glue in comparison to when you spray and the users will need totally different training. The proposal propose that the manufacturers should prepare the training material and we are worried that the contents of the training material will be prepared at a very genral level and not specifically addressing all different uses.  The Implementation as well as enforcement of Appendix 8 raises concern. It will be very hard for the inspectors to check all the details described in Appendix 8. SWEA think, based on our experience, that requirements on individual training certificate is crucial for an effective enforcement. When inspectors are visiting working places it is very easy and clear to see if all the employees have a training certificate instead of checking all details that should have been presented at the training.  In Sweden we have an organisation called Prevent, a Scandinavian leading provider of knowledge and training in the field of health and safety. Prevent are a non-profit organisation owned by the Confederation of Swedish Enterprise, the Swedish Trade Union Confederation (LO) and the Council for Negotiation and Co-operation (PTK). Prevent provides education, information and news on health and safety issues. They have produced information materials about safe work with diisocyanates for 6 different sectors and one general information, see: http://www.prevent.se/amnesomrade/kemiska-risker/isocyanater  Some General Swedish Work Environment Authority views  • We support training requirements for limiting the exposure of diisocyanates  • We propose education every 5th year  • We are concerned about the enforceability |
| **Answer to specific info request 3:**  In Sweden, we have had regulations that regulate the use of diisocyanates for more than 20 years. The regulations require training and medical examinations for workers exposed to diisocyanates and their supervisors. The requirement also includes hot jobs that release diisocyanates. The employer is responsible for carrying out the training but the training is usually carried out by expert consultantes for example Prevent. The rules are well known both by employers and by employees in Sweden and have reduced the number of employees receiving asthma at work.  The education shall contain at least information about the risks involved in the work and the risk management measures as required to ensure that the work can be performed safely. Some examples are shown below:  • Basic knowledge about the chemical hazards of the product containing diisocyanater Review of the handling operations that may be risky  • What happens during processing and thermal decomposition  • What protective measures are necessary for safe work  • What kind of ventilation is needed  • In what situations personal protective equipment is needed and what type of personal protective equipment is appropriate.  The trainers should have great knowledge of the regulations on chemical occupational safety hazards and of allergens. The trainers should also have knowledge of working environment regulation and other laws and regulations relating to the chemical field.  Training is required for those workers that actively performs the work and can be exposed to diisocyanates, but also for those that are leading the work. The training must be verified by a traing certificate not more than five years old. This means that a new education must be carried out every five years. Without the certificate the employer are demanded to pay a sanction fee.  The employer shall ensure that periodical medical examinations with an employability assessment are conducted for those employees who are or will be using chemical products containing diisocyanates. The medical examination shall decide if the workers are allowed to work with diisocyanates containing products or not. Employers which allows workers to perform work with diisocynate who do not have employability assessments are demanded to pay a sanction fee.  The medical examination shall be performed before the worker starts the work. Thereafter a new medical examination shall be performed after 3 to 6 month after the work has started. After that the next medical examination shall be performed after 24 month.  Our long experience of these Swedish requirement shows that is has been successful. We think that the re-education every fifth year is often enough. We also think that the medical examination program we have in Sweden is often enough. |
| **Dossier submitter response:**  Thank you for your comments and cautious support for our proposal.  In principle, manufacturers and importers as well as the trade associations of relevant downstream users will be responsible for providing the content for the training material. The involvement of the different trade associations shall ensure that the training material is adequately designed to the special needs of the workforce. It is envisaged to work out several modules which can be used at different work environments to address specific situations.  Your point of concentrating enforcement on checking the availability of a training certificate instead of checking all the details is well taken.  The four year repeat cycle in our proposal was chosen to reach an optimum between the need to repeat instructions to reach sustainable results and the practicality of setting up a training system and related infrastructure. Taking into account experiences from existing OSH training schemes e.g. on asbestos (6 years) and thermoset resins (SE, 5 years) and yearly instructions on hazardous goods (in DE) we decided to take 4 years as a reasonable compromise. |
| **RAC Rapporteurs comments:**  Thank you for your comments, for your detailed information on the obligations related to isocyanates in Sweden and your general support.  RAC has revised the conditions of the restriction proposal (including the appendices) - the revised conditions are included in the opinion. Thank you for the advice.  RAC acknowledges that the enforcement of the restriction presents some challenges. Particularly the inspection of the implementation of the appropriate technical risk management measures requires a special knowledge of occupational hygiene.  RAC supports your comments regarding training.  RAC also refers to the Dossier Submitter´s answer to your comments. |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  We regard that the proposal entails different training materials for different types of uses.  Thank you for the information on national regulation in Sweden. We have taken into account the existence of specific training in Sweden when writing the opinion. |
| **1565** | **Date:** 2017/07/24 13:49  **Content:**  Hazard or exposure;Transitional period  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** German Paint and Printing Ink Association (VdL)  **Org. country:** Germany | **Comment:**  Introduction  The German manufacturers of paints, coatings and inks, as represented by VdL, welcomes the opportunity to comment on the recently-published REACH Restriction dossier, as prepared by the German authorities. We confirm, through this statement, that certain products manufactured by our members for specific industrial sectors (e.g. 2-pack polyurethane topcoats for vehicle refinishing) are likely to fall within the current scope of this proposal. We would also like to mention that VdL has been a participant in the PU Exchange Forum (under the manufacturers ISOPA/ALIPA lead).  We would like to confirm the following points related to the proposed restriction for di-isocyanate use, and the dossier covering this proposal:  1. VdL supports a restriction approach to managing the risks associated with di-isocyanates, and improving the awareness of workers who use products based on these substances.  2. We believe that this approach is reasonable, and can be successfully implemented across the EU (despite the scale of training required) in order to address the concerns over the incidence of occupational asthma related to the misuse of di-isocyanate-based products, and hence reduce such occurrences.  3. This approach will allow the continued safe professional and industrial use of our products based on di-isocyanates (polyurethane coatings and printing inks), many of which are essential for the protection and decoration of metal, plastic, glass and wood surfaces for several key sectors, including cars, ships, aeroplanes, furniture, flooring & infrastructure.  4. 2-pack polyurethane coatings are used in certain specific sectors, either industrially or by professional users, often applied by spray application methods that require Personal Protective Equipment (PPE).  5. There are several key uses for this technology where there are no adequate alternative technologies available, especially polyurethane-based topcoats for exterior weather protection (light-fastness, clarity, corrosion & scratch resistance and durability).  6. Only certain di-isocyanates mentioned in the dossier are used for coating or ink applications, not all of them are relevant to our sector.  7. Some of our members’ polyurethane product lines will fall outside of the scope of the proposal, where these products contain less than 0.1% free di-isocyanatemonomer. Despite this, our members will continue to provide safe use information for these products, stipulating the required PPE for their use in Safety Data Sheets (SDS), as has been done for many years.  8. Di-isocyanates are also used for the manufacturing of polyurethane binders or PU dispersions which are essential commonly used raw materials for high performance coatings.  Comments on Mandatory Training  1. We acknowledge that there is a challenge to providing training on such a scale, to cover all EU workers who may be exposed to products within the dossier’s scope. However, we believe that, with sufficient support from the authorities, commitment from industry bodies and companies, and an appropriate transition period, this is achievable, and will ensure the introduction of changes in use behaviour where these are needed to safeguard workers’ health.  2. Training approach has already been proven to work, to reduce the cases of occupational asthma. A four-fold reduction in cases in the UK during the ten-year period 2004 to 2014, was achieved as a result of the focussed efforts of the UK’s Health & Safety Executive, with very active support from the coating industry trade association BCF, on the safe use of 2-pack polyurethane spray coatings in the vehicle refinish sector1  3. Legal responsibility for the training of personnel using products resides with their employers, under national worker legislation. No other parties may be held responsible for providing the actual training.  4. We are in close contact with associations and organisations representing our members’ customer base and downstream users of di-isocyanate-based coatings and inks, to discuss and identify training requirements.  5. We fully agree with the proposal that our sector may provide appropriate training content (on request) to those manufacturers/importers who shall prepare the training programme (training material, translations, etc.), so that we can share our knowledge and expertise with regard to our products, and provide recommendations regarding their correct and safe use under normal conditions. Our sector should not be legally or financially responsible for the overall training programme or final content contained therein, except where specific additional modules (parts of the training material) would be developed for certain of our uses.  6. Many of our members already provide information on safe handling of hazardous products to their customers, including hazards associated with di-isocyanates, and stipulating the correct PPE to use (including e.g. air-fed breathing apparatus)  7. There is already significant basic worker training readily available, for applying di-isocyanate-based products by spray application safely, from both National authorities (Denmark, UK and Sweden) and from training organisations and tradeassociations. Any new training programme should be built around this existing knowledge and best practice. Existing national programmes that meet the training requirements of the final restriction should be allowed to continue to be used.  8. Training should be, where possible, provided through an e-learning / distance learning approach for all levels to ease the accessibility, interest and better control of multi-lingual content (e.g. it solves the problem of foreign workers not being familiar with local language).  9. Any enforcement activities including compliance check should not move to the supply chain but remain the responsibility of the national authorities. Different situations can be illustrated as follows: - a coating manufacturer, in addition to his responsibility of employer for his worker, will have to demonstrate upon request of enforcement Authorities that he has communicated the obligation to have a training to his customers and where to find the training material. - in the case of an industrial plant where workers applying the coatings are under the responsibility of his employer, it should be the responsibility of the latter to maintain record of successful training of his employees. The enforcement Authorities are able to check at the employer level. - in the case of the use of a contracting company for the application of PU coatings on a certain building site, the knowledge of the risk resulting from the application of these coatings is with the contracting company, which should inform the site management in order to take appropriate protective measures (such as for bystanders). The enforcement Authorities can check both the contracting company for the completion of the trainings and the building site for the implementation of the appropriate protective measures. - in the case of small companies that can be a self-employed person or a small number of employees the local Authority should check the proof of training participation at the place of use of the coating.  10. Training material should be disseminated through web-links / sites, such as those associated with the relevant trade associations where available, or through EU or national authorities’ website. The information that workers should be trained should be included in SDSs with a reference of such website(s). This should be made freely-available and easily-accessible to those organisations who need to train their employees. Any barrier to access the training material would go against the objective of effective implementation of this Restriction.  11. Bureaucracy surrounding the provision of training and ensuring that the restriction is being successfully implemented should be kept to an absolute minimum, although we acknowledge that some kind of documentation will be needed to record the names of those who have successfully completed the training.  12. A transition period will be needed due to the high expected number of workers to be trained (the number of professionals that will need training in our sector is estimated to be in the hundreds of thousands), after the trainers are themselves identified and trained, and after the training material is ready, translated and disseminated. For the sake of level playing field it is not desirable to select some countries to start first.  13. In addition to the communication of the training obligation brought by SDSs, our members aim at pro-actively inform their customers. |
| **Answer to specific info request 1:**  5-7 years |
| **Answer to specific info request 2:**  comment in the SDS |
| **Answer to specific info request 4:**  No I have not. |
| **Answer to specific info request 5:**  It would have an immens affect on our member companies, because we think that thousands of people have to be trained. |
| **Dossier submitter response:**  Thank you for your comments and the support for our proposal.  To comment 7)  Existing material can be brought into the preparation of the proposed training.  To comment 8)  The restriction as proposed allows for a range of training options, suiting work schedule and economic considerations also for small firms. For “Measure Group 1” this also includes e-learning. Training is foreseen to be done in the local language.  To comment 9)  Enforcement itself (checking for compliance and issuing any sanctions) will remain in the hands of national authorities. However, it may be the responsibility of a supplier to ask for information of his customer, if the necessary trainings have been completed. This is especially important when dealing with SMEs and self employed workers as end users.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion. |
| **RAC Rapporteurs comments:**  Thank you for your comments, for your very detailed information and for your support.  RAC notes that enforcement is a governmental task.  RAC welcomes your offer to provide information about your sector with regard to the development of the training material.  RAC notes that the communication of the requirements of the restriction has to start at the top of the supply chain.  RAC appreciates the efforts of your members to inform their customers about the requirements of the restriction pro-actively.  RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is a political decision in the end.  RAC also refers to the Dossier Submitter´s answers to your comments. |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  We agree that bureaucracy surrounding the provisions should be kept as low as possible.  We agree that several years will be needed for the full implementation of the proposed restriction, but the final decision on this will be taken on political level. |
| **1568** | **Date:** 2017/07/25 08:32  **Content:**  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential:** Yes | **Comment:**  - |
| **Answer to specific info request 1:**  A minimum of 5 years will be required for the development of a training system.  Following the set-up of a functioning training system, an additional 2-year transition period will be required in order to successively train all concerned employees of the company. The training capacity of a company is based on the assumption that employees have to be trained upon taking up their assigned function, and then go through recurring training every 4 years. Should all employees of a company need to be trained within a 2-year period, then the training capacity must be twice as high as would be required under normal operational conditions. The provision of such capacities represents a challenge; a further reduction in the transition period will not be sustainable for a company due to the limitations in staff and organisational resources. |
| **Answer to specific info request 2:**  The industrial manufacturers of rigid PU insulants are organised in associations which can support their members in the implementation of training programmes. Branches with mostly smaller and craftsman-type operations still require support through government agencies, trade associations, the Chamber of Handicrafts etc. |
| **Answer to specific info request 3:**  The training sessions should preferably take place at the place of employment. For employees carrying out simple tasks, shorter and more frequent training sessions have proven more effective than classroom instruction lasting several hours. Shorter and repeated instruction sessions at the job site are more effective, as long as the workers‘ability to concentrate isn’t yet diminished. Training sessions exceeding one hour are ineffective in our experience.  The trainer should gear the content of his sessions individually to the workplace and be allowed to leave out content not relevant to that position. The focus must be the specific working environment. The content of the training sessions should be compressed to allow them to be taught over two hours in total (Scheme 1) or four hours in total (Scheme 2).  Good experience was gained with “basic instruction“ sessions lasting approximately one hour prior to taking up the position. Over time further position-related training sessions were held (“on-the-job training“).  Web-based training is a very effective option, since it is interactive and gives the participant immediate feedback. |
| **Answer to specific info request 4:**  No, such cases have not been reported. |
| **Answer to specific info request 5:**  The training programme causes less flexibility in temporary placements or reshuffles. Temporary workers or temporary holiday replacements that are short-term by nature must still first be trained, and can only be available to carry out the tasks after a certain period of time. Basic instruction provided by the company’s own trainers (“train the trainer“-concept), followed by short supplemental training sessions are the only practicable form of training for temporary workers or replacements. External training is not an option for temporary or replacement workers.  Training sessions and examinations should always be carried out in-house. It is the only way to make sure that company-specific conditions are taken into account.  The trainer has to make sure that the trainee manages the exam task on his/her own. The trainee must certify with his/her signature that the examination was completed independently according to the examination rules. A comparable procedure , e.g. for a Master’s thesis, is considered sufficient.  Training costs (loss of working hours and trainer’s pay) run up to approx. € 950 per employee and year.  Much higher costs are caused by the shut-down of the production lines, as production must be interrupted during training sessions. The stoppage of one or more shifts will lead to capacity restrictions and turnover losses.  A three-shift system requires training of 3 operator groups. During the training session, the production lines must be shut down with no production possible. Because of holidays and sick leave, it is usually not possible to train an entire operator group on the same date, making it necessary to arrange for two training dates. Consequently, the production lines will be shut down for six shifts. At around 600 shifts per year, this translates into a turnover loss of 1%. At a total turnover in the branch of 1bn, the annual loss amounts to 10m.  The intended training programme does not provide additional benefit, since the already existing training programmes completely fulfill their purpose. In companies that continually produce rigid PU insulants or block foam under industrial conditions, no illnesses from MDI have come up. |
| **Dossier submitter response:**  Thank you for your comments regarding our proposal.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 5)  The training length provided for the different training modules gives an estimate for the time needed to cover all topics and to conduct the exercises. The estimated training length of the different training modules is based on discussions with experts from industry and trade association of professional users. We do not think that the learning goals can be reached in a significantly shorter time.  In our opinion the proposed options to implement trainings are sufficiently flexible to adopt a scheme spread over time that optimally fits a company, without a need for total production stops.  In case you decide to run the trainings at the workplace, and for Measure Group 1 implement e-learning for some of the modules there would be, of course, more flexibility. However, documentation should be provided that shows that the total time will sum up to the required training length and cover the required topics.  We do not see the need to make a difference between temporary and permanent workers as far a training needs are concerned. Such needs should be considered in the assignment of tasks to such employees. |
| **RAC Rapporteurs comments:**  Thank you for your comments as well as for your answers to the specific information requests.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  To 2) Thank you for the offer to support users in implementing training programmes. RAC is aware of the fact that SMEs will require specific support through governmental agencies, chambers, trade associations, etc.  To 3) RAC agrees with your proposal regarding training (e.g. the training should preferably be conducted at the workplace itself). However, RAC is aware of the fact that this might not be possible in each case.  To 4) Noted.  To 5) RAC refers to the Dossier Submitter´s answer to your comment. |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  We agree that several years will be needed for the full implementation of the proposed restriction. The final decision on the length of the period will be taken on the political level.  We also agree that training sessions should preferably take place at the place of employment, however, we note that this might not always be possible in practice (at least it is not expected to be the least-cost option in certain cases). |
| **1570** | **Date:** 2017/07/25 17:45  **Content:**  Scope or restriction option analysis;  Hazard or exposure;  Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** CEPE  **Org. country:** Belgium  **Attachment:** | **Comment:**  Our position is explained in the submitted document |
| **Answer to specific info request 1:**  Our position is explained in the submitted document |
| **Answer to specific info request 2:**  Our position is explained in the submitted document |
| **Answer to specific info request 3:**  Our position is explained in the submitted document |
| **Answer to specific info request 5:**  Our position is explained in the submitted document |
| **Dossier submitter response:**  Thank you very much for your comments and your support of the restriction proposal.  You have commented that the national training programs covering the mandatory requirements should be allowed to continue. A combination of other existing training schemes, OSH trainings etc. with the mandatory trainings would be possible, and thus increase the practicability of the restriction.  You have proposed e-learning / distance learning as an effective option. In Annex 8 (Appendix 13 – Trainings and Measures) e-learning is foreseen as a possible training format for the defined measure group 1.  The distribution of information about the requirements of the restriction shall preferably be done via the trade associations of relevant downstream industrial and professional users. In addition, it is foreseen that the network of European and national industry shall contribute to the preparation of training contents. In principle, the training material will be distributed by a non-commercial platform, and shall be made available for free. But, training centres which will use the material commercially and companies that are not a member of a trade association may be requested to contribute to the production costs by paying a moderate fee.  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion. |
| **RAC Rapporteurs comments:**  Thank you for your comments, your advice and your support for the restriction proposal.  RAC refers to the Dossier Submitter´s answers to your comments. |
| **SEAC Rapporteurs comments:**  Thank you for your comments.  We agree that bureaucracy surrounding the provisions should be kept as low as possible.  We agree that several years will be needed for the full implementation of the proposed restriction, but the final decision on this will be taken on political level. |
| **1572** | **Date:** 2017/07/27 14:38  **Content:**  Scope or restriction option analysis  **Type:** MemberState  **Country:**  Ireland | **Comment:**  See information supplied below under Q3 - examples of training methods |
| **Answer to specific info request 3:**  The Irish Health and Safety Authority offer free online chemical safety courses. https://hsalearning.ie/mod/page/view.php?id=249  hsalearning.ie is an educational platform consisting of a range of free online health and safety courses. All of the courses have been developed by the Health and Safety Authority with the aim of improving awareness of workplace safety, health and welfare. The self-directed courses give learners the flexibility to choose a course, and to study it in their own time and pace. On successful completion of a course, learners can download a certificate of completion. This certificate is confirmation that they have completed an awareness raising course. It is not a qualification but may be used for training record purposes in work or education. The use of web based training/awareness with evaluation and certification may be suitable for specific lower risk categories under this restriction.  International Occupational Hygiene Courses  Occupational hygienists currently undertake internationally accredited occupational hygiene training through the OH learning network supported by the International Occupational Hygiene Association. This training network may provide an opportunity to ensure those providing advanced training under this restriction are trained to a recognized standard with support from manufacturers in developing appropriate training materials. http://www.ohlearning.com/default.aspx  Safe Pass  Safe Pass is a construction safety initiative in place in Ireland since 2000. It is a one day course for workers in the construction industry to raise the standard of safety awareness in the construction industry with the consequent aim of lowering risks associated with construction work. Participants undertake a one-day classroom based training course followed by an examination of comprehension. Participants are then issued with a Safe Pass card which is mandatory for work on any construction site. Further details are available at http://www.solas.ie/Pages/Safepass.aspx |
| **Dossier submitter response:**  Thank you for the comments to our proposal.  To 3)  The restriction as proposed allows for a range of training options, suiting work schedule and economic considerations also for small firms. For “Measure Group 1” (the lowest risk group in the scope of the restriction) this also includes e-learning. |
| **RAC Rapporteurs comments:**  Thank you for your comments regarding training methods.  To 3) Thank you for the interesting information. It is noted.  RAC also refers to the Dossier Submitter´s answer to your comments. |
| **SEAC Rapporteurs comments:**  Thank you for providing us with information on different types of training alternatives. We believe that this information will help organizers of diisocyanates training, when deciding on the most cost effective training methods. |
| **1580** | **Date:** 2017/08/10 11:16  **Content:**  Scope or restriction option analysis;  Information on costs;  Information on benefits;  Other socio economic analysis (SEA) issues;  Transitional period  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** Stockmeier Urethanes GmbH  **Org. country:** Germany  **Attachment:**  <redacted>  **Privacy comment:** These files are the property of our company and therefore should be considered as confidential.  By submitting isocyanate measurement protocols we will demonstrate that risks of exposure can be adequately controlled by suitable suction/ventilation measures. The found levels of isocyanates are extremely low. Further regulation is not required in our view. | **Comment:**  We support the positions of ISOPA / ALIPA. We strongly support the implementation of an e-learning tool.  The restriction proposal will seriously affect our company and all our customers, most of which are SMEs. SMEs and self employed persons will face very serious challenges. The costs for implementing the proposed training and documentation measures are high. The transition period should therefore be at least 6 years, before the restriction enters into full force.  It should be considered to exempt warehouse workers (loading, unloading) from all training measures, as risk of exposure is very low. In the event of a spill, other (trained) personnel can perform the required tasks.  The “hard” evaluation of the training (>70% success rate in test) should be omitted. What should be done with employees, who (repeatedly) fail the test? A “soft” evaluation scheme (meetings, talks with employees, who have problems) should be implemented instead.  Measures group 1: The medical examination should be performed every 2 years (not yearly), as is required in Germany (G27 examination). It will not be possible to create written instructions for every little task carried out e.g. in the lab, in the production, in the warehouse. Such documentation would be excessive.  The topic “chemistry” should be omitted from the training scheme. Workers are not interested in chemical details. The focus should lie on hazards and their prevention.  We agree with CECED that the following action should be taken:  In our opinion, the following statement: Member States may implement or continue to apply own practices for the use of these substances and mixtures as long as the minimum requirements of Appendix N are met, would leave room for each Member State to establish additional national requirements, thus challenging the organisational and technical requirements pursuant to Appendix on Training and Measures, and raising the compliance and administrative burden for companies.  If additional requirements should be considered by any Member State, they should be integrated into the legal specifications of the restriction under REACH in order to ensure harmonised conditions across the EU.  We would therefore like to request for the deletion of this clause in the legal text of the restriction. |
| **Answer to specific info request 1:**  At least 6 years to implement the extensive training and documentation scheme. We support the positions of ISOPA / ALIPA. |
| **Answer to specific info request 2:**  We support the positions of ISOPA / ALIPA. |
| **Answer to specific info request 3:**  We support the positions of ISOPA / ALIPA. |
| **Answer to specific info request 4:**  We have no information that such health cases occured. |
| **Answer to specific info request 5:**  a) The loss of employee time as well as the organizational efforts to be taken will seriously affect our company. E.g. organizing additional training sessions for ill employees or employees on vacation. Also the lost time and efforts for documenting this are very costly. We strongly support the implementation of an e-learning module.  b) no |
| **Dossier submitter response:**  Thank you for the comments to our proposal.  Your comments on preferred changes in the wording and in the topics of the curriculum are noted.  Regarding the topic “chemistry” – this was meant as a general placeholder that can be tuned to the audience for details. As a minimum, some workers will already have sufficient information if the concepts of reactive resins, hardeners and cure time are introduced. Higher level workers may need some more chemical details.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 5)  Regarding the costs of compliance under the restriction, in Annex 8 (Appendix 13 – Trainings and Measures) different options for the training format were defined depending on the measure group. This offers the opportunity to choose the training format which fits best to the conditions of your company to reduce work time losses and the administrative burden of the restriction as far as possible.  The restriction as proposed allows for a range of training options, suiting work schedule and economic considerations also for small firms. For “Measure Group 1” (the lowest risk group in the scope of the restriction) this also includes e-learning. |
| **RAC Rapporteurs comments:**  Thank you for your comments and your support for the restriction proposal.  RAC notes that if someone fails the exam, there is a possibility to repeat it without any limits. However, RAC considers that workers or self-employed workers who are not able to pass the exam after several attempts should not be allowed to work with hazardous substances (e.g. diisocyanates) as they might not be able to take the care needed to appropriately protect themselves.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  RAC welcomes the idea on the incentive to early training and the idea of a pilot project. However, it might not be easy to find a structured way to implement these ideas.  To 2) RAC points out that improvements regarding the documentation in safety data sheets are important as not all companies have fulfilled the requirements in the past (e.g. detailed information on the appropriate PPE (if needed) is sometimes lacking).  RAC notes that a well-functioning communication along the supply chain is needed for the restriction to achieve its goals (i.e. the safe handling of diisocyanates and the reduction of cases of occupational asthma)  To 3 and 4) Noted.  To 5) RAC refers to the Dossier Submitter´s answer to your comments. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. SEAC considers that e-learning is an acceptable training option in some situations but it has its limitations, therefore it has not been considered adequate for the intermediate and advanced level training. The requirement of a test at the end of the training session would definitely act as an additional motivator and as such improve the level of knowledge achieved; hence we find this requirement necessary for the appropriate implementation of the proposed restriction.  We agree that several years will be needed for the full implementation of the proposed restriction. The final decision on the length of the period will be taken on the political level. |
| **1620** | **Date:** 2017/09/05 18:02  **Content:**  Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Germany  **Company name confidential: Yes** | **Comment:**  <redacted> is a manufacturer of printing inks and auxiliaries. Some of the hardeners we provide for our inks contain residual traces of momomeric diisocyanates. We support the approach to achieve appropriate managing of the risk associated with diisocyanates by training, as according to our experience this approach can lead to the intented aim. Following a German legal requirement those persons within our company handling hazardous chemicals are instructed how to handle them safely once a year. Since at least 30 years none of our workers suffered adverse health effects related to isocyanates, like skin or respiratory sensitization. We assume that our customers do similar instructions for their workers, based on the information on hazards associated with diisocyanates and on correct PPE (including air-fed breathing apparatus in case of spraying and also with other operations if OELs are exceeded) we provide in our SDS for those products. The employer is responsible for workers‘ training/instruction – and this should remain as it is. Concerning the set of training material to be developped by the M/I of diisocyanates, this should be disseminated through web-links/sites, for example on the M/I’s website, and/or websites of concerned trade associations, and/or websites of EU or national authorities, in different languages. The training itself may also be provided through e-learning in different languages, thus giving „foreign“ workers the opporunity to get the necessary information in their mother language. Enforcement activities including compliance check should stay with the national authorities and not be passed on to the supply chain. Demonstrating that we have informed our customers buying our isocyanate hardeners on their duty to train their workers handling those hardeners, and how they can access the training material, should not be required by our raw material supplier, but by the relevant authorities. However, bureaucracy related to the provision of the training and ensuring implementation of the restriction should be as low as possible. A transition period for implementation will be necessary, as it will foreseeably take some time until the training material will have been put together by the M/I and then be passed on through the supply chain. |
| **Answer to specific info request 1:**  3 years |
| **Answer to specific info request 2:**  SDS |
| **Answer to specific info request 3:**  Instruction on safe handling once a year resulted in no adverse effect case within 30 years in our company |
| **Answer to specific info request 5:**  a) Loss of employee-time, as this training is additional to the already legally required yearly safety instruction  b) no |
| **Dossier submitter response:**  Thank you very much for your comments and support for our proposal.  Enforcement itself (checking for compliance and issuing any sanctions) will remain in the hands of national authorities. However, it may be the responsibility of a supplier to ask for information of his customer, if the necessary trainings have been completed. This is especially important when dealing with SMEs and self employed workers as end users.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 5)  Regarding the costs of compliance under the restriction, in Annex 8 (Appendix 13 – Trainings and Measures) different options for the training format were defined depending on the measure group. This offers the opportunity to choose the training format which fits best to the conditions of your company to reduce work time losses and the administrative burden of the restriction as far as possible.  The restriction as proposed allows for a range of training options, suiting work schedule and economic considerations also for small firms. For “Measure Group 1” (the lowest risk group in the scope of the restriction) this includes e-learning as well. |
| **RAC Rapporteurs comments:**  Thank you for your comments, your advice and your support for the restriction proposal.  RAC notes that enforcement is a governmental task and will remain in the hands of national authorities. However, RAC stresses that it will be the responsibility of a supplier to inform their customers about the requirements of the restricition once it enters into force.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  To 2 and 3) Noted.  To 5) RAC refers to the Dossier Submitter´s answer to your comment. |
| **SEAC Rapporteurs comments:**  Thank you for your comments and willingness to participate proactively in the dissemination of the training material.  We understand that not every company has encountered adverse health effects due to exposure to diisocyanates, however, this is obviously not the case everywhere in view of the reported number of occupational asthma cases. We agree that training should be organized in an effective way and that bureaucracy should be as low as possible.  We presume that several years will be needed for the full implementation of the proposed restriction. The final decision on the length of the period will be taken on the political level. |
| **1646** | **Date:** 2017/09/12 18:20  **Content:**  Information on costs;  Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Bundesverband Medizintechnologie e.V. (BVMed)  **Org. country:** Germany | **Comment:**  BVMed represents manufacturers of medical devices covering a very wide range of products such as single-use sterile devices, catheters, dialyzers and implants. Relevant uses of diisocyanates in the medical device sector include polyurethane applications, adhesives and sealants. In general, the definition of OHS requirements to control related risks in the use of isocyanates is appreciated. Nevertheless, proportionality and cost-benefit ratio of the current restriction are impaired by the very detailed and inflexible training provisions. A much smaller and more flexible requirement for training of concerned employees is needed, taking into account that  - The estimated personnel costs are not representative (too low) for the medtech sector.  - The strict, inflexible training requirements cause significant costs in concerned production sites for medical devices (e.g. several man years even for low and medium risk groups at a single location).  - 4 to 12 hours training sessions for all employees cause organisational constraints in case of continuous shift operations (24/24, 7/7), i.e. a full stop of such production.  - Existing OHS legislation already applies and requires adequate training of concerned staff.  - Concerned staff in medtech production is well qualified and performs very specific tasks. Even if some additional information/training on isocyanates might be helpful, this would not require 4 to 12 hours additional training.  - The training frequency required by the restriction proposal (each 4 years) is not consistent with applicable OHS legislation, which requires annual safety instructions. |
| **Answer to specific info request 1:**  The exact time needed for implementation depends on the concrete requirements. Due to the mentioned need for modification, especially of the training provisions, no exact time frame can be given.  In any case, transitional periods of more than 2 years would facilitate effective and efficient implementation of in-house training concepts that are adopted to the concerned individual workplaces. |
| **Answer to specific info request 3:**  Content, length and frequency of the training should be adopted to the concerned workplaces. Lengthy training sessions, training of irrelevant topics and doublicated training, which are needed for formal reasons only, can be counterproductive with regard to the training effectiveness and employees’ motivation and should be avoided. See Q5 for further details/concerns. |
| **Answer to specific info request 4:**  No such case known to us. |
| **Answer to specific info request 5:**  Relevant uses in the medical device sector e.g. include polyurethane applications, adhesives and sealants. An assessment by a member company identified unproportionally high training efforts (several man years even for low and medium risk groups) and constraints at concerned production sites. This is mainly caused by the extensive, inflexible training requirements defined by the proposed restriction:  - The proposal leads to organisational constraints in case of continuous shift operations (24/24, 7/7) as 4 to 12 hours training sessions for all employees would cause a full stop of such production.  - Existing OHS legislation already applies and requires adequate training of concerned staff.  - Concerned staff in medtech production is well qualified and performs very specific tasks. Even if some additional information/training on isocyanates might be helpful, this would not require 4 to 12 hours additional training.  - The frequency (each 4 years) is not consistent with applicable OHS legislation (annual safety instructions) and increases the training effort without having a positive effect on training results or occupational safety (see Q3).  The decribed efforts, inconsistencies and contraints do not increase safety and risk control. Thus smaller, more flexible training provisions should be defined in the restriction entry. |
| **Dossier submitter response:**  Thank you very much for your comments.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 3 and 5)  Regarding the costs of compliance under the restriction, in Annex 8 (Appendix 13 – Trainings and Measures) different options for the training format were defined depending on the measure group. This offers the opportunity to choose the training format which fits best to the conditions of your company to reduce work time losses and the administrative burden of the restriction as far as possible. Furthermore a combination of other existing OSH trainings with the mandatory trainings will be possible, and thus increase the practicability of the restriction. |
| **RAC Rapporteurs comments:**  Thank you for your comments.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  To 3 and 5) RAC refers to the Dossier Submitter´s answers to your comments. However, RAC stresses that RAC does not agree that the restriction proposal requires disproportionally high training efforts.  To 4) Noted. |
| **SEAC Rapporteurs comments:**  Thank you for your contribution!  We note your statement that the estimated personnel costs are not representative for the medtech sector. Specific information and analysis on the level of such costs (and if relevant the respective benefits) in this sector would be necessary to be able to in detail assess the possible consequences and draw conclusions.  We agree that several years will be needed for the full implementation of the proposed restriction, but the final decision on this will be taken on political level. |
| **1649** | **Date:** 2017/09/18 11:39  **Content:**  Information on costs;  Information on benefits;  Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Other contributor  **Org. name:** Bundesverband Farbe Gestaltung Bautenschutz (The Federal Association for Paint, Design and Building Protection,  **Org. country:** Germany | **Comment:**  General Comments:  The proposed training measures for handling diisocyanates need adaption for the different types of users (qualified by vocational training /not qualified) and their professional background. The extensive training program makes sense, if users have no professional qualification in handling coating materials and the specific application techniques.  The professional painter and automotive painter is informed about possible dangers and the necessary health and safety measures on the basis of the required risk assessment and the accompanying operating instructions. The use of PPE is a matter of course for e.g. professional automotive painters when doing spray application.  The regulated 3 year education of a craftsman like the painter and varnisher covers most of the topics, which the restriction proposal intends to train.  It is necessary to check whether a repetition of the training for qualified users is necessary at all, since a yearly instruction for employees on the handling of hazardous substances is mandatory by the Ordinance on Hazardous Substances anyway. |
| **Answer to specific info request 1:**  We refer to the typical applications of painters and varnishers (mostly brush, roller, spray application), no priorities in geographic regions can be specified.  Approximately 41000 professional painting companies, recorded in the register of skilled crafts and trades, are possibly using materials containing diisocyanates. Every painting company has in average 5-6 employees.  The transition period depends on the amount of necessary training measures. An addidional training as described and demanded in the restriction proposal is not necessary for these skilled painters and varnishers as well as automotive painters.  Employees without the vocational qualification mentioned above may require the proposed trainings.  Therefore a transition period of 3 years should be appropriate.  Explanatory statement:  Painters and varnishers / automotive painters in Germany have passed at least a 3 year vocational training. Master craftsman and firm owners usually need another 1-2 years. During this time, the use of two component coating materials is also trained, which naturally includes training in occupational health and safety.  In Germany, company owners are legally obliged to implement the health and safety at work in their company. For example, if the firm owner of a small company does not employ a work safety specialist, he has to attend at least every 5 years trainings himself. At least once a year, the firm owner has to instruct all employees in safe handling of hazardous materials.  This includes instruction in the safe handling of 2 pack materials like diisocyanates too, especially when products are applied by spraying.  Therefore, we do not see the need for an additional (practical) training for dealing with personal protective equipment for qualified painters and varnishers and automotive painters.  For workers without these qualifications, training as described in the proposed restriction (Annex 13) may be useful. |
| **Answer to specific info request 2:**  The most effective way to pass the restricted usage requirements is to inform the user by the supplier when purchasing the product. This should the obligatory way be. National authorities must ensure that these requirements are communicated through the supply chain and the products are sold only to a qualified person. Corresponding notes must be given on the packaging and data sheets.  In addition, companies are informed about the restriction by their statutory accident insurance.  Information on the restriction can also be effectively communicated by the craftsman’s associations or the chamber of crafts, who regularly inform their members over new developments. This could be an optional way of communication. |
| **Answer to specific info request 3:**  So far, we have had no experience with single substance-related trainings. They were not necessary because of the vocational training.  Voluntary trainings for renovation of mould infested buildings as well as the training of expert knowledge for maintaining asbestos cement products are successfully carried out by Germany’s painter associations. The training method is classical classroom training. The training courses ends with an examination leading to a certificate. Effectivity could be proven over the examination results.  For the here intended training, including awareness raising and training of mostly theoretical topics, e- learning seems to be the appropriate method. |
| **Answer to specific info request 5:**  a. what would be the most important cost to your company from the proposed training program – the €-cost of training, loss of employee time, else?  Given the current proposal of appendix 13, where application with brush, roller or spray application requires a group 2 training of 8 h, costs and loss of employee time are:  The painting companies in Germany employ in average 5 painters, who will all need the training program. Usually the whole staff will need the training program of group 2, i.e. in average a total of 40 hours of training. This will lead to an outage time of in sum 5 working days where no customers´ orders can be accepted.  On the assumption of an hourly turnover of the painter / automotive painter of approximately 70/80 € this will lead to a loss of turnover of about 3000 €.  Assuming hourly turnover of 70 € (netto) this will lead to a revenue los of approximately 3000 € for an average painting company.If a group 3 training is required the deficiency amounts to 4500 €.  b. would the training program benefit your company in other ways besides potential improvements in worker health, such as improved productivity/working methods?  No, as the three-year education of painters in Germany includes the handling of hazardous materials as well as the use of PPE anyway. The statutory provisions on occupational health and safety, such as the Ordinance on Hazardous Substances, oblige the firm owner to carry out regular trainings and instructions of his employees.  Therefore the benefit for the painting and automotive painting companies is considered to be negligible. |
| **Dossier submitter response:**  Thank you very much for your comments.  To 5)  Regarding the costs of compliance under the restriction, in Annex 8 (Appendix 13 – Trainings and Measures) different options for the training format were defined depending on the measure group. This offers the opportunity to choose the training format which fits best to the conditions of your company to reduce work time losses and the administrative burden of the restriction as far as possible. For “Measure Group 1” (the lowest risk group in the scope of the restriction) this includes e-learning as well.  The proposed concept does not prevent to combine the necessary trainings with other vocational or technical trainings. However in order to reach sustainable results, regular repeats will necessary. This goes beyond the yearly general OSH required instructions. |
| **RAC Rapporteurs comments:**  Thank you for your comments and your advice.  RAC agrees that there is a need for different type of trainings for different types of users (qualified/not qualified). RAC notes that this fact should be covered by industry which elaborates the training material and the training content.  RAC does not support the statement that skilled painters (incl. automotive painters) and varnishers do not need further training. There are data on occupational asthma of painters/varnishers at least in Austria, but the same might be valid for other Member States. In addition, RAC points out that in the past the trainings on diisocyanates covered mainly quality issues. Occupational safety and health was rather a side issue as workers did not even know in some cases how to use respiratory protective equipment adequately.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  To 2) RAC agrees with your comment but stresses that a well-functioning communication along the supply chain is needed for the restriction to achieve its goals (i.e. the safe handling of diisocyanates and the reduction of cases of occupational asthma).  To 3 and 5) RAC refers to the Dossier Submitter´s answer to your comments.  To 4) Noted. |
| **SEAC Rapporteurs comments:**  Thank you for your contribution. This proposal is aimed to set standardised training, which would improve the handling of diisocyanates and the use of PPE across the EU; we are aware of the fact that in some companies worker health protection can already be on a very high level, however a high number of occupational asthma cases still occur . The cost benefit analysis shows that the proposed measure is cost effective. |
| **1650** | **Date:** 2017/09/18 12:30  **Content:**  Scope or restriction option analysis;  Transitional period  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** Fa. Kömmerling Chemische Fabrik GmbH  **Org. country:** Germany | **Comment:**  This proposed restriction will concern a very large number of companies and their employees all over Europe. The success of this restriction will depend on the practicable implementing. |
| **Answer to specific info request 1:**  As producer of PUR sealants and adhesives we know, that these kind of products are used in a very huge amount of production facilities/construction sites etc. Therefore a large number of training programs and documents specific to the respective application conditions have to be developed. The training methods have to consider the current knowledge of the users about handling chemicals. Training materials and there distribution platforms have to be defined, to be developed and to be provided preferably together with partners in commercial associations. It needs time to bundle and to provide the ressources to implement these necessary measures. Six years from the date of final adoption of this restiction are the minimum time for this kind of duty. |
| **Answer to specific info request 2:**  It is not helpfull for the supply chain to create a separate communication channel to inform the donwstream users about their duties, because it would take several years before a new communication channel would be implemented and would be excepted in daily business. A SDS is a well known communication platform along the supply chain and therefore the preferred method. Beside some dealers the far majority of our customers uses the materials themselves and no further downstream exposition to isocyanates can be expected. Dealers usually transfer the SDS directly to the end users. |
| **Answer to specific info request 3:**  Educational films and handouts (accessible on web based platforms) adapted to the special kind of application (in all EU languages) in combination with a following discussion/training unit (directly at the working place) should be a good method to train the employees. This kind of training should not exceed a duration of maximium one hour, because then the persons to be trained will loose their concentration and the training unit will get boring and uneffective. Therefore the training units should not fixed by the number training hours but more by the necessary content which have to be trained for a save usage and may be a time frame for repetition. |
| **Answer to specific info request 4:**  Until today we did not receive any information on this kind of symptoms from our customers using this kind of products. |
| **Answer to specific info request 5:**  Development of trainung will absorb a significant time share of our experts. Additionally we expect that a significant part of our customers will expect, that we either provide the trainings (may be inclusive trainers) or initial support for independent trainers. Extra cost will be necessary to provide the translations in all EU languages. An effective and successfull training program will be sustainable only, if every company will get the possibilty to educate their own trainers. Internal trainers are able to supervise the employees in their daily business and are able to correct wrong handling in the following training session. The acceptance of the measures specified in the restriction will depend on granting of exemptions wherever it will be possible. |
| **Dossier submitter response:**  Thank you for your comments and suggestions.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To3) The idea of combining shorter, but repeated training sessions instead of one longer session may be interesting to pursue further.  To 5)  Regarding the costs of compliance under the restriction, in Annex 8 (Appendix 13 – Trainings and Measures) different options (including the training of local trainers) for the training format were defined depending on the measure group. This offers the opportunity to choose the training format which fits best to the conditions of your company to reduce work time losses and the administrative burden of the restriction as far as possible. |
| **RAC Rapporteurs comments:**  Thank you for your comments.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  RAC acknowledges that a large number of training programmes and documents specific to the respective application conditions have to be developed.  RAC agrees with your statement that clear roles and responsibilities of the different partners who are involved in the process to make the training a success have to be defined (e.g. distribution platforms).  To 2) RAC notes that a well-functioning communication along the supply chain is needed for the restriction to achieve its goals (i.e. the safe handling of diisocyanates and the reduction of cases of occupational asthma).  To 3) RAC notes your concern with regard to the duration of the training. However, RAC considers that industry experts working out the training material and content have some pedagogical knowledge.  To 4) Noted.  To 5) RAC refers to the Dossier Submitter´s answer to your comments. |
| **SEAC Rapporteurs comments:**  Thank you for your input. We agree with you that proper implementation will be of a paramount importance.  1) Training materials should be prepared in cooperation with downstream users to ensure the specific conditions of use for each sector are taken into account. We presume that several years will be needed for the full implementation of the proposed restriction. The final decision on the length of the period will be taken on the political level.  5) We agree that, based on the analysis presented in the dossier, exemptions to the training requirements are justified for those products which demonstrate a low potential for exposure. |
| **1651** | **Date:** 2017/09/18 16:47  **Content:**  Transitional period  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** Netherlands  **Company name confidential: Yes** | **Comment:**  We support a restriction approach to managing the risks associated with isocyanates, and improving the awareness of workers who use products based on these substances.  We believe that this approach is reasonable, and can be successfully implemented across the EU (despite the scale of training required) in order to address the concerns over the incidence of occupational asthma related to the misuse of isocyanate-based products, and hence reduce such occurrences.  This approach will allow the continued safe professional and industrial use of our products based on di-isocyanates (polyurethane coatings ), many of which are essential for the protection and decoration of metal, plastic, glass and wood surfaces for several key sectors, including cars, ships, aeroplanes, furniture, flooring & infrastructure.  2-pack polyurethaneisocyanate-based coatings are used in certain specific sectors, either industrially or by professional users, usually applied by spray application methods that require PPE.  There are several key uses for this technology where there are no adequate alternative technologies available, especially polyurethane-based topcoats for exterior weather protection (light-fastness, clarity, corrosion & scratch resistance and durability).  Only certain di-isocyanates mentioned in the dossier are used for coating or ink applications, not all of them are relevant to our sector. |
| **Answer to specific info request 1:**  We 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 to collect the training materials, align and harmonize the materials, 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 need to 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.  We support 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. |
| **Answer to specific info request 2:**  We believe in a concerted approach between industry and authorities. As a downstream user we will fulfil the legal requirements by documentation in the safety data sheet  We propose that European and national associations to reach out to the value chain including different media channels, e.g. dedicated websites, conferences or webinars.  We ask for equivalent support by authorities on European and member state level. |
| **Answer to specific info request 3:**  There is already significant basic worker training readily available, for applying isocyanate-based products by spray application safely, from both National authorities (Denmark, UK and Sweden) and from training organisations and trade associations. Any new training programme should be built around this existing knowledge and best practice. Existing national programmes, that meet the training requirements of the final restriction should be allowed to continue to be used.  The expected number of professionals that will need training in our sector is estimated to be in the number of hundreds of thousands. Hence, training should be, where possible, provided through an e-learning / distance learning approach for all levels to ease the accessibility, interest, and to minimise disruption to trainees (saving time and money). Classroom trainings off-site would be very burdensome and costly. |
| **Answer to specific info request 4:**  We have no such knowledge or information |
| **Answer to specific info request 5:**  We already train workers to safely use all raw materials used in coatings manufacturing under the various Worker Safety Directives , so we would not expect any major additional direct training to be needed to meet the restriction requirements. We can provide the appropriate training content for our customer sectors, as would be expected under the proper principles of product stewardship. |
| **Dossier submitter response:**  Thank you for your comments and support for our proposal.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 3)  You have commented that the national training programs covering the mandatory requirements should be allowed to continue. As long as the stated objectives are reached, a combination of other existing training schemes, OSH trainings, etc., with the mandatory trainings would be possible, and thus increase the practicability of the restriction.  To 5) We thank you for the offer of training content for your sector. |
| **RAC Rapporteurs comments:**  Thank you for your comments, the detailed information on the use of diisocyanates in your sector as well as for your support for the restriction proposal.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  RAC welcomes the idea of a pilot project. However, it might not be easy to find a structured way to implement this idea.  To 2) Your offer to provide adequate information is appreciated.  RAC notes that a well-functioning communication along the supply chain is needed for the restriction to achieve its goals (i.e. the safe handling of diisocyanates and the reduction of cases of occupational asthma).  To 3) RAC is aware of the already existing training requirements in Denmark, UK and Sweden. Thank you for the information.  To 4) Noted.  To 5) Thank you for the offer to provide training content. |
| **SEAC Rapporteurs comments:**  Thank you for your input.  1) We agree that several years will be needed for the full implementation of the proposed restriction. The final decision on the length of the period will be taken on the political level.  3) We consider that e-learning is an acceptable training option in some situations but it has its limitations, therefore it has not been considered adequate for the intermediate and advanced level training. We agree that training sessions should preferably take place at the place of employment, however, we note that this might not always be possible in practice (at least it is not expected to be the least-cost option in certain cases). |
| **1652** | **Date:** 2017/09/18 19:28  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** CNIM  **Org. country:** France | **Comment:**  The CNIM is a French equipment manufacturer and industrial contractor operating on a worldwide basis. The company provides products and services to major public and private sector organizations, local authorities and national governments in Environment, Energie, Defence, and high technology markets which include mechanics, electronics, optics, hydraulics and command & control systems. It can intervene throughout the value chain in design, manufacturing, assembly, installation, and maintenance.  The CNIMS agrees that the restriction and training requirements must not apply where exposure is low or minimal as presented in the Exemption Annex. However, the conditions fulfilling the criteria for exemption are not clearly stated and described in the proposal.  Moreover, since the assessment of fulfillment with the exemption provisions is to be stated by the manufacturer or importer of the substance, it may be useful to better detail these conditions and the ways of communication between the manufacturer/importer and the downstream user(s ); otherwise, it may dissuade the manufacturer to assume the responsibility of the assessment of the “low exposure condition”. |
| **Answer to specific info request 1:**  The CNIM company estimates that a transition period of 5 to 6 years as from the date of entry into force of the restriction will be appropriate in order to implement the restriction proposal measures.  Indeed, this duration is needed to first make a complete assessment of the “measures group” for each employee that may be exposed to diisocyanates and then implement the additional measures requested (RMM, operational conditions material, training).  A first assessment made by the CNIM regarding the impacts of this restriction reveals that one of the main impacts for the company would be the implementation of training for each employee. Indeed, depending on the results of the complete identification of “measures groups” and in order to facilitate the management of the training, the “group 3” requirements would probably be implemented for all the CNIM’ employees that may be exposed to diisocyanates, even for the one that may belong to the “group 1” or “group 2” and being so, submitted to less stringent requirements.  Moreover, based on the current employee turnover, the training implementation would be renewed far more often than every 4 years since every new employee will be trained but may not be operating anymore 4 years later.  As a result, building the training management system implementation specific for the CNIM as well as the collection and harmonisation of the materials, even with the help of the federation industries, will be time-consuming. |
| **Answer to specific info request 2:**  The CNIM uses diisocyanates to manufacture its own products but the substance is not used along the supply chain by its DU clients. However, according to the restriction, the company will fulfill the legal requirements for documentation in the safety data sheet.  However, the implementation of the restriction may require additional measures of communication from the manufacturer to the downstream users, particularly for benefiting from the exemption.  As a result, since the assessment of fulfillment with the exemption provisions is to be stated by the manufacturer or importer of the substance, it may be useful to have an external stakeholder that will give an opinion regarding whether the conditions of ‘very low potential exposure’ are fulfilled.  Without an external point of view, it may become tricky for the manufacturer of the substance to assess the effectiveness of the “low exposure” and it may dissuade the manufacturer to assume the responsibility of “allowing” an exemption. |
| **Answer to specific info request 3:**  The CNIM has developed and trained its employees for the proper handling of diisocyanates for numerous years but has not compared the effectiveness of its training methods with others.  Should the restriction proposal be effective, the CNIM would connect with the national trade associations in order to improve its training methods.  However, please note that regarding the current employee turnover, the training implementation would be renewed far more often than every 4 years by employee after the transition period since every new employee will be trained when he/her arrives.  As a result, it will be very expensive to imagine setting up immediately a training course when a new worker joins the company. Allowing to implement a more flexible approach (e-learning ?) for training will probably help and reduce the costs associated, without damage to the efficiency of the trainings. |
| **Answer to specific info request 5:**  a) Among the different costs that this restriction will generate, a first assessment made by the CNIM reveals that the main impact for the company would be the implementation and management of training for each employee.  Indeed, currently, there is no manual operation during the process of production of the CNIM that may be performed mechanically. As a result, all the current employees using the substance will be trained as defined in the restriction proposal.  Moreover, each employee using the substance may be involved in different types of operations that are identified whether in Measures Group 1, or 2 or 3 depending on the process. As a result, to simplify the implementation of the measures, each employee will probably be trained through the “Measures Group 3” standards which will add extra-costs but will make the management of the training easier and provide the CNIM company enough flexibility in the employee’ allocation of tasks during the process.  Finally, the employee turnover will require to renew very often the training sessions and to monitor the proper implementation of these sessions for each employee.  As a result, the management of the training will probably be the most expensive cost due to the complexity of the provision completion (many employees concerned, each of them will probably be trained with the most stringent requirements, training sessions that will be held on an ongoing basis).  b) As mentioned previously, there is no manual operation during the process of production of the CNIM that may be performed mechanically, and the operators involved already receive training regarding health and safety issues.  As a result, the training requirements of the restriction may create moderate additional improvement in worker health since the CNIM is already familiar with this kind of requirements (even if the degree of formalisation may be different from the one yet implemented by the CNIM). However, it may represent a high burden for the company in terms of time-consumption for the management of the trainings. |
| **Dossier submitter response:**  Thank you for the comments regarding our proposal.  We are currently working on a better description of the exemption criteria and the responsibilities for generating such data.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 5)  Regarding the costs of compliance under the restriction, in Annex 8 (Appendix 13 – Trainings and Measures) different options (including the training of local trainers, e-learning) for the training format were defined depending on the measure group. This offers the opportunity to choose the training format which fits best to the conditions of your company to reduce work time losses and the administrative burden of the restriction as far as possible. |
| **RAC Rapporteurs comments:**  Thank you for your comments as well as for your answers to the specific information requests and your general support for the restriction proposal.  RAC has revised the conditions of the restriction proposal (including the appendices) - the revised conditions are included in the opinion. Thank you for the advice.  To 1) RAC acknowledges that the turnover of employees may not be easy to handle with regard to the training. In addition, RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  To 2) Your offer to provide adequate information is appreciated.  To 3) As industry takes the responsibility to elaborate the training material and content, it would be helpful to provide information about your sector and the training material you have already worked out and applied.  To 5) RAC refers to the Dossier Submitter´s answer to your comments. |
| **SEAC Rapporteurs comments:**  Thank you for your contribution. It is envisaged in the proposal that manufacturer/ importer/ formulator when preparing training materials will communicate with downstream users.  1) We agree that several years will be needed for the full implementation of the proposed restriction. The final decision on the length of the period will be taken on the political level.  5) We refer to the response by the Dossier Submitter. |
| **1654** | **Date:** 2017/09/19 10:45  **Content:**  Scope or restriction option analysis;  Hazard or exposure;  Baseline;  Information on benefits  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. name:** Austrian Workers' Compensation Board (AUVA)  **Org. country:** Austria  **Attachment:** | **Comment:**  Comments by Austrian Workers’ Compensation Board (AUVA)  (see also detailed comments in attached document)  Ad regulatory basis:  It is doubtful if the provisions in the Treaty regulating the functioning of the internal market are the suitable basis for adopting measures on the improvement of the working environment to protect workers’ health and safety.  The restriction approach does not promote substitution. To overcome this shortage, the authorisation approach would be the preferable solution to protect workers’ health in the long run.  See chapter G of the attached document.  Ad Cut off level 0.1 wt%:  The concentration of monomeric diisocyanates may vary. The highest possible monomer concentration (but NOT the nominal concentration or the mean value) has to be taken to decide on the compliance with the 0.1% limit. MS should check randomly if products comply.  See chapter H of the attached document for details.  Ad Exemptions:  Exemptions from the restriction founded on ‘very low potential exposure’ are not feasible because, no very low risk applications can be identified especially in respect to skin contact. Draft paragraph 2 (b) and Appendix 12 shall be repealed.  ALL applications must be subject to adequate safety measures and to preceding training of the workers (for tasks consisting of uniform non-diversified activities reduced training hours may be sufficient).  Furthermore, the “precautionary principle” (which is an aim of the European chemical politics) demands trainings and measures preventing (dermal) exposures to isocyanates to reduce risks.  See chapters I and N of the attached document for further information and details.  Ad Enforceability, Certification:  Enforcement authorities will hardly be able to control compliance of all potential uses of diisocyanates. Thus, the DS himself/herself recommends a system of audits by non-governmental bodies to assure that diisocyanate uses will be compliant to the upcoming restriction.  We suggest that the best-informed parties shall audit their costumers, i.e. manufacturers and formulators shall play a prominent role within this audit system. These actors shall check if their clients are using the chemicals following the restriction (trainings and measures) as well as the SDS.  Benefits are:  1) The companies will take the restriction serious.  2) Measures and trainings will be compliant with the restriction and the training materials.  3) The knowledge about the uses and conditions of use in the supply chain is strengthened.  4) The supplier can observe directly if the training material is appropriate and if technical and organisational measures work as intended.  5) Enforcement authorities can check the certificate and the documentation of the audits in the company and take action if necessary.  6) Enforcement authorities can act when inspecting the supplier and do not have to check each of the innumerous downstream users.  Ad Advisory Board:  An advisory board shall be established to review the materials for training, consisting of experts from national labour inspectorates, industry, national enforcement authorities (including the Forum), compensation boards, European trade unions conference, retailers.  This board may initiate the review and update of training material if new information becomes available or trainings are insufficient.  Reports, summaries and detailed data about audits and their outcome should be accessible to the advisory board.  Ad: “Elements to be included into Appendix 13”  We cannot agree with different scores (Table 8-1, measure groups), e.g. in foundry application levels above the OEL are met regularly, application as a sealant often ends with skin contact, …  More examples that need a higher score in Table 8-1 will be found in the attached document chapter K.  Ad: Measures (“Elements to be included into Appendix 13”)  Good occupational hygiene standards are frequently not met in realistic workplaces. Technical measures have to be in place, accompanied by organisational measures, and – if these are insufficient – the last resort are behavioural appeals (98/24/EC).  We demand several changes within the restriction, e.g skin protection scheme is missing, air monitoring also for professional uses (till now just industrial), surface-contamination detection tools for isocyanates AND amines etc.  Biomonitoring should not be offered.  For further details, see chapters M, N, O of the attached document.  Ad Trainings:  We demand expanding the training for managers to 12 hours!  Today’s working environment gets more challenging, very fast: from shift work to flexible working times, temporary employment and labour leasing, rising workloads; diversity (different tongues, employees of all ages, …). Thus, trainers must have excellent skills in adult education to overcome these problems.  This has to be reflected in the training topics.  It is fundamental to keep in mind that trainers must have a considerable advance in knowledge, overlook the isocyanate application methods, their risks and avoiding them. Effective training of workers means the ability to answer questions of the participants, to discuss alternative approaches and to argue why certain proposals are not sufficient or safe.  Duration of the training referring to group 1:  In training measures group 1, the basic principles, relevant chemistry of diisocyanates, health hazard information, PPE requirements, skin protection program, critical handling, emergencies, safety instructions, preventive measures, etc are to be communicated.  To perform this training and give illustrative explanations in an understandable, a training period of 8 hours is needed.  Additionally provisions referring to training group 1:  Top priority is the avoidance of any skin contact, supplemented by information about the risk respiratory sensitization.  The risks originating from skin contact must be explained. This needs further explanations in the corresponding tables.  Workers must know that sensitization also can be without any symptoms for a long-term period. They are aware that the only way to escape from risk of sensitization is to avoid any skin contact and inhalation  Especially the risks of dermal exposure are lacking in the curriculum. This means training material must include knowledge and awareness of the risk of dermal exposure, cross-contamination, correct use of PPE, cleaning after dermal exposure and skin care.  Training for group 1 – 3:  Training formats have to be elementary and easy-to-realise – using demonstrative. The methods must base on trainer-to-trainee communication, enough time for questions and discussions. E-learning is no option here.  The test at the end of the courses should be performed in a classroom setting. No outdoor fill-in of multiple choice templets (or e-tests) should take place. Documented checks if the training issues are followed in every day work have to follow up!  Every 4 years and if training material is updated the trainings will be repeated.  For further details, see chapter L of the attached document.  Ad skin contact:  Dermal contact with isocyanates can induce respiratory sensitization. But, very small attention was and is given to the induction of asthma by skin contact. The restriction proposal does not take into account the toxicological knowledge referring to skin contact with isocyanates. Therefore, the dermal exposure stages presented in Table 5-4 are based on wrong prerequisites; they are associated with high sensitization risks. Avoiding any skin contact with isocyanates must be a top priority (besides observing the OELs and lowering the air concentrations as far as possible).  Risks arising from skin contact must be extensively addressed in the measures to be implemented in the work environment as well as in the training of employees.  Besides that, the aspect of carcinogenic amines, originating from hydrolysis on the skin and capable to be absorbed through the skin, needs to be addressed.  See chapters N, L and M of the attached document for further information and detail argumentation.  Ad Biomonitoring:  Due to physiological mechanism (not fully understood to date) recovery rates of diisocyanates (as their metabolites in urine) are very low (<0.5%) and varying, incapable to provide valid and reliable information. Biomonitoring as a routine surveillance tool may underestimate or overestimate isocyanate exposure. Referring to the assessment of potential sensitizing exposures, biomonitoring does not provide a prognostic nor specific patho-diagnostic significance (J. Pauluhn 2013). (Nevertheless, biomonitoring may be useable in special designed pre- and post-shift research studies.)  Offering “consultation in occupational health”, as provided in measures group 1, is sufficient (instead of optional biomonitoring in measures group 3).  See chapter O of the attached document for further information and details. |
| **Answer to specific info request 1:**  18 months seem to be a realistic timeline because a lot of training material and knowledge is available because of existing occupational health requirements. Asthma is a severe and irreversible disease demanding for urgent preventive measures; therefore, 12 months (or less) transition period should be considered for on-site technical, organisational and personal protective measures.  Especially requirements of REACH Annex II (indicating the fact of restriction in SDS Section 15) easily can complied have to implemented immediately.  As will be deeply discussed in the attached document, to the following processes or conditions should be given the have highest priority:  – Uses with enhanced risk of skin contact,  – Uses at high temperatures,  – Spray application without effective exhaust ventilation,  – Uses of TDI, again especially at enhanced temperatures. |
| **Answer to specific info request 2:**  (1) Marking / labelling of substances / mixtures:  The packaging of every individual container (and not even solely the overpack) has to be marked visibly, legibly and indelibly (without prejudice to other legislation concerning the classification, packaging and labelling):  “Strictly avoid any skin contact with the product! Skin contact as well as inhalative exposure can cause sensitisation to isocyanates resulting in asthma. Skin contact also can cause dermal diseases.  Use is restricted to persons specially trained under responsibility of the company. Technical, organisational and personal protective measures have to ensure that dermal and inhalative exposure is avoided.”  (2) Safety data sheet:  According to REACH Annex II section 2.1, in the SDS shall list the most important adverse human health effects in a way as to allow non-experts to identify the hazards of the mixture.  Therefore, in SDS section at least 2.1 the following information should be given:  “Strictly avoid any skin contact with the product! Skin contact as well as inhalative exposure can cause sensitisation to isocyanates resulting in asthma. Skin contact also can cause dermal diseases.  Use is restricted to persons specially trained under responsibility of the company. Technical, organisational and personal protective measures have to ensure that dermal and inhalative exposure is avoided.”  To state this in section 2.1 is important because often scare attention is drawn to sections 15 and 16  As explained thoroughly in the attached document, no very low potential of exposure can be identified and no exemptions are acceptable. In spite of the repeal of exemptions, in SDS section 16 safety information for bystanders and in section 7 reoccupation time shall be provided, each relating to the respective uses and conditions of use.  SDS section 15 shall clearly point out that specific safety measures have to be complied with and only specially trained persons are allowed to use the product, both in accordance with the restriction and the measures group. |
| **Answer to specific info request 3:**  Safety training of workers needs experts showing knowledge and experience in safe use of isocyanates as well as skills and competence in adult education.  More time is needed than suggested in the restriction proposal. Safe use of isocyanates has to be communicated in a lifelike manner and there has to be proof that workers can understand what they are told. E-learning is not a suitable tool to aim this goal. In courses performed by the Compensation Board on occupational health and safety practical handling by participants, demonstrations using chemicals, on-site-teaching is applied Teaching is complemented with discussions, case reports and a final test.  See chapter K of attached document for further information and details. |
| **Answer to specific info request 4:**  Question 4 cannot be answered, unless all contributing exposures are specified.  Induction of asthma is the result of a couple of dermal exposures and airborne peak exposure(s). Possibly, most of these exposures had not been detected at all. Together with the fact that nearly no awareness exists about the respiratory sensitization potency of skin contact and the almost impossible quantification of occurred skin contamination, usually no case documentations will be found on subtle and slow-growing asthma risk. |
| **Answer to specific info request 5:**  Overall, there will be supposedly no loss of employee time for companies because repeated education and training is a duty according to 89/391/EEC (article 10) and may be combined with training according to the restriction; avoided health impairment will reduce sick leave in the companies.  With this restriction, the same requirements would have to be complied with in the European Internal Market because it is based on provisions in the Treaty relating to the functioning of the internal market. EU-consistent instructions will help to standardize the safe use in each member state. They also can help to establish an elaborated curriculum on information and education according to 89/391/EEC.  All goals can only be reached under the precondition that emphasis can and will be given to effective enforcement (what is not the case in the actual draft).  Social security system, health care system, national economy and public welfare will benefit from minimising health damages and severely diseased persons irreversible caused by diisocyanate exposures.  The Austrian Workers’ Compensation Board (AUVA) will benefit from a reasonable reduction of following expands:  \* Reduction of respiratory and skin diseases occupationally caused by isocyanates,  \* reduction of medical surveillance costs,  \* reduced need of advice and information by our prevention department for  companies, this will reduce costs of manpower for consulting. |
| **Dossier submitter response:**  Thank you for the comments to the restriction proposal, the information supplied and ideas brought forward. We will try to consider and incorporate them as much as possible where appropriate.  Your suggestions of an audit system, in which the manufacturers and formulators shall play a prominent role, and of an advisory board for the trainings are welcomed. The idea of an advisory board is already under consideration.  The issue whether REACH or OSH is the better framework to regulate diisocyanates has been discussed vividly. Our positon to this issue was reformulated and expressed in Section A2.2.1 of the background document. In the end a political decision needs to be taken if REACH should address this issue as proposed.  The reason why we did prefer restriction over authorisation is also discussed in the dossier (Chapter A2.2.2).  Regarding the option to create “exempted products”, the DS would like to point out (see Appendix 5 in the BD) that such products are not to be considered as being without any risk. This option is included to identify such cases where the additional burden of a restriction is not proportional and normal OSH measures would be sufficient.  As is indicated in the dossier, assignments of typical tasks to measure groups are to be considered as generic, if further indications are not available, based on the judgement in our expert group. If data are available that may necessitate choosing a higher group this has to be communicated to the users. We appreciate your suggestions for some shifts and will use these for further discussions. Furthermore your suggestion to extend the sentence “Companies have documented the risk for neighbouring workplaces and bystanders (…)” to: “Companies have avoided the risk for neighbouring workplaces and bystanders and documented possible remaining risks …” will be incorporated in the revised BD.  We do not agree with your remark that “The restriction proposal does not take into account the toxicological knowledge referring to skin contact with isocyanates.” This is addressed at several parts of the dossier (e.g. A.2.1.1 and A.2.1.2) and several items in the Appendix on “Trainings and measures” relate to dermal exposure.  As you have read in the dossier, we see e-learning as a valid training option only for “measure group1” (the lowest risk group in scope of the restriction). |
| **RAC Rapporteurs comments:**  Thank you for your comments, your detailed answers to the specific information requests as well as for your recommendations.  RAC is aware of Article 153 of the Treaty on Functioning of the European Union. If the restriction is in conflict with the Treaty, it will have to be clarified by the corresponding bodies of the European Commission.  RAC is also aware of the fact that this specific restriction approach may not promote substitution of the diisocyanates per se. RAC notes that the legal requirements for substitution do exist aside of the restriction proposal.  RAC agrees that in general “very low potential exposure” might only be achieved by closed systems while applications in open or semi-closed systems present higher levels of exposure. This has been a serious matter of concern for RAC when assessing the exemptions proposed by the Dossier Submitter. Nevertheless, RAC has finally agreed that the criteria defined for exempted products (air concentration below 1 ppb, no aerosols generated, no warming or heating above 45 degrees and very low potential for dermal exposure) ensure that only uses with a very low potential for exposure will be exempted from the requirements of the restriction.  Thank you for your recommendation related to the enforceability of the restriction proposal. RAC considers that audits could facilitate the enforcement of the restriction, especially because the restriction proposal covers OSH issues and in many Member States REACH and OSH obligations are not executed by the same enforcement authority.  Thank you also for the recommendations related to establishing an advisory board, this is further considered in the opinion.  Thank you for your suggestions with regard to the measure groups and to the training duration and content.  To 1) RAC agrees with you that asthma is a severe disease and any new case of occupational asthma due to the use of diisocyanates should be prevented.  The length of the transition period is a political decision in the end.  To 2) RAC agrees with you that every individual container/package should be labelled visibly, legibly and indelibly with a warning about the risk of asthma due to skin contact or inhalation exposure. This is already a requirement according to the classification and labelling regulation.  RAC also confirms that the safety data sheets should contain clear and detailed information about the need to avoid skin contact.  To 3) RAC concurs with you that safety training of workers needs experts showing knowledge and experience in the safe use of diisocyanates as well as skills and competence in adult education. RAC also confirms that there has to be proof that workers understood what they learned.  To 4) RAC fully agrees with your statement related to the induction of asthma.  To 5) Noted. |
| **SEAC Rapporteurs comments:**  Thank you very much for your detailed comments.  We believe that the proposed restriction in fact promotes less dangerous alternatives, especially introduction of products with lower concentration of diisocyanates, which would then meet the criteria to be exempted.  Authorisation is not considered to be a real option due to the widely spread use of diisocyanates and the unavailability of alternatives. In addition, the diisocyanates are not identified as Substances of Very High Concern and are so not yet available for the authorisation process.  1) We agree that several years will be needed for the full implementation of the proposed restriction, but the final decision on this will be taken on political level.  5) We agree that proper enforcement is vital for the effective implementation of this proposal. |
| **1655** | **Date:** 2017/09/19 15:31  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Fachverband Schaumkunststoffe und Polyurethane (FSK) e.V.  **Org. country:** Germany | **Comment:**  As an association, we support the proposed restriction of diisocyanates according to the REACH Regulation for the following reasons:  1. There is no alternative to diisocyanates for the production of polyurethane. This means that substitution is excluded and a classification of diisocyanates as substances of very high concern (SVHC) would as a result destroy an entire industrial sector.  2. Compliance with the limit value by means of appropriate risk management measures and a responsible, competent handling of diisocyanates significantly reduces the risk of sensitization and occupational diseases.  3. The consequences of an illness due to exposure are not comparable to the effects of exposure to CMR substances (carcinogenic, mutagenic or toxic for reproduction). In many cases, a full recovery after the end of the exposure to diisocyanates is possible.  4. The occupational safety measures already taken in the past have had a positive effect, so that the number of sensitization cases has declined despite a growing PUR market.  We believe that the proposed restriction is suitable to ensure a qualified handling of diisocyanates by workers across Europe. Furthermore, the proposed restriction also provides protection to all parties even those only slightly involved in the actual production process (e.g. administration staff, bystanders ...). We consider a training scope adapted to the exposure risk as adequate.  Today, training and technical measures in the field of occupational safety and health are already being performed. The proposed restriction provides for a minimum level of training in the handling of diisocyanates based on standardised training documents and contents. A consistent level of occupational safety and health is, with the obligation to provide proof of training, thereby ensured throughout Europe. Despite the additional effort, the polyurethane industry supports the restriction proposal also in its own interest of a progressive and responsible employee protection.  However, it is essential that in the light of free movement of workers and the flexibility of enterprises (some with multiple European locations, for example), the training content and the obligation to provide proof are standardized and acknowledged across Europe.  The obligations provided for in the restriction proposal are already a major expense for the polyurethane-processing companies. Particularly for small and medium-sized enterprises, enormous additional costs are thus to be expected in the future. It is therefore to be feared that any requirement going beyond those currently proposed would amount to the prohibition of a substance, as companies, especially small and medium, could not pay for even higher costs. Consequently, planned facilitations such as e-learning and standardized European training documents must be maintained as proposed. |
| **Answer to specific info request 1:**  The FSK believes that from the decision to adopt the restriction for diisocyanates until the date of binding implementation in the company a transitional period of 6 years is required.  We regard this long transitional period as necessary since numerous prerequisites must be created at different levels for the training system and evidence of training system.  1. Necessary preparatory period at the level of the European Union  Within the implementation period, training contents must be coordinated and defined throughout Europe. A Europe-wide evidence of training system must be created. Only if the (minimum) standard of qualification of all parties involved in the PUR industry (including visitors of a company) is ensured across Europe, can the restriction have an effect in the sense of wide-ranging health protection. All across Europe, a couple of million workers in the polyurethane industry are affected.  For this purpose, a network of qualified trainers will have to be put together, which can establish training contents and occupy a multiplier position.  Training and evidences must be prepared and made available in such a way that at most, a translation into the national language is pending in order to begin with the training.  The European evidence of training system with mutual acknowledgement in the Member States must be set up in such a way that the free movement of workers is not affected.  2. The necessary preparatory period at Member State level  Member States must examine the extent to which the implementation of the restriction affects national regulations, authorities, institutions, enterprises and not least, workers. The Member States must establish structures in order to determine who is to be trained, to what extent and an evidence system for training courses performed. It must be ensured that a sufficient number of qualified trainers can perform training and that an assessment is possible.  3. Necessary preparatory time at company level  Companies must classify the entire workforce into training- and measure groups and ensure that all employees are fully trained for their assignment in the company. In particular, for small and medium-sized businesses, in the field of polyurethane specialties, this additional obligation is a great expense. Where only few employees are responsible for multiple work steps, the training effort is significantly greater and thus more time and cost consuming. |
| **Answer to specific info request 2:**  The REACH regulation itself provides for comprehensive information and communication obligations along the value chain. We communicate this obligation within the association. In addition, we regularly inform our members about the latest news on legislation in our newsletters and other channels, in Guides and other support means regarding the implementation of their legal obligations. |
| **Answer to specific info request 3:**  In Germany, according to the Occupational Health and Safety Act, companies are obliged to conduct a hazard assessment in conjunction with the Hazardous Substances Ordinance. The companies are already required by law to carry out an assessment for each chemical and each production process and to use this to create an operating instruction that describes the safe handling in the respective step. These operating instructions establish the foundation for training staff on handling the chemicals. Training is documented and operating instructions must be displayed visibly at the respective production stage, so that employees can access them for reassurance at any time. Training in advance is mandatory and cannot be replaced by the mere display of operating instructions. Even today, external visitors, production partners or employees of maintenance companies are trained in the handling of hazardous substances.  In Germany the German Social Accident Insurance Institution (Berufsgenossenschaft (BG) also plays an important role in the area of occupational health and safety. For one thing, it supports all businesses with assistance in implementing their legal obligations in the field of occupational health and safety. For example, it provides Guides, operating instruction templates, a Hazardous Substances Information System (GisChem). The BG also regularly visits and inspects companies and conducts workplace measurements to demonstrate compliance with limit values.  Finally, we believe the Guides, which are provided by ISOPA and ALIPA (in the meantime further associations have followed up with excellent Guides for the respective areas) are very helpful and effective, e.g. the "Walk the Talk" program and the various documents and checklists that describe the safe handling of chemicals and are used as training material.  The declining number of occupational diseases associated with diisocyanates demonstrates the effectiveness of the above-mentioned training methods. Despite the tremendous growth of the polyurethane market in Germany and across Europe and the use of diisocyanates in recent years, the number of diseases has declined. The German Ordinance on Hazardous Substances as well as increasing national and European regulations in the areas of environmental protection and occupational safety are already demanding that companies deal more intensively with chemicals. Workers in the polyurethane industry are therefore already very well trained.  In Germany, the occupational health and safety standard is already very high due to the pronounced chemicals and labour protection law. Examples include the Hazardous Substances Ordinance, the TRGS 430 (Isocyanate Hazard Assessment and Protective Measures) or the occupational medical examinations. The measures and codes of practice can and should serve as a foundation for European training courses.  In addition, experience with training has shown that workplace related and work-process related referrals, such as those made in Germany using operating instructions, are more successful than theoretical front-end teaching, conveying general information. The implementation of training courses and instruction is monitored by the safety officer and is an integral part of audits performed by the German Social Accident Insurance Institution, trade supervision or government presidencies and within the scope of ISO certifications, external audits and audits.  In our opinion, it is necessary, at the introduction of a training system, to orient oneself to the countries with high standards like e.g. germany and to examine the extent to which restructuring is necessary or compatible with a European system. |
| **Answer to specific info request 5:**  Many of our members are small and medium-sized companies producing polyurethane specialties. For these companies as well as for self-employed persons (one-man business), it can be assumed that few employees need be flexible in the production process (including logistics, repairs, production, maintenance). It can be assumed that all employees have to go through almost all training modules in order to be able to be used optimally in the company. Thus, with the introduction of the training program, SMEs and self-employed persons are facing enormous time and financial effort. This affects the smaller companies much harder, since the training expenditure per employee is greater, yet cost digression is less.  The proposed introduction of a generalized, unified training system must therefore be accompanied by facilitating techniques such as e-learning and web hosting.  Since many companies also rely on the use of short-term labour (contract and third party workers), training must be possible in such a way that the workers can be deployed quickly.  The restriction for diisocyanates must also provide a viable solution for short-term visits. The factory tour during a short visit (of a customer manager, joint inspection with a project partner / manufacturing partner, customer audits, certification, etc.) are customary business practices, a preceding multiple hour training is neither practicable nor effective. In such cases an exception must be made that allows a visit after a short briefing and provision of appropriate protective clothing.  For flexibility in the labour market and in light of the free movement of workers, it is also necessary that the qualification as trainer and the training both set a European minimum standard and are acknowledged throughout Europe. |
| **Dossier submitter response:**  Thank you for the comments and support for our restriction proposal.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 5)  Regarding the costs of compliance under the restriction, in Annex 8 (Appendix 13 – Trainings and Measures) different options for the training format were defined depending on the measure group. This offers the opportunity to choose the training format which fits best to the conditions of your company to reduce work time losses and the administrative burden of the restriction as far as possible.  The issue of short term visits needs to be dealt with on an ad-hoc basis and will depend on the local situation. |
| **RAC Rapporteurs comments:**  Thank you for your comments as well as for your answers to the specific information requests and your support for the restriction proposal.  Regarding your comparison of diisocyanate-related illness to CMR effects, RAC, however, considers that the consequences of an illness due to exposure to diisocyanates could also be rather severe and not fully reversible in a significant number of cases. Not all persons suffering from occupational asthma completely recover, and asthma should be considered as a serious illness, which shortens life expectancy and could significantly affect quality of life.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  To 2) RAC agrees that in principle the REACH regulation itself provides for comprehensive information and communication obligations along the supply chain.  RAC appreciates your efforts to inform your members pro-actively about the legislative developments that may affect them.  To 3) Thank you for your information about the requirements of the German TRGS 430 and about the collaboration with different actors (including the German Social Accident Insurance Institution) in occupational safety and health.  It is interesting that external visitors and production partners are trained in the handling of hazardous substances.  To 5) In the revised conditions the concepts of the Dossier Submitter have been retained and their reply is relevant. Additionally, it is to be noted that trainers are required to follow a specific training covering at least the aspects set out in the conditions of the restriction. |
| **SEAC Rapporteurs comments:**  Thank you for your proposals.  It is indeed planned by industry associations that training materials would be standardised as much as appropriate. Thank you for pointing out specific concerns for SMEs. SMEs should mostly benefit from manufacturer/ importer obligation to prepare materials in all EU languages.  1) We agree that several years will be needed for the full implementation of the proposed restriction, but the final decision on this will be taken on political level.  5) We refer to the response by the Dossier Submitter. |
| **1661** | **Date:** 2017/09/21 14:00  **Content:**  Scope or restriction option analysis;  Information on costs;  Information on benefits;  Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Other contributor  **Org. name:** Wirtschaftskammer Österreich (WKÖ)  **Org. country:** Austria  **Attachment:** | **Comment:**  see document attached |
| **Answer to specific info request 3:**  see document attached |
| **Answer to specific info request 5:**  see document attached |
| **Dossier submitter response:**  Thank you for your clear statement.  However we would like to point out following:   1. The issue whether REACH or OSH is the better framework to regulate diisocyanates has been discussed vividly. Our position to this issue was reformulated and expressed in Section A2.2.1 of the background document. In the end a political decision needs to be taken if REACH should address this issue as proposed.   The restriction as proposed allows for a range of training options, suiting work schedule and economic considerations also for small firms. The proposed concept does not prevent to combine the necessary trainings with other vocational or technical trainings. |
| **RAC Rapporteurs comments:**  Thank you for your comments.  RAC agrees with your statement that the appropriate legal instrument for the regulation of occupational health and safety is the EU workplace safety legislation. However, RAC stresses that this restriction proposal is not a replacement for OSH but builds on the requirements of the OSH legislation to identify a specific set of technical and organisational measures that will result in safer handling practices for diisocyanates across the Member States. The reasons why the REACH legislation might be of benefit in this case have been elaborated in the Background document and in RAC´s opinion.  In addition, RAC points out that a huge effort has been made by the Dossier Submitter to find a way to reduce the number of cases on occupational asthma which still occur (despite the OSH regulation(s)). RAC considers that the aim to reduce the number of cases of work-related occupational asthma can be effectively achieved through this restriction proposal. |
| **SEAC Rapporteurs comments:**  Thank you for your opinion. The choice of the legal framework to be used is a political issue which needs to be dealt with on a political level. |
| **1663** | **Date:** 2017/09/21 17:29  **Content:**  Hazard or exposure;  Transitional period  **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:** | **Comment:**  **Answer to specific info request 1:**  VDA believes 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 to collect the training materials, align and harmonize the materials, set up the training infrastructure in all member states and build up certified trainers and conduct all worker trainings as the key deliverables. |
| **Answer to specific info request 2:**  VDA believes that the Safety Data Sheet (SDS) is the best possibility to inform Downstream Users (DU) about the requirements.  The Safety Data sheet is an established and widely accepted format for the communication of information about hazardous substances and occupational safety measures.  Also additional information for exempted substances and mixtures compliant with appendix 12 of the proposed restriction could be provided without any problems.  Also for SMEs the SDS is the best way to get this information, because the SDS the standard information in the context of hazardous substances in the whole supply chain. |
| **Answer to specific info request 3:**  There is a sophisticated system to protect employees at the highest level by the Ordinance on Hazardous Substances and extensive technical regulations. Existing instruments of occupational safety is the risk assessment, the monitoring of exposure limits, preventive occupational health checks, the operating instructions and last but not least the annual occupational health & safety instruction. All these measures and instructions are coordinated with each other and ensure a high safety standard.  Also 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. |
| **Answer to specific info request 4:**  VDA didn’t notice that such health cases have occurred in the past. Even materials with higher concentrations than 0.1% didn’t cause health cases in the German automotive industry. |
| **Answer to specific info request 5:**  The proposed training program affects the automotive industry enormous, because of the high number of employees who are concerned. This high effort can be reduced by combining the training with existing instructions or by web-based trainings.  VDA desires more flexibility in the standards of the training programs. 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 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.  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.  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.  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. |
| **Dossier submitter response:**  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 3 and 5)  The restriction as proposed allows for a range of training options, suiting work schedule and economic considerations also for small firms and also allows for a “train the trainer” concept. For “Measure Group 1” e-learning is included as an option. |
| **RAC Rapporteurs comments:**  Thank you for your comments and your support.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  To 2) RAC notes that a well-functioning communication along the supply chain is needed for the restriction to achieve its goals (i.e. the safe handling of diisocyanates and the reduction of cases of occupational asthma).  To 4) Noted.  To 3 and 5) In the revised conditions the concepts of the Dossier Submitter have been retained and their reply is relevant. Additionally, it is to be noted that trainers are required to follow a specific training covering at least the aspects set out in the conditions of the restriction. |
| **SEAC Rapporteurs comments:**  Thank you for your input.  1) We agree that a transition period of several years will be needed for the full implementation of the proposed restriction. The final decision on the length of the period will be taken on the political level.  3) We believe that this information will help organizers of diisocyanates training, when deciding on the most cost effective training methods.  5) We consider that e-learning is an acceptable training option in some situations but it has its limitations, therefore it has not been considered adequate for the intermediate and advanced level training. |
| **1664** | **Date:** 2017/09/21 17:59  **Content:**  Scope or restriction option analysis;  Hazard or exposure  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. name:** ANSES  **Org. country:** France  **Attachment:** | **Comment:**  Please see the document attached below |
| **Answer to specific info request 2:**  Proposals to communicate the requirements of the restriction through the supply chain:  - implement the requirements of the restriction in the Exposure Scenarios annexed to SDS  - use ENES as a communication channel (the Exchange Network on Exposure Scenarios is a network built under the CSR/ES roadmap dedicated to communication through the supply chain)  - consider developing SUMIs ? (Safe Use of Mixtures Information, <https://echa.europa.eu/documents/10162/22848353/enes_10_1_h_sumis_j_robinson_en.pdf/ebfc0f93-a54b-4af3-8cc8-0d3635918b06> , <http://www.ducc.eu/News.aspx#news5> , <http://www.ducc.eu/Publications.aspx> ) for diisocyanates corresponding to requirements of Appendix 13.  - consider establishing a certificate/license for workers having sucessfully been trained?  - communicate to teachers/professors in engineering, plasturgy and occupational hygiene degrees. |
| **Dossier submitter response:**  Thank you for your comments and ideas brought forward.  The rationale for the 0.1wt% limit is now explained in the (revised) background document (Section A.2.2.3).  The issue whether REACH or OSH is the better framework to regulate diisocyanates has been discussed vividly. Our positon to this issue was reformulated and expressed in Section A2.2.1 of the background document. In the end a political decision needs to be taken if REACH should address this issue as proposed.  Thank you for the update on the registered tonnage band of TODI. We will update that in the dossier.  The editorial suggestions for clarifying some text phrases are appreciated.  It is envisaged that each worker that has completed the required training will receive a confirmation/certificate |
| **RAC Rapporteurs comments:**  Thank you for your detailed comments and for your advice.  RAC has revised the conditions of the restriction proposal (including the appendices) - the revised conditions are included in the opinion.  RAC notes that the Background document have already been updated and do provide better explanations with regard to several issues mentioned by you.  RAC stresses that this restriction proposal is not a replacement for OSH but builds on the requirements of the OSH legislation to identify a specific set of technical and organisational measures that will result in safer handling practices for diisocyanates across the Member States. The reasons why the REACH legislation might be of benefit in this case have been elaborated in the Background document and in RAC´s opinion.  In addition, RAC points out that a huge effort has been made by the Dossier Submitter to find a way to reduce the number of cases on occupational asthma which still occur (despite the OSH regulation(s)). RAC considers that the aim to reduce the number of cases of work-related occupational asthma can be effectively achieved through this restriction proposal. |
| **SEAC Rapporteurs comments:**  Thank you for your contribution. We refer to the response by RAC. |
| **1667** | **Date:** 2017/09/22 11:11  **Content:**  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** IVC  **Org. country:** Germany  **Attachment:**  <redacted> | **Dossier submitter response:**  Thank you for your comments and support of the restriction proposal.  We appreciate your support for an option for exempted products.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 5)  Our concept offers a range of options to implement the trainings. The idea of “blended training is possible. |
| **RAC Rapporteurs comments:**  Thank you for your comments and your support for the restriction proposal.  RAC agrees that safe handling of diisocyanates should be achieved not only through training measures but also through the implementation of appropriate technical risk management measures. This is reflected in the opinion.  IVC´s commitment to make the training a success is highly appreciated. RAC concurs that the key prerequisite to achieve this goal is the adaptability to the needs of industrial and professional uses, including self-employed persons.  RAC also agrees with your statement that clear roles and responsibilities of the different partners who are involved in the process to make the training a success have to be defined and that easy access to the training material is essential.  RAC has thoroughly assessed the proposal of the Dossier Submitter to exempt product-use-combinations which result in low potential of exposure and has defined the criteria (air concentration below 1 ppb, no aerosols generated, no warming or heating above 45 degrees and very low potential for dermal exposure) that the exempted products will have to comply with to ensure that only uses with a very low potential for exposure will be exempted from the requirements of the restriction.  RAC notes that enforcement is a governmental task and will remain in the hands of national authorities.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  RAC welcomes the idea on the incentive to early training and the idea of a pilot project. However, it might not be easy to find a structured way to implement these ideas.  To 2) RAC points out that improvements regarding the documentation in safety data sheets are important as not all companies have fulfilled the requirements in the past (e.g. detailed information on the appropriate PPE (if needed) is sometimes lacking).  RAC notes that a well-functioning communication along the supply chain is needed for the restriction to achieve its goals (i.e. the safe handling of diisocyanates and the reduction of cases of occupational asthma).  To 3 and 4) Noted.  To 5) RAC refers to the Dossier Submitter´s answer to your comments. |
| **SEAC Rapporteurs comments:**  Thank you for your input. |
| **1668** | **Date:** 2017/09/22 11:48  **Content:**  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** FEICA  **Org. country:** Belgium  **Attachment:** | **Comment:**  The Adhesive and Sealants industry see Exemptions as described in the "Annex Exemptions" of the proposal is a necessary element of the proposed restriction.  Details attached in the PDF below. |
| **Dossier submitter response:**  Thank you for your specific support for the option to provide the possibility of defining exempted products. We stress again these are not to be considered as “absolutely safe” but in our view do not need an extra burden on top of the normal OSH requirements that are needed anyway. |
| **RAC Rapporteurs comments:**  Thank you for your comments.  RAC has assessed the proposal of product-use-combinations which result in low potential of exposure according to FEICA. As the dermal exposure is crucial for the sensitisation effect and as there is no threshold known at the moment for this effect, RAC has thoroughly considered what kind of product-use-combination can be considered as ready for an exemption of this restriction proposal. The conditions for the exemptions as agreed by RAC are included in the opinion. |
| **SEAC Rapporteurs comments:**  Thank you for your contribution on the need for exemptions. We agree that based on the analysis presented in the dossier, exemptions appear useful for moderating the burden to industry. |
| **1669** | **Date:** 2017/09/22 12:02  **Content:**  Information on costs;  Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** MedTech Europe  **Org. country:** Belgium | **Comment:**  In general, the definition of OHS requirements to control risks related to the use of isocyanates is appreciated. Nevertheless, the proportionality and cost-benefit ratio of the current restriction are impaired by the very detailed and inflexible training provisions. A much smaller and more flexible requirement for training of concerned employees is needed, taking into account that:  - The estimated personnel costs are not representative (too low) of the medical technology (medtech) sector.  - The strict, inflexible training requirements impose a significant additional burden on concerned production sites for medical devices.  - Existing OHS legislation already applies and requires adequate (annual) training of concerned staff.  - The training frequency required by the restriction proposal (every 4 years) is not a constituent of applicable OHS legislation, which requires annual safety instructions.  - 4 to 12 hour training sessions for all employees cause organisational constraints in case of continuous shift operations (24/24, 7/7).  - Concerned staff in medtech production is well qualified and performs very specific tasks. Even if some additional information/training on isocyanates might be helpful, this would not require 4 to 12 hours additional training. |
| **Answer to specific info request 1:**  The exact time needed for implementation depends on the concrete requirements, and the performed tasks in the concerned company that entail specific risks. Due to the mentioned need for modification, especially of the training provisions, no exact time frame can be given.  In any case, a transitional period of a maximum of 2 years should be sufficient, given that the additional training is largely redundant with required chemical safety trainings. |
| **Answer to specific info request 3:**  Content, length and frequency of the training should be adapted to the concerned workplaces. Lengthy training sessions and duplicated training, which are needed for formal reasons only, can be counterproductive with regard to the training effectiveness and should be avoided. See Q5 for further details/concerns. |
| **Answer to specific info request 4:**  No such case known to us. |
| **Answer to specific info request 5:**  Relevant uses in the medical device sector e.g. include polyurethane applications, adhesives and sealants. An assessment by a member company identified disproportionally high training efforts and constraints at concerned production sites. This is mainly caused by the extensive, inflexible training requirements defined by the proposed restriction:  - The proposal leads to organisational constraints in case of continuous shift operations (24/24, 7/7).  - Existing OHS legislation already applies and requires adequate training of concerned staff.  - Concerned staff in medtech production is well qualified and performs very specific tasks. Even if some additional information/training on isocyanates might be helpful, this would not require 4 to 12 hours additional training.  - The frequency (every 4 years) is not consistent with applicable OHS legislation (annual safety instructions) and increases the training effort without having a positive effect on training results or occupational safety (see Q3).  The described efforts, inconsistencies and constraints do not increase safety and risk control. Thus smaller, more flexible training provisions should be defined in the restriction entry. |
| **Dossier submitter response:**  Thank you for your comments to the restriction proposal.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 5)  Regarding the costs of compliance under the restriction, in Annex 8 (Appendix 13 – Trainings and Measures) different options for the training format were defined depending on the measure group. This offers enough flexibility to choose the training format which fits best to the conditions of your company to reduce work time losses and the administrative burden of the restriction as far as possible.  As long as the stated objectives are reached and no negative effects on the effectiveness of the different single trainings are expected, a combination with existing trainings would, of course, be possible. However, as far as diisocyanates are concerned the topics covered in the restriction proposal go further. On the other hand they only need to be repeated every four years. |
| **RAC Rapporteurs comments:**  Thank you for your comments.  To 1) The length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  To 3) RAC agrees that there is a need for different type of trainings for different types of users (qualified/not qualified). RAC notes that this fact should be covered by industry which elaborates the training material and the training content.  To 4) Noted.  To 5) In the revised conditions the concepts of the Dossier Submitter have been retained and their reply is relevant. |
| **SEAC Rapporteurs comments:**  Thank you for your input. Current OSH training requirements are of general nature, which leads to different levels of health protection across the EU. In a situation where the requirements are vague, even a stronger enforcement would not lead to significant improvements.  Substantial number of occupational asthma cases still occur. Standardized training with better specified content seems an effective measure to improve the situation. |
| **1670** | **Date:** 2017/09/22 12:20  **Type:** BehalfOfAnOrganisation  **Org. type:** International organisation  **Org. name:** <redacted>  **Org. country:** Luxembourg  **Company name confidential: Yes** | **Comment:**  The proposed training measures for handling diisocyanates need adoption for the different types of users (qualified by vocational training /not qualified) and their professional background. The extensive training program makes sense, if users have no professional qualification in handling coating materials and the specific application techniques.  The professional painter and automotive painter is informed about possible dangers and the necessary health and safety measures on the basis of the required risk assessment and the accompanying operating instructions. The use of PPE is a matter of course for e.g. professional automotive painters when doing spray application.  The education of a craftsman like the painter and varnisher covers most of the topics, which the restriction proposal intends to train. Necessary however is only a consolidation of the knowledge (Employees Measures Group 1 training).  The legislation regulated training for painters or automotive painters covers the relevant topics which the restriction proposal intends to train.  It is necessary to check whether a repetition of the training for qualified users is necessary at all, since a continuous instruction for employees on the handling of hazardous substances is mandatory by the Ordinance on Hazardous Substances anyway. |
| **Answer to specific info request 1:**  We refer to the typical applications of painters and varnishers (mostly brush, roller, spray application), no priorities in geographic regions can be specified.  Approximately 60.000 european professional painting companies, member of <redacted>, are possibly using materials containing diisocyanates. Every painting company has in average 4-6 employees.  The transition period depends on the amount of necessary training measures. An addidional training as described and demanded in the restriction proposal is not necessary for these skilled painters and varnishers as well as automotive painters.  Employees without the vocational qualification mentioned above may require the proposed trainings.  Therefore a transition period of 3 years should be appropriate.  Explanatory statement:  Painters and varnishers / automotive painters in member association have passed at least a 3 year vocational training. Master craftsman and firm owners usually need another 1-2 years. During this time, the use of two component coating materials is also trained, which naturally includes training in occupational health and safety.  In European member associations, company owners are legally obliged to implement the health and safety at work in their company. The firm owner has to instruct all employees in safe handling of hazardous materials.  This includes instruction in the safe handling of 2 pack materials like diisocyanates too, especially when products are applied by spraying.  Therefore, we do not see the need for an additional (practical) training for dealing with personal protective equipment for qualified painters and varnishers and automotive painters.  For workers without these qualifications, training as described in the proposed restriction (Annex 13) may be useful. |
| **Answer to specific info request 2:**  The most effective way to pass the restricted usage requirements is to inform the user by the supplier when purchasing the product. This should the obligatory way. National authorities must ensure that these requirements are communicated through the supply chain and the products are sold only to a qualified person. Corresponding notes must be given on the packaging and data sheets.  In addition, companies are informed about the restriction by their statutory accident insurance.  Information on the restriction can also be effectively communicated by the craftsman’s associations or the chamber of crafts, who regularly inform their members over new developments. This could be an optional way of communication. |
| **Answer to specific info request 3:**  So far, we have had no experience with single substance-related trainings. They were not necessary because of the vocational training.  Voluntary trainings by expert knowledge are successfully carried out by European national painter associations. The training method is classical classroom training. The training courses ends with an examination leading to a certificate. Effectivity could be proven over the examination results.  For the here intended training, including awareness raising and training of mostly theoretical topics, learning seems to be the appropriate method. |
| **Answer to specific info request 5:**  a. Given the current proposal of appendix 13, where application with brush, roller or spray application requires a group 2 training of 8 h, costs and loss of employee time are:  The painting companies in the <redacted> member countries employ in average 4 painters, who will all need the training program. Usually the whole staff will need the training program of group 2, i.e. in average a total of 40 hours of training. This will lead to an outage time of in sum 5 working days where no customers´ orders can be accepted.  On the assumption of an hourly turnover of the painter / automotive painter of approximately 40/80 € this will lead to a loss of turnover of about 3000 €.  Assuming hourly turnover of 70 € (net) this will lead to a revenue loss of approximately 3000 € for an average painting company. If a group 3 training is required the deficiency amounts to 4500 €.  b. No, as the education of painters includes the handling of hazardous materials as well as the use of PPE anyway. The statutory provisions on occupational health and safety, such as the Ordinance on Hazardous Substances, oblige the firm owner to carry out regular trainings and instructions of his employees.  Therefore the benefit for the painting and automotive painting companies is considered to be negligible. |
| **Dossier submitter response:**  Thank you for the comments to the restriction proposal.  We would like to point out that the proposed concept does not prevent to combine the necessary trainings with other vocational or technical trainings, as long as the stated objectives are reached.  To 5)  Regarding the costs of compliance under the restriction, in Annex 8 (Appendix 13 – Trainings and Measures) different options for the training format were defined depending on the measure group. This offers the opportunity to choose the training format which fits best to the conditions of your company to reduce work time losses and the administrative burden of the restriction as far as possible. |
| **RAC Rapporteurs comments:**  Thank you for your comments and your advice.  To 1) RAC agrees that there is a need for different type of trainings for different types of users (qualified/not qualified). RAC notes that this fact should be covered by industry which elaborates the training material and the training content.  RAC does not support your idea that skilled painters (incl. automotive painters) do not need further training. There are data on occupational asthma of painters/varnishers at least in Austria, but the same might be valid for other Member States. In addition, RAC points out that in the past the training covered mainly quality issues. Occupational safety and health was rather a side issue as workers did not even know in some cases how to use respiratory protective equipment adequately.  To 2) RAC agrees with your comment but stresses that a well-functioning communication along the supply chain is needed for the restriction to achieve its goals (i.e. the safe handling of diisocyanates and the reduction of cases of occupational asthma).  To 3) Noted.  To 5) In the revised conditions the concepts of the Dossier Submitter have been retained and their reply is relevant. |
| **SEAC Rapporteurs comments:**  Thank you for your opinion.  Substantial number of occupational asthma cases still develop. Standardized training with better specified content seems an effective measure to improve the situation.  Manufacturers/ importers are responsible to prepare adequate training materials in cooperation with downstream users.  Thank you for the approximation of costs expected for the painting companies.  The analysis made by the Dossier Submitter implies that overall the expected costs are proportional to the benefits envisaged. We have not received specific information indicating that the estimates used by the Dossier Submitter for productivity loss would not suit to the painting sector. As mentioned by the Dossier submitter above the proposed concept does not prevent combining of necessary training measures with other vocational or technical training, as long as the stated objectives are reached. |
| **1672** | **Date:** 2017/09/22 16:25  **Content:**  Information on costs  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** Tata Steel UK  **Org. country:** United Kingdom | **Comment:**  The proposed training program would lead to increased costs for Tata Steel if any externally imposed mandatory procedures were imposed on the company. Internal training costs would be small as we already implement strong training. We would recommend that external training, unless it is “free of charge” e-learning, should not be mandatory. |
| **Answer to specific info request 1:**  As an end user, Tata needs only 12 months to implement but the limiting factor will be further upstream with the suppliers and trade associations. |
| **Answer to specific info request 2:**  This should not be a big issue for foam panel suppliers - this would mainly be for industry bodies. |
| **Answer to specific info request 5:**  (a)Most important cost - Costs would be increased mainly by any externally imposed mandatory procedures imposed on Tata. Internal training costs would be small as we already implement strong training.  (b)Benefits - An informed workforce is always a more effective workforce.  Additional comment : Recommend that external training (unless “free of charge” e-learning) should not be mandatory. |
| **Dossier submitter response:**  Thank you for your comments.  To1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 5)  The restriction as proposed allows for a range of training options, suiting work schedule and economic considerations also for small firms. For “Measure Group 1” this includes e-learning as well. Furthermore, internal trainings by application of the Train-the-trainer concept, and training at the workplace by a commissioned trainer also were considered as possible options to implement the mandatory trainings. Moreover, the proposed concept does not prevent to combine the necessary trainings with other vocational or technical trainings, as long as the stated objectives are reached. |
| **RAC Rapporteurs comments:**  Thank you for your comments.  To 1) RAC notes that you do not need that much time to be ready for complying with the requirements of the restriction. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  To 2) Noted.  To 5) In the revised conditions the concepts of the Dossier Submitter have been retained and their reply is relevant. Additionally, it is to be noted that trainers are required to follow a specific training covering at least the aspects set out in the conditions of the restriction. |
| **SEAC Rapporteurs comments:**  Thank you for your contribution.  1) We acknowledge the need for an appropriate transitional period. How long this period is going to be will be decided on the political level.  5) We consider that e-learning is an acceptable training option in some situations but it has its limitations, therefore it has not been considered adequate for the intermediate and advanced level training.  The analysis made by the Dossier Submitter implies that overall the expected costs are proportional to the benefits envisaged. |
| **1673** | **Date:** 2017/09/22 17:07  **Content:**  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Federation of European Producers of Abrasives (FEPA)  **Org. country:** France | **Comment:**  With the following statements FEPA would like to bring in its comments to the public consultation related to the restriction proposal. FEPA represents over 200 companies (140 headquarters) gathering 90% of European abrasives producers. With a turnover estimated at €3.5 billion and 20.000 salaries in the EU, the abrasives industry is of major importance for the European Union. This is further emphasized by the fact that (1) many industry sectors in Europe are supplied by the abrasive industry and depend on their products, and that (2) abrasives producers continuously develop new materials, new processes and technologies in order to achieve better performance for their customers, save raw materials and energy. Maintaining and developing the abrasives industry in Europe will ensure the independence of Europe’s industrial production, and help other industries to achieve EU competitive low carbon economy targets.  For the European Abrasive industry diisocyanates are essential raw material for the production of polyurethane which is used in different types of abrasive products like coated abrasives, bonded abrasives or non-woven abrasives.  The European Abrasive industry is well aware of its responsibility towards the protection of workers and has implemented appropriate exposure control and occupational safety measures to avoid a potential exposure of workers to diisocyanates. Appropriate technical and organisational measures including personal protective equipment (PPE) like eye protection, gloves, overalls, apron, special work clothes are standard in the European abrasive industry.  FEPA supports the approach to reduce the risk for workers by adequate training and information. However, the proposed restriction will result in additional efforts for the abrasive industry. Therefore, it is important that the requirements resulting from the restriction are implemented in a way that the financial and in particular the administrative burdens for the companies are as low as possible. For the abrasive industry it is also important that the requirements are implemented in a harmonised way in all European countries. |
| **Answer to specific info request 1:**  FEPA would expect a transition period of 5-6 years as appropriate to ensure the preparation of harmonized training materials and the set up the training infrastructure in all member states.  It is important that the transition period is applied uniformly to all EU member states. |
| **Answer to specific info request 3:**  FEPA would recommend to offer e-learning modules or web based trainings as this type of training allows high flexibility for the companies and reduces administrative burdens. |
| **Dossier submitter response:**  Thank you for the comments to the restriction proposal.  To 1)  The DS is aware that a significant transition time will be needed. The final decision on this will be taken as part of the political discussion on how to implement the restriction EU-wide. Nevertheless, your estimate is appreciated as a contribution to this discussion.  To 3)  The restriction as proposed allows for a range of training options, suiting work schedule and economic considerations also for small firms. For “Measure Group 1” this includes e-learning as well. Furthermore, internal trainings by application of the Train-the-trainer concept, and training at the workplace by a commissioned trainer also were considered as possible options to implement the mandatory trainings. The proposed concept does not prevent to combine the necessary trainings with other vocational or technical trainings, as long as the stated objectives are reached. |
| **RAC Rapporteurs comments:**  Thank you for your comments and your support.  To 1) RAC is aware of the fact that the preparatory work to comply with the restriction needs some time. However, the length of the transition period is, as pointed out by the Dossier Submitter, a political decision in the end.  To 3) In the revised conditions the concepts of the Dossier Submitter have been retained and their reply is relevant. Additionally, it is to be noted that trainers are required to follow a specific training covering at least the aspects set out in the conditions of the restriction. |
| **SEAC Rapporteurs comments:**  Thank you for your contribution.  1)We agree that several years will be needed for the full implementation of the proposed restriction, but the final decision on this will be taken on political level..  3) We consider that e-learning is an acceptable training option in some situations but it has its limitations, therefore it has not been considered adequate for the intermediate and advanced level training. |
| **1676** | **Date:** 2017/09/22 23:04  **Content:**  **Type:** BehalfOfAnOrganisation  **Org. type:** International NGO  **Org. name:** ChemSec  **Org. country:** Sweden | **Comment:**  Overall, ChemSec does not agree with the view that authorisation route should not be used for these type of substances and that restriction is the only option. Many substances have very complex supply chains, this is not a reason to disregard authorisation route. Moreover, socieconomic consicerations and substitution possibilities are also not reasons to not identify these substances as SVHCs. Authorisation route has also the additional benefit of the substances beeing identified as a SVHCs and add them to the candidate list wich gives consumers the right to know when these substances are present in a product and a clear incentives to phase out the substance.  ChemSec find respiratory sensitizers important to cover under chemicals legislation in addition to the already existing occupational safety and health legislation. We welcome the proposal that member states can continue to have more strict measures. We would suggest more strict measures as we believe that the 50-70 per cent reduction in the yearly number of cases of newly reported occupational diseases due to handling diisocyanates after the introduction of the compulsory training is a low figure.    The restriction proposal is targeted towards professional use. ChemSec would like to see an extended restriction also to products sold to the general public (more wide than the MDI restriction in REACH Annex XVII position 56). We cannot see that there are any measures to prevent professional users from using consumer products that contain more than 0,1% diisocyanates. Also to protect the general product we would like to see a more general restriction as no safe thresholds can be established.    ChemSec see the group approach is positive with the reasons given (difficult to know in the individual occupational disease data which isocyanates patients are exposed to and no thresholds could be established).    ChemSec agrees that compulsory training is important, but would like to stress that the training need to take into account the application routes the employee or self-employed person would be using. It will need to be tailor-made to suit different industry sectors and to protect the workers best. We see specific difficulties concerning the training of self-employed persons and would like to suggest that products with more than 0,1% isocyanates only should be sold to people with a certificate showing that training has been carried out. Or that the supplier has to provide training the first time the person is buying the product. |
| **Dossier submitter response:**  Thank you for your comment.  Our reasons to favour restriction over authorisation are described in detail in the dossier, Section A2.2.2  Thank you for your comment regarding the training of self-employed persons. Products with use by professionals (including self-employed persons) shall be covered by the present restriction. We agree that the risk management for products sold exclusively to consumers is not covered and should be re-evaluated in a separate process. The present restriction proposal is regarded as a first step in order to reduce health risks from diisocyanates.  We agree with the comment to address the application routes of products. We are of the opinion that to the degree required, this is addressed in our “Measure groups” concept. |
| **RAC Rapporteurs comments:**  Thank you for your comments.  RAC is also aware of the fact that this specific restriction approach may not promote substitution of the Diisocyanates per se. RAC notes that the legal requirements for substitution do exist aside of the restriction proposal.  RAC stresses that asthma is a severe disease and any new case on occupational asthma due to the use of diisocyanates should be prevented.  RAC did not find any literature showing a higher level of effectiveness in reducing the identified risks (cases on occupational asthma) as the one mentioned in the Background document (50-70%).  RAC notes your thoughts with regard to harmonisation of the legal requirements for workers and the general public. RAC would like to mention that there is already an existing entry in REACH/Annex XVII (entry 56) which addresses the use of Methylenediphenyl diisocyanate (MDI) for consumers. According to the Dossier Submitter´s researches on ECHA´s dissemination site, there are no registered consumer uses of diisocyanates that would not be covered by the existing Annex XVII restriction for MDI. However, the Dossier Submitter found out that spray paints containing a HDI-homopolymer are sold via Internet Marketing, and could pose a risk for consumers. Nevertheless, to be able to include consumers/the general public in the current restriction proposal, information on the risk characterisation and on the social economic issues would be needed for consumer use, which have not yet been elaborated. There is no available information on health risk of application of diisocyanates-containing products by consumers, and no new information on exposure and health risks related to consumer use of diisocyanates was provided during the Public Consultation. This issue is elaborated in the Background document (A.1.2).  RAC agrees with your statement that the training needs to be tailor-made with regard to sectors, uses and tasks. |
| **SEAC Rapporteurs comments:**  Thank you for your input.  We do not see authorisation as a preferable measure for diisocyanates due to the unavailability of alternatives and the extremely wide spread use. Even though authorisation in general might stimulate additional search for alternatives, substantial results are not envisaged in most sectors for a very long period. Consequently, an extremely high number of authorisation applications (or applications with very wide scopes) in need of long review periods would be expected. In the absence of appropriate training, the results of such procedure could lead to even a lower level of health protection than what is envisaged in this proposal. In addition, the diisocyanates are not identified as Substances of Very High Concern at this point so the authorisation process is not relevant.  Concerning expanding the proposal to consumer products: MDI restriction (REACH, Annex XVII, point 56) prescribes gloves for consumers as well as labelling requirements.  We agree with you that there are no measures to prevent professional users from using consumer products that contain more than 0,1% diisocyanates, but such users will be obliged to be appropriately trained (if the product is not exempted from the restriction). |