6 FEBRUARY 2014

Responses to Comments Document (RCOM) on ECHA's Draft 5th Recommendation for Diazene-1,2-dicarboxamide (C,C`-azodi(formamide)) (ADCA) (EC number: 204-650-8)

This document provides ECHA's responses to the comments received during the public consultation on the draft 5th recommendation for inclusion of substances in Annex XIV of REACH, which took place between 24 June and 23 September 2013. In addition to this Response to Comments table, on ECHA's website there are available zip-file(s) including all attachments to the individual comments (as far as not confidential):
http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/5th-recommendation (see column "Additional documentation" in substances' table)

PUBLIC VERSION

CONTENT

I - General comments on the recommendation to include the substance in Annex XIV, including the prioritisation of the substance:

#	Date	Submitted by (name, Organisation/MS CA)	Comment	Response
2482	2013/09/23 20:39	ACEA - European Automobile Manufacturers Association, Industry or trade association, Belgium	In the analysis of alternatives - the majority of substances proposed in the Annex XV Dossier carry a far greater risk than ADCA or are not adequately assessed. Currently no suitable alternatives with the correct expansion criteria and processing temperatures have been identified, please see also attachment under point IV.	**No alternatives / Socioeconomic benefits of use / Impacts of ceasing use / Low risks** Thank you for your comment and the information provided. Topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a use are important. Information regarding these topics should be provided as part of the application for authorisation (e.g. in the analysis of alternatives, the chemical safety report or the socio-economic analysis). This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation. However, it is to be stressed that the prioritisation for the inclusion in Annex XIV is based on the criteria set out in Art 58(3) and follows the agreed approach described in the general approach document (http://echa.europa.eu/docu+E2ments/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf). Consequently information on

				topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a particular use are not considered in the prioritisation for recommending substances for inclusion Annex XIV. **Scoring** The currently used prioritisation approach requires the application of two methods, a scoring method and the so called verbal-argumentative method. Whereas the outcome of the scoring method is expressed in quantitative terms (scores) the verbal argumentative method provides rather a more qualitative valuation. However, although the result of the scoring method is expressed in quantitative terms, it should be considered that the information basis (and the data requirements) for both the scoring method and the verbal-argumentative method are the same and that the assignment of scores bears the same uncertainties regarding the reliability of the data and a similar level of subjectivity as the verbal conclusions drawn with the verbal-argumentative method. This means that although the results are expressed in numbers the outcome of the scoring method is not necessarily more precise or correct than an argumentative verbal conclusion. **Please see our response to Comment # 2454 in this Section.**
2476	2013/09/23 19:52	Fédération de la Plasturgie, Industry or trade association, France	See attached non-confidential document "Fédération de la Plasturgie - ADCA Consultation Input 23sep2013.pdf" pages 2 to 23.	Thank you for your comment and the information provided. **Please see our response to Comment # 2454 in this Section.**

2470	2013/09/23 19:19	Company, France	As a EuPC member company, we fully support the statement given by EuPC.	Thank you for your comment.
2469	2013/09/23 19:17	ChemSec, International NGO, Sweden	ChemSec supports the listing and prioritisation of this substance to the Authorisation list (Annex XIV) due to its wide dispersive uses and high volumes. Wide dispersive use: According to registration information, ADCA is used in the manufacture of various plastic products and in various applications such as shoes, leisure products, construction products and artificial leather, air freshners etc. It has wide process applications and high exposure to workers are expected, in particular for the following registered uses (PROC 8a + 8b): transfer of substance or preparation (charging/discharging) from / to vessels/large containers at non-dedicated facilities, (PROC 12) blowing agent for foam manufacturing. Also a wide variety of consumer uses are registered, which should be regarded as wide dispersive use: Examples of entries in the ECHA database include manufacture of construction chemicals, automated application of water-borne adhesives, construction chemicals (Consumer use), air freshener for consumer use, manufacture of coatings and inks. It is expected that similar articles containing ADCA are imported in the EU. However there is no information on SVHC in imported articles notifications according to Art 7.2 of REACH available on the ECHA webpage (the official SVHC listing took place on 19 December 2012). High volumes: ADCA is used in high volumes (up to 100.000tonnes per year). The substance should therefore be prioritised for listing in Annex XIV on this basis.	Thank you for your support and for giving your reasoning.
2466	2013/09/23 18:47	GERFLOR, Company, France	We have asked an external laboratory to measure the level of ADCA in the air of our workshop (SOCOTEC – 08/2013). They found less than 0,008 mg/m3 during on shift. The result is much below (125 times) the threshold that is existing in England or Ireland (1 mg/m3). Moreover, analyses on our products confirmed this high degree of decomposition: an official laboratory (INTERTEK – 10/2012) was not able to measure residual ADCA in our floorings. The limit of detection is 4 mg/kg. So residual ADCA is less than 0,004 %, 250 times lower the existing threshold in Reach regulation for communicate the presence of any substance which included in the candidate list (0,1%).	Thank you for your comment and the information provided, including the measurements from your facility. **No alternatives / Socioeconomic benefits of use / Impacts of ceasing use / Low risks** Topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information

				on the low level of risk associated to a use are important. Information regarding these topics should be provided as part of the application for authorisation (e.g. in the analysis of alternatives, the chemical safety report or the socio-economic analysis). This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation. However, it is to be stressed that the prioritisation for the inclusion in Annex XIV is based on the criteria set out in Art 58(3) and follows the agreed approach described in the general approach document (http://echa.europa.eu/docu+E2ments/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf). Consequently information on topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a particular use are not considered in the prioritisation for recommending substances for inclusion Annex XIV.
2463	2013/09/23 18:26	Sekisui Alveo B.V., Company, Netherlands	Sekisui Alveo B.V., as a member company of the ADCA Task Force (there represented by Sekisui Alveo AG), fully endorses the concerted statement given by the ADCA Task Force group. In addition to that report on "Possible REACH Authorisation for ADCA", we would like to provide further company-specific comments and data. 1) Profile of Sekisui Alveo B.V. Sekisui Alveo B.V. was found in 1974 and has its registered place of business in Roermond (The Netherlands). In our plant currently about 280 employees are producing semi-finished, high-quality, physically or chemically crosslinked polyolefin foams in roll or block form. We are one of three foam producing contract manufacturers of Sekisui Alveo AG	Thank you for your comment and the company-specific comments and data provided. **With respect to the comments made by the ADCA Task Force, please see our response to Comment # 2350 in this section.**

			(vendor and headquarters of Sekisui Alveo Group). The Sekisui Alveo Group itself is part of the Sekisui Chemical Company (Japan), one of the world's largest chemical companies. Besides three foam producing plants in Europe, Sekisui Chemical operates three foam manufacturing plants in Japan, two in the USA, and one each in Australia, China, South Korea, and Thailand. 2) Use of ADCA and Risk of Exposure Sekisui Alveo uses ADCA (azodicarbonamide, diazene-1,2-dicarboxamide) as chemical foaming agent in granulate or pre-blended form (mixed with polyolefin). The granulate or the mixture itself is delivered in sealed polyolefin bags which are included in carton boxes (25 kg) to avoid accidental damage (see also Chapter V. Confidential Attachment). The general production process applied in our plant is well-established and improved for more than 40 years. In general physically crosslinked foam production comprises the following steps: Step 1: Weighting and mixing of raw materials; Step 2: Extrusion of the raw material mixture to obtain a polyolefin sheet; Step 3: Crosslinking the polyolefin sheet by electron beam irradiation; Step 4: Foaming of the crosslinked polyolefin sheet at a temperature higher than ADCA decomposition temperature (> 200 °C); In production steps 2 and 3, ADCA is embedded in the polymer matrix. Thus, ADCA exposure of workers in these stages is very unlikely. In foaming step 4, ADCA decomposes to generate gases (N2, CO, CO2) and solid by-products (Ref.: Handbook of Polymeric Foams and Foam Technology, D. Klempner, V. Sendijarevic, Hanser Publishers, Munich 2004, page 256 et ssq.). Due to the fact that our production process complies to the generally recognized code of good practice whereby the temperature of our foaming ovens is above the decomposition temperature of ADCA (> 200 °C), we expect that ADCA decomposes to more than 99.9 w%. Currently no established, standard method for ADCA determination in crosslinked polyolefin foams is available. Therefore no analytical test results can be provided. Only in step 1 our workers risk accidental exposure to ADCA. In each working shift, one specially trained employee in each production hall is handling the transfer of ADCA granulate or masterbatch from the plastic bag into the weighting machine (cabinet). The transfer takes place at designated areas and the affected worker is obliged to wear particular personal protection equipment (see below). The weighting cabinet is equipped with a ventilation system to avoid dust exposure. The final raw material mixture is transported in a closed pipe system from the weighting cabinet (step 1) to the extruder (step 2). 3) Risk Management Measures Step 1 - RMM: Foaming agent supplied in sealed plastic bags included in	

			carton boxes (25 kg); Local Exhaust Ventilation; closed process system (inlet: cabinet, outlet: extruder - polyolefin sheet); Designated inlet area - PPE: P3 respirator, protective goggles, protection gloves, protection clothes, protection shoes; Step 2-4 - RMM: PPE (not ADCA-specific) - working clothes, protection goggles, protection gloves, protection shoes; See also RMM documentation in Chapter V. (Confidential Attachment). 4) Occupational Health and Safety Assessment Since the early 1990's, when ADCA has been categorized as possible respiratory sensitizer, Sekisui Alveo B.V. installed and implemented adequate RMM and PPE (see above). All employees are trained in the safe handling of ADCA and are obliged to wear particular PPE in the designated weighting areas. Additionally, we are monitoring the workers lung function regularly (at least every 6th year) which hitherto showed no measureable negative influence on lung performance. Latest since improved RMM and PPE have been implemented, we have no reported case of illness which is demonstrably a result of ADCA exposure. 5) Health Hazard Assessment of Final Foam Products Our semi-finished foam products feed various converting processes of our customers like for example coating with foil and/or adhesive, cutting, milling, press-forming, etc. Their articles are used in different applications like tapes (e.g. sealing tapes, etc.), medical devices (e.g. ECG pads, etc.), orthopaedics (insoles, etc.), construction products (e.g. insulation, laminate flooring underlay, etc.), automotive products (e.g. NVH, interior, etc.) packaging (e.g. baggage, tool box inlays, etc.) and many more. We expect that the ADCA rest content in our semi-finished foams, as well as in the converted products made from semi-finished foams, is below 0.1 w%. This assumption is based on three facts: a) Our production process complies to the generally recognized code of good practice; b) the applied temperature in our foaming ovens is higher than ADCA decomposition temperature (> 200 °C); and c) ADCA decomposes to more than 99.9 w% at such temperatures. Currently no established, standard analysis for ADCA in crosslinked polyolefin foams is available. Therefore no analytical test results can be provided to proof this reasonable assumption. In order to evaluate the health risk concerning particular applications of our semi-finished foam products, especially those intended for medical devices and packaging, we regularly contract a certified laboratory to examine biocompatibility of representative foam samples. The laboratory assesses allergic potential (LLNA test - Local Nymph Node Assay), primary skin irritation (4-hour semi-occlusive application), and cytotoxicity potential of our polyolefin foams (in vitro XTT test). All examinations resulted in identical conclusions that our semi-finished foam products do	

			not exhibit any negative effects which means "no skin sensitizer", "not irritating" and "does not possess a cytotoxic potential". Thus we justify our foam material to be harmless to human health concerning possible sensitising effects upon foam contact. 6) Conclusions Sekisui Alveo B.V. supports and fully agrees on the concerted statement of ADCA Task Force ("Possible REACH Authorisation for ADCA"). In general we do not question the classification of ADCA as respiratory sensitizer, because we do not have the expertise in this particular scientific field and therefore trust the authorised classification institutions. However, we question the current attempt chosen by the Member States Committee to reduce the possible risk of end-consumers and workers to be exposed to hazard substances. In the case of crosslinked polyolefin foams any ADCA rest contents, which may be still present after the foaming process (= thermal decomposition of ADCA), are embedded in the polymer matrix. Therefore the release of ADCA and the exposure of consumers and workers down the supply chain is very unlikely, irrespective if the maybe present rest content is above or below 0.1 w%. Additionally, extended appropriate RMM and particular PPE have been implemented in the early 1990's to protect workers who are responsible for ADCA handling. These measures lead to decrease or even disappearance of health cases which are demonstrably a result of (accidental) ADCA exposure. In order to assure a uniform workers safety level within the whole ADCA using industry, we recommend to define and implement sufficient safe concentration levels of exposure based on available study results as proposed by ADCA Task Force. This commits all companies to comply with strict safety rules and ensures a high level of health protection avoiding disproportionately efforts and negative impact on the affected industry. In due consideration of the above mentioned we also recommend to re-evaluate the WDU Score concerning the expected "Release". We propose to reduce the highest scoring of 3 to 2 or even 1, because the significant potential for worker exposure is actually limited thanks to implemented adequate RMM in the 1990's especially at affected working places (transfer, weighting, mixing). Concerning alternative substances we would like to refer to the comments provided in ADCA Task Force report. We appreciate that the original idea of REACH Annex XIV was to stipulate the replacement of harmful substances by harmless alternatives. Concerning ADCA, currently available "alternatives" are not useful from a technical and/or hazardous point of view. Since ADCA usage as foaming agent would remain allowed in all other countries outside EU, this would most probably result in a shift of production to one of these countries and not in an enhanced interest in	

			cost intensive research for harmless foaming agent alternatives. Therefore production plants may be closed and imports of (crosslinked polyolefin foam) materials from outside the EU may rise. Finally, we would like to emphasize that we question the high prioritisation of ADCA determined in the draft recommendation. In our opinion there are numerous chemical substances on the SVHC list with much higher harmful risks (REACH art. 57(a)-(c)) and/or potentially more widespread distribution than it is the case for ADCA. It is not comprehensible why these, e.g. demonstrably carcinogenic or mutagenic, substances obtained an overall lower scoring than a "just" possibly respiratory sensitising chemical substance.	
2461	2013/09/23 17:59	Company, Ireland	Freefoam Plastics Limited would state that we have great concern as to the prioritization of ADCA for inclusion in Annex XIV and the speed at which this process has taken place. ADCA as a raw material is absolutely critical to our business as it enables us to manufacture and distribute products which is the core of our business. We are totally against the draft recommendation as we believe that the risks associated with the use of ADCA are well known and are managed and controlled effectively. We are not aware of any instances of sensitization as a result of using ADCA in our business or in the industry in general. There are currently no known alternatives to ADCA and therefore our business and the industry as a whole would suffer massively should ADCA be banned from use. We believe that there would be a substantial loss of manufacturing business in the EU as a result of such a ban and that this would potentially be replaced with imported product from less controlled and reliable sources around the world.Freefoam Plastics Limited fundamentally disagrees that ADCA should be in the draft recommendation of substances for inclusion in Annex XIV.	Thank you for your comment and the information provided. **Please see our response to Comment # 2454 in this Section.**
2460	2013/09/23 17:58	Baerlocher GmbH, Company, Germany	Baerlocher GmbH manufactures stabiliser and kicker systems for PVC. The company has five production sites in Europe (Germany, Italy, France, and UK) as well as ten manufacturing sites in other parts of the world. In Europe we employ more than 450 people. We supply stabilisers to all applications for PVC including rigid (U-PVC) and flexible (P-PVC). Baerlocher has participated in the ADCA task force and fully supports the comments submitted by this organisation. As well we are supporting the comments made by ESPA, the European Stabiliser Producers Association. Nonetheless we would like to highlight the importance of ADCA for the PVC processing industry additionally ourselves. Although Baerlocher is not a user of ADCA it is closely involved in the formulating of PVC recipes containing ADCA. The correct choice of stabiliser and kicker can have a major influence on the final properties of the foamed PVC article.	Thank you for your comment and the information provided. **Please see our response to Comments # 2350 (ADCA Task force) and 2388 in this Section.**

			Applications for PVC foam using ADCA include the following U-PVC:- Foam Core Pipes – Lightweight but rigid sewer pipes and ducts that provide valuable weight savings whilst maintaining stiffness using less PVC per metre and with a lower CO2 footprint and sound deadening properties in internal construction. Foam Profiles – used in many applications as a light weight low maintenance recyclable alternative to wood for interior and exterior construction. Completely eliminates the need to paint exterior applications. Foam Sheet – used as a lightweight product with reduced material use and unique printability properties. P-PVC:- Wallcoverings – sound and heat insulation as well as a low cost method of producing a wallcovering which can hide imperfections and small cracks in wall surfaces. Flooring – Sound deadening properties and heat insulation as well as decorative effects and lower material costs. Artificial Leather Cloth – unique properties with low carbon footprint. Interior Automotive Parts – lightweight and cushioning properties, lower car weight with resulting saving in fuel and CO2 emissions. ADCA is used as a single component or blended with other blowing agents depending on the application but all contain ADCA as a key component. When formulated properly with a suitable stabiliser and kicker the blowing agent containing ADCA releases a large amount of gas in the right processing temperature range, resulting in a fine cell structure due to specific gas mixtures released. The cell structure determines the finished product mechanical properties. Depending on application density reduction can be up to 60% with a saving in weight and materials used. U-PVC is made from 46% oil and the balance is derived from salt. Foamed PVC can reduce the quantity of oil consumed by up to 60% saving per metre of product. ADCA is used to foam PVC because it has a quick exothermic reaction. By adding appropriate kicking agents the decomposition temperature of ADCA can be adjusted very precisely to achieve a fast and complete decomposition leadig to a defined foam structure. Other blowing agents are available but can only be used with modification - for example Sodium Bicarbonate (SBC) as a potential alternative blowing agent decomposes in an endothermic reaction which is much more difficult to control in certain PVC recipes resulting in inferior mechanical properties and increased scrap rates. As a result at present the PVC industry does not have an alternative to ADCA, this is not an issue of cost but purely the lack of a technical alternative.	

			It may be argued that a ban on ADCA is not an appropriate way of controlling the risk. Within the UK exposure limits were set in 1996 based on a 8 hour maximum exposure limit of 1mg/m3 and a short term 3 hour exposure limit of 3mg/m3. Since then no cases of occupational asthma relating to ADCA exposure have been reported. The risk from ADCA exposure relates only to powder forms and the industry has developed alternative product forms of blowing agents such as damped or dust reduced powders, pellet, encapsulated products, liquid and paste. This significantly reduces the risk or eliminates the risk of exposure. In many, if not all, applications the producer of the foamed article could move away from dusty powder materials to less or non-dusty lower risk blowing agents containing ADCA and therefore an exposure limit could be established to control the risk to humans. This is unlikely to cause industry a big problem as many companies have introduced safety measures to reduce exposure to dust in general which has benefit to reduce exposure to ADCA. The risk is only to the primary handler of powder ADCA. We believe there are no manufacturers in Europe of the pure ADCA but all material is imported and the powder is handled by intermediate companies such as compounding and blending companies and some producers of finished products. In the finished product a number of tests carried out that show in most cases the residual ADCA is below 0.1 % and it is not considered unreasonable to expect the PVC industry to achieve this level for all applications with some modifications to recipe design. Of course the residual ADCA is encapsulated so there is no risk to the general public of exposure to ADCA. Baerlocher believes that the industry has no feasible alternatives to ADCA as a component in blowing agents. It may be possible given 5 years or more to develop alternative blowing agent systems which are free of ADCA but this cannot be guaranteed. It is not clear at this moment whether the possible alternatives being considered would be safer however we believe there is an alternative to banning ADCA. Ultimately banning ADCA could lead to factory closures within Europe as manufacturers shift production out of Europe and import finished product from outside of Europe. Some estimate the effect on jobs across Europe could be greater than 80,000 jobs. However working to establish an Occupational Exposure Limit could reduce the risk of exposure without loss of jobs or industry. The advantages of light weight foamed products would continue with the resulting savings in CO2 emissions compared to non-foamed alternatives.	
2458	2013/09/23 17:47	EUPC, Industry or trade association,	As a EuPC member company, we fully support the statement given by EuPC. Further to this we like to add that without ADCA our would not survive.	Thank you for your comment. **Please see our response to Comment #**

		Belgium		**2454 in this Section.**
2454	2013/09/23 17:38	EuPC, European Plastics Converters, Industry or trade association, Belgium	Please find 2 attached documents /zip file section IV	Thank you for your comment and for the information provided. **Disputing SVHC identification** Your point with regard to the hazardous inherent properties of ADCA is not relevant for this part of the authorisation process, as the identification of the substance as a Substance of Very High Concern has already been agreed by the Member State Committee, based on the harmonised classification in force for this substance (Regulation (EC) No 1272/2008) and on the equivalent level of concern arguments put forward in the Annex XV dossier. **Exemption for specific form(s)** When considering whether to include an exemption of a use of a substance under Art. 58(2) REACH, the following elements have to be considered: there is existing EU legislation addressing the use or categories of use that is proposed to be exempted; the EU legislation imposes minimum requirements for the control of risks of the use; the EU legislation properly controls the risks to human health and/or to the environment from the use of the substance arising from the intrinsic properties of the substance which are specified in Annex XIV to REACH. According to Article 58(2) REACH: 'In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and environment related to the nature of the substance, such as where the risk is modified by the physical form'. Thus, it does not seem that the form is to be considered independently from the mentioned elements in order to exempt uses or categories of uses from the authorisation requirement. In other words,

				while the form and how it may affect the exposure potential is not alone a sufficient basis for an exemption, the form should be taken into account when assessing whether the existing legislation provides a justification for an exemption. Please note also that the prioritisation approach which was agreed and applied here to prioritise and recommend substances from the Candidate List for inclusion in Annex XIV is not intended to assess the risks exerted by the particular applications of a substance at particular sites (in particular countries) but to provide a very basic and general assessment of the use pattern and whether there is evidence based on which it could be concluded that relevant exposure does not occur. By doing so a conservative approach needs to be taken considering in particular any uses of the substance in which relevant exposure may occur. Therefore, ECHA's conclusion that some of the uses appear to have a potential for significant worker exposure and therefore – in combination with other criteria – qualify for prioritisation and inclusion in Annex XIV was drawn although risks might be controlled in other instances. Note that it is the obligation of the potential applicant for authorisation to demonstrate that the risks arising from the applied for uses are properly controlled or that there are no alternatives available and the socio-economic benefits of the use outweigh its risks. **Court cases on HHPA & MHHPA** The Court cases T-134/13 and T-135/13 are actions brought by a number of companies for partial annulment of ECHA's decision ED/169/2012 concerning the inclusion, respectively, of hexahydrophthalic anhydride (HHPA) and methylhexahydrophthalic anhydride

				(MHHPA) as substances meeting the criteria set out in Article 57(f) REACH, in accordance with Article 59 REACH. As general principle, ECHA highlights that actions before the European Court of Justice have no suspensive effect and that therefore there is no need to wait for the outcome of the Court's judgments before deciding whether or not the substance meets the criteria for inclusion of the substances in Annex XIV to REACH. Furthermore, it has to be outlined that assessment of substances under Article 57(f) REACH has to be done on a case-by-case basis, in accordance with the procedure set out in Article 59 REACH. The referred cases are related to the inclusion in the Candidate List of other substances than ADCA; thus, the related arguments and motivations cannot be simply applied by analogy to the inclusion of ACDA in the Candidate List nor the following step in the authorisation process, i.e., recommendation process. Based on the above, it is ECHA's opinion that the mentioned Court cases have no impact on the current prioritisation process for ADCA. **Inherent properties scoring** The question as to whether the respiratory sensitisation effects of ADCA are elicited by a mechanism for which it is possible to determine a no-effect threshold is important for the next stage of the authorisation process, namely application for and granting of the authorisations.. However ECHA does not assess at this stage of the authorisation process (i.e. recommendation for inclusion in Annex XIV) whether on the basis of the available scientific evidence it can be concluded that a no-effect level for the

				respiratory sensitisation effects ADCA exists. This is an issue to be addressed in the authorisation applications and be scrutinised by the Risk Assessment Committee when preparing its opinions on the authorisation applications..ECHA recognises that currently there is uncertainty with regard to whether it is possible to determine a threshold and that further work is ongoing with this respect. **Volumes scoring** The estimation of volumes in the scope of authorisation for priority setting relied on data from the registration dossiers as provided in section 3.2 of the IUCLID dossiers. The cumulative volume provided by all registrants is clearly within the range 10,000 - 100,000 t/y. Having the correct volumes reported in the registrations is responsibility of the registrants. ECHA cannot rely on external estimates of the assessment for the volume, as completeness and adequacy of the estimates cannot be verified properly. **WDU scoring re: Sites** It should be noted that, according to the general prioritisation approach, the "total number of sites where the substance is used in the scope of authorisation" has to be considered. In this context, uses need to be considered in a lifecycle perspective when exposure resulting from use of articles containing a substance cannot be excluded. ECHA had calculated the original "sites" score on the basis of data and best-knowledge estimations, which are set out in the background document. Taking into account the information that already has been available (submitted in response to the consultation performed during preparation of the Annex XV Dossier, during the

				consultation on SVHC identification of the substance, and in the registrations) and the new information submitted in this consultation on the site numbers, ECHA does not find sufficient grounds to change the assessment of wide dispersiveness of the use. Regarding the request that only the number of sites using powder forms should be considered, we note in addition the following: ECHA acknowledges that for ADCA the SVHC property relates to inhalation exposure, and that use in forms of negligible fugacity may, under certain conditions, make it less likely that significant exposure levels arise. However, it is emphasized that: • powder forms are not only used in the formulation stage; survey data provided by industry during public consultation show that various forms are supplied on the market, with powders used by many of the ADCA users, including also several compounders and converters • not only the pure powder form, but also pre-blended powders and powder pre-mixes are forms which would be expected to lead to significant air concentrations; already these forms seem to occur at around 100 sites based on estimates provided in public consultation • there is a large variety of forms supplied on the market and it is difficult (in particular at this stage of the authorisation process) to conclude that certain categories of forms would by default entail negligible exposure potential. For instance, there is a difference between "dust-free" and "low-dust" forms as for the latter significant exposure levels cannot be excluded – especially as for

				ADCA there are indications that it can cause effects already at low exposure levels. Furthermore, forms such as liquid dispersions may form liquid aerosols and may as well lead to significant exposure. **WDU scoring re: Releases** It should be noted that the prioritisation step in the authorisation process comprises a general evaluation of the use pattern and exposure potential a substance may have. The inclusion in Annex XIV is per substance and not per use (or installation). Therefore screening of release potential in the prioritisation phase does not assess the exposure levels from single uses (at specific sites), but aims to deduce whether there are uses/situations where potential for exposure cannot be excluded. ECHA had assessed that there are identified uses of ADCA which have a potential for significant occupational exposure at formulation, compounding, and conversion steps of the life cycle of ADCA. In particular, potential for exposure cannot be excluded during not enclosed or partially enclosed operations such as mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact), transfer / loading, and calendering operations. **No suitable alternatives** The prioritisation for inclusion in Annex XIV is based on the criteria set out in Art 58(3) and follows the agreed approach described in the general approach document (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf). Information on topics such as the availability and suitability of alternatives is not a criterion for prioritisation as, apart from proper control of risks arising from the uses of substances of very high concern, a further

				objective of authorisation is the progressive replacement of SVHCs by suitable alternative substances or technologies where these are economically and technically viable. Indeed, Article 55 stipulates that applicants for authorisation shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution (this has to be included in the analysis of alternatives to be submitted as part of the authorisation application in accordance with Art. 62 (4e)). Therefore, the present lack of alternatives to (some of) the uses of a substance is not a viable reason for adjourning the subjection of the substance or some of its uses to authorisation. Information regarding lack of alternatives is however important information for inclusion in an authorisation application. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period. **Other RMO** Please note that in the process of assessing whether a substance on the Candidate List has priority for inclusion in Annex XIV and therefore should be recommended for inclusion in this annex we are not in the position to assess the pertinence of alternative regulatory risk management options for the substance or some of its particular uses or physical forms. Note also that authorisation is not comparable to a ban or restriction of a substance but rather to a requirement to request authorisation for

				carrying out particular uses with the substance. Recognised substances of very high concern maybe granted an authorisation if the applicant can show adequate control of risks arising from the applied for uses or if there is no suitable alternative available to the substance available and the socio economic benefits of a use outweigh the associated risks for health and environment.
2450	2013/09/23 17:14	Swish Building Products, Company, United Kingdom	ADCA has been used by Swish since the business started in 1976 in our foamed rigid PVC applications. Over the years Swish has introduced some sodium bicarbonate into the blowing agent system but we never been in a position to totally replace ADCA. In fact Swish has found that ADCA cannot be removed from our application completely as this causes unacceptable quality. Further details of the reasons we use ADCA can be seen in the attached report which highlights the benefits and the measures we have taken to minimise risk when using this substance.	Thank you for your comment and for the information provided. **Please see our response to Comment # 2466 in this Section.**
2443	2013/09/23 16:32	Company, Germany	ADCA (Azodicarbonamid, CAS 123-77-3, EC Nr. 204-650-8 = Diazene-1,2-Carboaxmide (CC'- azodi (formamide))) ADCA is a substance in powder form which we use as a blowing agent in our pvc-plastisols in the wallcovering production processs. The Tapetenfabrik Rasch located in Bramsche (northern part of Germany near Osnabrueck) has a usage of approx. 200 to p.a. of this substance for the production of wallcoverings. For 95% of the wallcoverings being produced in Bramsche ADCA is an indispensable raw material. In the production process the printed wallcovering passes a hot air oven as final step in the process. ADCA which is contained in the pvc-plastisols that we print on a paper base material is being activated by the temperature and produces gases (Nitrogen and Ammoniak) which give foam structure and 3D-effect to our product. Function of ADCA is similar to baking powder. By increasing the volume of our product ADCA helps to reduce the usage of precious resources such as pvc significantly. ADCA is used in many products such as construction materials, artificial leather, flooring, automobile etc. In the USA ADCA is used as an additive in the food industry for baking products. In the European wallcovering industry there was only one disease of one worker due to ADCA (asthma). That was back in 1989. Working conditions have been improved significantly since then and after this single event no other case of disease occurred. In other industries (especially the chemical industry) 30 other diseases	Thank you for your comment and for the information provided. **No suitable alternatives** The prioritisation for inclusion in Annex XIV is based on the criteria set out in Art 58(3) and follows the agreed approach described in the general approach document (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf). Information on topics such as the availability and suitability of alternatives is not a criterion for prioritisation as, apart from proper control of risks arising from the uses of substances of very high concern, a further objective of authorisation is the progressive replacement of SVHCs by suitable alternative substances or technologies where these are economically and technically viable. Indeed, Article 55 stipulates that applicants for authorisation shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of

			occured until 1996. After that only one more case was recorded (2008). This history of diseases due to ADCA shows that manufacturers and processors have improved working conditions and the risk of ADCA is under good control. We –the Tapetenfabrik Rasch- use ADCA since approx. 30 years for the production of pvc-based wallcoverings. We did not have any case of disease due to ADCA in all these years. Our workers are checked by our factory doctor on regular bases. All these examinations did not show any negative health effects due to ADCA. In principle every substance which comes in powder form can be respired by humans: chalk, TiO2, dust, flour. Our workers which handle the ADCA are being specially protected by dust exhausts and dust masks. We also buy the ADCA in a „dust reduced" (a more humid form) form since years. It would also be possible to buy in the ADCA as a masterbatch (ADCA dispensed in fluid). We then would not have any ADCA in powder form in our factory at all. Our Customers and the consumers cannot get in touch with the ADCA because it is fixed in the vinyl matrix. That means that our product is save. We have no alternatives for the ADCA. Some blowing agents are not suitable for our process temperatures (e.g. baking powder). Others are not useable for us for economic reasons: they are too expensive, do not give enough gas volume and the available amounts are much too small (e.g. OBSH). If we are not allowed to use ADCA anymore we are not competitive to manufactures outside the EU anymore. Another problem is that other blowing agents give other relief to the surface of a wallcovering. And that means that we cannot produce an existing item with another blowing agent. Our portfolio includes approx.. 6.500 different items. For all of them we use ADCA in the production process. Prohibition of ADCA usage in the EU would have an immense effect on the European wallcovering industry. We do not think that it would be possible to avoid closing our Bramsche site. In Bramsche we make a turnover of 140 Mio. € p.a. and we have 450 employees. We are one of the biggest employers in Bramsche. At the same time it would be possible for non-EU wallcovering manufacturers to sell their products in the EU as long as they are below the 0,1 mass % ADCA-threshold in their products. To achieve this is no problem at all. The Tapetenfabrik Rasch has a production site in the Ukraine with similar equipment compared to our German site too. In the end a prohibition of ADCA in the EU would force the European wallcovering industry to move bigger parts of their assets to non-EU sites. We estimate that the European wallcovering industry makes a turnover of	substitution (this has to be included in the analysis of alternatives to be submitted as part of the authorisation application in accordance with Art. 62 (4e)). Therefore, the present lack of alternatives to (some of) the uses of a substance is no viable reason for adjourning the subjection of the substance or some of its uses to authorisation. Information regarding lack of alternatives is however important information for inclusion in an authorisation application. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period. **Imported articles** As regards the probable limited benefit of authorisation in relation to import of articles containing the substance, please note that REACH Article 69(2) requires ECHA to consider for all substances included in Annex XIV (after their sunset dates as defined in Annex XIV) whether the use of these substances in articles poses a risk to human health or the environment that is not adequately controlled. If it is considered that the risk is not adequately controlled ECHA shall prepare a restriction dossier in accordance with Annex XV.

			500 – 750 Mio. € and employs approx. 3.000 people.	
2442	2013/09/23 16:30	SVITAP J.H.J. spol. s r.o., Company, Czech Republic	It is not so simple to suppose the ADCA in the artificial leather by another blowing agent and it takes time for tests of new blowing agents and for approvals by our customers - it concerns to cca 30% of our customers. new and approvals from our customers.	Thank you for your comment and for the information provided.
2440	2013/09/23 16:12	Kestrel, Company, United Kingdom	Kestrel has been using ADCA since 1990 to produce our PVC-ue building products. ADCA isn't the lowest cost blowing agent but due to its efficient and effective manner of producing the best cell structure for our products we have continued to use this additive. At this time we have yet to find a suitable alternative. Please find attached our brief report demonstrating the key benefits of the continued use of ADCA.	Thank you for your comment and for the information provided.
2438	2013/09/23 16:04	Company, Portugal	As a member company we fully endorsed the statement given by ADCA Task Force. Further to this we like to add some comments. Use and exposure The criteria applied to obtain the high scoring for wide dispersive use do not consider that the risk of exposure inside a company could be very restricted. ADCA is used as blowing agent in PVC paste spread coating processing in our company. Within this process, the risk of exposure to ADCA is only relevant in powder form. The only person exposed to inhalable ADCA in our company is one worker that opens the bags to prepare a pre-blended paste of ADCA. This operation took no more than one hour per day and two or three times a week. This opening bags operation is done in a chamber with local exhaustion that assures ADCA concentration in air below relevant limit values such as the STEL of 3 mg/m3 and TWA for 8 hours of 1 mg/m3 defined in UK, as we confirmed by direct measurements. Even with these values, the worker uses protective mask, goggles, gloves and disposable coveralls, according to work instructions and training. The mixing operation is done in a closed mixer. In next step, ADCA is incorporate in PVC paste as a pre-blended paste. As blowing agent, ADCA decomposes during submission to high temperature and, at the end, just residual quantities stays embedded in the polymer matrix. There is no risk of exposure during handling and processing of finished articles, there is no risk of exposure for end users. We consider that the risk management measures proposed by producers in safety data sheets assure a high level of protection for workers that contact with ADCA powder. In our company, only one, out of more than	Thank you for your comment and the information provided. **Please see our response to Comment # 2350 in this section.**

			350 workers, contact with ADCA powder. Actual safety conditions were improved since 7+ years ago. Before, with worst safety conditions, and we are using ADCA for more than 40 years, there was no health effect reported. Internal Market According to REACH Article 55, the aim of authorization is also to ensure the good functioning of the internal market. Authorization procedure applied to ADCA is disproportionate and is a competitive distortion for EU industry. 90% of our turnover depends on articles were ADCA is used; it is not possible to maintain the same kind of business without an alternative. There are no alternatives for this process and the timescale for developing potential alternatives could compromise the entire business. Any small change in formulations spends between one to three years to test and approve by the industry; working with new raw materials, new process conditions and new way of conduct characterization, testing, processing, and all activities related, spend, at least, 3 to 5 years. However, major and/or new changes on potential alternatives raw materials may lead to 5+ years for full validation depending on field tests conducted by OEMs. Impact on formulation and process conditions to compensate lower performance alternatives may lead to very expensive solutions, not competitive to other technologies. There is a higher risk that our Customers will change to other type of materials or will buy out of EU even before, in worse case, the authorization process becomes to a conclusion.	
2435	2013/09/23 15:53	Wirtschaftsverband der deutschen Kautschukindustrie e. V. (wdk), Industry or trade association, Germany	ADCA uses in rubber industry do not meet the criterion for prioritization 'wide-dispersive use'. Furthermore there is no significant exposure of workers in the rubber sector. Subsequently no occupational diseases have been reported. Due to the decomposition of ADCA in the curing process the substance content in the respective rubber articles is zero or below detection limit. Entirely bonded in the cured polymer matrix potential residuals are not available for the exposition of workers in follow up operations or for consumers. As a consequence of these facts wdk is questioning the high priority assigned to ADCA for inclusion in 1907/2006/EC Annex XIV. wdk is representing 85% of German rubber industry, which is about 25% of overall EU rubber sector. Nine out of 86 member companies are using ADCA. The total number of employees in our sector is at 75.000 of which 105 are working at workplaces where ADCA is handled. However most workers do not handle ADAC during the full shift: workers h/d	Thank you for your comment and for the information provided. **Questioning WDU** Please note that the prioritisation approach which was agreed and applied here to prioritise and recommend substances from the Candidate List for inclusion in Annex XIV is not intended to assess the risks exerted by the particular applications of a substance at particular sites (in particular countries) but to provide a very basic and general assessment of the use pattern and whether there is evidence based on which it could be concluded that relevant exposure does not occur. By doing so a conservative approach needs to be taken considering in particular uses or situations in

			50 8 28 1,5 20 0,5 11 <0,2 ADCA is used for very specific applications. Predominantly uses concentrate on - sealings - shock absorbing articles - noise absorbance - floorcoverings The average annual ADCA consumption in German rubber industry is 200 t/y. For an evaluation of a potential exposition the physical appearance of ADCA at the workplaces has to be considered. According a classification of three groups of ADCA physical appearance the distribution is as follows: class t/y dusty 21 low dust 42 no dust 137 Most of ADCA uses consume already material without dust emissions or with a significantly reduced potential for emitting dust. This is a snapshot on technical improvements which will carry on. In the Annex XV dossier a number of alternative blowing agents and techniques are reported. The production of cellular rubber articles is very specific and only chemical blowing agents can be used. The two potential alternatives for cellular rubber are OBSH and TSH. However the physical properties of the rubber articles designed for meeting the technical requirements of costumers in particular automotive industry can only be achieved by using ADCA. There is no full technical substitute to ADCA. Considering the hazard classification of the two alternative substances their use would even worsen the situation from an environmental point of view as well as occupational health issues are concerned. Rubber industry is experienced since decades with the proper handling and adequate use of substances with certain risks to the environment or to humans. As a substantial element of good industrial hygiene practice the use of appropriate personal protection equipment is compulsory and following strictly the recommendations set out in SDS's. Contrary to Annex XV dossier no occupational diseases have been reported in rubber industry. The sector can demonstrate the save use of the substance. Rubber processing is a multiple step process of which only in the first two steps ADAC is handled as a single substance. After storage (PROC 8b) and weighing (PROC 9) the substance is mixed in a closed system with natural / synthetic rubber, active filler and further chemicals. After mixing ADCA	which relevant exposure may occur. Therefore, ECHA's conclusion that some of the uses appear to have a potential for significant worker exposure and therefore – in combination with other criteria – qualify for prioritisation and inclusion in Annex XIV was drawn although risks might be controlled in other instances. Note that it is the obligation of the applicant for authorisation to demonstrate that the risks arising from the applied for uses are properly controlled or that there are no alternatives available and the socio-economic benefits of the use outweigh its risks. **More hazardous alternatives** Please also note that authorisation does not restrict the use of the substance as long as it is shown in the authorisation applications (and supported in the authorisation granting process) that either the risks arising from the use(s) applied for are properly controlled or that there are no suitable alternatives available and the socio-economic benefits are outweighing the risks arising from the uses. Concomitantly, the obligation to apply for authorisation is a strong incentive (or duty) to search for and develop suitable alternatives. The meaning of "(suitable) alternative" in the context of authorisation means the possibility of replacement of the substance in a particular use by another in technical and economic terms feasible substance or technology, thereby reducing the overall risk to human health and environment arising from the use in question. In cases where you consider substitution, we would suggest to comparatively assess the feasibility aspects and the overall risks to human health and the environment exerted by the substance / technology you currently use and of any potential alternative substance or

			is bound in the polymer compound and even dusty material is not available for respiratory exposition. Rubber curing temperature is in general above ADCA decomposition temperature. Voluntary measurements of remaining ADCA in finished rubber articles had been executed by an independent certified German institute. The findings confirmed the absence of ADCA in articles. No ADCA was found at a detection limit of 0,02%. Even assuming a presence of residual ADCA below detection limit in a rubber article the substance is entirely bound in the polymer matrix not able to emit. ADCA use in rubber industry is not a wide-dispersive one. The exposition to workers is very limited in terms of number of workers concerned, potential exposition per shift, quantity of ADCA used, physical appearance of the substance and the practice of proper industrial hygiene. The substance decomposes in the curing process and is not present in the finished article. There is no potential risk to workers in further production and it is of high importance to note that consumers are not exposed to ADCA when using cellular rubber articles.	technology.
2430	2013/09/23 15:35	Company, Germany	In our view, this material should not be included in Annex XIV. Adequate substitutes are classified more hazardous than ADCA	Thank you for your comment and the information provided.
2419	2013/09/23 14:33	Allgemeine Unfallversicherungsanstalt, National Authority, Austria	We support that diazene-1,2-dicarboxamide [C,C'-azodi(formamide)] gets high priority for inclusion in Annex XIV. Having in mind the Process Categories of the Registration Dossiers calendering operations ((PROC 6), industrial spraying (PROC 7), roller application, brushing (PROC10)) workers‘ exposure might still be a problem to solve. Especially because there seem to be less harmful alternatives for some oft he uses of ADCA. The sunshine date will be another driving force for the testing of substitutes like it seemed to be for the quality of the registration dossiers that miss now uses of professionals and consumers.	Thank you for your comment.
2416	2013/09/23 14:08	International organisation, Belgium	Response to the EU public consultation on ECHA recommendation to include “Azodicarbonamid” (ADCA) in REACH Annex XIV The use of ADCA for automotive products is crucial due to its functional and technical properties. At the moment ADCA is the most important blowing agent for the manufacturing process for the production of	Thank you for your comment and the information provided. **Please see our response to Comment # 2350 in this Section.**

			expanded thermoplastics, elastomers and rubbers. Further typical applications are in tapes, structural foams providing assistance in crash performance or lightweight solutions for polymers such as foamed EPDM, PVC, PE and CR which are reducing the overall vehicle weight, improving fuel economy and lowering tailpipe emissions. It furthermore is used in the production of sealants and other materials that support the reduction of wind and structure born noises and vibrations. At the same time it is improving corrosion performance of vehicles by preventing moisture to enter the cavities. It is mainly applied in the body in white area and expands during electro-coat. The risk associated with ADCA are at the very beginning of the value chain, when ADCA powder is added by the material formulators to the polymer matrix and formulated into the solid polymer or pumpable paste product. Workers in the automotive supply chain are therefore not exposed to respirable ADCA dust. The related production processes are furthermore often robot applied - any workers that may come into contact with materials containing ADCA are required to follow the RMMs provided in the Safety Data Sheets. These RMMs are well established and strictly adhered to in our industry. During manufacturing of parts ADCA decomposes to less than 0.1% weight/weight in the final article if processes are conducted appropriately. Remaining ADCA residues are embedded in the polymer matrix and thus do not pose any risk of release and exposure to the consumers. In the analysis of alternatives - the majority of substances proposed in the Annex XV Dossier carry a far greater risk than ADCA or are not adequately assessed. If these alternatives are used in the same quantities as ADCA, then their risk assessment score would be far higher than ADCA, meaning that they would also need to be substituted - this is not an effective sustainable solution and this approach should be avoided at all costs. The only substitute that was not worse from a toxicological viewpoint was sodium bicarbonate - this is already used in our industry when products of a higher density can be used. It is not a suitable alternative for lower density products as it does not have the expansion performance of ADCA (400% vs. 4000%). If used as a substitute it would add weight and cost to our vehicles and hampering our tailpipe CO2 efforts. Most other alternative chemical blowing agents are inappropriate for the production of expanded polymers / elastomers. The temperature range for	

			decomposition is too low (in case of TSH, Toluensulfonylhydrazid) or to high (in case of TSS, p-Toluolsulfonylsemicarbazid – for thermoplasts), the particle size is too big (NaHCO3) or they produce undesirable Nitrosamines (5-PT, 5-Phenyltetrazol). ADCA is used in the processing of more than a hundred of different parts per vehicle which would require a redesign of past and current models. As the materials produced with ADCA blowing agents include crash / safety performance applications in the vehicle, a change in product specification would invalidate the EU Type Approval - this could require all vehicles to be re-assessed for crash performance and re-type approved at great expense to the industry. Currently no suitable alternatives with the correct expansion criteria and processing temperatures have been identified. If a technically suitable alternative were to be identified in the future, the automotive industry would require a 5 to 7 year introduction period for the developments and homologation of new vehicles. Therefore it is crucial to our industry that sufficient lead time is provided in case of any necessary substitution. For the production of spare parts, industry does not see the possibility to substitute the use of ADCA as we need to maintain the integrity of the performance of the parts in relation to the performance of the vehicle as a whole, due to the inavailabity of "old" vehicles for validation purposes. Additionally, the automotive industry has to question the high scoring for the prioritisation of ADCA for Authorisation. The scoring points for volume and dispersive uses are too high. As the risks associated with ADCA are in the dispersive powder form, the industry volumes should only be attributed to the volumes of ADCA in the powder form. In this case a volume of 10,000 – 100,000 tonnes per annum is too high. Dispersive uses are only relevant where the powder is handled and are irrelevant when ADCA is bound to a polymer matrix, where it cannot be released. We believe if the powder form of ADCA was assessed, addressing the real concerns, then the scoring would not warrant prioritisation for authorisation. Effective risk management measures at this stage is a far more efficient method to enable industry to address the concerns of ADCA usage, rather than subjecting the industry to the uncertainties of the Authorisation process, which is incompatible to the automotive development process and would force our industry to seek alternative solutions such as sourcing parts produced with ADCA from outside of the EU.	

2407	2013/09/23 13:23	Company, Sweden	as member of the ADCA task force managed by reachcentrum, we want you to take de comments introduiced by the task force into consideration	Thank you for your comment. **Please see our response to Comment # 2350 in this Section.**
2406	2013/09/23 13:19	Company, Romania	as member of the ADCA task force managed by reachcentrum, we want you to take the comments introduiced by the task force into consideration	Thank you for your comment. **Please see our response to Comment # 2350 in this Section.**
2405	2013/09/23 13:15	Company, Czech Republic	as member of the ADCA task force managed by reachcentrum, we want you to take the comments introduiced by the task force into consideration	Thank you for your comment. **Please see our response to Comment # 2350 in this Section.**
2402	2013/09/23 13:01	Company, Poland	as member of tha ADCA Task force managed by reachcentrum, we support the comments introduiced by the task force.	Thank you for your comment. **Please see our response to Comment # 2350 in this Section.**
2401	2013/09/23 12:54	Company, Finland	as member of the ADCA Task Force managed by reachcentrum, we support the comments given directely from reachcentrum and ask you to take it into consideration	Thank you for your comment. **Please see our response to Comment # 2350 in this Section.**
2390	2013/09/23 12:11	ETRMA, Industry or trade association, Belgium	ETRMA questions the prioritisation of ADCA for inclusion in Annex XIV. ETRMA considers the defining the use of ADCA as "wide-dispersive" is incorrect, as is the statement that the substance is "expected to be used in applications where a significant exposure of workers cannot be excluded". ******** ADCA is a blowing agent which intentionally decomposes during article manufacturing processes. Most of the measurements of ADCA concentrations in finished articles shown concentrations below 0,1 %. Unreacted traces of ADCA in finished articles are bound in the polymer matrix in a way that prevents releases. Exposure to users is therefore not consistent with what is described in the Annex XV dossier itself. Uses of articles manufactured with ADCA do not result in significant releases of the substance. ADCA use may be considered only as 'widespread' but not as 'wide-dispersive'. ********	Thank you for your comment and the information provided. **Questioning priority** The potential for exposure may indeed in certain steps of the life cycle of the substance be relatively limited. However, at the same time there are also steps, as you also note, where control of risks may not be obvious in all cases, and that the proper implementation of Risk Management Measures (RMM) is essential. Registration is a requirement for all substances manufactured or imported above 1 tonne / year. SDS' have to be provided for all hazardous substances. For hazardous

			Potential inhalation exposure is limited to only early stages of rubber article manufacturing processes (namely: storage and weighing). ADCA is handled in powder form only by a limited number of workers (for example, in a plant of 217 workers only 7 handle ADCA in power form). Following the mixing phase, potential inhalation exposure disappears because the substance gets embedded in the polymeric matrix. ADCA in rubber manufacturing plants is handled in strict compliance with the specifications contained in the extended Safety Data Sheets, which are considered to be sufficient to avoid human health risks during the manufacturing of rubber goods, according to the risk assessment performed by manufacturers/importers during the REACH registration phase. The following personal protection measures are required, as reported in the REACH registration dossier. - Respiratory protection: Dust mask - Good ventilation and respiratory protection during dust formation - respiratory filter device (filter P2) in case of brief exposure or low pollution user - self-contained respiratory protective device in case of intensive or longer exposure. - Protection of hands: Protective gloves - The glove material has to be impermeable and resistant to the product/the substance/ the preparation - Preventive skin protection by use of skin-protecting agents is recommended. - Eye protection: Safety glasses - Body protection: Protective work clothing	substances registered in volumes >10t/y registrations need to include a CSR and SDS' communicated in the supply chain need to include ESs. Downstream users have an obligation to implement the recommended RMMs and OCs or prepare their own assessment. Compliance with these registration, SDS and downstream user obligations is not a reason for not subjecting the substance to the authorisation process. The authorisation requirement aims at enhancing substitution when technically and economically viable alternatives are available. Until this aim is achieved the aim is to ensure proper control of risks. For this later purpose , Risk Assessment Committee assesses also the appropriateness and effectiveness of the risk management measures as described in the application and there is a possibility to specify in the authorisation decision further conditions, including monitoring requirements. This provides an additional level of scrutiny of the appropriateness of the control measures compared to the registration and DU obligations. Prioritisation is a task of comparing the substances on the Candidate List based on certain agreed criteria. One of these criteria relates to the nature of the processes/activities involved in its uses (in the context of a rough assessment of "dispersiveness") **Low exposure/risk** Information on the low level of risk associated to a certain use should be provided as part of the application for authorisation. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the

				applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.
2388	2013/09/23 12:06	European Stabiliser Producers Association, Industry or trade association, Belgium	The members of ESPA (European Stabiliser Producers Association) have been involved in the plastic additives business for many years, manufacturing and supplying stabilisers and packages for plastic applications. They supply these additives globally and are familiar with the foamed plastics industry, both in EU and non-EU regions. They support their customers in laboratory based technical service and plant trials aimed at the assessment of alternative additives.	Thank you for your comment. **No alternatives / Socioeconomic benefits of use / Impacts of ceasing use / Low risks** Topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a use are important. Information regarding these topics should be provided as part of the application for authorisation (e.g. in the analysis of alternatives, the chemical safety report or the socio-economic analysis). This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation. However, it is to be stressed that the prioritisation for the inclusion in Annex XIV is based on the criteria set out in Art 58(3) and follows the agreed approach described in the general approach document (http://echa.europa.eu/docu+E2ments/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf). Consequently information on topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a particular use are not considered in the prioritisation for recommending substances for

				inclusion Annex XIV. **Authorisation perceived as a ban, favouring move of market share outside EU and import of finished articles into EU** Please note that REACH is an EU Regulation aiming to ensure a high level of protection of human health and the environment while enhancing competitiveness and innovation. The obligation to apply for authorisation is to ensure that risks are adequately controlled or that socio-economic benefits are outweighing the risks, while concomitantly it is a strong incentive to search for and develop suitable alternatives. Authorisation does not ban or restrict the use of the substance as long as it is shown in the authorisation applications (and supported in the authorisation granting process) that either the risks arising from the use(s) applied for are adequately controlled or that there are no alternatives available and the socio-economic benefits are outweighing the risks arising from the uses. Regarding import of articles containing the substance, please note that REACH Article 69(2) requires ECHA to consider for all substances included in Annex XIV (after their sunset dates as defined in Annex XIV) whether the use of these substances in articles poses a risk to human health or the environment that is not adequately controlled. If it is considered that the risk is not adequately controlled ECHA shall prepare a restriction dossier in accordance with Annex XV. **Burden for SMEs to prepare applications for authorisation, and restriction as a better RMO**

				Please note that in the process of assessing whether a substance on the Candidate List has priority for inclusion in Annex XIV and therefore should be recommended for inclusion in this annex we are not in the position to assess the pertinence of alternative regulatory risk management options for the substance or some of its particular uses. Note also that in accordance with Art. 62(1, 2) applications for authorisation may be made by the manufacturer(s), importer(s) and/or downstream users of a substance and for one or several uses. Applications may be made for the applicant's own uses and/or for uses for which he intends to place the substance on the market. From these specifications of Art. 62 it is evident that not each actor on the market has to apply for authorisation of his use(s) because he can benefit from the authorisation granted to an actor up its supply chain. It is further possible to submit joint applications by a group of actors.
2387	2013/09/23 11:49	British Plastics Federation, Industry or trade association, United Kingdom	The British Plastics Federation, BPF, is the leading trade association for the UK Plastics Industry. Encompassing the whole plastics industry supply chain, including; raw materials producers, additive suppliers and manufacturers of semi-finished and finished plastic products. Diazene-1,2-dicarboxamide more commonly referred to as Azodicarbonamide, and from herein ADCA, is the key chemical foaming agent for use in cellular thermoplastics and rubber applications. ADCA is widely used as a base technology for foaming many common plastics including; PVC, Polyethylene, Polypropylene, EVA, numerous rubber applications and polymer recycling. Common applications include; profiles for the construction industry (cladding, pipes, hygienic wall covering), thermal insulation products, cushioned flooring, wall coverings, car interiors, crash protection. We have significant concerns relating to the supporting information upon which the decision to recommend ADCA for authorisation has been made. We believe that information to be outdated and not representative of	Thank you for your comment and the information provided. **No alternatives / Socioeconomic benefits of use / Impacts of ceasing use / Low risks** Topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a use are important. Information regarding these topics should be provided as part of the application for authorisation (e.g. in the analysis of alternatives, the chemical safety report or the socio-economic analysis). This information will

			current industrial exposure to ADCA in the UK Plastics Industry. We include below further information which will provide supporting evidence to show the continued safe use of ADCA. Supply and Use of ADCA in the UK Plastics Industry: Following the decision to prioritise ADCA for inclusion in Annex XIV, BPF undertook a survey of those Member companies who use ADCA in their manufacturing processes. A total of 42 responses were received, split between the plastics (74%), coatings (21%) and rubber (5%) industries in the UK. Participants to the survey comprised of companies who either, compound and distribute mixtures and masterbatches containing ADCA, or, end processors using ADCA to produce foamed articles. There is no manufacturing capacity for ADCA in either the UK or Europe with the majority of supply predominantly coming from China (circa. 80%). The volume of ADCA being used by the 25 end processors who completed the survey represented a total volume of 1,000 tonnes per year being converted into a total of 95,000 tonnes per year of finished products with an estimated value of £284.2 million pounds. ADCA is supplied in a variety of physical forms. Our feedback from Members indicates that around 35% receive ADCA in pure powder form, 29% as pre-blended powder with secondary additives, 21% as a liquid dispersion, 9% as a solid masterbatch and 6% as a damped powder. Where ADCA is being used in a powder form, either closed systems have been installed or in the case of open or semi-open systems, personal protective equipment such as gloves, goggles, overalls and masks are used in the production steps where the most important exposure can be expected. In all forms, our Members indicate that personal protection equipment is always used. Companies also confirmed that staff with direct access to the material are aware of any potential handling risks and trained in the correct level of risk management. Our survey confirmed that no instances of worker health issues have arisen in the past 10 years related to the use of ADCA. A majority of our Members monitor dust in air and have found levels of both general dust (and ADCA) to be well below the safety limit set in place under the Control of Substances Hazardous to Health (COSHH) Regulations 2002. Why is ADCA used? The use of chemical foaming agents in polymer processing is a well established technology resulting in technical, environmental and commercial enhancements in the final product. Whilst weight reduction might be the key role associated with the use of foaming agents, many other benefits can also be found including; reduced polymer requirement, improved thermal insulation and design aesthetics. There are a number of possible chemical foaming agents available. The choice of which agent to use will be based upon their specific properties	be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation. However, it is to be stressed that the prioritisation for the inclusion in Annex XIV is based on the criteria set out in Art 58(3) and follows the agreed approach described in the general approach document (http://echa.europa.eu/docu+E2ments/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf). Consequently information on topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a particular use are not considered in the prioritisation for recommending substances for inclusion Annex XIV. **Regarding the impacts of inclusion of ADCA in Annex XIV, please see our response to Comment #2388 in this section.** **Regarding the applied RMM, see also response to comment #2390 in this section.**

			including; decomposition point, gas yield, colour, food contact approval, price etc. ADCA provides a unique blend of properties including a high gas yield compared to its alternatives helping to minimize use. Similarly, the flexibility it can provide during processing cannot be matched by any available alternatives. A large number of our Members have previously considered alternative foaming agents and technologies (including physical techniques) with little success; Respondents to the BPF survey indicated none were able to find a suitable alternative for their products. The key reasons for failure of alternatives included; the inability to achieve a finished article suitable for application use, unable to achieve a product which would meet national / international standards, issues on cell control, increased density of final product, poor dimensional stability, loss of surface finish and definition, reduction of mechanical properties, and a reduction in insulation properties. Some of the proposed alternatives would also result in a negative health and environmental impact of the final products. In addition, the substitution of ADCA for alternatives will have a dramatic effect on polymer demand as lower molecular weight resins may be required to obtain the same level of foaming resulting in products with lower tensile strength and durability. To put this into context, one Member company estimated a potential raw material cost increase of between 8 and 42%. Potential Impact for the UK Plastics Industry: Should ADCA proceed to be listed on Annex XIV, the potential detrimental effect for UK businesses cannot be underestimated. Consumers would be forced to accept a reduced choice of products of an inferior quality to those currently available and likely at an increased cost. In addition, many companies will be forced to shed jobs and potentially close their businesses or relocate to areas outside of the European Union. Our survey indicates in excess of 14,000 jobs, in the UK alone, could be at risk. One should also consider that this does not account for other dependant industries not included in the survey so the true number of potential job losses will be much higher.	
2380	2013/09/23 10:46	Benecke-Kaliko AG, Company, Germany	Benecke-Kaliko AG fully supports the statement of ADCA Taskforce concerning the prioritization of ADCA (summary can be found as item 6). Items 1-5 are statements from Benecke-Kaliko AG. 1.)The case studies mentioned in the original proposal are several decades old. No data is given on the concentration of ADCA in the breathable air and on which safety equipment had been applied.	Thank you for your comment and the information provided. **Please see our response to Comment # 2350 in this section.**

			Therefore, the data from these case studies is non transferable to the actual situation of working places in the EU. 2.)There is no indication of an increased illness level in our manufacturing process. On our shop floor, ADCA is handled for decades under safety precautions like local exhaust ventilations and personal protective equipment (e.g. gloves and dusk masks). We do not observe any increased illness rates, especially not on asthma cases in relevant work places where ADCA is processed. 3.)Evaluation of the ADCA exposure in our plants and from the final products: A Production General Remark: ADCA is received as a powder, as a plasticizer batched material or compounded in a PE or PP matrix. First Process Step: Batching ADCA powder to paste Measurements of short time exposure show a dust concentration of 0.60 mg/m³ and an alveolar dust concentration of 0.67 mg/m³ in the area of the working places where ADCA is handled as a powder. These values are far below the German limits of 10 mg/m³ for dust and 3 mg/m³ for alveolar dust. Furthermore we are far below the limit of 3 mg/m³ for ADCA short time exposure as given by United Kingdom regulations. As to further minimize the amount of incorporated dust we have local exhaust ventilations in place and the operators carry gloves and dusk mask as personal protective equipment. Further Process Steps: Mixing, coating, extrusion In further process steps only ADCA plasticizer pastes or ADCA polymer blends are handled. Therefore there is no contamination of the breathable air by ADCA and thus no exposure to workers. B Final Product In the step of foam generation ADCA is decomposed and does in principle not remain in the product. In addition, exposure to end consumers by our automotive car interior products, consisting of PVC foam foils (unsupported expanded vinyl), coated textiles (“artificial leather”, supported expanded vinyl), TPO foam foils can be excluded because ADCA is only added to one out of several layers of the product to generate a foam during the foaming process step in order to make the material soft and light weight according to the automotive customers’ specifications. As this foam layer forms the middle layer of the product which is covered by solid layers of material from both sides no ADCA can be exposed. 4.)Concerning this item we have included a renowned German university toxicologist when ADCA was added to the Candidate list. He stated clearly that the health risk of ADCA is far below the one of CMR substances, especially because the ADCA exposure risk is only observable in the field of professional workers. Here the exposure can be controlled	

			by technical installations and personal protective equipment for the workers. Furthermore see the statement of the ADCA Task force (point 6) where AMEC was included with toxicologists. 5.)Evaluation of alternatives: The alternatives mentioned in the dossier do not perform for the products we produce. Automotive interior PVC and TPO foam foils made with ACDA alternatives are not processable to final parts (as proven by internal studies and a 2012 Master thesis at the University of Reutlingen). For coated textiles only specific products can be made with less mechanical stability. Thus the alternatives are not suitable for most automotive material requirements. 6.)Summary of ADCA Taskforce statement: A)Prioritisation Criteria as such When we analyse all these new inputs (after the survey performed by AMEC on behalf of the ADCA TF) and check the proposed scoring for each aspect we would have the new proposed scoring as follows: - Aspect: Intrinsic properties; Scoring 1 (before 1); Comments: It could be reconsidered if a threshold could be established and agreed and a possible revision of classification with the new methods and tests developed for sensitization and the fact that ADCA produced in the past (when studies were performed) could be contaminated with some small amount of sensitizers (Cr) used in the production process which are not used nowadays in the current standard production processes. - Aspect: Wide Dispersive Use (Sites); Scoring 2 (before 3); Comments: Number of sites using powder (the potential higher sensitive one) in the several tens (not hundreds), so only 2 points according to the criteria followed by ECHA - Aspect: Wide Dispersive Use (Release); Scoring 1 (before 3); Comments: Release of ADCA is generally controlled, so 1 point according to the criteria followed by ECHA. - Aspect: Wide Dispersive Use (Total); Scoring 2 x 1 = 2 (before 9) - Aspect: Volume (Imports/Exports); Scoring 9 (before 9); Comments: It could be also reconsidered if we take into account that ADCA decomposes during foaming being transformed to another product different from the original and based on that it could be considered as a quasi-intermediate and hence a lower score could be applied. - Total scoring: 1 + 2 + 9 = 12 (before 19) Hence the total score based on the supply chain data is significantly lower than before without taking into account further arguments that could also lead to modifying the intrinsic properties and volume considered. For that reason, we hope that the proposal for inclusion in the Authorisation List will be revisited and ADCA should not be proposed for authorisation at	

			this current stage. B) Summary The substance ADCA is a substance with high importance for the EU industry, integrated in many technical developments and running projects all over the EU. State of the art thermal insulation is the essential condition to achieve EU energy and CO2 reduction targets; modern data cables produced in the European Union as well as essential parts in the automotive industry help to safeguard a high technological level. Thousands of jobs are directly linked to the continued use of the substance. It would be disproportionate to bring numerous supply chains or parts of them under authorisation - whilst only limited numbers of workers at sites handling ADCA are actually exposed to the substance - whilst today the very limited number of workers exposed to the potentially dangerous inhalable powder form, and hence at risk, can be assumed to be well-trained and adequately protected by the RMMs in place. Amongst the Task Force members, there has been no case of occupational asthma that could clearly be attributed to ADCA. We would like to stress that throughout Europe hundreds of downstream users would be subject to authorise their manifold uses – disregarding the fact that only very few of their workers are exposed at their sites and disregarding the fact that those exposed are protected by existing RMMs and hence not at risk to develop occupational asthma relating to their work. We believe that the inclusion of ADCA in Annex XIV would be legally questionable, disproportionate and, at a minimum, premature. Moreover, from a risk management perspective the authorisation route is not at all the most appropriate and effective RMO to protect workers in Europe against potential exposure resulting from handling ADCA. Introducing a binding OEL, which can be done in a similar timescales to the likely sunset date, would be a much better and effective RMO in order to safeguard EU's targets of occupational health, consumer protection, environmental protection and global competitiveness. Further efforts should be made towards deriving a threshold. Any consumer of professional use could be restricted. Taking into account the results of the technical report from AMEC as well as the issues presented in our general comments it is considered highly disproportionate to decide about the future of an important industrial substance primarily on basis of data collected and based mostly on an industrial surrounding 20 to 30 years ago. Adequate time should be granted to allow an appropriate scientific review of the present risks and the most efficient risk management.	

			Benecke-Kaliko is a world leading manufacturer of decorative automotive trim material (foils and coated textiles), the annual turnover being about 300 million Euros. Out of our ca. 1,600 employees 1,300 work in our EU plants. Roughly 75% of our materials are products with an included foamed sheet layer under the use of ACDA in our manufacturing process. As far as we know our competitors have in principle the same foaming techniques and comparable products as we do.	
2371	2013/09/22 11:06	Tropal, Company, Romania	Tropal and its Israel based Parent company - Palziv- are strongly against the inclusion of ADCA in Annex XIV. Palziv have worked for more than 20 years with ADCA, and if prioritised, would cause severe issues for Tropal, its fully owned subsiduary in Romania. Palziv/Tropal have joined the ADCA Taskforce and fully agree with everything mentioned in the document supplied by them to ECHA, against any further action taken with regards to ADCA.	Thank you for your comment. **Please see our response to Comment # 2350 in this Section.**
2370	2013/09/23 00:59	West and Senior Limited, Company, United Kingdom	As a company formulating foaming agent preparations, we have been handling ADCA, together with other chemical foaming agents since the 1980's. During this period we have witnessed huge levels of technical innovation related to the foaming of polymers across a broad spectrum of application, process, polymer and geographical (Global) region. ADCA is not the lowest cost option for chemical foaming but where used it is essentially because ADCA works efficiently and allows finished products to be manufactured which would not or have not been possible by any other chemical means. In many cases ADCA may be used in conjunction with a second chemistry yet it remains in place as the function of use, flexibility and controllable levels of foaming created by this material is irreplaceable in many sectors. Many day to day items incorporate this technology and these have been a significant factor in our population's wellbeing and in the majority of cases the applications have benefited the environment. For example areas of use include – Automotive interiors – crash protection, sound insulation, comfort and reduced weight allowing for improved efficiency. Construction – house cladding with improved insulation, low weight drainage pipes and wall panels resistant to microbial and termite attack. Household – domestic comfort and design in wallcoverings and cushioned flooring. Insulation – lagging of hot and cold water pipes, door and window seals. Safety – crash protection, buoyancy, sports flooring, cushioned footwear. The list of uses of ADCA is not limited to those mentioned above and many small yet critical applications have also evolved through the use of this chemical. The polymer processing industry has grown greatly in its short life and	Thank you for your comment and the process-specific information provided. **Please see our response to Comment # 2350 in this Section.**

			this has only been possible through a thorough and rigorous program of development and evaluation. Many finished products have been evaluated using a wide range of foaming chemistry and where ADCA has been selected, it has been selected on technical grounds and the knowledge that it will work and continue to work in a consistent manner. In many areas polymers have replaced historical materials which have a time served basis of approval. Wood and metals for example were known construction and engineering materials and to replace these and allow applications to evolve rather than simply replicate, polymer technology had not only to match but also improve on performance. The choice of ADCA has not been taken light-heartedly by any user, it has been based upon years of development. In many of these areas you will find the polymer system contains a series of components for example; stabilizer, lubricants, pigments, plasticiser etc. If these raw materials are examined further it is possible to see that the grades now used differ to those from first inception yet ADCA remains a constant. It remains constant as it is difficult and in some cases impossible to replace without compromise to performance and the levels of compromise will result in products which are no longer fit for purpose. The polymer industry is highly competitive and also highly regulated through numerous standards, it strives for new advancements and technological gain. Since the question regarding ADCA first appeared in 2012, we as an organisation have travelled extensively across Europe to assess the views of industry across various sectors of use. In all cases the industry has responded with shock and high levels of concern. Contrary to being a potential stimulus for new development, it is felt that this will hinder new product application and lead to regression, diverted funds and resource and possible exit from numerous market sectors whilst imports of foamed product manufactured outside of the EU will continue to grow and continue to use ADCA as the base chemistry. Industry knows there is a risk handling this material and this risk is now managed and managed to a high level. The lack of incident in recent years bears testimony to this controlled use as a powder, and the risk to consumer could be considered non-existent from the low residual levels and encapsulation within the polymer matrix. It has however made light of a further consideration, if ADCA had not been used and the products would never have been created, how many lives would have been lost through lack of impact protection or buoyancy, how many homes would be colder, how much more of the Worlds resources would have been wasted through excessive weight in transportation, increased level of polymer consumption and lack of thermal insulation? If these factors are also considered, use of ADCA should be congratulated not restricted. Attached you will also find two short technical summary reports	

			highlighting the impact on product performance if ADCA is removed from use. To further highlight the impact, the applications chosen already use a combination of technology rather than purely ADCA yet they cannot function correctly without it. As a company, West and Senior Ltd are responsible members of the ADCA Defence Task Force and fully support the detail highlighted in the Groups response document. We have also been in discussion with local and pan European trade associations and base chemistry manufacturers from Asia (no European manufacture remains) and wish to emphasise the level of concern created in all which is unprecedented within the normal workings of industry.	
2364	2013/09/22 20:46	Individual, France		Thank you for your comment and for the information provided. **Please see our response to Comment # 2350 in this section.**
2362	2013/09/22 10:30	PVC4Pipes, Industry or trade association, Belgium	We are writing to contribute details of our knowledge and experience of the above substance that has been used in the PVC pipe industry for many years. PVC4Pipes is the trade association set up in 2003 with the mission of developing and promoting sustainable PVC piping systems in the global market. Our members are drawn from all sections of the industry, from raw materials supply to pipe systems manufacture, testing institutes and promotional organisations. As such, we are in a position to offer a consensus view on the use of ADCA by the European PVC pipe industry. ADCA is used to create a rigid PVC foam in the core of a three-layer PVC pipe as show on figure 1a of the attachment in section IV. As described in detail in the attachment, the ADCA decomposes during the pipe manufacturing process and the residual level of ADCA in the finished pipe is almost zero. Analysis of several pipes has shown the level to be 0.02% or less, well below the 0.1% level that would require labelling of the product. Details of the test method and the results can be found in the attachment. Any residual ADCA is locked inside foam layer of the finished pipe which itself is encapsulated by outer layers of solid, impermeable PVC-U. ADCA has been the blowing agent of choice following many years of research and development. It is often used in conjunction with sodium bicarbonate to optimise the foam structure and hence pipe properties. Although sodium bicarbonate is much cheaper than ADCA and is therefore an attractive alternative to ADCA, the foam structures produced when it is	Thank you for your comment and for the information provided. **Low risks** Please note that the prioritisation approach which was agreed and applied here to prioritise and recommend substances from the Candidate List for inclusion in Annex XIV is not intended to assess the risks arising from the uses but to compare the Candidate List substances, based on, amongst other criteria, a very basic and general assessment of the use pattern and exposure potential they may have for humans (workers, consumers) and/or the environment. If a substance is included in Annex XIV it is then the obligation of the applicant for authorisation to demonstrate that the risks arising from the applied for uses are properly controlled or that there are no alternatives available and the socio economic benefits of the use outweigh its risks. Please also note that in addition to proper control of risks, substitution of SVHCs where

			used on its own are highly inferior to those produced using ADCA, leading to unacceptable pipe properties. No other blowing agent has been found to be suitable for this application. During the pipe manufacturing process, ADCA is used almost exclusively in non-dusting form. ADCA is often added directly at the throat of the extruder through enclosed delivery systems, eliminating any possibility of exposure of workers to it. Where a powder is used, operators wear dust masks and other protective clothing to eliminate any exposure to ADCA. During the installation and use phases of the foam core PVC pipes, it may be necessary to cut the pipes to length. This is normally carried out on site by building workers who will wear protective clothing. Once installed underground, there is no possibility of exposure to ADCA. In conclusion, it can be stated that the use of ADCA in the of PVC foam core pipes does not result in production workers to significant risk of exposure to ADCA, which decomposes during the production process. During installation of the finished pipes, the possibility of exposure is miniscule and during the use phase it is zero. Consequently, whilst there may be widespread use of ADCA in the manufacture and use of PVC foam core pipes (there are many producers in Europe), it is in no way dispersive.	technically and economically viable and good functioning of the internal market are also objectives of the authorisation title.
2357	2013/09/20 20:56	Global P - Polímeros e Aditivos, Lda., Company, Portugal	We know that ADCA is in the Draft Recommendation of Substances for the Authorization List and we totally disagree	Thank you for your comment.
2355	2013/09/20 19:58	Company, United Kingdom		Thank you for your comment and for the information provided.
2350	2013/09/20 19:26	ADCA TASKFORCE, Industry or trade association, Belgium	Under this section we would like to highlight those points that the ADCA Task Force feels are most important in answering to the recommendation of including ADCA for authorisation proposed by ECHA in June 2013. Concrete numbers to reinforce the arguments can be found in the attached report prepared by AMEC on behalf of the Task Force. The ADCA Task Force consists of 51 member companies representing next to manufacturers and importers above all Downstream Users from all major supply chains throughout Europe. A list is can be found in the attachments. 1. On authorisation of ADCA as such and the appropriate RMO for ADCA (A) Preliminary legal and RMO remarks There are still many open issues in the legal, scientific and political	Thank you for your comment and the information provided. **Process is premature for Resp Sens & EloC** Article 57(f) REACH states that substances may be included in Annex XIV that are "*substances — such as those having endocrine disrupting properties or those having PBT properties or vPvB properties, which do not fulfil the criteria of a PBT or a vPvB substance – for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those*

			discussions around respiratory sensitizers. As a result, the inclusion of ADCA in Annex XIV is inappropriate, disproportionate and, at a minimum, premature. First, respiratory sensitization is not an explicit category meeting the criteria of "equivalent level of concern" to a CMR or PBT under Article 57(f) of REACH. Indeed, the only example of substances of equivalent concern given by Article 57(f) are endocrine disruptors, i.e. substances with yet unknown effects and for which there were no objective criteria at the time that REACH was tabled. By contrast, respiratory sensitization was a known effect already covered by the CLP Regulation on the basis of objective criteria. If the legislator had intended to include respiratory sensitizers under Article 57 of REACH, they could – and indeed would - have done it explicitly. By failing to do so, the legislator must have deliberately decided not to subject this very well-known category to the authorisation process. By adding ADCA to Annex XIV ECHA would act ultra vires and without proper legal basis. Second, even if respiratory sensitization was considered as a category giving rise to an "equivalent level of concern" to a CMR or PBT under Article 57(f), ECHA's own guidance document on the preparation of the Annex XV dossier states that there must be, at a minimum, scientific evidence that the substance causes probable serious effects of equivalent concern to a substance falling under points (a) to (e) of Article 57 (i.e. CMRs and PBTs). Such evidence must come from "risk-based" considerations that the substance may cause "serious effects" during use, the nature of which is "irreversible" (like CMRs or PBTs), and after thorough consideration, it should have been established that the inclusion of the substance in the Candidate list and eventually in Annex XIV constitutes the most effective "risk management" option. Those general criteria are not met for respiratory sensitizers such as ADCA. Indeed, sensitization is a two-step process, which comprises: (i) induction, a symptomless phase where the immune system develops a heightened susceptibility to react to the sensitizer, and (ii) elicitation, a phase involving clinical (and reversible) symptoms, such as rhinitis and conjunctivitis. The second phase is critical because it is reversible. Indeed, if the worker is removed from exposure once the initial mild symptoms appear, these will gradually disappear and no permanent damage will ever occur. This is not quite an 'equivalent concern' to a CMR, as in such a case there are no "early markers" nor is it possible to reverse the effects by removing the person from exposure once the symptoms appear. The practical consequence of this is that effective risk management	*of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59 REACH*". It is clear from the wording of Article 57(f) that substances having endocrine disrupting properties or those having PBT/vPvB properties are merely examples of substances that can be identified as substances of equivalent level of concern to those listed in Article 57(a) to (e) (ELoC) ("*such as*"). Accordingly Article 57(f) can be used as a basis to identify substances with other properties (e.g., as a respiratory sensitiser) as ELoC. The criteria listed in the Guidance for the preparation of an Annex XV dossier were followed for the identification of ADCA as SVHC. In accordance with this Guidance the following elements were considered in the identification process of ADCA as a substance of very high concern: • The seriousness of the effect • Irreversibility of health effects • The consequences for society • Difficulty in performing concentration-based risk assessment • Other factors: Quality of life For further details ECHA refers to the supporting document justifying the inclusion of the substance in the Candidate List, available on ECHA's website. **Sensitisation & reversibility** ECHA agrees that many of the symptoms of the elicitation phase may be reversible over a period ranging from days to years. However, the induction phase is not reversible therefore the effected worker is at greater risk for permanent damage to their health throughout

			measures can be taken to prevent any serious health effects associated with respiratory sensitizers (e.g., asthma). This management option can be easily implemented, as employers are required by law to carry out regular health monitoring actions where there is a risk of exposure. And in any event, as noted, the presence of "early markers" (i.e. symptoms occurring during the elicitation phase) is such, that those symptoms can be cured and any further permanent effect avoided. Hence, sensitization is not automatically a concern of "equivalent level" to a CMR or PBT. Furthermore, as an example, we would like to refer to the recent activity by ECETOC and its new "Respiratory Sensitization Task Force" set up in May 2013. This task force has been looking at issues such as possibilities of establishing a threshold or further investigating how far respiratory irritation can clearly be distinguished from hypersensitivity. The classification and labeling as respiratory sensitizer is based on human data. Not all animal tests showed sensitization evidence and, so far, there is no validated test method to investigate the respiratory sensitizing potential of a substance. Two court cases are ongoing in the European Court of Justice relating to two other respiratory sensitizers where the inclusion of respiratory sensitizers as such is challenged. It would be consistent to wait for the outcome and a general judgment on this before moving ahead with ADCA in isolation. Indeed, the inclusion of ADCA in Annex XIV would be inappropriate, premature and disproportionate, as the EU Court may very well conclude that there is no basis for adding respiratory sensitizers to Annex XIV. That, in turn, not only would oblige ECHA (and the Commission) to revisit all past inclusions on grounds of respiratory sensitization, but also would give rise to possible damage claims from companies who have prepared costly requests for authorisations for substances that were not supposed to be listed in Annex XIV, as well as those which didn't prepare such requests and thus have been prevented from using the substance after the 'sunset date'. (B) Scientific and practical remarks Relating to ADCA, AMEC's toxicological experts have analyzed existing literature and models and came to the conclusion that it should be possible to derive a concentration of exposure that would make ADCA sensitization indistinguishable from background adult onset asthma rates. The time dictated by the ongoing regulatory speed was, and is too short to allow sufficient time for a better and more thorough understanding and further investigation on this. Since exposure limits were set in the UK for an 8 h maximum exposure at 1mg/m3 in 1996, and short-term exposure limit of 3mg/m³ in 1996 no more cases of occupational asthma clearly relating to ADCA exposure	their career. In addition, if the symptoms are not recognised in time, they may progress to asthma, a permanent, debilitating disease. **Court cases on HHPA & MHHPA** The Court cases T-134/13 and T-135/13 are actions brought by a number of companies for partial annulment of ECHA's decision ED/169/2012 concerning the inclusion, respectively, of hexahydrophthalic anhydride (HHPA) and methylhexahydrophthalic anhydride (MHHPA) as substances meeting the criteria set out in Article 57(f) REACH, in accordance with Article 59 REACH. As general principle, ECHA highlights that actions before the European Court of Justice have no suspensive effect and that therefore there is no need to wait for the outcome of the Court's judgments before deciding whether or not the substance meets the criteria for inclusion of the substances in Annex XIV to REACH. Furthermore, it has to be outlined that assessment of substances under Article 57(f) REACH has to be done on a case-by-case basis, in accordance with the procedure set out in Article 59 REACH. The referred cases are related to the inclusion in the Candidate List of other substances than ADCA; thus, the related arguments and motivations cannot be simply applied by analogy is important for the next stage of the authorisation process, namely application for and granting of the authorisations process. Based on the above, it is ECHA's opinion that the mentioned Court cases have no impact on the current prioritisation process for ADCA. **Other RMO**

			were reported to databases that collect workplace health information in the UK (OPRA6 and THOR-GP7). A third database SWORD lists one case in 2008. In almost all measurements provided by the Task Force Members, exposure time is significantly shorter and the value is not reached as companies now apply much more protective RMMs than they did in the past, partly also as a result of REACH. Moreover, no occupational asthma occurrence clearly relating to ADCA exposure was reported. So one of the open questions is whether or not authorisation clearly is the preferred Risk Management Option (RMO) when it comes to better protecting workers in the EU or whether concerns relating to the workers' exposure are not better addressed by a derivation of an EU wide OEL. 2. Use and exposure – wide dispersive use ADCA is not manufactured in Europe anymore and the attached report explains in more detail how the supply chains are organized. The only persons exposed to inhalable ADCA in Europe are workers handling ADCA powder at certain points in the supply chains, notably in the formulating and compounding stages. Basically, ADCA enters Europe in pure powder form and is then treated or processed by formulators and compounders, who sell or use preparations containing ADCA in various concentrations and delivery forms (dusting mixtures and preblends and non-dusting mixtures, pastes, dispersions and granules). In the final processing stage, the ADCA is already embedded in a polymer matrix (either thermoplastic or rubber) and decomposes to expand the matrix into a foam. All handling and processing steps take place in industrial settings. Although the end application of the finished articles (in automotive, civil engineering, decoration, advertising etc.) is manifold the ADCA is always just used as foaming agent for plastics and rubber in an industrial surrounding. Due to the decomposition of the ADCA in the final industrial processing step, the finished article does not contain ADCA anymore (typically just in traces below 0,1% or embedded in a polymer matrix). Therefore, we would like to ask ECHA to reconsider the criteria applied to derive the high scoring for wide dispersive use report. a. Based on the survey conducted among the Task Force members, ADCA is handled only at a limited number of the sites by workers in inhalable form – in the remaining companies non-or low-dusting delivery forms such as low-dust or diluted formulations, granular masterbatches or liquid dispersions or pastes containing ADCA already in a bound form are used.	Please note that in the process of assessing whether a substance on the Candidate List has priority for inclusion in Annex XIV and should therefore be recommended for inclusion in this annex, we are not in the position to assess the pertinence of alternative regulatory risk management options for the substance (e.g. the development of a binding OEL for the EU) or some of its particular uses. Note also that authorisation is not comparable to a ban or restriction of a substance but rather to a requirement to request authorisation for carrying out particular uses with the substance. Recognised substances of very high concern maybe granted an authorisation if the applicant can show adequate control of risks arising from the applied for uses or if there is no suitable alternative available to the substance available and the socio economic benefits of a use outweigh the associated risks for health and environment. **WDU scoring re: Sites** It should be noted that, according to the general prioritisation approach, the "total number of sites where the substance is used in the scope of authorisation" has to be considered. In this context, uses need to be considered in a lifecycle perspective when exposure resulting from use of articles containing a substance cannot be excluded. ECHA had calculated the original "sites" score on the basis of data and best-knowledge estimations, which are set out in the background document. Taking into account the information that already has been available (submitted in response to the consultation performed during preparation of the Annex XV Dossier, during the consultation on SVHC identification of the

			b. At sites where ADCA is handled be it as pure powder or already in a bound form, only a limited number of workers is potentially exposed to ADCA as only few workers of a shift are in contact with the substance and this at rather short time periods during the shift. c. Although the assumption that "formulations containing ADCA appear to be prepared in industrial settings and then further distributed to downstream users (Austria, 2012).This suggests a supply chain structure with tens of formulator sites and hundreds of use sites in the EU.", is correct, it is not realistic to conclude that in all those sites also all workers are exposed to ADCA – and even more so to ADCA in inhalable form. The number of those sites is in the order of several tens. d. Finally, the risk management measures applied by the companies (and a lot of Task Force members are smaller Downstream Users) in order to protect their limited number of workers are effective as no more cases of occupational asthma relating to ADCA have been reported in recent years. Sites are throughout Europe regularly monitored (controlled release) and CLP regulation is applied. e. The registration dossiers now clearly advise against professional and consumer uses, and hence some of the PROCs mentioned in the prioritisation document are not present. 3. Other information Regarding socio-economic impacts it needs to be understood that, whereas only a limited number of workers are exposed to ADCA in inhalable powder form, the number of workers affected in case of a refused authorisation or shifting of sites would be more than double this number. In case of ADCA being put under authorisation, companies might either close down or shift activities outside Europe. Finished articles foamed with ADCA would not be produced in Europe anymore – hence entire DU industry supply chains would potentially be moved to Non-EU countries, entailing the loss of jobs that according to some estimates might well go into 100,000s. For the wide majority of the industrial uses there is currently no alternative available. The proposed requirement for authorisation would have significant impacts for the European industry. Any consumer use or uses by professional workers are now clearly advised against in the registration dossiers. 4. Conclusion (A) Prioritisation Criteria When we analyse all these new inputs (after the survey performed by AMEC on behalf of the ADCA TF) and check the proposed scoring for each aspect we would have the new proposed scoring as follows:	substance, and in the registrations) and the new information submitted in this consultation on the site numbers, ECHA does not find sufficient grounds to change the assessment of wide dispersiveness of the use. Regarding the request that only the number of sites using powder forms should be considered, we note in addition the following: ECHA acknowledges that for ADCA the SVHC property relates to inhalation exposure, and that use in forms of negligible fugacity may, under certain conditions, make it less likely that significant exposure levels arise. However, it is emphasized that: • powder forms are not only used in the formulation stage; survey data provided by industry during public consultation show that various forms are supplied on the market, with powders used by many of the ADCA users, including also several compounders and converters • not only the pure powder form, but also pre-blended powders and powder pre-mixes are forms which would be expected to lead to significant air concentrations; already these forms seem to occur at around 100 sites based on estimates provided in public consultation • there is a large variety of forms supplied on the market and it is difficult (in particular at this stage of the authorisation process) to conclude that certain categories of forms would by default entail negligible exposure potential. For instance, there is a difference between "dust-free" and "low-dust" forms as for the latter significant exposure levels

			Aspect Scoring Comments Intrinsic properties: 1 (before 1) It could be reconsidered if: • a threshold could be established and agreed. • a possible revision of classification with the new methods and tests developed for sensitization and the fact that ADCA produced in the past (when studies were performed) could be contaminated with some small amount of other sensitizers (Cr) used in the production process which are not used nowadays in the current standard production processes. Wide Dispersive Use (Sites) 2 (before 3) Number of sites using powder (the potential higher sensitive one) in the several tens (not hundreds), so only 2 points according to the criteria followed by ECHA Wide Dispersive Use (Release) 1 (before 3) Release of ADCA is generally controlled, so 1 point according to the criteria followed by ECHA. Wide Dispersive Use (Total) 2 x 1 = 2 (before 9) Volume (Imports/Exports) 9 (before 9) Total 1 + 2 + 9 = 12 (before 19) Hence the total score based on the supply chain data is significantly lower than before without taking into account further arguments that could also lead to modifying the intrinsic properties and volume considered. For that reason, we hope that the proposal for inclusion in the Authorisation List will be revisited and ADCA should not be proposed for authorisation at this current stage. B) Summary The substance ADCA is a substance with high importance for the EU industry, integrated in many technical developments and running projects all over the EU. State of the art thermal insulation is the essential condition to achieve EU energy and CO2 reduction targets; modern data cables produced in the European Union as well as essential parts in the automotive industry help to safeguard a high technological level. Thousands of jobs are directly linked to the continued use of the substance. It would be disproportionate to bring numerous supply chains or parts of them under authorisation - whilst only limited numbers of workers at sites handling ADCA are actually exposed to the substance - whilst today the very limited number of workers exposed to the potentially dangerous inhalable powder form, and hence at risk, can be assumed to be well-trained and adequately protected by the RMMs in place. Amongst the Task Force members, there has been no case of occupational asthma that could clearly be attributed to ADCA. We would like to stress that throughout Europe hundreds of downstream	cannot be excluded – especially as for ADCA there are indications that it can cause effects already at low exposure levels. Furthermore, forms such as liquid dispersions may form liquid aerosols and may as well lead to significant exposure. **WDU scoring re: Releases** It should be noted that the prioritisation step in the authorisation process comprises a general evaluation of the use pattern and exposure potential a substance may have. The inclusion in Annex XIV is per substance and not per use (or installation). Therefore screening of release potential in the prioritisation phase does not assess the exposure levels from single uses (at specific sites), but aims to deduce whether there are uses/situations where potential for exposure cannot be excluded. ECHA had assessed that there are identified uses of ADCA which have a potential for significant occupational exposure at formulation, compounding, and conversion steps of the life cycle of ADCA. In particular, potential for exposure cannot be excluded during not enclosed or partially enclosed operations such as mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact), transfer / loading, and calendering operations. **No alternatives / Socioeconomic benefits of use / Impacts of ceasing use / Low risks** Topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a use are important. Information regarding these topics should be provided as part of the application for

			users would be subject to authorise their manifold uses – disregarding the fact that only very few of their workers are exposed at their sites and disregarding the fact that those exposed are protected by existing RMMs and hence not at risk to develop occupational asthma relating to their work. We believe that the inclusion of ADCA in Annex XIV would be legally questionable, disproportionate and, at a minimum, premature. Moreover, from a risk management perspective the authorisation route is not at all the most appropriate and effective RMO to protect workers in Europe against potential exposure resulting from handling ADCA. Introducing a binding OEL, which can be done in a similar timescales to the likely sunset date, would be a much better and effective RMO in order to safeguard EU's targets of occupational health, consumer protection, environmental protection and global competitiveness. Further efforts should be made towards deriving a threshold. Any consumer of professional use could be restricted. Taking into account the results of the technical report from AMEC as well as the issues presented in our general comments it is considered highly disproportionate to decide about the future of an important industrial substance primarily on basis of data collected and based mostly on an industrial surrounding 20 to 30 years ago. Adequate time should be granted to allow an appropriate scientific review of the present risks and the most efficient risk management. 5. The ADCA Task Force Until very recently there has been no sectorial group to unite ADCA users in Europe. The REACH registration dossier was not commonly developed by a consortium – one of the non-European manufacturers took the lead, prepared the dossier on its own and sold Letters of Access to the core dossier. Communication in the beginning proved difficult to organize. EU users of ADCA have been taken by the unexpectedness and quickness of the regulatory action especially as adequate RMMs, monitored by the national and local authorities, have been put in place over the last two decades at EU downstream user sites to allow safe handling of a substance classified as respiratory sensitizer. Only in mid-May, a kick-off meeting of what is now called ADCA Task Force took place. 4 month later, mid-September, the Task Force counts already 51 members from all stages of different supply chains and is ready to operate together. The Task Force is managed by ReachCentrum. Provided more time is given, it might very well be a future task for the group to co-operate amongst themselves but also with relevant authorities on issues such as define reliable exposure-response relationships with regard to respiratory sensitization with the view of	authorisation (e.g. in the analysis of alternatives, the chemical safety report or the socio-economic analysis). This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation. However, it is to be stressed that the prioritisation for the inclusion in Annex XIV is based on the criteria set out in Art 58(3) and follows the agreed approach described in the general approach document (http://echa.europa.eu/docu+E2ments/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf). Consequently information on topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a particular use are not considered in the prioritisation for recommending substances for inclusion Annex XIV. The currently used prioritisation approach requires the application of two methods, a scoring method and the so called verbal-argumentative method. Whereas the outcome of the scoring method is expressed in quantitative terms (scores) the verbal argumentative method provides rather a more qualitative valuation. However, although the result of the scoring method is expressed in quantitative terms, it should be considered that the information basis (and the data requirements) for both the scoring method and the verbal-argumentative method are the same and that the assignment of scores bears the

			deriving a safe health-based OEL or pursuing a voluntary initiative aiming at reducing uses of ADCA in pure powder form or consider restrictions for certain unwanted non-industrial uses.	same uncertainties regarding the reliability of the data and a similar level of subjectivity as the verbal conclusions drawn with the verbal-argumentative method. This means that although the results are expressed in numbers the outcome of the scoring method is not necessarily more precise or correct than an argumentative verbal conclusion. **Inherent properties scoring** The question as to whether the respiratory sensitisation effects of ADCA are elicited by a mechanism for which it is possible to determine a no-effect threshold is important for the next stage of the authorisation process, namely application for and granting of the authorisations.. However ECHA does not assess at this stage of the authorisation process (i.e. recommendation for inclusion in Annex XIV) whether on the basis of the available scientific evidence it can be concluded that a no-effect level for the respiratory sensitisation of ADCA exists. This is an issue to be addressed in the authorisation applications and be scrutinised by the Risk Assessment Committee when preparing its opinions on the authorisation applications. ECHA recognises that currently there is uncertainty with regard to whether it is possible to determine a threshold and that further work is ongoing with this respect, as reported in your comment. **WDU Score too high** Thank you for your comment regarding the overall pattern of use of the substance in the EU, as well as the information on your specific application. ECHA considers that the potential for uncontrolled occupational exposure may indeed in many cases be relatively limited. However, at the same time there are also aspects which

				indicate that control of risks may not be obvious in all cases, and that the proper implementation of Risk Management Measures (RMM) such as suitable gloves and LEV is very often essential. **Please see also response to comment #2390 ("Questioning priority") in this section.**
2346	2013/09/20 18:06	Europacable, Industry or trade association, United Kingdom	Europacable, the European cable manufacturer association, would like to urge ECHA not to include ADCA in the upcoming recommendations of substances that should be subject to authorisation. The inclusion of ADCA in Annex XIV would have a high impact on the European wire and cable industry: • ADCA is a blowing agent used in the production of power, data and telecommunication cables for many years. • Today, no alternative substances have been technically qualified and implemented to replace ADCA for the application in wire and cable industries. The current proposals will have a major detrimental impact on the manufacture of the identified products as long as there is no similar alternative and will have significant implications for the future deployment of communication systems in Europe.	Thank you for your comment and the information provided. **Lack of alternatives/Impact on business** Please note that REACH is an EU Regulation aiming to ensure a high level of protection of human health and the environment while enhancing competitiveness and innovation. The obligation to apply for authorisation is to ensure that risks are adequately controlled or that socio-economic benefits are outweighing the risks, while concomitantly it is a strong incentive to search for and develop suitable alternatives. As ADCA is a respiratory sensitiser, there is a strong societal interest to protect humans, in particular workers handling the substance, from risks potentially arising from its uses. An authorisation requirement for ADCA will accordingly ensure that the health of workers in the EU involved in the uses of ADCA is protected. Please note further that authorisation, inter alia, is a means to promote the development of alternatives. Article 55 explicitly stipulates that applicants for authorisation shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution (this has to be included in the analysis of alternatives to be submitted as part of the authorisation application in accordance

				with Art. 62 (4e)). Therefore, the present lack of alternatives to (some of) the uses of a substance and the need to complete R&D programmes to get qualified alternatives is not a viable reason for adjourning the subjection of a substance or some of its uses to authorisation. Information regarding lack of alternatives is however important information for inclusion in an authorisation application. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.
2345	2013/09/20 18:05	United Kingdom, MemberState	We retain reservations about the prioritisation of ADCA for inclusion on Annex XIV as it is based on relatively old data. We have seen a decline in the number of UK cases of respiratory sensitisation since the early 1990s, which coincided with the time (1994) when ADCA was considered by the UK's Advisory Committee on Toxic Substances and it is likely that the process of setting an exposure limit initiated the application of effective workplace control measures in the UK. Consequently we would propose not to prioritise ADCA at this point until we have confidence that occupational asthma caused by this substance is still a problem and that Authorisation is an appropriate and proportional measure to take.	Thank you for your comment and the information provided.
2344	2013/09/20 17:37	NRK Dutch Rubber and Plastic Converters, Industry or trade association, Netherlands	The input is provided in the attachment	Thank you for your comment and the information provided. **Please see our response to Comment # 2454 and Comment # 2390 in this section.**
2342	2013/09/20 17:23	Company, Portugal	Endutex manufactures coated fabrics with PVC, PU and other polymers. Endutex uses ADCA as blowing agent to produce PVC foamed synthetic/artificial leather. This synthetic/artificial leather is sold to other	Thank you for your comment and the information provided.

			companies (mainly inside EU) to manufacture a range o articles as: - Clothing (rainwear, cold wear, …) - Protective suits - Mattress protection - Automobile Leather like products - Upholstery Endutex is concerned that the inclusion of ADCA in the authorisation process will lead to an increase of prices in EU, resulting in decrease competitiveness and losing business. Particularly in favour of imports from non EU countries. (Especially from China). If this trend is not stopped, EU industry will continue to disappear, with all the social consequences. Exposure Endutex, as Downstream User, buys ADCA in a powder form. In a semi-open system with local exhaust ventilation, ADCA is mixed with a plasticizer and transformed in a wet pasty product to avoid dust formation. This production step is the most important exposure that can be expected and operators use protective equipment such as gloves, goggles and masks. Regular medical checks did not show any situation of workers developing asthma due to a suspected exposure to ADCA. Potential alternatives have been tested and neither turned out to be appropriate for a complete substitution of ADCA due to inferior quality of foamed products and a negative health and environmental impact of the final products.	**Please see our response to Comment #2388 in this section.**
2339	2013/09/20 16:36	Hebron, S.A., An Otsuka Chemical Group Company, Company, Spain	Hebron, as a member company fully endorsed the statement given by ADCA Task Force. Further to this we like to add that: • Hebron - Otsuka Chemical, as Blowing Agents producer and one of the biggest importing ADCA into Europe, have not identified any other feasible alternative that could give the same foam properties and could assure the safe use and handling of the substance. At the day of today ADCA is the most important blowing agent for the manufacturing process for the production of expanded thermoplastics, elastomers and rubbers, and it is not on the near horizon possibility to develop, through R&D, a real, feasible and economical alternative to substitute ADCA without major and expensive changes in the production processes of thousands of companies using ADCA right now. • The majority of substances proposed in the Annex XV Dossier are even more dangerous than ADCA (in either physical or chemical hazards), most of them are not yet REACH Registered and has not been assessed, and so, there is a lack of information about is REAL danger for Humans and the Environment. If ADCA could be substituted by one of the	Thank you for your comment and the information provided. **Regarding alternatives and socioeconomic benefits/impacts of continuing/ceasing use, please see also our responses to Comments # 2350 and 2435 (sub-response "More hazardous alternatives") in this section.** Please also note that although the potential for exposure may in certain cases be relatively limited; at the same time there are also cases where (e.g. based on the form of ADCA and/or the process involved in its use) control of risks may not be obvious, and that the proper implementation of Risk Management Measures

			proposed substances (quite improbable technically speaking), we could find the situation that in the end, after the chemical safety assessment of these alternatives, the result could be much worse than using ADCA, and so, more investment to find another suitable alternative. This is not an effective sustainable solution and this approach should be avoided at all costs. • The particle size claimed in the EChA prioritization proposal "ADCA is a low molecular weight amide. It is manufactured predominantly as a yellow/orange powder with a particle size in the 2-10 micron range (Annex XV report, 2012), which is in the respirable range for humans" is not totally correct as you can find ADCA in the range of 2-25 microns. In fact the majority (almost 60 %) of the product sold in EU is higher than 10 microns and the one below 10 microns is usually blended or mixed with a polymer matrix or plasticizer before its handling. Furthermore, the majority of the powder product that enters into Europe is a coated powder which generates almost no dust to the pure ADCA.	(RMM) is very often essential. **Please see also response to comment #2390 ("Questioning priority") in this section.**
2331	2013/09/20 15:35	Company, Sweden	ETRMA questions the high priority assigned to ADCA for inclusion in Annex XIV; in particular it considers incorrect the definition of ADCA use as "wide-dispersive", as well as the statement that the substance is "expected to be used in applications where potentially significant exposure of workers cannot be excluded".. ******** ADCA is a blowing agent which intentionally decomposes during article manufacturing processes. Most of the measurements of ADCA concentrations in finished articles shown concentrations below 0,1 %. Unreacted traces of ADCA in finished articles are bound in the polymer matrix in a way that prevents releases. Exposure to users is not expected as described in the Annex XV dossier itself. Uses of articles manufactured with ADCA, even if taking place at many places do not result in significant releases of a substance. Release of ADCA may be considered only as 'widespread' but not as 'wide-dispersive' use. ******** Potential inhalation exposure is limited to early stages of rubber articles manufacturing processes (namely: storage and weighing)*. ADCA is handled in powder form only by a limited number of workers (as example, for a plant of 217 workers only 7 are handled ADCA in power form). Following the mixing phase, independently of the physical form in which ADCA is supplied to rubber manufacturing plants, risk of inhalation disappear completely because the substance ends up embedded into the polymeric matrix. ADCA in rubber manufacturing plants is handled in strictly compliance with the specifications contained in the extended Safety Data Sheets,	Thank you for your comment and the information provided. **Please see our response to Comment # 2390 in this section.**

			which are considered to be sufficient to avoid human health risks during manufacturing of rubber goods, according with the risk assessment performed by manufacturers/importers during the REACH registration phase. The following personal protections are required, as reported I the REACH registration dossier**. - Respiratory protection: Dust mask - Good ventilation and respiratory protection during dust formation - respiratory filter device (filter P2) in case of brief exposure or low pollution user - self-contained respiratory protective device in case of intensive or longer exposure. - Protection of hands: Protective gloves - The glove material has to be impermeable and resistant to the product/ the substance/ the preparation - Preventive skin protection by use of skin-protecting agents is recommended. - Eye protection: Safety glasse - Body protection: Protective work clothing * Tyre manufacturing process scheme ** http://apps.echa.europa.eu/registered/data/dossiers/DISS-9c802b65-15b3-5d0f-e044-00144f67d249/AGGR-47087da0-69c1-466f-a83c-89580bd878b0_DISS-9c802b65-15b3-5d0f-e044-00144f67d249.html#SU_HANDLING_STORAGE_HD	
2330	2013/09/20 15:35	Polifoam Plastic Processing Ltd, Company, Hungary	We do NOT recommend to include ADCA in Annex XIV. We do NOT recommend to priorisate this substance. Reasons: 1. We have been using this material for the last 25 years in industrially pure (99%) powder form. During this time period none of our operators have been affected neither by the stated problems, like allergy or asthma symptoms or breathing difficulties. If it is required we can give detailed info including operators' name etc. Naturally we follow the specific rules regarding the dust concentration limit in the air. Therefore following the specific rules the stated problems can be avoided. 2. This substance is allowed as food additive in USA according to "21CFR172.806". Code of Federal Regulations. April 1, 2012. This FOOD ADDITIVE (E927)is a flour bleaching agent and improving agent - used in the form of fine dust! 3. Recommendation states that ADCA (in industrially pure form aka 99%) contains 2-10 microns particles which is in the respirable range for humans. MEANWHILE ADCA formulations 1-95% are liquid (paste) and dust-free solids (granules). Recommendation states that "Formulations containing ADCA appear to	Thank you for your comment and the information provided. **Please see our response to Comment # 2350 in this section.**

			be prepared in industrial settings and then further distributed to downstream users (Austria, 2012). This suggests a supply chain structure with tens of formulator sites..." Therefore, except for the above mentioned formulator sites, the 2-10 micron particles are NOT PRESENT - they are aggregated (masterbatched), so the affected sites - as the Recommendation stated - are FEW TENS. According to Scoring approach "Uses - wide dispersiveness (WDU)" Site-# should be 1. In this case the Total Score (= IP + V + WDU)would be 13.	
2328	2013/09/20 15:36	SFEC, Industry or trade association, France	SFEC is a French umbrella association of Plastics Converters making PVC floors, PVA wall covering and PVA waterproofing sheets. SFEC members are converters, making flexible/ plasticized PVC (pPVC) . The processes used are calendaring and extrusion. ADCA is used to reduce energy and resources, thus contributing to EU targets regarding the efficient use of energy, mineral oil, fuel and CO2 emission reduction. Foaming with ADCA can contribute to raw material savings. This results in reducing substantially the weight of the finished products. ********** Adca is not a public health issue: O Adca remaining rate is very low (<0,1 % w/w) in the final products. (PVC flooring, wall covering). O Even if there is Adca remaining, (for flooring for example), the Adca cannot be emitted because of the closed top layer above the layer made of foam with Adca. So, it is a plant workers issue. O The Adca rate in the air is much below the only threshold (England: 1 mg/m3). We have done measurements in the air of different workshops and we got: * 0,012 mg/m3 * 0,04 mg/m3 * 0,08 mg/m3 * 0,33 mg/m3 * 0,012 mg/m3 These results are much below the only threshold existing which is in England. (Rate of 1mg/m3). More, workers wear masks (P22 or FFPP3), gloves and specific overall suit. So the exposure is insignificantly low. Local exhaust ventilation and efficient ventilation in the working area are installed. For many plants and workshop the Adca is in an automatic closed system.	Thank you for your comment and the information provided. **Please see our response to Comment # 2454 in this section.**

			So the exposure is also very low. (And during a short time). We can say also that, as far as we know, among the workers in Adca workshop, no one had any asthma disease. Alternative substances: • There is no alternative suitable substance. (Irregular cells of foam, speed of machine not suitable, foam not stable, quantity needed much more important, costly alternative,.). • Potential alternatives are also in hazard lists: Among the substances listed in the Austrian case (Annex XV, Table 14 on page 43), that recommended for PVC (OBSH) is classified as carcinogenic and mutagenic 1B 2. It is more volatile, and requires storage at a temperature below 50 ° C. There is no acceptable substitute for DCAA OBSH. • Mechanical foam is also impossible and too costly. (Too high Capex). Economic situation: • For PVC flooring Adca is mainly used for acoustic insulation floors. If the Adca is in the authorisation list, these kinds of floors will not be available. To get the sound insulation requirements, with PVC floorings, the building has to be build in a different way. It cost 5 % more for the all building. It's unbearable. • And, of course it will increase the unemployment rate if some product should be stopped.	
2326	2013/09/20 15:29	Company, Sweden	ETRMA questions the high priority assigned to ADCA for inclusion in Annex XIV; in particular it considers incorrect the definition of ADCA use as "wide-dispersive", as well as the statement that the substance is "expected to be used in applications where potentially significant exposure of workers cannot be excluded".. ******** ADCA is a blowing agent which intentionally decomposes during article manufacturing processes. Most of the measurements of ADCA concentrations in finished articles shown concentrations below 0,1 %. Unreacted traces of ADCA in finished articles are bound in the polymer matrix in a way that prevents releases. Exposure to users is not expected as described in the Annex XV dossier itself. Uses of articles manufactured with ADCA, even if taking place at many places do not result in significant releases of a substance. Release of ADCA may be considered only as 'widespread' but not as 'wide-dispersive' use. ******** Potential inhalation exposure is limited to early stages of rubber articles manufacturing processes (namely: storage and weighing)*. ADCA is handled in powder form only by a limited number of workers (as example, for a plant of 217 workers only 7 are handled ADCA in power form).	Thank you for your comment and the information provided. **Please see our response to Comment # 2390 in this section.**

			Following the mixing phase, independently of the physical form in which ADCA is supplied to rubber manufacturing plants, risk of inhalation disappear completely because the substance ends up embedded into the polymeric matrix. ADCA in rubber manufacturing plants is handled in strictly compliance with the specifications contained in the extended Safety Data Sheets, which are considered to be sufficient to avoid human health risks during manufacturing of rubber goods, according with the risk assessment performed by manufacturers/importers during the REACH registration phase. The following personal protections are required, as reported I the REACH registration dossier**. - Respiratory protection: Dust mask - Good ventilation and respiratory protection during dust formation - respiratory filter device (filter P2) in case of brief exposure or low pollution user - self-contained respiratory protective device in case of intensive or longer exposure. - Protection of hands: Protective gloves - The glove material has to be impermeable and resistant to the product/ the substance/ the preparation - Preventive skin protection by use of skin-protecting agents is recommended. - Eye protection: Safety glasse - Body protection: Protective work clothing * Tyre manufacturing process scheme ** http://apps.echa.europa.eu/registered/data/dossiers/DISS-9c802b65-15b3-5d0f-e044-00144f67d249/AGGR-47087da0-69c1-466f-a83c-89580bd878b0_DISS-9c802b65-15b3-5d0f-e044-00144f67d249.html#SU_HANDLING_STORAGE_HD	
2325	2013/09/20 15:28	Company, France	ETRMA questions the high priority assigned to ADCA for inclusion in Annex XIV; in particular it considers incorrect the definition of ADCA use as "wide-dispersive", as well as the statement that the substance is "expected to be used in applications where potentially significant exposure of workers cannot be excluded". ******** ADCA is a blowing agent which intentionally decomposes during article manufacturing processes. Most of the measurements of ADCA concentrations in finished articles shown concentrations below 0,1 %. Unreacted traces of ADCA in finished articles are bound in the polymer matrix in a way that prevents releases. Exposure to users is not expected as described in the Annex XV dossier itself. Uses of articles manufactured with ADCA, even if taking place at many places do not result in significant releases of a substance. Release of ADCA may be considered only as 'widespread' but not as 'wide-dispersive' use. ********	Thank you for your comment and the information provided. **Please see our response to Comment # 2390 in this section.**

			Potential inhalation exposure is limited to early stages of rubber articles manufacturing processes (namely: storage and weighing)*. ADCA is handled in powder form only by a limited number of workers (as example, for a plant of 217 workers only 7 are handled ADCA in power form). Following the mixing phase, independently of the physical form in which ADCA is supplied to rubber manufacturing plants, risk of inhalation disappear completely because the substance ends up embedded into the polymeric matrix. ADCA in rubber manufacturing plants is handled in strictly compliance with the specifications contained in the extended Safety Data Sheets, which are considered to be sufficient to avoid human health risks during manufacturing of rubber goods, according with the risk assessment performed by manufacturers/importers during the REACH registration phase. The following personal protections are required, as reported I the REACH registration dossier**. - Respiratory protection: Dust mask - Good ventilation and respiratory protection during dust formation - respiratory filter device (filter P2) in case of brief exposure or low pollution user - self-contained respiratory protective device in case of intensive or longer exposure. - Protection of hands: Protective gloves - The glove material has to be impermeable and resistant to the product/ the substance/ the preparation - Preventive skin protection by use of skin-protecting agents is recommended. - Eye protection: Safety glasse - Body protection: Protective work clothing * Tyre manufacturing process scheme ** http://apps.echa.europa.eu/registered/data/dossiers/DISS-9c802b65-15b3-5d0f-e044-00144f67d249/AGGR-47087da0-69c1-466f-a83c-89580bd878b0_DISS-9c802b65-15b3-5d0f-e044-00144f67d249.html#SU_HANDLING_STORAGE_HD	
2322	2013/09/20 15:12	Company, Sweden	ETRMA questions the high priority assigned to ADCA for inclusion in Annex XIV; in particular it considers incorrect the definition of ADCA use as "wide-dispersive", as well as the statement that the substance is "expected to be used in applications where potentially significant exposure of workers cannot be excluded".. ******** ADCA is a blowing agent which intentionally decomposes during article manufacturing processes. Most of the measurements of ADCA concentrations in finished articles shown concentrations below 0,1 %. Unreacted traces of ADCA in finished articles are bound in the polymer matrix in a way that prevents releases. Exposure to users is not expected as described in the Annex XV dossier itself. Uses of articles manufactured	Thank you for your comment and the information provided. **Please see our response to Comment # 2390 in this section.**

			with ADCA, even if taking place at many places do not result in significant releases of a substance. Release of ADCA may be considered only as 'widespread' but not as 'wide-dispersive' use. ******** Potential inhalation exposure is limited to early stages of rubber articles manufacturing processes (namely: storage and weighing)*. ADCA is handled in powder form only by a limited number of workers (as example, for a plant of 217 workers only 7 are handled ADCA in power form). Following the mixing phase, independently of the physical form in which ADCA is supplied to rubber manufacturing plants, risk of inhalation disappear completely because the substance ends up embedded into the polymeric matrix. ADCA in rubber manufacturing plants is handled in strictly compliance with the specifications contained in the extended Safety Data Sheets, which are considered to be sufficient to avoid human health risks during manufacturing of rubber goods, according with the risk assessment performed by manufacturers/importers during the REACH registration phase. The following personal protections are required, as reported I the REACH registration dossier**. - Respiratory protection: Dust mask - Good ventilation and respiratory protection during dust formation - respiratory filter device (filter P2) in case of brief exposure or low pollution user - self-contained respiratory protective device in case of intensive or longer exposure. - Protection of hands: Protective gloves - The glove material has to be impermeable and resistant to the product/ the substance/ the preparation - Preventive skin protection by use of skin-protecting agents is recommended. - Eye protection: Safety glasse - Body protection: Protective work clothing * Tyre manufacturing process scheme ** http://apps.echa.europa.eu/registered/data/dossiers/DISS-9c802b65-15b3-5d0f-e044-00144f67d249/AGGR-47087da0-69c1-466f-a83c-89580bd878b0_DISS-9c802b65-15b3-5d0f-e044-00144f67d249.html#SU_HANDLING_STORAGE_HD	
2321	2013/09/20 15:06	Ongropack Ltd., Company, Hungary		Thank you for your comment and the information provided. As regards your request for exemption please note that uses (or categories of uses) can only be exempted from the authorisation requirement on the basis of Art 58(2) of REACH, unless they are already explicitly

				exempted in REACH Art 2(5 or 8) or in Art 56 (3-6). Please note that according to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses "*provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled*". A list of uses that in accordance with the REACH Regulation are exempted from authorisation can be found at http://echa.europa.eu/documents/10162/17232/generic_exemptions_authorisation_en.pdf. Information on the low level of risk associated to a use or related to the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use, as well as the (adverse) impacts of ceasing a use are important. Information regarding these topics should be provided as part of the application for authorisation. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation
2310	2013/09/20 12:46	British Coatings Federation , Industry or trade association, United Kingdom	British Coatings Federation Comments to ECHA on proposal to Add ADCA to the Authorisation List The British Coatings Federation is the sole UK Trade Association representing paint, wallcovering and ink manufacturers with a turnover of €3 billion.	Thank you for your comment and the information provided. Please note that REACH is an EU Regulation aiming to ensure a high level of protection of human health and the environment while enhancing competitiveness and innovation. The

			Study We are concerned that the recommendation to authorise diazene – 1,2 dicarboximide (ADCA) [CAS no. 123-77-3, EC 204-650-8] has been substantially based on a study (Occupational asthma caused by a plastics blowing agent, azodicarbonamide by A J M Slovak) published over 30 years ago which itself is based on practices in industry from the 1970s. General health and safety practices in industry nowadays are far improved from when the study was carried out and we believe that the risks from ADCA are now minimal. The data below will demonstrate current exposure and usage of the product in the wallcovering industry. Data The chemical is widely used in the wallcovering industry in the production of liquid PVC plastisol and PVC plastisol spread coating which is further used to produce printed vinyl wallcoverings. These products make up a large proportion of the product sold by UK wallcovering manufacturers, (see below). In our industry ADCA is used by companies to compound and distribute mixtures and masterbatches containing ADCA and by end processors to produce articles containing ADCA, we have no manufacturers or importers of ADCA within our sector. UK manufacturers produce annually 20,000 tonnes of vinyl wallcoverings which use about 250 tonnes of ADCA as the blowing agent in their production. This represents just over 50% of the total value of wallcoverings produced in this country. The total workforce that are involved in the handling and processing of ADCA in our industry is around 175 with direct possible contact and a further 200 production support staff. This represents a total of 375 staff out of a workforce of 900 people employed (42%) by the wallcovering industry. The use of ADCA is an industrial use and the residual amount of it in the finished product after the full thermal expansion has taken place is generally between 0,07% and 0,2% with a few products containing up to 1%. Why the industry uses ADCA This blowing agent has at the processing temperatures used in wallcovering manufacture a high gas release volume per unit weight which makes it a very efficient product. This gas release can be controlled during production by use of activators and leads to, at the necessary processing temperatures, it being the best product. Other alternatives do not work efficiently at the temperatures used in PVC processing. The efficiency of ADCA is due to its gas release temperature being close to the fusing temperature of PVC. Expandable PVC coated wallcoverings create 3D effects for relief and deep embossing effects, the texture produced is aesthetically desirable for	obligation to apply for authorisation is to ensure that risks are adequately controlled or that socio-economic benefits outweigh the risks, while concomitantly it is a strong incentive to search for and develop suitable alternatives. **Alternatives / socioeconomic impacts of ceasing use / low risks of specific use** Topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a use are important. Information regarding these topics should be provided as part of the application for authorisation (e.g. in the analysis of alternatives, the chemical safety report or the socio-economic analysis). This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation. However, it is to be stressed that the prioritisation for the inclusion in Annex XIV is based on the criteria set out in Art 58(3) and follows the agreed approach described in the general approach document (http://echa.europa.eu/docu+E2ments/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf). Consequently information on topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a particular use are not considered in the prioritisation for recommending substances for inclusion Annex XIV.

			consumers who do not like flat products. These products have sophisticated textures at the lowest possible weights which improve raw material usage. Without this blowing agent it is estimated that three times as much PVC would be required to produce the same effects on wallcoverings. The use of PVC coated wallcoverings additionally give these products improved water resistance, increased impact resistance and chemical resistance compared to uncoated wallcoverings thus prolonging life of the product in key areas. Other blowing agents that have been looked at have lower gas release volume which would require higher concentrations to be used and they do not work at the PVC processing temperature which to date has excluded their use. Some blowing agents are also flammable. The industry is evaluating alternatives but to date up to 500% increase in the blowing agent would be required to achieve similar results to ADCA and less process control can be achieved with the alternatives. It is estimated at least 5 to 10 years development work would be required to find alternatives to ADCA and success is not guaranteed. Health and Safety Companies that handle ADCA powder use dust extraction at point of use, all workers in contact with ADCA containing products wear dust masks, overalls and gloves. Those that handle ADCA dispersed in plastisols ensure that all workers wear protective overalls, gloves and dust masks. All companies carry out staff training in handling and use of ADCA and compounds containing it. Companies have in place health and safety monitoring of their workforce and for example in a company a specialist doctor has been conducting 6 monthly checks of workers for over 20 years; this frequency has recently been reduced (following recommendation from the doctor) to once every 12 months due to no adverse health effects being found. Companies have in place occupational health monitoring and no company has found any respiratory incidents from handling of ADCA products. No evidence of any respiratory sensitisation has been observed by any companies in our sector. The industry is aware of potential problems with the use of ADCA but it takes sensible precautions and has done so for years with the result that good quality products can be produced with no risks of health damage to those making or using them. Impact on business If ADCA became unavailable then the impact on the wallcovering business would be significant. For consumers there would be reduced choice of products, with possibly only inferior products being available. Replacement products would, if available, have increased costs that could make them not economically viable in the wallcoverings industry.	**Authorisation perceived as a ban, favouring move of market share outside EU** Note also that in accordance with Art. 62(1, 2) applications for authorisation may be made by the manufacturer(s), importer(s) and/or downstream users of a substance and for one or several uses. Applications may be made for the applicant's own uses and/or for uses for which he intends to place the substance on the market. Generally we advise downstream users to aim for a good communication within the supply chain to identify and agree on the most appropriate actor to apply for authorisation for certain use and how the different actors can best contribute to this work – potentially with the further support of industry associations. Please refer also to the Guidance on preparation of an application for authorisation, especially Appendix 2 on applications by several legal entities (http://www.echa.europa.eu/documents/10162/17229/authorisation_application_en.pdf). From these specifications of Art. 62 it is evident that not each actor on the market has to apply for authorisation of his use(s) because he can benefit from the authorisation granted to an actor up its supply chain. It is further possible to submit joint applications by a group of actors.

			However the real impact is that vinyl wallcovering manufacture would move out of Europe and this would result in loss of jobs, with such a significant percentage of each company's turnover being based on vinyl wallcoverings this could result in all companies in our sector closing or re-locating outside Europe. The impact would go beyond the wallcovering manufactures with most of the base (paper or non-woven) being European production it is possible that paper mills could close. Other raw material and equipment suppliers such as ink, adhesive, print roller, carton etc. would be affected and these are generally European based. Resultant job losses, if listing of ADCA in Annex XIV were to take place, are likely to be well in excess of 1,000 for our sector due to the uncertainty this would create that would affect business decisions in investing or continuing production in the UK. Hugh Williams British Coatings Federation 18 September 2013 (see also attached document, which is same as these comments but on our headed paper giving contact information)	
2275	2013/09/19 16:37	Company, United Kingdom	ColorMatrix have been using Azodicarbonamide (ADCA) as a chemical foaming agent for several years, as a result of our experience with this material we are certain that the hazard presented can be adequately controlled to minimise the risk of exposure, therefore we are against the proposal that this be added to the authorisation list. Worker exposure to ADCA can be effectively managed. ColorMatrix have had no incidences of worker health issues relating to exposure to ADCA. The risk management measures in place are: 1. Supply packaging is sealed – Material is bagged, boxed, palletised and shrink-wrapped. 2. General dust extraction is in place and this is serviced annually. Although we only have data on file for dust in general and not ADCA specifically we do have information on file for the last 5 years showing general dust levels to be well below the ADCA work exposure limit of TWA 8hrs = 1mg/m3, STEL 15 minutes = 3mg/m3 3. All staff coming into contact with ADCA wear 3M 4251 organic vapour and particulate respirators. 4. All staff coming into contact with ADCA wear nitrile gloves, safety goggles and protective overalls. 5. All tasks involving the handling of ADCA are carried out under local exhaust ventilation. 6. Down flow booth is used for weighing out the material which significantly reduces operator exposure. 7. All staff working with ADCA are trained in the Control of Substances Hazardous to Health (COSHH) and are aware of the hazards associated	Thank you for your comment and the information provided. **Please see our response to Comment # 2350 in this section.**

			with ADCA. We have specific standard operating procedures (SOPs) for activities involving ADCA; all necessary staff are trained in these on a regular basis to ensure a safe working practice is maintained. 8. All tasks are conducted in accordance with a documented COSHH risk assessment. 9. All tasks are conducted within the parameters specified in the exposure scenario of the supplier extended safety data sheet. Also ADCA does not present a risk to the consumer; the formulations produced by ColorMatrix contain 15-20% ADCA. Our customers dose these products at ~1%, this results in 0.15-0.2% ADCA that may potentially be present in the finished article however as ADCA decomposes during processing the actual amount of ADCA remaining in the finished product will be <0.1% and this amount will be embedded in the polymer matrix and not available for inhalation. The primary application for our formulations containing ADCA is PVC sheet. The ADCA formulations produce a fine and consistent cell structure within the extruded polymer creating a smooth surface finish enabling excellent print clarity and definition. The benefits of using ADCA in our foam additive formulations include reduced polymer requirements, reduced weight and excellent surface aesthetics. To date ColorMatrix have not thoroughly investigated the use of any alternatives in our formulations however we have done a brief analysis of potential alternatives. If we were to simply switch out the ADCA in our formulations and replace with alternative chemistries that we have investigated would be looking at a raw material cost increase of between 8 and 42%. We would need to pass this increase onto our customers. We have not yet done any work surrounding if the alternative formulations would foam to the same extent so we are unable to confirm but, based on our experience, we suspect the alternative formulations would not give as much gas as the ADCA formulation at the same use level therefore an increased use level would be required which would lead to additional cost implications for the customer. As discussed above our primary application for our formulations containing ADCA is PVC sheet. From the studies that we have conducted it is clear to see that the alternative formulations give a much larger, coarser cell structure which will mean a rougher sheet surface. The resulting product may have the same density but the aesthetics of the sheet are not of the same quality, this will have an adverse effect on the print quality. There is no denying that Azodicarbonamide (ADCA) is a respiratory sensitiser however it is our understanding that, with sufficient protocols in place, exposure can be significantly reduced therefore the risk can be	

			managed without the material being added to the authorisation list.	
2267	2013/09/19 15:01	Hungarian Chemical Industry Association, Industry or trade association, Hungary	1. In 2005, in the process of drafting REACH the proposal to add respiratory sensitizers to Art. 57 as an SVHC was rejected, which clearly indicated that there was a lack of reliable and convincing argument for the inclusion. Consequently, there was no intention to consider sensitizers as SVHCs. It is a well-known fact, too, that in professional circles there are several open issues regarding respiratory sensitizers even up to now. In Hungary not a single case of occupational asthma caused by ADCA exposure had been reported. As far as we know, the situation is similar in Europe since 1996, when the 1 mg/m3 exposure limit was set in the UK. Based on these facts it is clear that merely on a professional basis ADCA could not be a prioritized substance, and should not fall under authorization. 2. ADCA – authorisation „Article 55 Aim of authorisation and considerations for substitution The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.” Proceeding from the above two aims, one may ask whether authorization would help achieving them vis-á-vis ADCA? The answer of the industry is negative based on the following arguments: The risks raised from the uses of ADCA are well controlled. ADCA is used in non- or very low dusting formats at most companies. At companies where ADCA is used in pure powder form, several collective technical and personal safety equipments are applied in order to protect the workers. Several risk management measures are also applied, therefore only a limited number of workers are in contact with ADCA, and only during a short period of time during their shift. ADCA is in a very low concentration and bounded form in the end-products, so consumers cannot be exposed to it. In contrast to the statement of the draft prioritization proposal of ECHA, currently there are no alternatives which could be used, by for example, by the plastic industry. The alternatives listed in ECHA’s proposal are not suitable for technical reasons, or the given alternative would be much more dangerous than ADCA. Since the authorisation is not suitable for providing a higher level protection for workers against potential exposure resulting from handling	Thank you for your comment and the information provided. **Please see our responses to Comments # 2350 and 2388 in this section.**

			ADCA, why should the companies – mainly SMEs - be burdened by yet another highly bureaucratic and costly measure like authorisation?	
2266	2013/09/19 14:56	Company, United Kingdom	We are a leading manufacturer of pvc flexible films and coated fabrics. We have 2 alternative vinyl products: solid pvc and expanded pvc. Expanded pvc uses ADCA as the blowing agent. 76% of our total sales is for expanded pvc (i.e. Includes ADCA). The potential banning of ADCA has the potential to close our plant with a loss of 250 direct jobs. We don't understand the reason for adding ADCA to the SVHC list nor prioritising it for authorisation as it is not a CMR. We outsourced the dispensing of our ADCA powder 18 years ago to a company that has the equipment to safely mix the powder into a liquid format. The ADCA rules in the UK are clear and the 6 monthly medical checks for sensitisation have demonstrated that the UK rules work. Why were the rules in the UK not adopted or adapted rather than a decison to potentially ban a substance in Europe with no clear substitute? Of course, we could offer all customers solid pvc instead of expanded pvc but customers (particularly Automotive customers) have specified expanded pvc for the following reasons: 1) An approximate 50% reduction in polymer weight for a set material thickness over solid pvc. I.e: reduced material weight in car. 2) Mouldability: expanded pvc can be moulded in vacuum formers without a further layer of material required, whereas solid pvc needs a foam backing normally a polyolefin foam, which also contains ADCA! 3) Soft touch: the expanded pvc flexes when touched to give a more tactile surface. 4) Improved elongation and tensile performance. This allow better draping characteristics and the ability to be easily sewn e.g; for car seats. The banning of ADCA in Europe would have a significant effect on the European pvc industry as the Rest Of the World would continue to use it. In our case the solution would be to move all expanded pvc production to our parent company site based in the USA and many other companies would have a similar choice. In our opinion this would have devasting effect on pvc resin, plasticiser, stabiliser, lacquer suppliers and many others.	Thank you for your comment and the information provided. **Please see our response to Comment # 2350 in this section.**
2257	2013/09/19 13:32	Norway, Member State	The Norwegian CA supports the prioritisation of Diazene-1,2-dicarboxamide (C,C`-azodi(formamide)) (ADCA) for inclusion in Annex XIV	Thank you for your support.
2252	2013/09/19 12:30	Sweden, Member State	We support the prioritisation of C,C'-azodi(formamide) for inclusion in Annex XIV. The substance has high priority due to very high volume and	Thank you for your support and for giving your reasoning.

			wide dispersive use.	
2250	2013/09/18 19:32	Sika Services AG, Company, Switzerland	These comments are given by Sika Services AG, a non-operative, Switzerland based service organisation within the Sika group, on behalf of Sika's legal entities operating in 24 EU member states. We are handling ADCA since more than 15 years globally without major adaptations in the related processes and with some of our workers being involved in these processes since the beginning. During this time period we have not become aware of any health issue with regard to the respiratory tract. Adequate risk management measures have been put in place for all the time. These are local exhaust ventilation, exhaust gas filtration and respiratory filter masks. This further corroborates the indication by the toxicological evaluation in the comment given by ReachCentrum on behalf of the ADCA industry taskforce, that ADCA can be handled safely and that an EU wide OEL would be a more effective regulation than authorization. After the initial processing and during most of the processing steps, where ADCA is involved, it is enclosed in a solid polymer matrix with no further inhalation exposure. Given the lack of viable technical alternatives with lower risk profiles, that could achieve our product profiles, we are evaluating relocation of ADCA uses to our facilities outside of Europe and reimport of the finished articles as an alternative to application for authorization and/or substitution.	Thank you for your comment and the information provided. **Please see our response to Comment # 2350 in this Section.**

2249	2013/09/18 17:44	Industry or trade association, France	Azodicarbonamide (ADCA) An intended ban of this chemical by the European Chemical Agency (ECHA) has serious implications for the wallcovering industry and other users. This chemical is the foaming agent used in expanded plastics and rubbers. In the 1980's ADCA was identified as a respiratory sensitizer that can cause industrial asthma. The UK Health and Safety Executive proposed safe working practises, and steps were taken by companies to protect workers, which was successful, as 27 cases of workers suffering sensitization occurred before the year 2000, and only one since. Under the REACH (Registration, Evaluation, and Authorization of Chemicals) regulations, ECHA have decided to target respiratory sensitizers, and prioritized ADCA to be banned. A public consultation period of 90 days commenced on June 20th . If after this period ECHA cannot be persuaded against this, then it will be banned from use in Europe by 2017. It is the ideal foaming agent for plastics and rubbers. It foams at the right temperature, and foaming can be controlled to achieve different textures. This is particularly ideal for wallcoverings and due to the blowing process enables less material to be used. At the present time, there is no viable alternative. ADCA is no longer made in Europe – all production comes from the Far East. There is an emerging wallcovering market in China, and the Far East producers of ADCA will be happy to sell it in China. If the Chinese can use it and Europe can't, it could sound the death knell for our industry. ADCA is compounded into the plastic or rubber, and decomposes during manufacture, so cannot be identified as a hazard to the consumer. The potential hazard is to the workers handling it, but by risk management, this has been controlled for the last 25 years. This as a disproportionate regulatory measure of significant impact, that has no consumer uses and is already well regulated.	Thank you for your comment and the information provided. **Please see our responses to Comments # 2350 and 2388 in this section.**
2242	2013/09/18 15:53	INEOS Chlorvinyls Limited, Company, United Kingdom	INEOS Chlorvinyls does not manufacture or sell ADCA but has decades experience of working with formulations containing it. It recognises the importance of the substance and the extreme difficulty in the identification of viable alternatives. Alternative substances have been evaluated but decomposition temperatures and rates of gas evolution make their use on their own in flexible PVC systems unable to meet exacting product standards. Owing to its manufacture and use of hazardous substances INEOS Chlorvinyls keeps extensive occupational hygiene records and has no record of the induction of occupational	Thank you for your comment and the information provided. **Please see our response to Comment # 2350 in this Section.**

			asthma from the use of ADCA in its research and development laboratories. Given that the substance can be used in non-dusting, compounded or pasted forms, it can be used without the hazard – respiratory sensitisation of the pure powder – being encountered. Indeed, this seems to be a sensible outcome and we think it more appropriate that the substance be referred to the restriction rather than the authorisation process. ADCA is one of the most expensive components of a foamed PVC formulation. It is not used because of any low cost characteristics and alternative products that are far cheaper, such as sodium bicarbonate, foam at different temperatures and with less gas evolution so that there is no match of melt viscosity with the gas generation when used alone. The effect of using sodium bicarbonate alone is similar to using it alone, without yeast, in bread making: less expansion and only used for certain speciality products. This is not a case of inmdustry opposing an authorisation proposal on the grounds of cost. The level of expansion in expanded vinyl depends upon several factors. One of the most important is to ensure that gas expansion occurs when the melt viscosity and melt strength of the vinyl formulation are correct so as to ensure the correct level of expansion and the optimum cell structure. Very small changes in temperature cause dramatic changes in melt viscosity and melt strength, causing loss of foam properties, since the viscosity of the polymer melt can change dramatically with just a few degrees of temperature change. These adverse properties include surface disruption, poor cell structure and collapse of foam. The science behind the foaming of these products is well researched and well understood. Foamed PVC products are sold according to several demanding specifications. Only slight changes in foam characteristics will mean that such standards will not be able to be met, as is evidenced by the observations that a change in activator for ADCA makes the foam properties inferior: changing to a different foaming agent completely is worse. Loss of ADCA will result in enormous disruption to the supply of these products and since the ADCA can be used safely this seems to serve no purpose. We have attached a full description of the uses and science behind the foaming process. We doi this to show that the science behind the use of ADCA is both well researched and well understood. Moreover the understanding of the chemical foaming process can only be obtainmed through the sudying of foam samples and photographs are given in the attached report. The report author is also the author of chapters on chemical foams in academic textbooks and encyclopaedias.	

2215	2013/09/13 18:15	Company United Kingdom		Thank you for your comment and the information provided. Please note that REACH is an EU Regulation aiming to ensure a high level of protection of human health and the environment while enhancing competitiveness and innovation. The obligation to apply for authorisation is to ensure that risks are adequately controlled or that socio-economic benefits are outweighing the risks, while concomitantly it is a strong incentive to search for and develop suitable alternatives. **Alternatives / socioeconomic impacts of ceasing use / low risks of specific use** Topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a use are important. Information regarding these topics should be provided as part of the application for authorisation (e.g. in the analysis of alternatives, the chemical safety report or the socio-economic analysis). This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation. However, it is to be stressed that the prioritisation for the inclusion in Annex XIV is based on the criteria set out in Art 58(3) and follows the agreed approach described in the general approach document (http://echa.europa.eu/docu+E2ments/10162/17232/axiv_priority_setting_gen_approach_201

				00701_en.pdf). Consequently information on topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a particular use are not considered in the prioritisation for recommending substances for inclusion Annex XIV. **Authorisation perceived as a ban, favouring move of market share outside EU** Note also that in accordance with Art. 62(1, 2) applications for authorisation may be made by the manufacturer(s), importer(s) and/or downstream users of a substance and for one or several uses. Applications may be made for the applicant's own uses and/or for uses for which he intends to place the substance on the market. Generally we advise downstream users to aim for a good communication within the supply chain to identify and agree on the most appropriate actor to apply for authorisation for certain use and how the different actors can best contribute to this work – potentially with the further support of industry associations. Please refer also to the Guidance on preparation of an application for authorisation, especially Appendix 2 on applications by several legal entities (http://www.echa.europa.eu/documents/10162/17229/authorisation_application_en.pdf). From these specifications of Art. 62 it is evident that not each actor on the market has to apply for authorisation of his use(s) because he can benefit from the authorisation granted to an actor up its supply chain. It is further possible to submit joint applications by a group of actors.

2210	2013/09/11 15:18	Company United Kingdom	My company is a producer of plastic building products manufactuiring pipe and fittings from PVCu it has been producing foam core pipe for over 20 years without any Health and Safety issues with the workforce.I currently manufacture pipe for both the UK and export markets and banning the substance ADCA would dramatically impact sales and profits which inturn could mean the loss of jobs for the current personnel producing these products ,there is currently around 13 persons involved in the manufacture and sales of this product (sales of around £750k) .There is currently no substitute materials that give quality ,cost and productivity that is found in ADCA which also delivers benefits for the installers ie light weight .This product is approved for recycling and therefore its carbon footprint reduced against its rigid counterpart .I would be more than happy to supply our health and safety dust monitoring figures to help quantify my statements if required ,but to emphasise we have not had any related issues during the life time of the product which is also encapsulated to eliminate airboune dust.The workforce involved in this process is monitored through health suveylance regularly (every two months).Without ADCA we as acompany will not be able to produce foam core products that will restict or sales and put jobs at risk whilst not having any gains on health and safety by its removal	Thank you for your comment and the information provided. **Please see our response to Comment # 2350 in this Section.**
2204	2013/09/10 17:42	Company United Kingdom	i should like to make the following comments re inclusion of ADCA on the REACH Authorisation list. The use of ADCA in the materials we manufacture poses no threat to the general consumer. The ADCA is used as a blowing agent to produce a foam/cellular structure, this is achieved by the decompossition of the ADCA to produce Nitogen. Very little,if any of the ADCA remains after proceessing into the final product and what does remain is fully encapsulated in the polymer matrix and hence no exposure risk to the consumer. We are a producer of PVC compounds mainly used in the construction industry for exterior applications as wood replacement. ADCA allows us to produce products that are lightweight, durable and with good insulating properties. Over the yearts we have done several projects to look at alternative blowing agents but none have given us the same technical performance. Should ADCA be lost to us then this would have a significant impact on our business. 7.5% of sales would be affected.	Thank you for your comment and the information provided. **Please see our response to Comment # 2350 in this Section.**

			Risk reduction measures have been taken to reduce worker exposure and fall well within the exposure scenarios listed in Material Safety datasheet. Material is purchased in pre-weighed sachets which are fed directly into the process. We see no compelling evidence why this product should be on the Authorisation list.	
2203	2013/09/10 15:23	REHAU AG + Co. Company Germany	According to my opinion this recommendation is an incorrect decision. This substance is classified as a respiratory sensitizer but it is impossible to inhale dust of ADCA if used as a dust-free granulated material. There is no abrasive wear from dust-free granulated material which could be inhaled. Produced articles which could show abrasive wear don't contain undecomposed rests of ADCA.	Thank you for your comment and the information provided. **Please see our response to Comment # 2350 in this Section.**
2202	2013/09/10 14:53	Individual United Kingdom	JSC Rotational Ltd is a rotational moulding company based in Worcestershire, UK. We are a contract moulding company supplying numerous market sectors including leisure, hygiene, automotive, agriculture and general engineering with large hollow components. We are an innovative company who work with our clients to develop and supply many types of products and components. It is very important for us to have a full range of materials to offer our clients so that we can fully match the property criteria of the products required. Foam PE incorporating ACDA as a blowing agent is an important part of what we offer our clients. By using this material we can offer strength, weight reduction, buoyancy and insulation properties. Our current usage of this material is a relatively low percentage of our total production but if we were unable to offer foams our international competitiveness will be affected. At the moment we use PE foam in the production of parts for a two man hovercraft. As there is no alternative blowing agent manufacture of this product would have to more to our competitors outside of the EU.	Thank you for your comment and the information provided. **Relocation outside EU** Please note that REACH is an EU Regulation aiming to ensure a high level of protection of human health and the environment while enhancing competitiveness and innovation. The obligation to apply for authorisation is to ensure that risks are adequately controlled or that socio-economic benefits are outweighing the risks, while concomitantly it is a strong incentive to search for and develop suitable alternatives. As the ADCA included in the draft recommendation is a respiratory sensitiser, there is a strong societal interest to protect humans, in particular workers handling the substance, from risks potentially arising from its uses. An authorisation requirement for ADCA will accordingly ensure that the health of workers in the EU involved in the uses of ADCA is protected. Authorisation does not ban or restrict the use of the substance as long as it is shown in the authorisation applications (and supported in the authorisation granting process) that either the

				risks arising from the use(s) applied for are properly controlled or that there are no alternatives available and the socio-economic benefits are outweighing the risks arising from the uses. Information and concerns brought forward in your comments can be included in the application, should you decide to apply for authorisation of your uses of the substance or if your supplier applies for you. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.
2197	2013/09/08 17:45	L&L Products Company France	In order to prepare the ban of ADCA, the recommendation takes in account specific uses of ADCA, like spraying, dispersing in liquid carriers,... However, most of the processing in the plastic industry involve encapsulation of the blowing agent in a polymer matrix. Handling of encapsulated ADCA by extruding, injection molding… is much less hazardous than spraying. Instead of a general prohibition of this substance, why not going for a restriction to safe and harmless use of it? Restriction proposal : use of ADCA in an encapsulated shape. End users of ADCA foamed articles are in contact with articles which contain the remains of ADCA decomposition. Since the conversion ratio is higher than 99.9% and since the remains are embedded in plastic, there is no probability for the end user to be contaminated through breathing or contact with hands. In the document, calendaring was identified as a high ADCA exposure process. This is not relevant since for calendaring, ADCA is embedded in molten plastic. What is more, the number of workers exposed to ADCA seems to be overestimated in the prioritization dossier.	Thank you for your comment and the information provided. **Low risks** The inclusion in Annex XIV is per substance and not per use (or installation). Therefore screening of release potential in the prioritisation phase does not assess the exposure levels from single uses (at specific sites), but aims to deduce whether there are uses/situations where exposure may potentially not be controlled. The use and user specific conditions can be reflected in the authorisation application and they will be taken into account by ECHA's Committees when developing their opinions on the applications and by the Commission when taking the final decisions. In a potential application for authorisation, the exposure assessment shall consider the emission during all relevant parts of the life-

				cycle of the substance resulting from each of the uses applied for. The life-cycle stages resulting from identified uses cover, where relevant, the service life of articles. In this context, a very low residual concentration of ADCA after a certain stage of production can be given as justification for not considering, in the exposure assessment, the subsequent life-cycle steps.
2192	2013/09/04 16:47	KE MONE Company France	Our Company KEM ONE is today the third European producer of PVC. We are involved in this business since 1939 and we are supplying all major PVC convertors in Europe since decades. Several applications and customers we are serving are processing expanded PVC, using mainly Azodicarbonamide as blowing agent because of its outstanding properties and the quality of final products that can be obtained. Several examples of PVC applications we are serving can be mentioned: - floorings, wall coverings, coated fabrics, sealings, capsulating (food contact) - foam core pipes, expanded profiles, partition walls, doors, rigid foam, - cables, hoses - shoe soles… For KEM ONE, it is representing sales of several tens of thousand tons of PVC resin We are strongly supporting our customers in our Technical and Application Laboratories to optimize their products and it can be considered as a fact that no viable alternative to ADCA is existing today, providing equivalent product quality. Ban of ADCA would strongly impact our customers businesses and obviously our Company's business as a direct consequence, opening our market's doors to foamed products manufacturers producing outside Europe. It is also important to mention that such decision would have a significant impact on the global European PVC business (from resin and additives suppliers to final manufacturers) that is already strongly suffering from repeated crisis for the past 6 years. We all know and recognize in the "PVC World" that ADCA has been identified as a respiratory sensitizer with documented evidences but since	Thank you for your comment and the information provided. **Please see our response to Comment # 2350 in this section.**

			it has been known for a long time already, all our customers handling ADCA have taken this risk into consideration to manage it at best and protect their employees. For instance, the UK Health and Safety Executive proposed more than 10 years ago a guide of safe working practises that has been implemented step by step by all PVC foam manufacturers, resulting in drastic reduction of workers suffering sensitization and almost no case since the year 2000. As far as we are concerned, we have never experienced in our research and application laboratories any incident of respiratory sensitization with our research technicians. As good practise, we are most of the time using by the way azodicarbonamide that is already dispersed in liquids like plasticizers to avoid any dust issues and thus respiratory sensitization. We are a responsible Company considering of paramount importance the health of our employees. As they are telling us, we are sure that all our customers have the same consideration for their employees and convinced that they are all managing the risk of ADCA handling properly. Considering limited and poor performance additives that could be used in PVC foamed products as alternatives to ADCA, its ban would be at the end extremely detrimental to a major part of the whole PVC business in Europe that is already facing today strong difficulties due to the poor economic situation in Europe. In addition, it would open the doors to imported materials (from Asia in particular) that would not be concerned by this type of regulation. We think that the PVC industry still needs some time to develop viable alternatives to remain competitive on our markets. We hope that our arguments will hold your attention. Patrick MOREL KEM ONE Innovation & New Business Development Director	
2180	2013/09/02 16:42	Speciality Coatings Ltd Company United Kingdom	We strongly oppose the inclusion in Annex XIV and prioritisation of this substance for the following reasons:- We have no equivalent alternative for expanded vinyl wallcoverings. ADCA is ideally suited for expanded PVC, because it releases gas at the correct temperature for PVC processing, and gas release temperature can be tightly controlled with the use of activators. It is for this reason that ADCA is chosen for PVC, with no bearing on the cost of this blowing agent. Other suggested alternatives (sodium bicarbonate for example)	Thank you for your comment and the information provided. **Please see our response to Comment # 2350 in this section.**

			would be significantly cheaper, but ADCA is chosen on performance. The chemical blowing agents that are suggested as alternatives have gas release temperatures that are not suitable for PVC. Some release gas at higher temperatures at which PVC would thermally decompose, and others release gas at lower temperatures at which PVC would not fully fuse, resulting in coarse blistered foam to the detriment of product quality. In addition, the volume of gas released by the suggested alternatives is less than ADCA, which would result in higher usage of other PVC ingredients to achieve the same 3-dimensional effects, with less efficient use of materials, higher energy consumption, increased emissions, and of course increased cost. To achieve the same level of relief and surface textures desired by consumers from non-expanded PVC would result in at least a trebling of consumption of PVC and its other ingredients. The use of gaseous blowing agents is not practical for the typical wallcovering processes and equipment installed throughout the world, which rely on temperature activated chemical blowing agents. As with all chemicals, ADCA does not represent a safety hazard for process workers if the risks are correctly managed and the product is handled safely. Immediately ADCA was identified as a respiratory sensitizer and workplace exposure limits issued by the UK Health & Safety Executive, this company took steps to ensure that our employees were not put at risk. Dust extraction equipment was upgraded at point of use, and regular measurements taken to ensure exposure limits were not exceeded. Operators were issued with personal protective equipment and given training on correct handling. These precautions were implemented in the early 1980's and since then we have had all our employees given regular health screening every 6 months by a specialist doctor, and no adverse health effects have resulted in over 25 years. We continue to use ADCA in powder form, but would be prepared to use it as paste if it were agreed that all ADCA imported into Europe were in this form. As ADCA performs its role by decomposing during processing, then only trace amounts will remain in the wallcovering end product, and to the best of our knowledge and belief, there have been no known cases of consumer end users suffering health effects from residual ADCA in	

			finished wallpaper. Working with our trade associations – IGI internationally, and the British Coatings Federation in the UK - we have attempted to have tests conducted to determine the level of residual ADCA in finished product. However, there is no established reliable test method for determining level of residual ADCA, but indications are that levels can be slightly above or slightly below 0.1%. We are therefore working with our raw material suppliers and customers to develop ways of ensuring that residual levels are maintained at below 0.1%.	
2171	2013/08/29 12:42	Holden Decor Limited Company United Kingdom	The Importance of ADCA (Azodicarbonamide) Holden Decor Ltd (Holden) is a UK based wallcovering supplier to over 55 countries. Although the manufacture of its products is outsourced, the overseeing of the design, development and specification of its wallcoverings is essential to ensure that its designs meet the aesthetic and technical demands of its customers. Currently Holden use UK, German, French, Italian and Belgian companies to manufacture its wallcoverings; but we would need to seek supplies outside the EU if ADCA is banned for use by European manufacturers. Over 50% of the company's turnover and approximately 33% of the total sales volume is for textured vinyl wallcoverings that provide the customer with both desirable and durable product. Holden is heavily dependent on the sale of products within this category. In 2012 it sold circa 700,000 units of products of this nature. This trend is continuing in 2013, with circa 455,000 units sold in the period from January to July 2013. In order to create the desirable relief effects the chemical ADCA is employed as an efficient blowing agent during the production of both its screen- printed expanded vinyl wallcoverings and heat embossed solid vinyl wallcoverings. We would urge you not to commit to any restriction on the use of these materials in wallcovering manufacture for the following reasons: 1. Holden invest heavily in both the design and manufacture of these products, with significant sums of money, in excess of £200,000, being invested in printing screens, gravure printing cylinders and embossing rollers. If a less effective blowing agent were to be introduced, the screens, cylinders and rollers would have to be destroyed, and new ones manufactured, because it would be impossible to replicate the look	Thank you for your comment and the information provided. **Please see our response to Comment # 2350 in this section.**

			of the existing product with the original printing and embossing rollers. This is a cost Holden cannot afford to bear, and there is a significant doubt if the roller engraving industry would have the capacity to replace them within a reasonable period. This would result in both lost sales and the imposition of financial penalties from Holden's major retail customers. 2. Even with new printing cylinders it is unlikely that the resulting new interpretations would look exactly the same as the originals, because an exact 'balance' of colours and relief would be nearly impossible to achieve, with different screen mesh sizes and blowing characteristics. Holden's distributors have invested in the cost of tens of thousands of pattern books, which could be rendered redundant if the re-worked wallcoverings are different from those displayed in the sample books. 3. Alternative blowing agents, e.g. sodium bicarbonate, are cheaper but ineffective. ADCA is expensive; but because it is the most efficient material, producing the most gas for the least weight, it minimises material use. 4. If Holden is obliged to source its wallcoverings from outside the EU, its reputation as a supplier of premium quality, European sourced, wallcoverings would be compromised: it is doubtful that Holden would be able to maintain its existing high quality standards. Again, all the printing cylinders to manufacture existing designs would need to be re-made at enormous cost, without any guarantee that the products would appear and perform as before. In addition, the logistical and stock holding costs of importing product would affect both Holden's profitability and ability to service its customers economically and effectively. DEREK HOLDEN Director Holden Decor Ltd Grimshaw Street, Darwen, Lancashire, BB3 2QJ England. 28.08.13	
2164	2013/08/23 11:26	Company United Kingdom	A disproportionate measure to control industrial uses	Thank you for your comment. **Please see our responses to Comments # 2388, 2390, and 2465 in this section**.

2154	2013/08/21 11:49	European Trade Union Confederation Trade union Belgium	ETUC supports the recommendation to include ADCA in the REACH Authorisation list. ADCA is included in the Trade Union Priority List for Authorisation: http://www.etuc.org/a/6023	Thank you for the information, and for providing your support/opinion
2153	2013/08/20 14:05	Company Russia		
2103	2013/07/18 15:50	S.O.R.A.C. Company France	Re : ADCA – Public consultation Dear sirs, We note that you officially made the decision on June 24th last to recommend that ADCA is included in the Authorization list. SORAC, as an importer and supplier of ADCA from our principal KUM YANG and CO, especially on the French market, is of course concerned. Through the public consultation opened, we wish to comment as follows: I personally have been selling azodicabonamide since it began to be used as a blowing agent at the end of the sixteen's. Many customers, in floor and wall covering, leather clothes, PVC or PE piping as well as industrial structural foams or profiles for the automotive industry, have then worked with ADCA for more than 50 years. Indeed, we have never known about any serious health problems resulting of its applications. Of course, the material safety data sheets have always recommended basic protection rules to prevent them. And they are the same now. Another point should be considered: in most of the usual applications, it does not exist any alternative material. In case ADCA cannot be used any longer, this would be an even stronger concern for our customers themselves. And it could result in a critical situation for them. Although being only a small actor on the European market, SORAC wished to give also this sound advice. Thanking you for your attention, we are Sincerely yours Ch. HOFFMANN Managing Director	Thank you for your comment and the information provided. **Please see our response to Comment # 2350 in this section.**

II - Transitional arrangements. Comments on the proposed dates:

#	Date	Submitted by (name, Organisation/MSCA)	Comment	Response
2476	2013/09/23 19:52	Fédération de la Plasturgie, Industry or trade association, France	See attached non-confidential document "Fédération de la Plasturgie - ADCA Consultation Input 23sep2013.pdf" pages 23 to 24.	Thank you for your comment. **Please see our response to Comment # 2454 in this section**
2469	2013/09/23 19:17	ChemSec, International NGO, Sweden	It is assumed that the Commission Regulation including the substances of this 5th Recommendation in Annex XIV would enter into force only in February 2015. Keeping the proposed application date would mean an application date by November 2016 with an extra 18 months to sunset the substance. There is no reason why the date for inclusion in Annex XIV for this substance should be so far ahead, and in this case even deferred by a further 3 months, leading in a delay for the realisation of effective protection objectives i.e. May 2018. Potential applicants are already informed of the likely inclusion of the substance in Annex XIV or will be when a decision on inclusion in Annex XIV is taken. A 2 years preparation period for application submissions should be more than sufficient to prepare for applications. According to REACH (Art 58.1 ii) a minimum 18 months period is only foreseen between the sunset date and the application deadline, but nothing prevents ECHA / the European Commission to foresee an earlier deadline for application. Therefore ChemSec would propose to provide for an effective deadline for application of maximum 2 years from the date of the EU Commission's decision to include the substance in Annex XIV.	Thank you for your comment. Please note that latest application date (which is the application deadline in order to benefit from the transitional arrangements, i.e. to be able to continue the use after the sunset date even if no decision has been taken by the Commission on granting or refusing authorisation) for ADCA is already proposed by ECHA to be less than 2 years (21 months) after inclusion in Annex XIV. ECHA made its proposals for the latest application dates on the basis of discussions by the stakeholder expert group that was following the development of the Guidance for including substances in Annex XIV. This expert group estimated that the time needed for preparation of an authorisation application of sufficient quality might in standard cases require 18 months (roughly 12 months work-time for drafting the application plus an additional buffer of 6 months for consulting required external expertise). As there is yet no reliable information available that

				would suggest shortening or prolonging this time interval, we consider that a period of 18 months should normally be given to allow for the preparation of a well-documented application for authorisation. The anticipated workload of the Agency with regard to processing of authorisation applications was accounted for by grouping the proposed substances in 3 groups and spreading the application and sunset dates over a period of six months.
2466	2013/09/23 18:47	GERFLOR, Company, France	Potential alternatives have been tested, but the properties are lower to ACDA ones and the substitute present more hazardous risk phrases According to the literature, the alternatives to the ADCA may be another molecule chemical blowing agent. Among the substances listed in the Austrian case (Annex XV, Table 14 on page 43), that recommended for PVC (OBSH) is classified as carcinogenic and mutagenic 1B 2. It is more volatile, and requires storage at a temperature below 50 ° C. This solution is not acceptable. Other alternatives (such as sodium bicarbonate) are not a suitable alternative for lower density products as it does not have the expansion performance of ADCA (400% vs. 4000%). It's possible to produce foam without any chemical (mechanical way). Our foams generally have density around 0,3. We obtain appropriate acoustic properties. With mechanical foam, we would obtain density near 0,6. So the acoustic properties are too much lower. We can't reduce the density value without decreasing the mechanical properties of our end products. More over, the process is very critical, we have to adapt the flow rate of the foam and the product. Otherwise the amount of waste will increase too much.	Thank you for your comment. **Please see our response to Comment # 2454 in this section**
2461	2013/09/23 17:59	Company, Ireland	Freefoam Plastics Ltd and the industry as a whole, has great concerns as to the fact that we are already at this stage of the Annex XIV process in such a short space of time. ADCA has been used in our application since the 1960's and since that time companies have been trying to find suitable alternatives from a purely commercial stand point. To date this has not provided any suitable alternatives. With a possible deadline of 2017, we would not be able to predict, with any	Thank you for your comment. **Please see our responses to Comments # 2454 in this section and 2370 in section IV.**

			confidence, that any such alternatives could be found. Another concern then would be that should such an alternative be found, then the demand on the material could be so great that it would out-strip the global capacity. The creation of additional capacity could take a very long time. Therefore the potential deadline is not reasonable in our opinion.	
2454	2013/09/23 17:38	EuPC, European Plastics Converters, Industry or trade association, Belgium	In the prioritising suggestion from ECHA, the last date planned for submitting an application (application date) is November 2016 (21 months after inclusion in the authorisation list) – assuming ADCA will appear on Annex XIV in February 2015. The expiry date (sunset date) should be 18 months later according to ECHA's suggestion. The period between the inclusion of the substance in the authorisation list and the submission of the complete authorisation application is too short. Every company which has to submit an application has never wrote an application request before and has no experience in writing a socio-economic analysis. For the socio-economic analysis many data have to be collected, this cannot be done especially for the SME within the given time frame. The sunset date is also too short. Many EuPC member companies explained that they already conducted trials in the past to substitute the substance with very unsatisfying results. Our survey clearly indicates technical feasibility problems for all EuPC members. Plastic converters need at least 5 - 8 years to develop feasible alternatives. In contrast to the hint given from ECHA, EuPC is of the opinion that the decision about the adequate date for the sunset date should particularly take into account the existence of suitable alternatives. Otherwise EuPC members cannot continue the production with all negative consequences like product line loss, sales losses, less turnover and job losses. The lack of alternatives is of course a viable reason for prolonging the proposed sunset date and even more so if it is of importance for the authorisation application in a later stage.	Thank you for your comment. **Sunset date vs substitution** Please note that the sunset date does not need to consider the timeframe in which it may be possible to substitute the substance in question in its uses. Authorisation, inter alia, is a means to promote the development of alternatives. Article 55 explicitly stipulates that applicants for authorisation shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution (this has to be included in the analysis of alternatives to be submitted as part of the authorisation application in accordance with Art. 62 (4e)). Therefore, the present lack of alternatives to (some of) the uses of a substance (as well as established safety requirements or performance standards) and the need to complete R&D programmes to get qualified alternatives to it are not viable reasons for adjourning the subjection of a substance or some of its uses to authorisation. Information regarding lack of alternatives (as well as established safety requirements or performance standards) is however important information for inclusion in an authorisation application. This

				information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation. **LAD gives too little time to prepare application – especially for SMEs** Note that in accordance with Art. 62(2) applications for authorisation may be made by the manufacturer(s), importer(s) and/or downstream users of a substance (or any combination thereof) and that they may be made for one or several substances that meet the definition of a group of substances in Section 1.5 of Annex XI, and for one or several uses. Applications may be made for the applicant's own uses and/or for uses for which he intends to place the substance on the market. From these specifications of Art. 62 it is evident that not each actor on the market has to apply for authorisation of his use(s).A supplier (manufacturer, importer or downstream user) may cover in his application use(s) of his downstream users. Furthermore, it is possible to submit joint applications by a group of actors. To get the required application(s) ready in time is therefore rather a matter of

				communication, organisation and agreement between the relevant actors in the supply chain and efficient allocation of work than dependent on the size and expertise of individual enterprises in the supply chain or on the complexity of the supply chain. Generally we advise downstream users to aim for a good communication within the supply chain to identify and agree on the most appropriate actor to apply for authorisation for certain use and how the different actors can best contribute to this work – potentially with the further support of industry associations. Please refer also to the Guidance on preparation of an application for authorisation, especially Appendix 2 on applications by several legal entities (http://www.echa.europa.eu/documents/10162/17229/authorisation_application_en.pdf). **Please also see our response to Comment # 2469 in this section.** **No experience in preparing applications** ECHA has created a dedicated webpage "applying for authorisation" the aim of which is to guide applicants in the preparation of their applications (http://echa.europa.eu/web/guest/applying-for-authorisation). A guidance document on how to apply for an authorisation for the use

				of substances included in Annex XIV is available and can be directly downloaded from ECHA's website (http://echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf). This guidance is primarily intended for use by manufacturers, importers and downstream users placing on the market or using a substance included in Annex XIV of REACH. The document intends to help and guide potential applicants through the authorisation process. Further guidance to potential applicants is provided via pre-submission information sessions with ECHA, in which future applicants for authorisation have the opportunity to ask case-specific questions regarding the regulatory and procedural aspects of the authorisation application process. The availability of all this information and guidance shows that even if the authorisation process is perceived as "new" it is nevertheless already a process that has been carefully thought through and for which in-depth documentation and guidance is available.
2450	2013/09/23 17:14	Swish Building Products, Company, United Kingdom	With respect to risk, Swish was amazed to hear about ACDA being entered on the SVHC list. ADCA has known associated risks; however, these are well understood and managed. Furthermore, the speed at which ADCA has been prioritised for review is even more of a shock. The risks highlighted back in the 1980's have been managed now for a long period and we are not aware of any issues for many years in the UK. Furthermore, it does appear strange to Swish, to compare sensitizers as an equivalent to toxins or carcinogenic materials. The associated risks in finished articles for example, would appear to be almost none existent.	Thank you for your comment. **Please see our response to Comment # 2370 in this section**

2442	2013/09/23 16:30	SVITAP J.H.J. spol. s r.o., Company, Czech Republic	2017 2018	Thank you for your comment. **Please see our responses to Comments # 2454 and 2197 in this section**
2440	2013/09/23 16:12	Kestrel, Company, United Kingdom	The risks associated with using ADCA are well known and are managed accordingly. There is a shock around our industry regarding the speed at which ADCA has been prioritised when this area hasn't had any recent incidents with using ADCA. Surely the lack of incidents demonstrates that industry is managing this known risk. The criteria for including sensitizers as an equivalent concern to toxins or carcinogens are not thought to be comparable. There are many examples where higher degrees or risk would be associated with known carcinogens or toxic materials.	Thank you for your comment. **Please see response to Comment # 2370 in this section**
2430	2013/09/23 15:35	Company, Germany	No possibility to substitute ADCA in the event of early including in Annex XVII	Thank you for your comment. Please note, authorisation would mean the substance would be included in Annex XIV, not Annex XVII. Annex XVII lists restrictions for substances. **Please see response to Comment # 2454 in this section**
2416	2013/09/23 14:08	International organisation, Belgium	ADCA is used in the processing of more than a hundred of different parts per vehicle which would require a redesign of past and current models. As the materials produced with ADCA blowing agents include crash / safety performance applications in the vehicle, a change in product specification would invalidate the EU Type Approval - this could require all vehicles to be re-assessed for crash performance and re-type approved at great expense to the industry. Currently no suitable alternatives with the correct expansion criteria and processing temperatures have been identified. If a technically suitable alternative were to be identified in the future, the automotive industry would require a 5 to 7 year introduction period for the developments and homologation of new vehicles. Therefore it is crucial to our industry that sufficient lead time is provided in case of any necessary substitution. For the production of spare parts, industry does not see the possibility	Thank you for your comment. **Please see our response to Comment # 2454 in this section (that response is relevant for your concerns regarding both: parts for new vehicles and spare parts)**

			to substitute the use of ADCA as we need to maintain the integrity of the performance of the parts in relation to the performance of the vehicle as a whole, due to the inavailabity of "old" vehicles for validation purposes. .	
2407	2013/09/23 13:23	Company, Sweden	see task force comments	Thank you for your comment. **Please see response to Comment # 2350**
2406	2013/09/23 13:19	Company, Romania	see ADCA task force comments	Thank you for your comment. **Please see response to Comment # 2350**
2405	2013/09/23 13:15	Company, Czech Republic	see ADCA task force comments	Thank you for your comment. **Please see response to Comment # 2350**
2402	2013/09/23 13:01	Company, Poland	see comments introduiced by ADCA task force	Thank you for your comment. **Please see response to Comment # 2350**
2401	2013/09/23 12:54	Company, Finland	see Comments on the draft recommendation introduced by ADCA Task force	Thank you for your comment. **Please see response to Comment # 2350**
2390	2013/09/23 12:11	ETRMA, Industry or trade association, Belgium	Industrial validation tests on alternative substances have been conducted by several companies. For most existing applications, there are currently no known alternatives which meet the required product specifications for the automotive and aerospace applications, for example. The main problem is that the volume of air generated is lower, and thus the density of the final material is not good. The vulcanization kinetics are also different. Individual companies find that most of the alternatives proposed in the Annex XV dossier do not give satisfactory results: low decomposition temperatures, generation of holes that worsen a vehicle's resistance to corrosion. Additionally, certain identified substances (TSH, TSSC, DNPT) pose serious health hazards, and sometimes, risks of	Thank you for your comment. **Please see responses to Comments # 2454 in this section and 2370 in section IV.**

			explosions. Reformulation is critical and products with new formulations might need to be, in most of the cases, "requalified" without the guarantee that they will meet the necessary safety performances. There is currently great uncertainty on the possibility to find available alternatives and on the timeline necessary for substitution.	
2370	2013/09/23 00:59	West and Senior Limited, Company, United Kingdom	There is great concern regarding the rate at which this assessment has progressed and been prioritised especially when it is considered there have been no major incidents for many years. The criteria for including sensitizers as an equivalent concern to toxins or carcinogens are not deemed comparable by any user of this technology. In many sectors companies have moved away from known carcinogens or toxins, often on a voluntary basis prior to legislation. When discussing ADCA the reality is simply met with disbelief and questions of why. Technology in application has taken many many years to evolve, to see possible restriction of use within a period of a few years cannot be comprehended. The possibility of restricted use would prove highly detrimental to European business. Loss of application or poor competiveness against non-European manufacture could result in the closure and loss of significant manufacturing bases across our region. This should not be under estimated. Industry is responding but the speed in of process is hindering business. Many technical managers have dedicated time to supporting defence at the expense of product development. Industry and innovation is losing momentum and if the rate of review continues at this pace and continues in favour of restricted use, many industries, associated industries, consumers and families will suffer loss based upon a chemical removal which has benefited society and the environment for many years.	Thank you for your comment. Please note that the sunset date does not need to consider the timeframe in which it may be possible to substitute the substance in question in its uses. Topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a use are important. Information regarding these topics should be provided as part of the application for authorisation (e.g. in the analysis of alternatives, the chemical safety report or the socio-economic analysis). This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation. However, it is to be stressed that the prioritisation for the inclusion in Annex XIV is based on the criteria

				set out in Art 58(3) and follows the agreed approach described in the general approach document (http://echa.europa.eu/docu+E2ments/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf). Consequently information on topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a particular use are not considered in the prioritisation for recommending substances for inclusion Annex XIV. **Please see also our response to Comment # 2350 in section I.**
2350	2013/09/20 19:26	ADCA TASKFORCE, Industry or trade association, Belgium	not applicable	Thank you
2346	2013/09/20 18:06	Europacable, Industry or trade association, United Kingdom	NONE	Thank you.
2331	2013/09/20 15:35	Company, Sweden	SU11 Manufacture of Rubber Products PC32 Polymer Preparations and Compounds Industrial validation tests on alternative substances have been conducted. For most of existing applications, currently known alternatives did not achieve the required product specifications such as for instance in case of automotive and aerospace applications. The main problem is that the volume of air generated is lower and thus the density of the final material is not good. Vulcanization kinetics is also different. It was reported by individual companies that most of the alternatives proposed in Annex XV dossiers do not give satisfactory results: too low decomposition temperatures, generating holes that cause a deterioration of the resistance to corrosion resistance of the vehicle. Additionally, certain identified substances identified (TSH, TSSC, DNPT) pose serious health hazards and sometimes risk of explosions. Reformulation is critical and products with new formulations might	Thank you for your comment. **Please see our response to Comment # 2390 in this section.**

			need to be, in most of the cases, "requalified" without the guarantee that they will comply with the safety related performances. Feasibility in finding available alternatives and related timing are currently unknown factors.	
2328	2013/09/20 15:36	SFEC, Industry or trade association, France	In the prioritising suggestion from ECHA, the last date planned for submitting an application (application date) is November 2016 (21 months after inclusion in the authorisation list) – assuming ADCA will appear on Annex XIV in February 2015. The expiry date (sunset date) should be 18 months later according to ECHA's suggestion. The period between the inclusion of the substance in the authorisation list and the submission of the complete authorisation application is too short. Every company which has to submit an application has never wrote an application request before and has no experience in writing a socio-economic analysis. For the socio-economic analysis many data have to be collected, this cannot be done within the given time frame. The sunset date is also too short. Many of our member companies explained that they did already trials in the past to substitute the substance with very unsatisfying results (see XY). Our survey clearly indicates technical feasibility problems for nearly all. Of course the decision about the right date for the sunset date should take into account the existence of suitable alternatives. Otherwise our member companies cannot continue the production with all consequences like product line loss, sales losses, less turnover and job losses. We cannot understand the hint from ECHA. The lack of alternatives is of course a viable reason for prolonging the proposed sunset date and even more so if it is of importance for the authorisation application.	Thank you for your comment. **Please see our response to Comment # 2454 in this section**
2326	2013/09/20 15:29	Company, Sweden	Industrial validation tests on alternative substances have been conducted. For most of existing applications, currently known alternatives did not achieve the required product specifications such as for instance in case of automotive and aerospace applications. The main problem is that the volume of air generated is lower and thus the density of the final material is not good. Vulcanization kinetics is also different. It was reported by individual companies that most of the alternatives proposed in Annex XV dossiers do not give satisfactory results: too low decomposition temperatures, generating holes that cause a deterioration of the resistance to corrosion resistance of the vehicle. Additionally, certain identified substances identified (TSH, TSSC, DNPT) pose serious health hazards and sometimes risk of explosions. Reformulation is critical and products with new formulations might	Thank you for your comment. **Please see our responses to Comments # 2454 in this section and 2370 in section IV.**

			need to be, in most of the cases, "requalified" without the guarantee that they will comply with the safety related performances. Feasibility in finding available alternatives and related timing are currently unknown factors.	
2325	2013/09/20 15:28	Company, France	Industrial validation tests on alternative substances have been conducted. For most of existing applications, currently known alternatives did not achieve the required product specifications such as for instance in case of automotive and aerospace applications. The main problem is that the volume of air generated is lower and thus the density of the final material is not good. Vulcanization kinetics is also different. It was reported by individual companies that most of the alternatives proposed in Annex XV dossiers do not give satisfactory results: too low decomposition temperatures, generating holes that cause a deterioration of the resistance to corrosion resistance of the vehicle. Additionally, certain identified substances identified (TSH, TSSC, DNPT) pose serious health hazards and sometimes risk of explosions. Reformulation is critical and products with new formulations might need to be, in most of the cases, "requalified" without the guarantee that they will comply with the safety related performances. Feasibility in finding available alternatives and related timing are currently unknown factors.	Thank you for your comment. **Please see our responses to Comments # 2454 in this section and 2370 in section IV.**
2322	2013/09/20 15:12	Company, Sweden	Industrial validation tests on alternative substances have been conducted. For most of existing applications, currently known alternatives did not achieve the required product specifications such as for instance in case of automotive and aerospace applications. The main problem is that the volume of air generated is lower and thus the density of the final material is not good. Vulcanization kinetics is also different. It was reported by individual companies that most of the alternatives proposed in Annex XV dossiers do not give satisfactory results: too low decomposition temperatures, generating holes that cause a deterioration of the resistance to corrosion resistance of the vehicle. Additionally, certain identified substances identified (TSH, TSSC, DNPT) pose serious health hazards and sometimes risk of explosions. Reformulation is critical and products with new formulations might need to be, in most of the cases, "requalified" without the guarantee that they will comply with the safety related performances. Feasibility in finding available alternatives and related timing are currently unknown factors.	Thank you for your comment. **Please see our responses to Comments # 2454 in this section and 2370 in section IV.**

2266	2013/09/19 14:56	Company, United Kingdom	The sunset is presumed as May 2017 As there are no clear substitutes no sunset date should be applied otherwise the only solution is to move production outside the EU.	Thank you for your comment. **Please see our responses to Comments # 2454 and 2197 in this section.**
2252	2013/09/19 12:30	Sweden, MemberState	We agree with the proposed dates.	Thank you.
2249	2013/09/18 17:44	Industry or trade association, France	We are all SME's and do not have the time or resources to immediately develop alternative foaming compounds. We all fear for our future if ADCA were banned and it would be difficult for us to compete with manufacturers from outside Europe.	Thank you for your comment. **Please see our response to Comment # 2454 in this section**
2210	2013/09/11 15:18	Company United Kingdom	The dates given are unrealistic and are proved that no alternative material has been found during the life cycle which would lead to inferior products alongside job losses	Thank you for your comment. **Please see our response to Comment # 2454 in this section.**
2203	2013/09/10 15:23	REHAU AG + Co. Company Germany	Alternatives told in the annex XV dossier are no technically reliable alternatives for extrusion of rigid PVC foam. This part of the annex XV doosier is a pure lie. The wrtiter of this annex XV-dossier was a technically clueless amateur. A sunset date for ADCA would be the end for articles like PVC-foam-core pipe or other foamed PVC-profiles because the proposed alternatives do not work.	Thank you for your comment. **Please see our responses to Comments # 2454 in this section and 2370 in section IV.**
2197	2013/09/08 17:45	L&L Products Company France	Several automotive suppliers use ADCA. According to the standard time plan, the sunset date of ADCA should occur around May 2016. At this time, many car programs will be launched, whose design will be frozen in 2014. 2014 is too early to develop a robust alternative to ADCA. The sunset date, if any comes to ADCA, should be postponed to 2021 to allow the suppliers to propose to the OEMs robust cellular materials solution right from the beginning of the car design and production program.	Thank you for your comment. Please note that according to ECHA's recommendation, assuming the Commission Regulation including the substances of this fifth Recommendation in Annex XIV would enter into force in February 2015, the latest application date would be November 2016, and the sunset date May 2018. **Please also see our response to Comment # 2454 in this section.**
2180	2013/09/02 16:42	Speciality Coatings Ltd	We have instigated a technical programme in conjunction with suppliers and customers to develop alternative ways of expanding PVC	Thank you for your comment.

		Company United Kingdom	to the same efficiencies as achieved with ADCA. However, given the current lack of viable alternatives, we believe that this will take some considerable time and expense. Most wallcovering companies are small or medium sized enterprises, and as such do not have the facilities for costly and time consuming technical development programmes. While we are putting every effort into developing alternatives to ADCA, we find the sunset date of 2017 too restrictive to achieve this aim, and fear for our future if this date is implemented.	**Please see our responses to Comments # 2454 and 2197 in this section.**

III - Comments on uses that should be exempted from authorisation, including reasons for that:

#	Date	Submitted by (name, Organisation/MSCA)	Comment	Response
2482	2013/09/23 20:39	ACEA - European Automobile Manufacturers Association, Industry or trade association, Belgium	ADCA is used in the processing of more than a hundred of different parts per vehicle which would require a redesign of past and current models, please see also attachment under point IV.	Thank you for your comment. **Please see our response to Comment # 2482 in Section I.**
2476	2013/09/23 19:52	Fédération de la Plasturgie, Industry or trade association, France	See attached non-confidential document "Fédération de la Plasturgie - ADCA Consultation Input 23sep2013.pdf" page 24.	Thank you for your comment.
2469	2013/09/23 19:17	ChemSec, International NGO, Sweden	ChemSec supports the proposal of ECHA to not allow any exemptions.	Thank you for your comment.
2466	2013/09/23 18:47	GERFLOR, Company, France	Our products are resilient PVC flooring Products with ADCA represent about 20% of our turnover. If we confirm we have no solution to find alternative for ADCA, we will loose the acoustic market for floorings. The employment of hundred workers is threatened. Technical solutions exist for improving insulation of a new building, but it costs 5% more	Thank you for your comment **Please see our responses to Comments # 2442 and 2346 in this section.**
2461	2013/09/23 17:59	Company, Ireland	Freefoam Plastics Ltd believes that all users of ADCA into polymeric applications should be exempted because as stated in the general and transitional comments, we fundamentally disagree with ADCA being in the draft recommendation of substances for inclusion in Annex XIV.	Thank you for your comment. **Exemption for polymeric uses** As regards your request for exemption please note that uses (or categories of uses) can only be exempted from the authorisation requirement on the basis of Art 58(2) of REACH, unless they are already explicitly exempted in REACH Art 2(5 or 8) or in Art 56 (3-6).

				Please note that according to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses "*provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled*". A list of uses that in accordance with the REACH Regulation are exempted from authorisation can be found at http://echa.europa.eu/documents/10162/17232/generic_exemptions_authorisation_en.pdf.
2454	2013/09/23 17:38	EuPC, European Plastics Converters, Industry or trade association, Belgium	EuPC agrees with ECHA; there is no specific Community legislation in force that would allow consideration of exemption(s) of (categories of) uses from the authorisation requirement on the basis of Article 58 (2) of REACH.	Thank you for your comment.
2450	2013/09/23 17:14	Swish Building Products, Company, United Kingdom	ADCA should be allowed for continued use in all polymeric systems as it is an essential part of producing a foam structure and provide humanity all the associated benefits.	Thank you for your comment. **Please see our response to Comment # 2461 in this section.**
2442	2013/09/23 16:30	SVITAP J.H.J. spol. s r.o., Company, Czech Republic	Our consumption of ADCA is about 3 tons per year, the reason is that we have not found the relevant supply of ADCA till now.	Thank you for your comment. **Please see our response to Comment # 2461 in this section.** **No suitable alternatives** In addition, information on the low level of risk associated to a use or related to the availability and suitability of alternatives, socio-economic considerations regarding

				the benefits of a use, as well as the (adverse) impacts of ceasing a use are important. Information regarding these topics should be provided as part of the application for authorisation. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.
2440	2013/09/23 16:12	Kestrel, Company, United Kingdom	All plastic materials should be allowed to continue to use ADCA as a foaming agent.	Thank you for your comment. **Please see our response to Comment # 2461 in this section.**
2435	2013/09/23 15:53	Wirtschaftsverband der deutschen Kautschukindustrie e. V. (wdk), Industry or trade association, Germany	Due to the limited and save use in rubber industry, the non existance of environmentally sound chemical alternatives with a reduced health risk and the absence of ADCA in the corresponding articles the use of ADCA in the production of cellular rubber articles should be exempted from the authorization requirement.	Thank you for your comment. **Exemption for uses in production of rubber** As regards your request for exemption please note that uses (or categories of uses) can only be exempted from the authorisation requirement on the basis of Art 58(2) of REACH, unless they are already explicitly exempted in REACH Art 2(5 or 8) or in Art 56 (3-6). Please note that according to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses "*provided that, on the basis of the existing specific Community*

				legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled". A list of uses that in accordance with the REACH Regulation are exempted from authorisation can be found at http://echa.europa.eu/documents/10162/17232/generic_exemptions_authorisation_en.pdf. Information on the low level of risk associated to a use or related to the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use, as well as the (adverse) impacts of ceasing a use are important. Information regarding these topics should be provided as part of the application for authorisation. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.
2430	2013/09/23 15:35	Plastics KG, Company, Germany	In our view, ADCA should be available for all processes, including extrusion of foamed sheets, in which the substance ADCA is no longer detectable in the finished product. The final product (extruded foamed sheets) can be imported from third countries, out side european union, since ADCA is in the foamed sheet no longer detetectable (Competitive advantage).	Thank you for your comment. **Please see our response to Comment # 2435 in this section.**

2407	2013/09/23 13:23	Company, Sweden	see task force comments	**Please see response to Comment #2350 in this section (ADCA task force comment).**
2406	2013/09/23 13:19	Company, Romania	see ADCA task force comments	**Please see response to Comment #2350 in this section (ADCA task force comment).**
2405	2013/09/23 13:15	Company, Czech Republic	see ADCA task force comments	**Please see response to Comment #2350 in this section (ADCA task force comment).**
2402	2013/09/23 13:01	Company, Poland	see comments introduiced by ADCA task force	**Please see response to Comment #2350 in this section (ADCA task force comment).**
2401	2013/09/23 12:54	Company, Finland	see Comments on the draft recommendation introduced by ADCA Task force	**Please see response to Comment #2350 in this section (ADCA task force comment).**
2390	2013/09/23 12:11	ETRMA, Industry or trade association, Belgium	Considering the current impossibility to substitute the use of ADCA, and the absence of human health exposure risk, as indicated above, we find an exemption from authorisation is needed and necessary for the manufacturing of rubber articles, including: • Sealing gaskets • Sealing components • Expandable mastic for insulation and soundproofing • Tyres foam filler • Parts of anti-vibration rubber components • Expandable polymer for thermal insulation for aerospace applications. Such rubber applications are very important within a vehicle since, among others benefits, they prevent the leakage of liquids, and contribute to shock absorption, both in normal vehicle use conditions and in the case of accidents. Major identified risk in case it becomes impossible to use ADCA in rubber goods manufacturing, or due to costs associated with the REACH authorisation procedure: delocalization of manufacturing outside EU to satisfy the current market demand.	Thank you for your comment. **Please see our response to Comment # 2435 in this section.**
2370	2013/09/23 00:59	West and Senior Limited, Company,	All aspects of polymeric foaming	Thank you for your comment.

		United Kingdom		**Please see our response to Comment # 2435 in this section.**
2362	2013/09/22 10:30	PVC4Pipes, Industry or trade association, Belgium	ADCA should be exempt from the Authorisation requirement for the production and use of foam core PVC pipes because: 1. During the manufacturing process, ADCA is used almost exclusively in a non-dusting form, such a seal sachets, prills or tablets. In some cases, it is used in powder form. In all cases, dust extraction systems are used and employees wear masks to prevent inhalation of dust, gloves, goggles and protective overalls. 2. During the manufacturing process, ADCA decomposes into nitrogen, carbon monoxide and ammonia. Analysis has shown that this decomposition results in less than 0.02% of ADCA remaining in the finished pipes. This ADCA is trapped within the foam structure of the pipe which itself is surrounded on both sides by solid, impervious PVC-U. 3. During the use (installation) phase of the foam core pipes, it may be necessary to cut the pipes to length. This is normally carried out on site by building workers who will wear protective clothing. Once installed underground, there is no possibility of exposure to ADCA. 4. Hence, in this application there is no widespread and/or dispersive use of ADCA, so the application should be exempted.	Thank you for your comment. **Please see our response to Comment # 2435 in this section.**
2350	2013/09/20 19:26	ADCA TASKFORCE, Industry or trade association, Belgium	not applicable - however all consumer and professional uses are strictly advised against in all registration dossiers. All all industrial uses shall not be subject to authorisation.	Thank you for your comment. **Exemption for all industrial uses** As regards your request for exemption please note that uses (or categories of uses) can only be exempted from the authorisation requirement on the basis of Art 58(2) of REACH, unless they are already explicitly exempted in REACH Art 2(5 or 8) or in Art 56 (3-6). Please note that according to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses "*provided that, on the basis of the existing specific Community legislation imposing minimum*

				requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled". However, there seems to be no specific Community legislation in force that would allow consideration of exemption(s) of (categories of) uses from the authorisation requirement on the basis of Article 58(2) of the REACH Regulation. A list of uses that in accordance with the REACH Regulation are exempted from authorisation can be found at http://echa.europa.eu/documents/10162/17232/generic_exemptions_authorisation_en.pdf. Information on the low level of risk associated to a use or related to the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use, as well as the (adverse) impacts of ceasing a use are important. Information regarding these topics should be provided as part of the application for authorisation. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited

				review period of the authorisation.
2346	2013/09/20 18:06	Europacable, Industry or trade association, United Kingdom	• Azodicarbonamide (ADCA) is used in the manufacturing processes for some power, data- and telecommunication cables, which demand specific, high protective insulation. Europacable is aware that ADCA was recently identified as a Substance of Very High Concern (SHVC) and is under consultation for inclusion in the Annex XIV (substances subject to authorization). • Europacable is concerned that having discussed the issue with suppliers of ADCA, there are currently no substitute products available to replace ADCA. In the event that the use of this substance is restricted it will have serious implications on the future availability of power, telecommunication and data cables produced in Europe. • The restriction of ADCA without a replacement material would limit the availability of power, telecommunication and data cables with this high protective insulation and have an adverse impact on the growth in these markets with serious financial implications for the manufacturing companies and users of these products. • Europacable is aware that manufacturers of ADCA have expressed their concerns which are shared by many of the users of this product. • As responsible manufacturers of cables, Europacable considers Health and Safety initiatives as important issues and supports improvements to protect the environment and users of materials.	Thank you for your comment. **Please see our response to Comment # 2435 in this section.** Also note that authorisation does not ban or restrict the use of the substance as long as it is shown in the authorisation applications (and supported in the authorisation granting process) that either the risks arising from the use(s) applied for are adequately controlled or that there are no alternatives available and the socio-economic benefits are outweighing the risks arising from the uses.
2339	2013/09/20 16:36	Hebron, S.A., An Otsuka Chemical Group Company, Company, Spain	If finally, regrettably, pure ADCA is unfairly authorized, exemption of authorization should be considered for ADCA at any dust-free format like pastes, dispersions and granules where ADCA is embedded in the Matrix (polymer or plastisol) as there is no possibility to have hazardous dust in the environment. These products, in fact, are not classified as they do not represent a hazard to human health by inhalation. According to EC 1272/2008 Regulation, ANNEX I, PART 1.3.4 and 1.3.4.1, the product is not classified as Hazardous: "1.3.4. Metals in massive form, alloys, mixtures containing polymers, mixtures containing elastomers 1.3.4.1. Metals in massive form, alloys, mixtures containing polymers and mixtures containing elastomers do not require a label according to this Annex, if they do not present a hazard to human health by inhalation, ingestion or contact with skin or to the aquatic environment in the form in which they are placed on the market, although classified as hazardous in accordance with the criteria of this Annex."	Thank you for your comment. **Exemption for specific form(s) based on exemption from labelling (CLP)** Under the CLP Regulation, the specific form of the substance may be relevant for exemption from labelling requirement. Article 23 of CLP sets derogations from labelling requirement in special cases and it refers to section 1.3.4 of Annex I to the same Regulation; that section provides derogation from labelling for metals in massive form, mixtures

				containing polymers, mixtures containing elastomers, providing that they do not present a hazard to human health by inhalation, ingestion or contact with the skin or to the aquatic environment in the form in which they are placed on the marked, although classified as hazardous in accordance with the criteria of Annex I to CLP However, please note that the derogations for specific forms of the substance refer to labelling requirements, not classification. ADCA's harmonised classification (which was the basis for its identification as SVHC) applies to all its forms. The substance just does not necessarily need to be labelled in all forms. Therefore, use of forms (of ADCA as such or in mixtures ≥0.1%) exempted from labelling will still require authorisation in case the substance is included in Annex XIV. **Please see also response to comment #2454 in section I (sub-response "Exemption for specific form(s)").**
2331	2013/09/20 15:35	Company, Sweden	Considering the current impossibility to substitute the use of ADCA and the absence of human health exposure risk, as indicated above, exemption from authorisation is deemed to be necessary for the manufacturing of rubber articles, including: • Sealing gaskets • Sealing components • Expandable mastic for insulation and soundproofing • Foam filler for (certain) tyres • Parts of anti-vibration rubber components • Expandable polymer for thermal insulation for aerospace	Thank you for your comment. **Please see responses to Comments # 2435 and # 2322 in this section.**

			applications. Such rubber application are very important within a vehicle since, among others benefits, they prevent leakage of liquids or contribute to shock absorption during foreseeable vehicle use conditions and in case of accidents. Major identified risk: delocalization of manufacturing outside EU to satisfy the current market demand.	
2330	2013/09/20 15:35	Polifoam Plastic Processing Ltd, Company, Hungary	The Recommendation is based on the statement (H334: "May cause allergy or asthma symptoms or breathing difficulties if inhaled"). This substance "is manufactured predominantly as a yellow/orange powder with a particle size in the 2-10 micron range (Annex XV report, 2012), which is in the respirable range for humans." HOWEVER, industry uses this substance mainly in liquid (paste) and dust-free solids (granules) - as Recommendation states: "tens of formulator sites" - use powder form and "hundreds of use sites in the EU" - use liquid (paste) and dust-free solids (granules) forms. The original statement cannot be appied to the majority of use sites because the 2-10 micron range of substance, which may cause allergy or asthma symptoms or breathing difficulties if inhaled, is NOT PRESENT at these sites! In conclusion, use of non-powder forms of the substance (Diazene-1,2-dicarboxamide [C,C'-azodi(formamide)]) should be exempted.	Thank you for your comment. **Please see responses to comments #2250 and 2190 in this section.**
2328	2013/09/20 15:36	SFEC, Industry or trade association, France	Acoustic vinyl floors should be exempted because it's impossible to have Adca in the air. There is a closed top layer on the surface of the final product. Also vinyl wall covering, artificial lether, vinyl floor have to be exempted. The Adca rates are below 0,1 % (w/w) and the emission simulation shows a rate less than the only treshold existing (England, 1 mg/m3).	Thank you for your comment. **Please see our response to Comment # 2435 in this section.**
2326	2013/09/20 15:29	Company, Sweden	SU11 Manufacture of Rubber Products PC32 Polymer Preparations and Compounds Considering the current impossibility to substitute the use of ADCA and the absence of human health exposure risk, as indicated above, exemption from authorisation is deemed to be necessary for the manufacturing of rubber articles, including: • Sealing gaskets • Sealing components • Expandable mastic for insulation and soundproofing • Foam filler for (certain) tyres • Parts of anti-vibration rubber components • Expandable polymer for thermal insulation for aerospace applications. Such rubber application are very important within a vehicle since, among	Thank you for your comment. **Please see response to Comment # 2322 in this section.**

			others benefits, they prevent leakage of liquids or contribute to shock absorption during foreseeable vehicle use conditions and in case of accidents. Major identified risk: delocalization of manufacturing outside EU to satisfy the current market demand.	
2325	2013/09/20 15:28	Company, France	Sector of Use: SU11 Manufacture of Rubber Products Chemical Product Category: PC32 Polymer Preparations and Compounds Considering the current impossibility to substitute the use of ADCA and the absence of human health exposure risk, as indicated above, exemption from authorisation is deemed to be necessary for the manufacturing of rubber articles, including: • Sealing gaskets • Sealing components • Expandable mastic for insulation and soundproofing • Foam filler for (certain) tyres • Parts of anti-vibration rubber components • Expandable polymer for thermal insulation for aerospace applications. Such rubber application are very important within a vehicle since, among others benefits, they prevent leakage of liquids or contribute to shock absorption during foreseeable vehicle use conditions and in case of accidents. Major identified risk: delocalization of manufacturing outside EU to satisfy the current market demand.	Thank you for your comment. **Please see response to Comment # 2322 in this section.**
2322	2013/09/20 15:12	Company, Sweden	SU11 Manufacture of Rubber Products PC32 Polymer Preparations and Compounds Considering the current impossibility to substitute the use of ADCA and the absence of human health exposure risk, as indicated above, exemption from authorisation is deemed to be necessary for the manufacturing of rubber articles, including: • Sealing gaskets • Sealing components • Expandable mastic for insulation and soundproofing • Foam filler for (certain) tyres • Parts of anti-vibration rubber components • Expandable polymer for thermal insulation for aerospace applications. Such rubber application are very important within a vehicle since, among others benefits, they prevent leakage of liquids or contribute to shock absorption during foreseeable vehicle use conditions and in case of accidents. Major identified risk: delocalization of manufacturing outside EU to satisfy the	Thank you for your comment. **Please see response to Comment # 2435 in this section.** **Market share away from EU** Please also note that REACH is an EU Regulation aiming to ensure a high level of protection of human health and the environment while enhancing competitiveness and innovation. The obligation to apply for authorisation is to ensure that risks are adequately controlled or that socio-economic benefits are outweighing the risks, while concomitantly it is a strong incentive to search for and develop

			current market demand.	suitable alternatives. As ADCA is a respiratory sensitiser, there is a strong societal interest to protect humans, in particular workers handling the substance, from risks potentially arising from its uses. An authorisation requirement for ADCA will accordingly ensure that the health of workers in the EU involved in the uses of ADCA is protected. Authorisation does not ban or restrict the use of the substance as long as it is shown in the authorisation applications (and supported in the authorisation granting process) that either the risks arising from the use(s) applied for are properly controlled or that there are no alternatives available and the socio-economic benefits are outweighing the risks arising from the uses. Information and concerns brought forward in your comments can be included in the application, should you decide to apply for authorisation of your uses of the substance or if your supplier applies for you. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.
2267	2013/09/19	Hungarian Chemical	If in spite of the convincing arguments ADCA will fall under authorisation all uses with non- or low-dusting formats should be exempted.	Thank you for your comment.

	15:01	Industry Association, Industry or trade association, Hungary		**Please see responses to comments #2250 and 2190 in this section.**
2266	2013/09/19 14:56	Company, United Kingdom	I can't see any categories that should be exempt but it would be better to control the processes that have to be used according to the substance format: powder, pellets, damped, liquid.	Thank you for your comment. **Other RMO** Please note that in the process of assessing whether a substance on the Candidate List has priority for inclusion in Annex XIV and therefore should be recommended for inclusion in this annex we are not in the position to assess the pertinence of alternative regulatory risk management options for the substance or some of its particular uses or physical forms. **See also response to comment #2461 in this section.**
2250	2013/09/18 19:32	Sika Services AG, Company, Switzerland	We request to exempt those uses of ADCA from the authorisation requirement, where ADCA is enclosed in a solid polymer matrix. The only identified hazard of ADCA is effective solely via the inhalation route and in the form of dust, given its practically non-existent volatility (vapour pressure of the pure substance at 25°C is 2x10-8Pa acc. ECHA dissemination database). Therefore the risk from ADCA is properly controlled by its inclusion in a solid matrix. Article 58(2) of the REACH regulation specifically mentions the physical form as a risk modifier to be taken into account. Because the risk is controlled not by the type of use but by the physical form of the mixture community legislation cannot reasonably be expected to exist in this case, as there is no risk beforehand. The described situation is comparable to articles with the only difference being, that a function determining form is not yet given. Recital 32 of the regulation's preface indicates that in analogy to very low concentrations in liquid mixtures, solid mixtures should not need chemical safety assessments and be exempted from authorization.	Thank you for your comment. **Exemption for specific form(s)** When considering whether to include an exemption of a use of a substance under Art. 58(2) REACH, the following elements have to be considered: there is existing EU legislation addressing the use or categories of use that is proposed to be exempted; the EU legislation imposes minimum requirements for the control of risks of the use; the EU legislation properly controls the risks to human health and/or to the environment from the use of the substance arising from the intrinsic properties of the substance which are specified in Annex XIV to REACH.

				According to Article 58(2) REACH: 'In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and environment related to the nature of the substance, such as where the risk is modified by the physical form'. Thus, it does not seem that the form is to be considered independently from the mentioned elements in order to exempt uses or categories of uses from the authorisation requirement. In other words, while the form and how it may affect the exposure potential is not alone a sufficient basis for an exemption, the form should be taken into account when assessing whether the existing legislation provides a justification for an exemption. **Please see also our response to Comment # 2435 in this section.**
2249	2013/09/18 17:44	Industry or trade association, France	The French wallcovering market is estimated at 600 million at retail sales value: 12% of this part is made in France (UGEPA has become the single industrial manufacturer in France since February). 60% of this is sold as blown vinyl. Without this, our company will cease trading immediately. (150 persons from UGEPA plus many other small companies of roughly 100 persons would lose there jobs) We are represented by IGI. UGEPA is the single industrial manufacturer in France: 50% of our production is made of foamed vinyl wallcoverings whose coatings contain compounds using ADCA. We are all SME's and do not have the time or resources to immediately develop alternative foaming compounds. We all fear for our future if ADCA were banned and it would be difficult for us to compete with manufacturers from outside Europe. We urgently need the government help and support to ensure that France opposes the ban of one of our major raw materials as proposed by ECHA.	Thank you for your comment. **Please see responses to Comments # 2435 and 2346 in this section.**

2203	2013/09/10 15:23	REHAU AG + Co. Company Germany	The production of dustfree granulated foaming agents and the use of these dustfree granulated preparations in the extrusion of PVC-profiles should be exempted from any obligation to ask for an authorisation. This granulated material cannot bear any risk for workers or other persons, if during the production of these granulated preparations a closed system for mixing and granulation process is used.It is impossible to have dusty wear of a granulated preparation containig EVA as a carrier for ADCA.	Thank you for your comment. **Please see responses to comments #2250 and 2190 in this section.**
2197	2013/09/08 17:45	L&L Products Company France	See general comments	Thank you for your comment. **Please see response to Comment # 2197 in Section I**
2190	2013/09/04 11:57	Individual Italy	our wallcoverings are 3 dimensional and this is a significant part of their appeal. Foaming PVC reduces the amount of PVC required to achieve the required relief. ADCA is the most efficient blowing agent in terms of amount required to achieve the desired relief and in terms of foam quality it is unsurpassed. in our opinion there is no valid alternative.	Thank you for your comment. **Low level of risk / No suitable alternatives / Socioeconomic considerations** Information on the low level of risk associated to a use or related to the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use, as well as the (adverse) impacts of ceasing a use are important. Information regarding these topics should be provided as part of the application for authorisation. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.
2180	2013/09/02	Speciality Coatings	We believe that wallcoverings should be exempted. The vast majority of vinyl wallcoverings are expanded using ADCA – it is 80%	Thank you for your comment.

	16:42	Ltd Company United Kingdom	of our output – and our survival would be seriously threatened by imports from outside EU if a ban goes ahead. We believe a ban on ADCA in the EU would precipitate a wider use in less regulated parts of the world where employees may not enjoy EU standards of protection. All wallcovering companies in the EU belong to trade associations who have codes of conduct and are responsible companies who regard the welfare of their employees as paramount.	**Please see response to Comment # 2435.**
2176	2013/08/30 13:55	Zebra-chem GmbH Company Germany	Use of ADCA in specific masterbatch forms: We request an exemption of preparations (specific physical forms) of ADCA which are available in so called masterbatches which are dust free and if this dust free property is testified by an authorised laboratory like the BAM. These properties are tested and proved by the BAM (Bundesanstalt für Materialprüfung) and this certifies that this form of ADCA does not cause any risk in the sense of being a sensitizer as mentioned by the Hazard statements H334. This classification and the consequently required statement H334 is the only reason why ADCA was put on the list of SVHC and why it is planned to put it on Annex XIV, no other reason lead to this classification. It is not understandable, it is not acceptable and it proves that basic scientific methods have been ignored during decision making when this facts where ignored and not taken into account by the persons or by the committee making this de cision. We therefore repeat our request to exempt dust free ADCA preparations from including in Annex XIV.	**Thank you for your comment.** **Please see responses to comments #2250, 2339, and 2190 in this section.**
2164	2013/08/23 11:26	Company United Kingdom	All industrial uses where the exposure is managed by routine technical measures	Thank you for your comment. **Please see response to Comment # 2461 in this section.**
2153	2013/08/20 14:05	Company Russia	ADCA is a common or even a must-have blowing agent in the production of expanded-vinyl wallcoverings in Russia and the CIS. It is a part of PVC formulations every wallpaper factory uses daily. We have never had any issues with ADCA in terms of it being irritant for the plastisol-mixing or production-line operators, raw-materials and finished-goods warehouse personnel, retail shop assistants or the end users. It is an industry standard material and we do not really know a substitute that would perform equally well in case ADCA is banned for some reason.	Thank you for your comment. **Please see response to Comment # 2190 in this Section**

2100	2013/06/28 17:49	Poppe GmbH Company Germany	We are using ADCA as a blowing agent for the production of cellular rubber. ADCA is used as a non-dusting preparation, hence it cannot cause any respiratorial sensitation at our site. So far, no such problems have been registrated in the past. If ADCA vanishes from our raw material portfolio, non-EU manufacturers will benefit, since the substance is no longer present in the final product.	Thank you for your comment. **Please see response to comment #2322 in this section.**

IV - Comments on uses for which review periods should be included in Annex XIV, including reasons for that:

#	Date	Submitted by (name, Organisation/MSCA)	Comment	Response
2476	2013/09/23 19:52	Fédération de la Plasturgie, Industry or trade association, France	See attached non-confidential document "Fédération de la Plasturgie - ADCA Consultation Input 23sep2013.pdf" page 24.	Thank you.
2469	2013/09/23 19:17	ChemSec, International NGO, Sweden	ChemSec supports the proposal of ECHA to not allow any review periods.	Thank you for your comment.
2461	2013/09/23 17:59	Company, Ireland	It is not possible to predict when suitable alternative materials could be developed as an alternative to ADCA therefore it is not possible for us to comment on review periods.	Thank you for your comment. Please note that setting 'upfront' review periods for any uses requires that the Agency has access to adequate information on different aspects relevant for a decision on the review period. ECHA currently assessed that the information available is not sufficient to conclude upfront on specific review periods. Therefore, ECHA did not propose such review periods. It is to be stressed that all authorisation decisions will include specific review periods which will be based on concrete case specific information provided in the applications for authorisation. Furthermore, note that guidance on the type of information in an application for authorisation which may impact the review period when granting authorisation can be found in RAC's and SEAC's approach for

#	Date	Submitted by (name, Organisation/MSCA)	Comment	Response
				establishing the length of the review period (http://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf).
2454	2013/09/23 17:38	EuPC, European Plastics Converters, Industry or trade association, Belgium	No comments from EuPC.	Thank you.
2450	2013/09/23 17:14	Swish Building Products, Company, United Kingdom	The timing issue needs to reflect the fact that there are no recognised alternative chemical or physical methods of achieving the same foam structure. ADCA appears to provide a unique solution which we currently cannot match.	Thank you for your comment. **Please see response to Comment # 2461 in this section**
2442	2013/09/23 16:30	SVITAP J.H.J. spol. s r.o., Company, Czech Republic	As mentioned above	Thank you for your comment.
2440	2013/09/23 16:12	Kestrel, Company, United Kingdom	When looking at the alternatives raised by the Austrian Authorities there is some concern that these materials may also face restricted use or other processes suggested may create further risk to our operators. As stated earlier we have no acceptable alternatives at this time.	Thank you for your comment. **Please see responses to Comments # 2461 and 2370 in this section**
2430	2013/09/23 15:35	Company, Germany	Technical conversion, new tests for certifications necessary, Time for new formulations and engineering of new technical equipments	Thank you for your comment. **Please see response to Comment # 2461 in this section**
2407	2013/09/23 13:23	Company, Sweden	see task force comments	**Please see our response to Comment # 2350 in Section I**
2406	2013/09/23 13:19	Company, Romania	see ADCA task force comments	**Please see our response to Comment # 2350 in Section I.**
2405	2013/09/23 13:15	Company, Czech Republic	see ADCA task force comments	**Please see our response to Comment # 2350 in Section I.**

#	Date	Submitted by (name, Organisation/MSCA)	Comment	Response
2402	2013/09/23 13:01	Company, Poland	see comments introduiced by ADCA task force	**Please see our response to Comment # 2350 in Section I.**
2401	2013/09/23 12:54	Company, Finland	see Comments on the draft recommendation introduced by ADCA Task force	**Please see our response to Comment # 2350 in Section I**
2370	2013/09/23 00:59	West and Senior Limited, Company, United Kingdom	We would wish to ask regarding the basis of potential alternatives listed and the timing that these may be considered as applicable alternatives according to Austrian Authorities who created the Annex XV document. ADCA is a chemical which is commercially available and in sufficient volume to cater for current demand and continued growth. The alternative chemistries listed can be considered to be inappropriate technically but in the event that a listed chemical may prove a technical alternative (irrespective of technical compromise or cost), the chemistry may not be available on a commercial basis in sufficient volume to replace ADCA across European manufacture. The commercial as well as technical availability must be considered if listed as an option and review periods must be predetermined which may allow continued elongation of timed assessment should the feasibility not prove a commercial reality.	Thank you for your comment. **Background Dcoument – Section on al ternatives** Please note that information on the alternatives-related sections of A.XV reports and Background documents does not aim to identify potential alternatives or to assess the technical or economic feasibility of such alternatives, risks related to them, or their availability. These sections aim only at obtaining a rough overview of the level of information available on the alternatives and their nature. In other words, this part of the assessment is not judging whether the alternatives are feasible or safer or how long it could take to transfer to the alternatives; but whether or not information seems to be available that facilitates compiling an analysis of alternatives by the future potential applicants. Such an overview is relevant when proposing a Latest Application Date for a recommended substance.

#	Date	Submitted by (name, Organisation/MSCA)	Comment	Response
				However, indeed in the "analysis of alternatives", to be submitted as part of an application for authorisation for a substance in A.XIV, applicants should assess – and Committees will evaluate - both the suitability (reduced risks, and technically and economically feasible) and availability of potential alternatives to the applicant. Regarding your request for "predetermined review periods", **please see also our response to Comment # 2461 in this Section.**
2350	2013/09/20 19:26	ADCA TASKFORCE, Industry or trade association, Belgium	not applicable	Noted
2331	2013/09/20 15:35	Company, Sweden	Non	Thank you.
2322	2013/09/20 15:12	Company, Sweden	None	Thank you.
2266	2013/09/19 14:56	Company, United Kingdom	No idea on review preiods	Thank you.
2249	2013/09/18 17:44	Industry or trade association, France	The French wallcovering market is estimated at 600 million at retail sales value: 12% of this part is made in France (UGEPA has become the single industrial manufacturer in France since February). 60% of this is sold as blown vinyl. Without this, our company will cease trading immediately. (150 persons from UGEPA plus many other small companies of roughly 100 persons would lose there jobs) We are represented by IGI. UGEPA is the single industrial manufacturer in France: 50% of our production is made of foamed vinyl wallcoverings whose coatings contain compounds using ADCA. We are all SME's and do not have the time or resources to immediately develop alternative foaming compounds. We all fear for our future if ADCA were banned and it would be difficult for us to compete with manufacturers	Thank you for your comment and the information provided. **Please see response to Comment # 2461 in this Section.**

#	Date	Submitted by (name, Organisation/MSCA)	Comment	Response
			from outside Europe. We urgently need the government help and support to ensure that France opposes the ban of one of our major raw materials as proposed by ECHA.	
2203	2013/09/10 15:23	REHAU AG + Co., Company, Germany	None	Thank you.