reachcentrum

ADCA - GENERAL COMMENTS FOR INPUT TO PUBLIC CONSULTATION

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 52 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 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 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 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.

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:

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 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 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.

Company	Country of operation
Amik Italia SPA	Italy
Armacell	Germany
AS Création	Germany
Baerlocher	Germany – United Kingdom - Italy - France
Benecke-Kaliko AG	Germany
BN International	Netherlands
Borealis AB	Sweden
Chemson	UK
China System(OR: ReachMastery)	China/ Italy
COPCI Metamine	France
Crown	Belgium
Dongjin Semichem Co.,Ltd	Korea
EIWA	Japan
Erismann & CIE. GmbH	Germany
ESN Deutsche Tischtennis Technologie GmbH	Germany

Follmann & Co. GmbH & Co. KG	Germany
Gebr. Rasch GmbH & Co. KG	Germany
Graham&Brown	United Kingdom
GrandDeco	Belgium
Hebron	Spain
Henkel AG & Co. KGaA	Germany
HPL Additives	India
Hutchinson	France
Interep	France
Kaimann GmbH	Germany
Kist Europe	Germany
Konrad Hornschuch AG	Germany
L&L Products SAS	France
Lanxess	United Kingdom
Lehmann & Voss & Co.KG	Germany
L'Isolante Flex	Italy
Marburger Tapetenfabrik	Germany
MasterPlast S.r.l.	Italy
Muraspec	United Kingdom
Nitto Europe	Belgium
NMC	Belgium
Otsuka Chemical Co., Ltd.	Japan
Overseas Konstellation (O.K.) Company, S.A.	Spain
Palziv Foam Manufacturers	Romania
Sekisui Alveo AG	Switzerland - Netherlands - United Kingdom
Sika	Switzerland
Speciality Coatings Ltd	United Kingdom
TMG Automotive	Portugal
Tramaco	Germany
Trocellen GmbH	Germany / Italy / United Kingdom / Hungary/ Spain
UFM	Hungary
Union Foam	Italy
Vinnolit	Germany
Vita Liquid Polymers Ltd	United Kingdom
Wallcover Tapetenproduktionsgesellschaft mbH	Germany
West and Senior Ltd	United Kingdom
Zebra-chem GmbH	Germany

This position is also fully supported by:

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