Authorisation Process

Mohammad Hayatifar

4 April 2019

Content

- Authorisation process
- Update on ADCA
- Microplastics
- Substance Watch

Authorisation: Why?

Aim of authorisation (Art. 55 REACH):

- to ensure good functioning of the internal market
- to assure risks from SVHCs are properly controlled and
- to assure SVHCs are
  - progressively replaced by less dangerous substances/technologies
  - where technically and economically feasible alternatives are available.

Authorisation: Why?

Substances with the following hazard properties may be identified as SVHCs:

- Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction **(CMR) category 1A or 1B** in accordance with the CLP Regulation.
- Substances which are persistent, bioaccumulative and toxic **(PBT)** or very persistent and very bioaccumulative **(vPvB)** according to REACH Annex XIII.
- Substances on a case-by-case basis, that cause an **equivalent level of concern** as CMR or PBT/vPvB substances.

Authorisation: What?

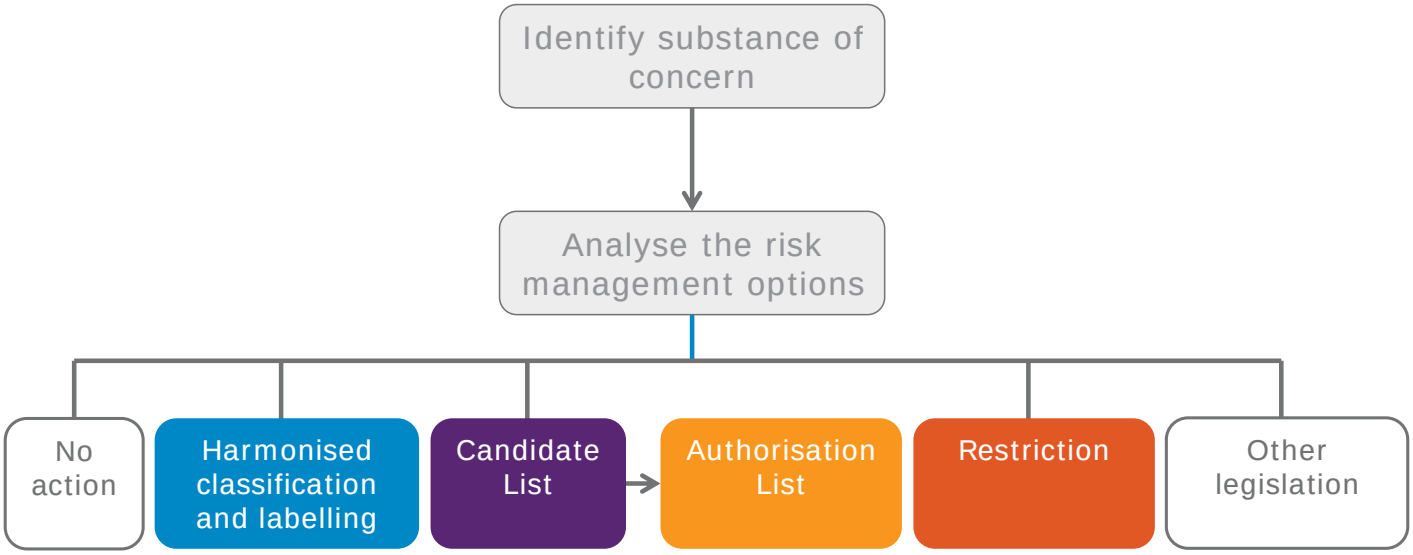
Authorisation requirement:

Substances subject to authorisation **may not be placed on the market for a use or be used unless the use has been authorised**

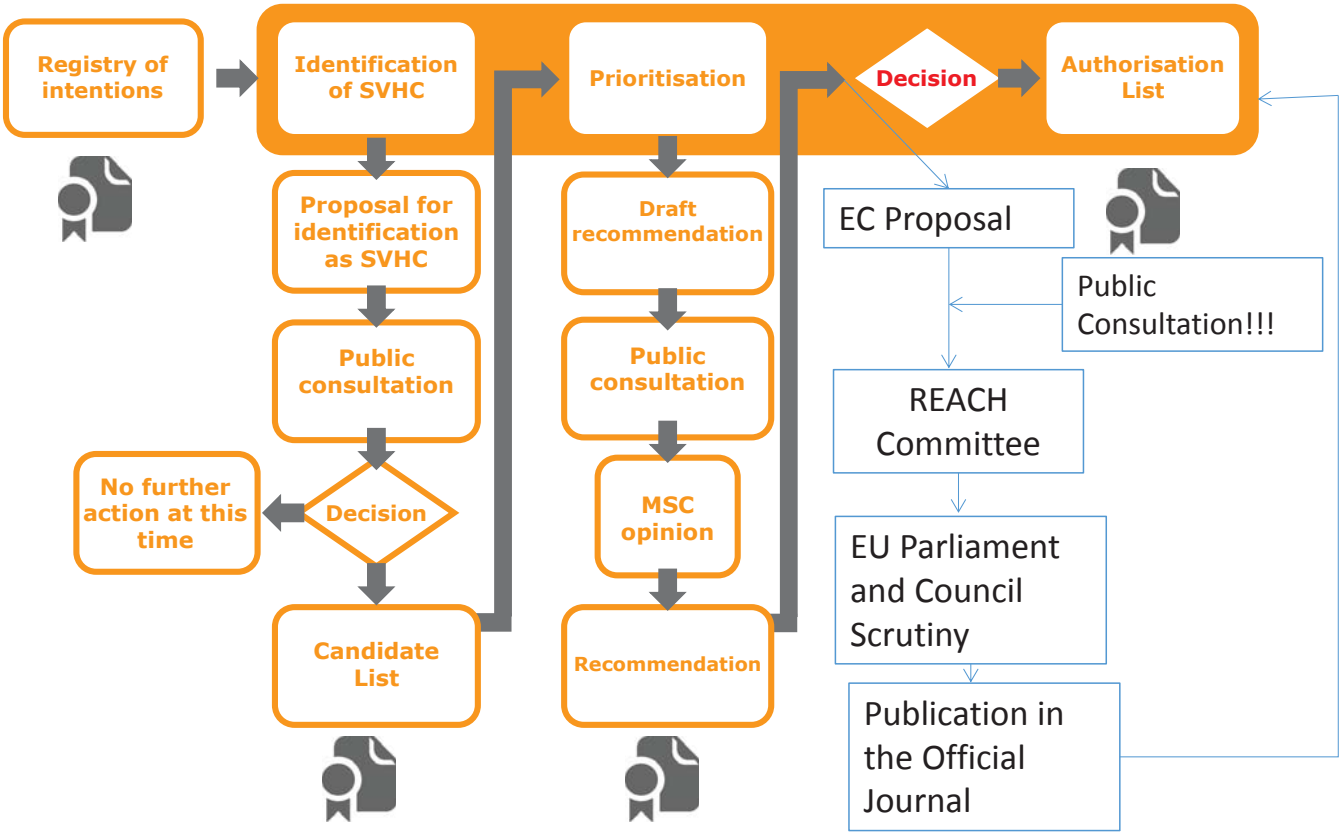
- Authorisation is always related to a use
- All uses are covered unless
  - excluded from the scope
  - exemption is foreseen in Annex XIV
- Authorisation is linked to the applicant
- Imported articles are not subject to authorisation
- No volume threshold
- Time dimension: transitional periods (latest application date and sunset date), review period (general / specific)

Substances of Concern

Authorities control risks at a regulatory level by identifying and regulating substances of concern under REACH and CLP. The typical approach is:



The process:



Recommendation for inclusion

- ECHA has the obligation to recommend substances included in the Candidate List for inclusion in Annex XIV (Article 58 of REACH).
- ECHA prioritises substances from the Candidate List to determine which ones should be included in the Authorisation List (Annex XIV of the REACH Regulation) as a priority
- ECHA is required to submit recommendations at least every second year.

Prioritisation

According to Article 58(3), priority shall normally be given to substances with

(a) PBT or vPvB properties, or
(b) wide dispersive use, or
(c) high volumes.

It is clear from this wording that these three criteria for prioritisation are not exclusive and that a substance may be prioritised for the recommendation for other reasons.

The assessment of priority needs to be performed on a substance-specific basis. This is because inclusion in Annex XIV is per substance and not per use.

In particular with regard to criterion b) of Article 58(3) ('wide dispersive use'), it is important to remember that all uses of a substance in the scope of authorisation need to be assessed.

Prioritisation

- Inherent property
- Volume
- Wide-dispersive use

Table 1 Overview of scoring and ranges for each criterion

Inherent properties		Volume		Wide dispersive use	
57(a) or/and 57(b) or/and 57(c) or/and 57(f) [13,14]	1	no volume	0	no use	0
57(f) (ED)	7	< 10 t/y	3	IND	5
57(d) or 57(e)	13	10 – <100 t/y	6	PROF	10
57(d) and (at least) one other SVHC property or 57(e) and (at least) one other SVHC property	15	100 – <1,000 t/y	9	CONS	15
		1,000 – <10,000 t/y	12		
		≥ 10,000 t/y	15		

Total score:

The individual scores are added to the total score as follows:

The individual scores are added to the total score as follows:

$$\mathbf{Score_{Total}} = \mathbf{Score_{Inh\ prop}} + \mathbf{Score_{Volume}} + \mathbf{Score_{WDU}}$$

with

Score [min – max]:	[1 – 45]	[1 – 15]	[0 – 15]	[0 – 15]
Relative maximum weight (%):		33.3	33.3	33.3

In each prioritisation round, substances added in June of the previous year (or earlier) and not yet recommended will be assessed. Substances added to the Candidate List in December of the previous year will not be considered for the priority setting immediately in the following year. Instead they will be considered in subsequent rounds (e.g., if added in December year 1 the substance will be considered in year 3).

Recommendation for inclusion

The draft recommendation includes, amongst other things, this information:

- **Sunset date** from which the placing on the market and the use of a substance is prohibited, unless an authorisation is granted or the use is exempt from authorisation;
- **Latest application date** by which applications must be received if the applicant wants to continue placing the substance on the market or using it after the sunset date; (normally 18 months before sunset date)
- **Review periods** for certain uses, if any;

- **Uses exempted** from the authorisation requirement, if any.

Member states opinion:

- The Member State Committee prepares its opinion on the draft recommendation taking into account the comments received during the public consultation.

Recommendation and decision

- European Commission proposal for inclusion
  - European Commission is expected to draft a Legislative Proposal
  - The Legislative proposal will include: the latest application date and sunset date
  - There is no timeframe in which the Commission has to submit a legislative proposal
- REACH Committee
  - The European Commission's REACH-Committee* needs to vote on the legislative proposal
  - The REACH Committee consists of representatives of the 28 Member states

*Committee set up under Regulation (EU) No 182/2011

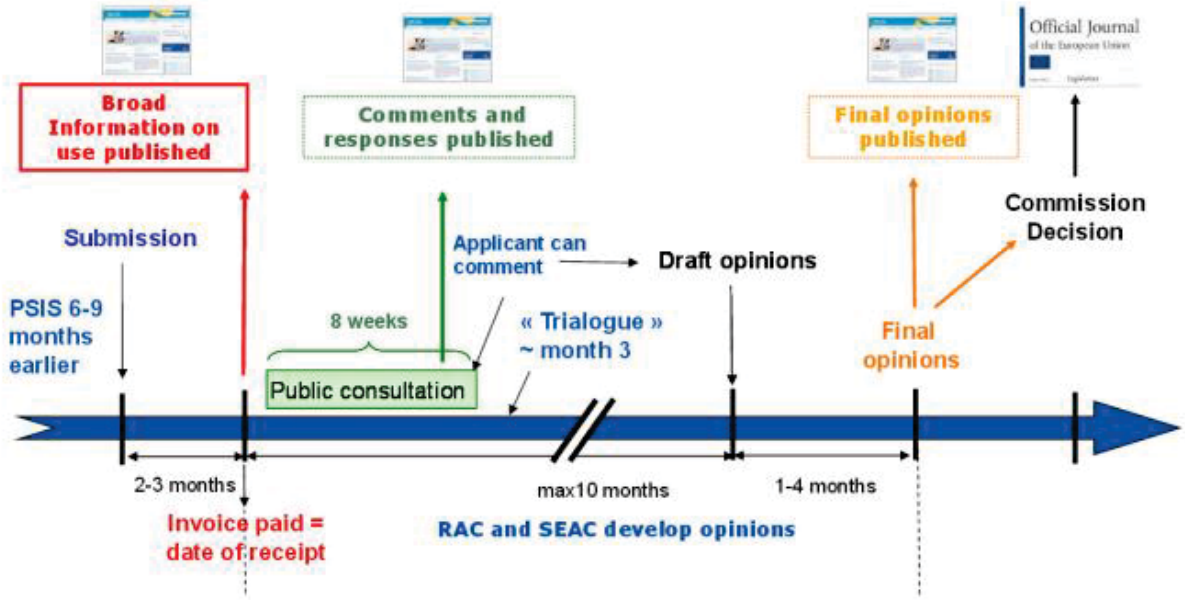
- The REACH Committee votes examination procedure, meaning:
  - Positive votes representing 65% of the EU population needs to support the proposal*. i.e. we need the combined support of member states representing 35% of the EU population to block the authorization procedure

- **EU Parliament and Council Scrutiny**
- **Publication in the EU official journal**
  - If the legislative proposal is passed the proposal will be published in the official journal and companies will have to apply for authorization in order to keep using the substances

*Examination procedure referred to in Regulation 182/2011

REACH authorisation process

Diagram 1: timelines of the REACH authorisation process



ADCA Brief

Azodicarbonamide/1,2-diazenedicarbonamide
Potential for listing on Annex XIV within the framework of the REACH Regulation

ERFMI Meeting 04-04-2019

Content presentation

1/Introduction to the ADCA issue

2/ Advocacy Timelines

3/Use of ADCA in plastics and rubber products in Europe

4/ADCA classification and equivalent level concern

5/Socio economic impact

6/Updated scientific information

7/Conclusions & recommendations

Introduction/key messages

- ADCA, 1,2-dicarboxamide [C,C'-azodi(formamide)], CAS Number: 123-77-3, is a blowing agent used to manufacture plastics and rubber products
- ADCA was classified as respiratory sensitiser - *Resp. Sens. 1 H334, May cause allergy or asthma symptoms or breathing difficulties if inhaled*
- The European Commission proposal of including ADCA in Annex XIV of REACH Regulation (EC) No 1907/2006 to force the use of substitutes is impossible to achieve by plastics converters and rubber producers: **currently, there are no adequate alternatives to ADCA**
- Risk management measures in place to control workers' exposure are effective to control the potential risk the substance may pose for workers: **no cases of occupational asthma or rhinitis that could be attributed with certainty to ADCA exposure in the plastics and rubber sector were found during the past 20 years**
- **The authorization process should be stopped for this substance as it is not a proportionate risk management option (unnecessary administrative costs, uncertainty leading to stop of investment and delocalization)**
- **Alternative regulatory options should be investigated so as to further support the implementation of industry best practices and provide an additional safety net.**
  - **setting of an EU wide OEL (beginning with the UK level as reference)**
  - **Setting a Reference Maximum Inhalation Exposure value to be met at work place through an annex XVII restriction under REACH**

Timelines

REACH Committee

- Mid April – discussion
- June vote on annex XIV proposal

WTO consultation

- 15 February-16 April

The timeframe for submission of authorisarion dossier for ADCA is 34 months, the sunset date is 20 month after the LAD

Feedback mechanism consultation

- *Not started yet – end March early April? Lasts 4 weeks.*
- **Potential scrutiny by Council and EP** starting on 10/07/2019 and lasting 3 months

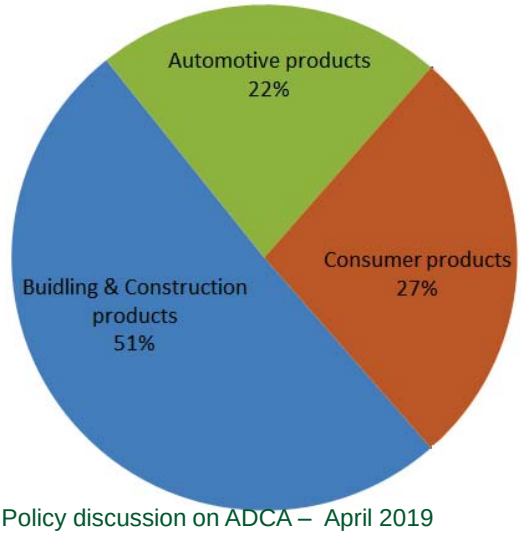
Authorization timeline

- If no objection publication in Official journal follows immediately, hence entry into force end of October 2019
- Latest application date August 2022 (latest available month for application within the window period) and sunset date End April 2024

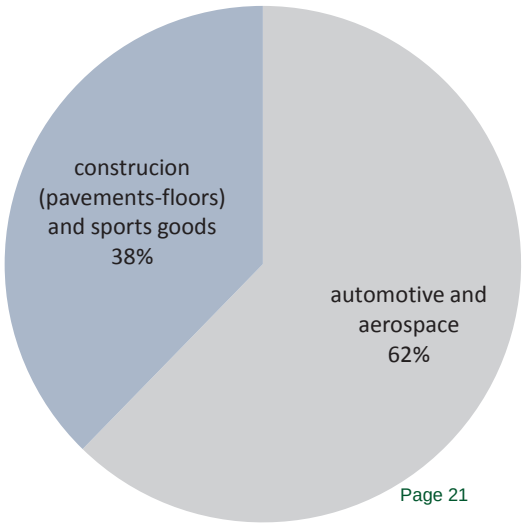
Use of ADCA in the plastics and rubber industry

- According to the last available data (2018), **about 23,300 tonnes of ADCA are imported in the EU**
- **About 75% of this tonnage is used by the plastics industry and about 25% by the rubber industry**
- It is estimated that in Europe **at least 3 million tons of plastics and rubber products are foamed with ADCA**: this substance is used in many different end applications: **building and construction, automotive and consumer products**
- In the rubber sector, the main applications are **automotive, aerospace, construction and sport goods**

Plastics industry



Rubber industry



Typical supply chains of ADCA, exposure to powder is possible, but Risk Management Measures are already in place

Producers /importers

- Outside Europe: ASIA
- Export of ADCA to 'Europe
  - 95% as POWDER
  - 23.300 t/y

Importers / Distributors

- Europe
- **Reconditioning** and **distribution** **powder form**

OR

- **Already under another physical form (low dust, master batches, granulates)**

Manufacturers

- Used in powder limited few applications
- Integrated in plastic compounds
- Encapsulated
- Manufacture of articles of rubber and plastic
- **Decomposition of ADCA in the process**

End use markets

- Industrial Sectors
- Construction
- Automotive
- Aerospace
- Telecommunic.
- Packaging
- Leisure/sports
- EVERYWHERE
  - Noise
  - Sound
  - Shock absorption

Regulatory process that triggered ADCA inclusion in ECHA´s 5th Authorization proposal

Scoring approach

Score			Total Score
Inherent properties (IP)	Volume (V)	Uses - wide dispersiveness (WDU)	(= IP + V + WDU)
1 Art. 57 (f);	9 (Very high volume used in the scope of authorisation)	Overall score: 3 * 3 = 9 Site-#: 3 (Substance is used at a high number of sites) Release: 3 (Significant potential for worker exposure from uses within the scope of authorisation)	19

Registry of intention: August 2012

Annex XV dossier: Sept 2012

Candidate List: Dec 2012

Draft recommendation: June 2013

ADCA´s inclusion on 5th Authorization proposal was a really quick process that did not take into account actual number of worker´s exposure and the Risk Management Measures that are in place.

Latest scientific findings make doubtful current classification is adequate

Following ECJ Case law, the equivalent level of concern of a substance cannot be based only on its hazardous classification. Cases C-323/15 P (Polynt v ECHA) and C-324/15 P (Hitachi Chemical Europe and Polynt v ECHA)
7 years have passed since then, new evidence must be considered as part of the EC decision process. Reasonable time should allow to provide the most up to date information

Socio-economic impact

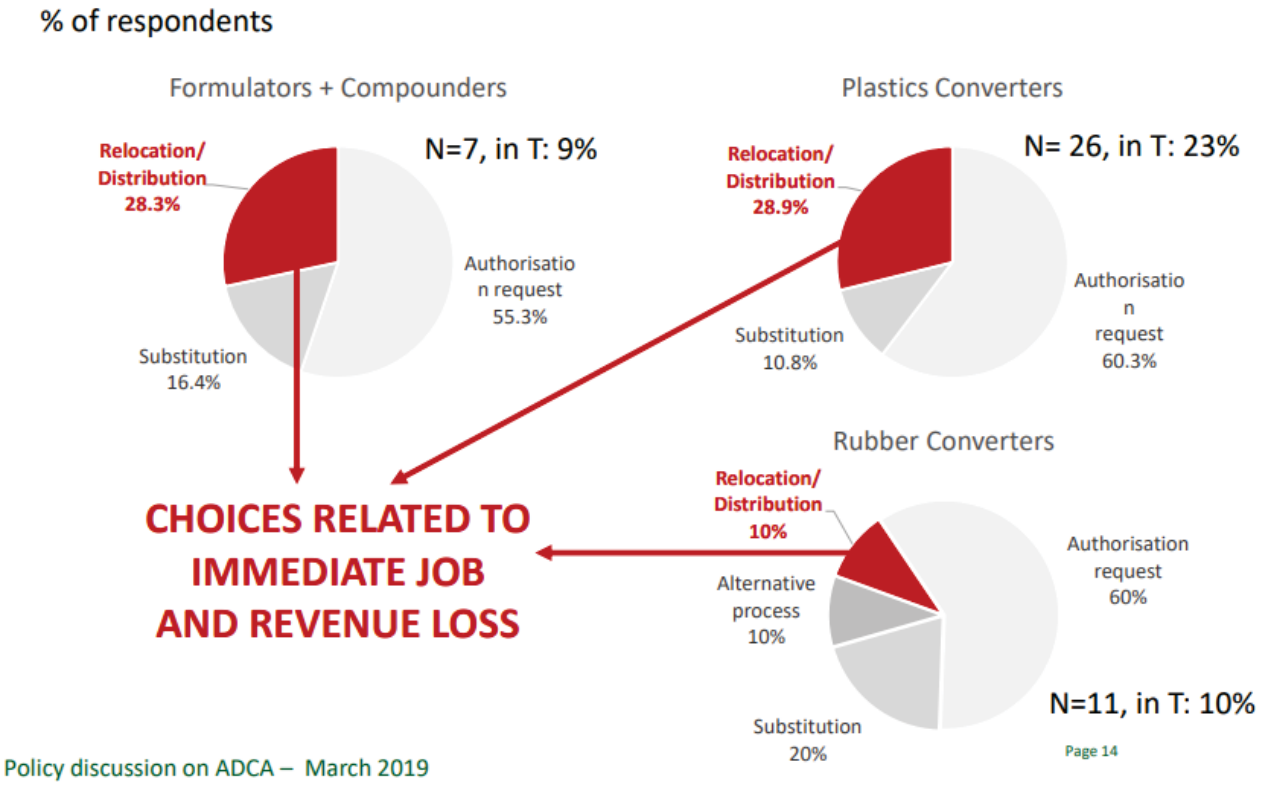
	Formulators/ Compounders		Plastics Converters		Rubber converters	
	Annex XIV	Non-use	Annex XIV	Non-use	Annex XIV	Non-use
Revenue loss (turnover/year) (billion €)	0.1	0.3	1.3-2.2	3.4-3.5	0.5	0.8
Job loss (#workers)	250	1,500	3,750-6,100	15,900-16,400	1,940	5650

Annex XIV : immediate impact of inclusion in annex XIV regardless if authorization would eventually be granted

Non use :
Impact if ADCA not available following not granted authorization

	Total	
	Annex XIV	Non-use
Revenue loss (turnover end use/year) (billion €)	1.8-2.7	4.2-4.3
Job loss (#workers)	5,940-8,290	23,050-23,550

Socio-economic analysis: immediate consequence of inclusion in Annex XIV



New studies suggest that the Bronchial hyperactivity response due to irritation and not to an immunological mechanism.

Accepted Manuscript

Azodicarbonamide (ADCA): A reconsideration of classification as a respiratory sensitiser

Josje Arts, Ian Kimber

PII: S0273-2300(17)30214-3
DOI: 10.1016/j.yrtph.2017.07.018
Reference: YRTPH 3880

To appear in: *Regulatory Toxicology and Pharmacology*

Received Date: 18 April 2017
Revised Date: 30 June 2017
Accepted Date: 19 July 2017

Please cite this article as: Arts, J., Kimber, I., Azodicarbonamide (ADCA): A reconsideration of classification as a respiratory sensitiser, *Regulatory Toxicology and Pharmacology* (2017), doi: 10.1016/j.yrtph.2017.07.018.

In conclusion:

- The data available from clinical and experimental animal studies indicate that ADCA is not a true respiratory allergen (& do not support the classification of ADCA as a respiratory allergen)
- The evidence available from clinical investigations is insufficient to conclude that ADCA has the potential to cause allergic sensitisation of the respiratory tract

Exposure control

- There is an Occupational Exposure Limit defined in the United Kingdom set at 3 mg/m³ for short-term exposure (15 minutes) and 1 mg/m³ long-term exposure (8-hour average) in 1996. In Finland, the OEL is 0.5 mg/m^3 for long-term exposure
- According to the report compiled by AMEC on behalf of the ADCA it appears that a safe concentration of exposure can be projected to be between 0.5 and 1.5 mg/m³ time weighted over an 8-hour work day

Medical data (official statistics)

- Surveillance of Work-Related and Occupational Respiratory Disease (SWORD) database
  - 27 cases of asthma were reported in the UK between 1989 and 1996, which led to the adoption of an occupational exposure limit in this country.
  - This seems to have been an adequate risk management measure since only one case of asthma of UK workers exposed to ADCA has been observed since the exposure limit came into force (causal link between exposure and asthma uncertain).
- **3 potential asthma cases in the last 20 years related to exposure to ADCA** are reported in official statistics of UK, France and Netherlands (one per country), **but the occupational nature of this asthma is uncertain**

Medical data (industry survey 2019)

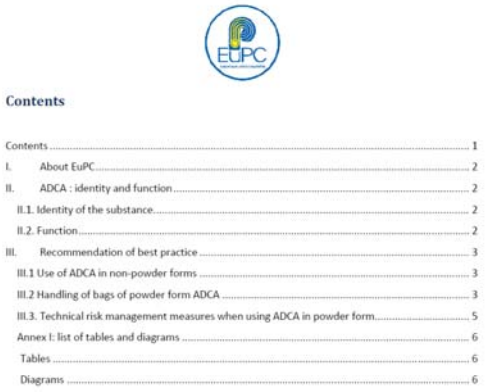
- **Estimated exposed workers population plastics and rubber industry 2019 : 17,000**
- **For the medical survey carried out in 2019, a coverage of about 2800 potentially exposed workers was considered**
- All companies carry out specific procedures and/or tests aimed at diagnosing the symptoms of both asthma and rhinitis
- 57% of the companies refer to a defined protocol for assessing the origin of asthma and rhinitis and determine their potential occupational nature
- **No occupational asthma and rhinitis cases** were observed during the last 20 years
- 1 case of asthma was found in 2013, but its occupational nature remains uncertain (cf. FR official statistics)

Best Practice in Europe : Industry Risk Management Measures Guidance for the safe use of ADCA at the workplace

Recommendations of best practice in handling and using ADCA blowing agent,

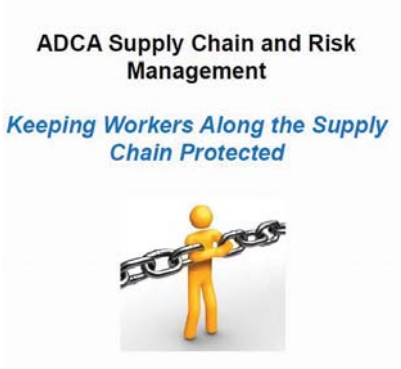
Developed in the framework of the ADCA Plastics Users Consortium by Polymer Comply Europe and PolyComplyHoechst, January 2015,

European Plastics Converters, Avenue Cortenbergh 71, 1000 Brussels, Belgium


Contents

Contents 1
I. About EuPC 2
II. ADCA : identity and function 2
II.1. Identity of the substance 2
II.2. Function 2
III. Recommendation of best practice 3
III.1 Use of ADCA in non-powder forms 3
III.2 Handling of bags of powder form ADCA 3
III.3. Technical risk management measures when using ADCA in powder form 5
Annex I: list of tables and diagrams 6
Tables 6
Diagrams 6

ADCA Supply Chain and Risk Management Keeping Workers Along the Supply Chain Protected



Conclusions and recomendations

- The exposure data from 2014 and the results from the medical survey carried out in 2019 clearly show that **the risk is limited and may be adequately controlled**
- It is clear that **no relation between occupational asthma and ADCA exposure** can be found in a sample of about 2800 potentially exposed workers
- The inclusion of ADCA in annex XIV (authorization scenario) would cause a **revenue loss between 1.8 and 2.7 billion € and a job loss between 5,940 and 8,290 workers** A non-use scenario would have a definitely worse impact on both revenue and employment, causing a **revenue loss between 4.2 and 4.3 billion € and a job loss between 23,050 and 23,550 workers**
- **The authorization process should be stopped for this substance as it is not a proportionate risk management option (unnecessary administrative costs, uncertainty leading to stop of investment and delocalization)**
- **Alternative regulatory options should be investigated so as to further support the implementation of industry best practices and provide an additional safety net.**
  - **setting of an EU wide OEL (beginning with the UK level as reference)**
  - **Setting a Reference Maximum Inhalation Exposure value to be met at work place through an an annex XVII restriction under REACH**
- ***Industry will continuously apply Risk Management measures to control the risk and secure safe levels of worker´s exposure***

EC initiatives on Microplastics

- Restriction on intentionally added microplastics
- Action on unintentionally added/released microplastics

Restriction on intentionally added microplastics

- Call for evidence in semester 1 2018
- 2 Echa workshop : February and May2018
- Echa prepared a Restriction Proposal earlier this year end
- Public consultation was launched recently in March 2019

EC action on unintentionally added microplastics

- Policy option for uninitentionally added microplastics (**abrasion**, tyres textires..)
- Plastic pellets losses reduction
- Evaluation water treatment directive

Industry actions

- PlasticsEurope microplastics HSE TF (science) and microplastics (regulatory) TF
- CEFIC microplastics Task force and some long range research initiative
  - Literature review (look at studies in detail, critical review) : identify data gaps on science and methodology gaps
  - Monitor any study on microplastics
  - Recommendation on next steps such as science development
  - Implement agreed recommendation
  - Looking for associations that want to join, with SETAC
  - Kick off meeting October
- **EuPC : set up task Force within raw materials committee**
- **Probably need for advocacy in 2019 and understanding microplastics generation parterns (EuPC/ plastics industry project in 2019), more in second half of October.**

Characterization of unintended microplastics

- **Issue :**
  - Proposal by EC in the course of 2019
  - Current default information(OECD) very coarse and probably much overestimating release of microplastics in the environment
  - Need to understand unintended microplastics generation patterns
- **Project :**
  - Gather industry available information on
    - Ageing
    - Product durability
    - Abrasion
  - Investigate in the application uses patterns
  - Define release factors during service life (may also be used to characterize release of dangerous additives that would be contained in the microplastics)
- **Cost :**
  - To be refined. **Estimate 25 to 30 KEUR**
- **Financing :**
  - Association or companies