OPINION OF THE MEMBER STATE COMMITTEE
ON THE FIFTH DRAFT RECOMMENDATION
OF THE PRIORITY SUBSTANCES AND ANNEX XIV ENTRIES

Adopted on 12 December 2013

OPINION

This opinion of the Member State Committee (MSC) on the fifth draft recommendation of European Chemicals Agency (ECHA) concerning priority substances to be included in Annex XIV was adopted on 12 December 2013 in accordance with Article 58(3) of the REACH Regulation (EC) No 1907/2006[1].

PROCESS FOR ADOPTION OF THE OPINION

ECHA consulted MSC in the spring of 2013 on its draft 5th Recommendation of priority substances for inclusion in Annex XIV, including the results of the prioritisation of the Substances of Very High Concern (SVHC) on the Candidate List and the proposed draft Annex XIV entries for the priority substances. The Committee further discussed the draft recommendation and draft Annex XIV entries of the substances suggested for inclusion in the recommendation on 11-14 June 2013. After that, ECHA published its draft recommendation on 24 June 2013 on its website for public consultation.

MSC appointed a Rapporteur for preparing its opinion on ECHA's draft recommendation for Annex XIV at its 30th meeting (11-14 June 2013) and, in addition, a Working Group to support the Rapporteur.
For the preparation of its opinion the Committee has been provided with the following documents:

- ECHA's priority setting approach[2] and its application to the substances on the candidate list to be included in Annex XIV[3]
- General approach for defining the Annex XIV entries[4]
- ECHA's draft recommendation of priority substances for inclusion in the list of substances subject to authorisation (available for public consultation on 24 June 2013 and further revised as regards DecaBDE on 5 July 2013)[5] and its updates (dated 5 July, 24 October and 22 November 2013, respectively)
- Draft Background documents for each substance[6] summarising the available information used for priority setting and specification of draft Annex XIV entries prepared by ECHA (published on 24 June 2013 on the ECHA website in the context

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[1] Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

[2] http://echa.europa.eu/documents/10162/17232/axiv_prioritysetting_general_approach_20100701_en.pdf

[3] http://echa.europa.eu/documents/10162/13640/prioritisation_results_5th_rec_en.pdf
http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_summarytable_5th_en.pdf

[4] http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_5th_en.pdf

[5] http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list

[6] The published Background documents on Al- and Zr - RCFs were further updated on 31 July 2013.

of the public consultation and in updated versions made available to the Committee on 22 November and 27 November 2013)
- Comments of the interested parties provided during the public consultation period that started on 24 June 2013 and closed on 23 September 2013
- Draft Responses to comments provided by the ECHA Secretariat (on 24 October 2013 and in updated version on 22 November and 27 November 2013).

The opinion provided to the Committee by the Rapporteur was finalised and adopted on 12 December 2013 after discussion at the 33rd meeting of MSC. The support document for the MSC opinion is attached to this opinion (Annex II).

THE FIFTH DRAFT RECOMMENDATION OF ECHA AND FOCUS OF THE OPINION

MSC is requested to provide an opinion to ECHA on the draft recommendation for inclusion of SVHCs from the candidate list to the authorisation list (Annex XIV). The focus of the opinion is whether ECHA has followed the criteria of REACH Article 58(3) for prioritisation of substances from the candidate list for inclusion in Annex XIV, using the agreed approach presented in the document on General approach for Prioritisation of SVHCs for inclusion in the list of substances subject of authorisation[7] and the document on General approach for Preparation of draft Annex XIV entries for substances to be included in Annex XIV[4]. ECHA will take the opinion of the MSC, as well as comments received during the public consultation, into account when finalising the recommendation to be sent to the European Commission for decision making.

Other issues not directly related to comparison of the substances against the criteria in Article 58(3) of REACH, e.g. considerations on the most appropriate risk management option, are included under the heading "Other issues" in Annex II to this opinion.

The fifth draft recommendation prepared by ECHA for Annex XIV of the REACH Regulation specifies the following information for priority substances:

- The identity of the substance as specified in section 2 of Annex VI
- The intrinsic property(ies) of the substance referred to in Article 57
- Transitional arrangements
    - The sunset date
    - The application date
- Review periods for certain uses, if appropriate
- Uses or categories of uses exempted from the authorisation requirement, if any, and conditions for such exemptions, if any
- Possible PPORD exemptions

ECHA's draft recommendation for Annex XIV that was used while developing the opinion of MSC is attached to this opinion (Annex III). The opinion of the Member State Committee focuses on the prioritisation of substances and items of Annex XIV entries.

OPINION ON THE DRAFT FIFTH RECOMMENDATION FOR PRIORITISATION OF SUBSTANCES

The Member State Committee supports ECHA's proposal for the following priority substances to be included Annex XIV:

- N,N-Dimethylformamide (DMF),
- Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA),
- Aluminosilicate Refractory Ceramic Fibres (Al-RCF), [*fibres covered by Index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No*

[7] http://echa.europa.eu/documents/10162/13640/axiv_priority_setting_gen_approach_20100701_en.pdf

1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions: a) oxides of aluminium and silicon are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm) c) alkaline oxide and alkali earth oxide ($Na_2O+K_2O+CaO+MgO+BaO$) content less or equal to 18% by weight],

- Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF), [*fibres covered by Index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions: a) oxides of aluminium, silicon and zirconium are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm). c) alkaline oxide and alkali earth oxide ($Na_2O+K_2O+CaO+MgO+BaO$) content less or equal to 18% by weight*],
- 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues] (4-tert-OPnEO).

ANNEX XIV ENTRIES

Substance identities

1. N,N-Dimethylformamide (DMF)
EC Number: 200-679-5
CAS Number: 68-12-2
IUPAC Name: N,N-Dimethylformamide

2. Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA)
EC Number: 204-650-8
CAS Number: 123-77-3
IUPAC Name: Diazene-1,2-dicarboxamide [C,C'-azodi(formamide)]

3. Aluminosilicate Refractory Ceramic Fibres (Al-RCF)
EC Number: -
CAS Number: -
IUPAC Name: -

4. Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF)
EC Number: -
CAS Number: -
IUPAC Name: -

5. 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-Octylphenol ethoxylates) (4-tert-OPnEO)
EC Number: -
CAS Number: -
IUPAC Name: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]

Regarding the prioritisation of Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA), some MSC members [IT, SI, EL, MT, CY, ES, HU and CZ] disagreed with the prioritisation and provided a minority view, as expressed in Annex I.

Intrinsic properties
The intrinsic properties of all of the prioritised substances are as outlined in the relevant Annex XV dossier for each substance.

Transitional arrangements
MSC has previously agreed that, in general, the application dates should be established as close as possible to the date of the entry into force of the updated Annex XIV. Normally, the application dates should not be set more than 12 to 18 months after that date. However, if justified in individual cases, longer application periods may be acceptable. Also, the transitional arrangements for groups of substances may need to be spread over time in order to distribute the workload of the ECHA secretariat, ECHA's committees and the Commission.

Article 58(1)(c)(ii) provides that the application date should be set at least 18 months before the sunset date. MSC considers that the application dates should be set at 18 months before the sunset dates as the default choice.

Although Article 58(1)(c) provides the option for setting a sunset date and application date per use (category of use), the Member State Committee supports ECHA's present position not to differentiate the dates for various uses of prioritised substances.

MSC supports the draft recommendation for the latest application dates and sunset dates.

Review periods for certain uses
MSC agrees with ECHA's position that upfront specified review periods are not warranted in the recommendation for Annex XIV inclusion. The review periods should be set in accordance with Article 60(8) only after consideration of all the elements listed in Article 60(4) and in the Commission decisions on individual applications for authorisation.

Uses or categories of uses exempted from the authorisation requirement
Although there were comments requesting exemption from authorisation for many uses or categories of uses of the prioritised substances, no existing specific community legislation imposing minimum requirements relating to the protection of human health or the environment against the use of these substances, which proves that the risk is properly controlled, was referred to in those comments.

MSC agrees with ECHA that no exemptions for any particular use(s) or categories of uses are warranted in the recommendation for Annex XIV inclusion. This issue is further elaborated on in Annex II to this opinion.

Exemptions for the use in product and process oriented research
MSC considers that there is an inconsistency between the main purpose of REACH formulated in Article 55 to progressively replace SVHCs by suitable alternative substances or technologies and the possibility of optional PPORD exemptions provided in Article 56(3). This apparent conflicting objective of the legislation to substitute a substance subject to authorisation and at the same time to allow its use in product and process oriented research and development activity is difficult to address. It is also recognised by MSC that formulation of a PPORD exemption in such a way that it would be specific enough but applicable to all possible similar cases would be difficult. A PPORD exemption to be included in the legislation cannot be addressed only to one company.

Based on the considerations above, MSC supports ECHA's view that upfront specified PPORD exemptions in Annex XIV are not warranted.

Annex I: Minority position on prioritisation of ADCA for inclusion in Annex XIV
Annex II: Support document for the opinion of MSC
Annex III: ECHA's draft recommendation for inclusions of substances in Annex XIV

ANNEX I

MINORITY POSITION
OF ITALY, SLOVENIA, GREECE, MALTA, CYPRUS, SPAIN,
HUNGARY AND CZECH REPUBLIC
ON PRIORITISATION OF ADCA FOR INCLUSION INTO ANNEX XIV OF REACH

As representatives of Italy, Slovenia, Greece, Malta, Cyprus, Spain, Hungary and Czech Republic in the Member State Committee, we would like to express our minority position to the decision regarding the opinion of the Member State Committee on the fifth recommendation of the European Chemicals Agency concerning priority substances to be included in Annex XIV which will be discussed for adoption on 9-13 December 2013.

Taking into account "General Approach for Prioritisation of Substances of Very High Concern for Inclusion in the List of Substances Subject to Authorisation" as well as available information on the uses of Diazene-1,2-dicarboxamide (C,C`-Azodi (formamide)) (ADCA) we would like to express the opinion that high priority should not be given to this substance and as the consequence it should not be recommended for inclusion to Annex XIV.

In our opinion several aspects should be taken into account:

Although ADCA is widely used throughout Europe in different supply chains, the number of workers at risk of respiratory sensitization is very limited: Not all sites use ADCA in powder form and not all workers on the site are actually exposed during work.
In fact:

a) ADCA is no longer manufactured in Europe, it is totally imported in the form of pure powder and it is then used by formulators, who sell or use preparations containing ADCA in various concentrations and supply forms (powder mixtures, preblends, not powder mixtures, pastes, dispersions and granules). Therefore, ADCA is handled only in a limited number of sites by workers in inhalable form, the only form capable of causing respiratory sensitization in the remaining companies the used forms are low-level powders or formulations in non-dusty form, granular masterbatch or liquid dispersions or pastes containing ADCA in bound form.
b) In sites where ADCA is manipulated either as pure powder or already in bound form, just a limited number of workers (suitably equipped with personal protective equipment) are potentially exposed to ADCA since only a few employees of a turn are in contact with the substance and for short periods of time during the shift.
c) The risk management measures implemented within the companies (many are small SMEs), in order to protect the limited number of workers, are effective because in recent years no more cases of occupational asthma have been reported. The sites are checked regularly throughout Europe, CLP applies with the resulting risk management measures.
d) Registration dossiers now clearly advise against professional use and consumer use, therefore some of the mentioned PROC in the prioritization document are not present.

Based on these considerations, we believe that the criteria used to derive the high score related to the dispersive use of the substance should be reconsidered.

Taking into account this new information and the fact that the REACH Registration dossier have recently been amended to remove from the dossier all professional and

consumer uses as well as certain industrial applications considered in the prioritization process (e.g. industrial spraying) which, if they occur, would lead to a more significant exposure, we believe that the score for this substance should be lowered:

- The number of sites that use powders (the form with the greatest potential for sensitization) is counted in tens (not hundreds).
- The release of ADCA is generally controlled. The substance as such no longer exists after the application phase and therefore there is no possibility of exposure of the workers as downstream users nor the consumers; therefore there is no or minimal releases, not only because risk management measures are implemented, but mainly because the substance is no longer actually present.

Consequently, we also think that the inclusion of ADCA in Annex XIV can create a disproportionate burden for both authorities and industry, without any significant added benefits.

For this reason, we hope that the proposal of ADCA inclusion in the list of substances subject to Authorisation would be at this stage reconsidered.

ANNEX II

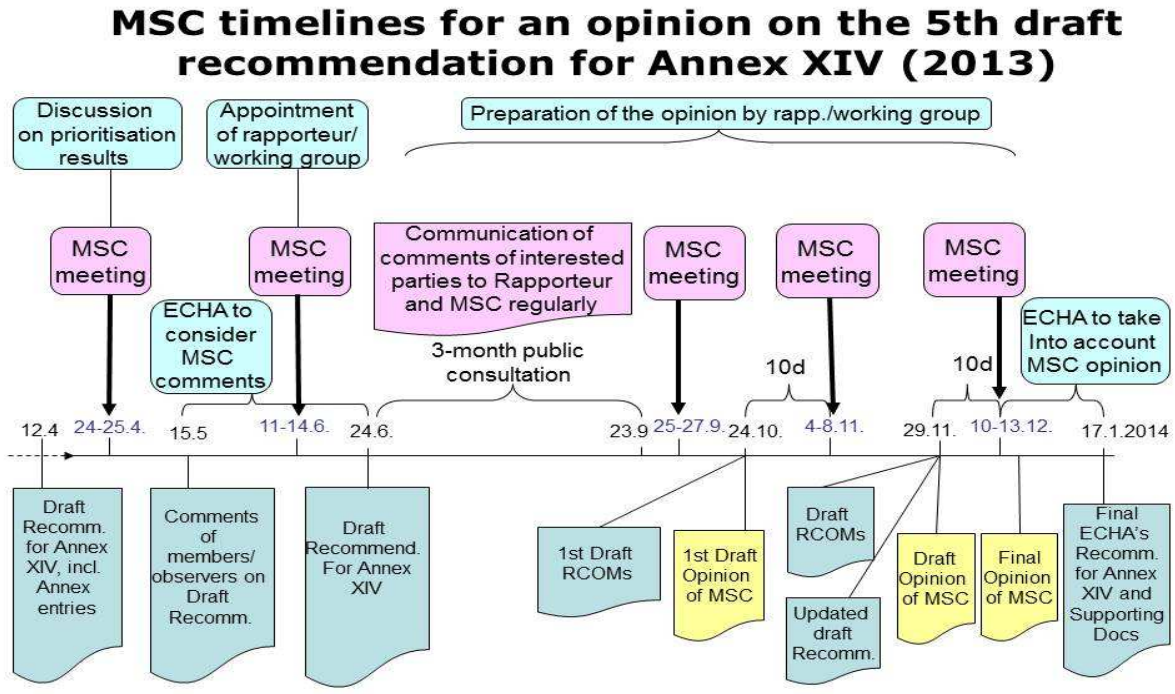
Support document for the opinion of MSC

1. Introduction

In accordance with REACH Article 58(3), MSC must provide an opinion on ECHA's draft recommendation for priority substances to be included in Annex XIV. The relevant Article 58(3) states:
"*Prior to a decision to include substances in Annex XIV, the Agency shall, taking into account the opinion of the Member State Committee, recommend priority substances to be included [...]. Priority shall normally be given to substances with: (a) PBT or vPvB properties; or (b) wide dispersive use; or (c) high volumes. [...]*"

Prioritisation determines the order in which substances are included in Annex XIV, i.e. more relevant substances are included before less relevant substances. Furthermore, prioritisation of substances from the Candidate list for inclusion in Annex XIV based on the agreed general approach is not based on a risk management option analysis, a socio-economic analysis, a risk assessment or an exposure assessment. 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. 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.

For this fifth recommendation of substances, ECHA developed the following time-frame for the development of the MSC opinion:



2. MSC views on comments received from stakeholders during the public consultation

During the three month public consultation on the draft recommendation, round 400 stakeholder comments were received. Stakeholders submitted a number of general comments and also comments on specific substances or specific issues. Some of these issues are summarised below, together with the views of MSC.

2.1 N,N-Dimethylformamide (DMF)

Justification for prioritisation

N,N-Dimethylformamide (DMF) was identified as an SVHC according to Article 57 (c) as it is classified in Annex VI of Regulation (EC) No 1272/2008 as toxic for reproduction, Repr. 1B, H360D ("May damage the unborn child"). It was included in the Candidate List for authorisation on 19 December 2012 following ECHA's decision ED/169/2012.

Most of the quantity manufactured in or imported into the EU (10 000 – 100 000 tonnes/year) seems to be used in applications in the scope of authorisation; except limited uses such as intermediate in synthesis and uses in scientific research and development.

According to registration information, the substance is used mainly as a solvent in a variety of applications. These uses include for example: the synthesis of chemicals; the production of polyurethane coated textiles; the production of synthetic fibres; and in other applications such as in the electronic industry, the formulation of mixtures, as a stabiliser/solvent in acetylene cylinders, as a cleaning solvent, as an intermediate, as a laboratory chemical, etc. No use of DMF by professionals has been registered except as laboratory chemical. No consumer uses were identified.

The registration information suggested a potential for significant exposure from some uses (e.g. uses covered by PROC4, PROC5, PROC8a). According to these use descriptors and taking into account additional information provided in the registration dossiers and during the public consultations, potential for exposure is potentially associated with various steps which could be generally described as control, transfer/loading, mixing (potentially in open or semi-open systems), maintenance and cleaning operations. The use of DMF at industrial sites in solvent-based corrosion inhibitor product(s) has been confirmed in recent registration dossier(s). The number, range and types of uses indicate that the substance is used at a large number of sites. This would indicate that there is a potential for widespread dispersive use.

Priority setting

During the public consultation, two MSCAs questioned whether authorisation was the most effective regulatory approach for the risk management of this substance. Three MSCAs and one NGO specifically supported the proposal.

Comments were received from a large number of industrial users and from a range of trade organisations. The uses covered included production of: pharmaceuticals; agrochemicals; other chemicals; membranes, coated textiles, artificial leather; coated glass; fibres; and in-vitro-diagnostic devices. Comments were also received from users in the petrochemical and aerospace sectors and from one company using the solvent to clean the internal parts of industrial reactors.

One comment was received from an organisation representing suppliers of an alternative solvent. This suggested that the alternative solvent could be a viable replacement in some circumstances, but also acknowledged some of the potential reasons for non-viability highlighted by existing users of DMF.

Most companies claimed that the substance is used in well-controlled processes with very limited worker exposure. In some instances (e.g., when used as a solvent for pharmaceutical production) the controls were the "strictly controlled conditions" required to use the derogations in Articles 17 or 18 for the use of intermediates.

It was also pointed out that national and EU legislation is in place to minimise the exposure of workers, consumers and the environment, with emphasis placed on adherence to the indicative OEL for the substance and the solvent emission controls. These arguments were used to contest the prioritisation of the substance or to suggest exempting industrial uses of the substance

Some companies suggested not prioritising the substance for authorisation, but instead to consider a more co-ordinated approach to the control of aprotic solvents. This

appeared to be driven by the concern that different solvents in the same class, with analogous properties are being taken along separate regulatory routes.

Several companies indicated that there are no alternatives for the substance or only alternatives with a lower performance. This is due to the specific properties of DMF and the comparable hazard profile of potential alternative solvents. Substitution would therefore not lead to lower risks for workers, consumers or the environment, according to these companies.

For the use in *In Vitro* Medical Devices (IVD), it was claimed that substitution of DMF for alternative solvents would require re-approval of a large number of test systems. An additional factor raised for IVD production related to authorisation being required to produce the IVD (e.g. for re-packaging DMF into small containers), but the subsequent use of such IVD may become exempt from authorisation as it could be classed as Scientific Research and Development. It was claimed that this could lead to all production of such devices taking place outside the EU.

MSC understands that the main use of DMF is as a polar aprotic solvent. There are a limited number of polar aprotic solvents in use and industry claims that these substances all have a more or less similar toxicological profile (three of them are already included in the candidate list as Rep 1B, namely DMF, DMAC and NMP). Industry suggests that substitution between these substances will therefore have limited possibilities and many companies are advocating alternative risk management options.

As regards the lack of suitable alternatives, MSC agrees with the response provided in ECHA's RCOM that information on alternatives should be provided as part of the application for authorisation and will be taken into account by the Risk Assessment Committee and Socio-Economic Analysis Committee when forming their opinions and by the Commission when taking the final decision.

Taken together, the comments received suggest that for some uses of DMF the exposures are well controlled and would not lead to significant risks. However, other uses (transfer/loading, mixing (potentially in open or semi-open systems), maintenance and cleaning operations) remain in which exposure may not be well controlled.

MSC is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of DMF. As there is currently no proposal for an alternative risk management route, MSC is of the opinion that the current recommendation process should not be delayed.

Transitional arrangements: Latest application date and Sunset date

ECHA initially proposed the following transitional arrangements for DMF:

i. Latest application date: 18 months after entry into force of the Regulation
ii. Sunset date: Latest application date plus 18 months

One NGO suggested revision of the Latest Application Date such that the total time to the Sunset Date was 2 years from entry into force (i.e., to shorten the application time to six months). However, they did not provide any justification for this proposal.

Several companies suggested setting Sunset Dates (transitional periods) at between 7 and 12 years; this was claimed to be necessary to optimise the processes for suitable alternative solvents. For the IVD applications timescales or 7-10 years were cited to allow for re-approval of the devices. Similar timescales were suggested for the use of the solvent in synthesis, especially for pharmaceuticals as solvent changes could lead to differences in the end product that require re-approval or re-evaluation. For the use of DMF in acetylene cylinders, it was claimed that validation of an alternative solvent would take around 10 years and a further 5 years to manufacture the replacement cylinders.

MSC is of the view that whilst such a long transitional period could be proposed, it may not offer a solution for those uses affected. The absence of any alternatives would form part of an application for authorisation. Previous discussions have indicated that due to the complexity of preparing an application, a minimum time of 18 months from entry into

force should be set for the Latest Application Date. The NGO provided no reasons why this should not be the case for DMF.

MSC is of the opinion that no information has been provided during the public consultation that would challenge the suggested latest application date and sunset date.

Proposed review period for certain uses

No review period was suggested by ECHA.

Similar comments to those submitted for the latest application date were submitted for the review periods. In particular, for the use of DMF in acetylene cylinders, it was claimed that validation of an alternative solvent would take around 10 years and a further 5 years to manufacture the replacement cylinders.

MSC considers that the long service life of acetylene cylinders (above 50 years) does suggest that for this use a longer review period may be appropriate. However, this could be taken into account in any applications for authorisation and need not be specified in Annex XIV.

MSC is of the opinion that upfront specified review periods are not warranted in the recommendation for Annex XIV inclusion.

Proposed exempted (categories of) uses

ECHA did not propose any exemption of uses or categories of uses or any exemption of uses or categories of uses.

One NGO supported the ECHA proposal.

General exemptions were requested for all uses. These were mainly based on an argument of low worker exposure and low emissions. There was also a request for an exemption for refilling from bulk to small packaging.

Exemptions were requested based on the applicable EU legislation, e.g. Regulation (EC) No 726/2004 and Directive 2001/83/EC, relating to medicinal products for human use, Chemical Agents Directive (98/24/EC), Solvent Emissions Directive (1999/13/EC), Carcinogens and Mutagens Directive (2004/37/EC), Directive relating to Pregnant Workers (92/85/EEC), as well as Waste Incineration Directive (2000/76/EC). Additionally, an exemption request was made based on Directive 2009/161/EU establishing an indicative occupational exposure limit value (i-OEL) for DMF. As these Directives do not impose binding minimum requirements for imposing risks to workers health and/or the environment for this substance, the MSC is of the opinion that a specific exemption is not warranted in accordance with Article 58(2) of REACH.

In relation to the request for an exemption for the use of the substance in medical devices, MSC notes that this exemption was already addressed in Recital 18 of Commission Regulation 143/2011 of 17 February 2011, amending Annex XIV to REACH for the first time. This indicates that applications for authorisation should not include the risks to human health arising from the use of a substance in a medical device regulated under Directives 90/385/EEC, 93/42/EEC, or 98/79/EC. It follows that an application for an authorisation should not be required for a substance used in medical devices regulated under those Directives if such a substance has been identified in Annex XIV to Regulation (EC) No 1907/2006 for human health concerns only. Therefore, MSC considers that an assessment as to whether the conditions for an exemption pursuant to Article 58(2) of Regulation (EC) No 1907/2006 apply, is not necessary.

MSC is of the opinion that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses.

PPORD exemptions

No exemptions for PPORD were suggested by ECHA.

Requests for PPORD exemptions were made during the public consultation. Two responses gave identical requests to give a PPORD exemption for up to 50 t/a for use in medical products.

MSC considers that where there is currently no alternative solvent, PPORD activity with the aim to reduce the use of DMF could be justified. In such a case, the PPORD activity could be justified in the authorisation application covering the use for which a replacement solvent is being sought.

MSC supports ECHA's view that upfront specified PPORD exemptions in Annex XIV are not warranted.

Other issues

During the public consultation and MSC discussions, a number of MSC members expressed concern as to whether authorisation is the most appropriate risk management measure for DMF and were of the opinion that other risk management options should be considered. Furthermore, the MSC recognises that ECHA is not in a position to assess at the recommendation step the pertinence of alternative regulatory risk management options for the substance or some of its particular uses. In addition, taking into account the on-going consultations on Annex XV restriction dossier for NMP and ECHA's recommendation for inclusion of DMAC in Annex XIV, as well as the recently notified intention of Italy to submit an Annex XV proposal for restriction of DMF, MSC recommends to discuss in the appropriate fora, what would be a proper approach in the regulatory context for the polar aprotic solvents included in the candidate list, like for DMAC, NMP and DMF.

2.2. Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA)

Justification for prioritisation

Diazene-1,2-dicarboxamide [C,C´-azodi(formamide)] is classified as respiratory sensitiser, Resp. Sens. 1, in Annex VI, part 3, Table 3.1 (the list of harmonized classification and labelling of hazardous substances) of Regulation (EC) 1272/2008 and was identified as an SVHC according to Article 57(f) of REACH. It was included into the candidate list for authorisation on 19 December 2012, following ECHA´s decision EC/169/2012.

The substance is used in high volumes (10 000-100 000 t/y) within the scope of authorisation. The main use is as a blowing agent in the rubber and plastics industry. The substance is mainly used in downstream user sectors (e.g. automotive, electrical application etc.). No registration identifies the use of the substance by professionals and consumers and the majority of the dossiers advice against these uses.

The level of containment during industrial use of ADCA varies among its different processes and sites. Based on the updated registration dossiers, processes categories relevant for the use of ADCA such as mixing or blending in batch processes for formulation of mixtures and articles (multistage and/or significant contact) (PROC 5), transfer/loading (PROC 8) and calendering operations (PROC 6), are likely to be associated with the highest potential for inhalation exposure levels in comparison to other processes, due to the nature of these activities.

At the start of the supply chain almost the entire volume is in pure powder form. According to information provided in the public consultation, ADCA is estimated to be used in this form by more than one third of its users, including not only formulators and compounders, but also several converters. Overall in the EU market ADCA is supplied in various forms, such as pure powder, pre-blended powder, low dust powder, solid master batch, liquid dispersions, paste, non-dusting preparations, seal sachets, and dust-free solids (granules, pills).

Based on this, Diazene-1,2-dicarboxamide (ADCA) meets the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation two MSCAs supported the prioritisation of ADCA for inclusion in Annex XIV. One environmental NGO and one insurance company expressed support for the proposal. One MSCA expressed its reservations about the prioritisation of ADCA because of the relatively old data taken into account for the identification of the substance as a SVHC. The MSCA proposed not to prioritise ADCA at this point until there is confidence that occupational asthma caused by this substance is still a problem and that authorisation is an appropriate and proportional measure to take.

Many comments were received from industry associations, individual companies and two individuals. The main arguments brought forward concern:

- SVHC identification: the equivalent level of concern to CMR and PBT/vPvB properties is not sufficiently and scientifically justified in the identification dossier;
- Legal uncertainty: no legal basis exists to identify respiratory sensitisers as SVHC as they are not covered by Article 57(f); additionally, as court cases on two other respiratory sensitisers are on-going where their identification as respiratory sensitisers is challenged, the outcome of the general judgment should be awaited before the inclusion of ADCA in Annex XIV;
- Prioritisation score too high: ADCA may only cause sensitising effects on the respiratory system when it is used in dry powder form and in specific particle size; in all other physical forms no sensitising effects are found; the quantities and sites where the substance is used as a powder only should be taken into account in the prioritisation;
- Other: lack of suitable alternatives; higher risk of the possible alternatives, overestimation of the potential risk, ADCA predominantly used in closed production systems and in non-inhalable forms (e.g. granules, liquid dispersion, paste), low concentration of the substance in articles, the risk at workplaces is well controlled, the number of exposed workers is low; no health effects clearly related to ADCA in the last twenty years reported by the companies; an OEL of ADCA introduced in UK and workplace measurements are below the threshold.

MSC agrees with ECHA`s response provided in the RCOM, that information on issues such as 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, should be provided as part of an application for authorisation and will be taken into account by the Risk Assessment and Socio-Economic Analysis Committee when forming their opinions and by the Commission when taking the final decision, therefore it should not be considered in the prioritisation for recommending substances for inclusion Annex XIV.

Several MSC members questioned the prioritisation score related to wide dispersive use of the substance, based on the fact that no registration currently identifies the use of the substance by professionals and consumers and the registration dossiers now advise against these uses. It was also stated that the substance is not manufactured in EU, its release is generally controlled and the number of sites where workers could be exposed is limited.

Following the agreed prioritisation approach, majority of the MSC members agrees with ECHA's conclusion that for the uses of ADCA in the scope of authorisation, potentially significant exposure to workers cannot be excluded and, in combination with other prioritisation criteria, the substance qualifies for prioritisation and inclusion in Annex XIV. MSC considers that whether the substance is manufactured or imported prior to those uses is not relevant for that priority setting (manufacture is not in the scope of authorisation). ADCA's harmonised classification applies to all its forms, so that although the pure powder form is of the highest concern from the exposure point of view, other forms, such as pre-blended powders and liquid dispersions, are also susceptible to formation of aerosols.

MSC is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of Diazene-1,2-dicarboxamide (ADCA).

Transitional arrangements: Latest application date and Sunset date

In its draft recommendation ECHA proposed the following transitional arrangements for Diazene-1,2-dicarboxamide (ADCA):

(i) Latest application date: 21 months after entry into force of the Regulation
(ii) Sunset date: Latest application date plus 18 months

During the public consultation there were a number of requests from the industry for prolonged transitional periods to ensure sufficient time for development of alternatives. Comments were also received indicating that some companies have no experience with the preparation of applications and socio-economic analysis and need more time for that. It was also indicated in the comments that many SMEs will have to collect data for the socio-economic analysis and need more time for the preparation of applications for authorisation. One MSCA agreed with the proposed transitional arrangements. One environmental NGO proposed application dates of maximum 24 months from the date of COM decision to include the substance into Annex XIV, without any justification.

MSC is of the opinion that no new information was submitted during the public consultation that would support changes to the proposed transitional arrangements and therefore MSC agrees with ECHA´s recommendation for the transitional arrangements.

Proposed review period for certain uses

No review period was proposed by ECHA in its draft recommendation.

During the public consultation one environmental NGO supported ECHA's proposal not to include review periods.

One company indicated the need for review periods allowing enough time for introducing alternatives, another company requested for review periods allowing continued production if potential alternatives would fail (both not indicating the time period).

MSC is of the opinion that specification of review periods is not warranted in the recommendation for inclusion of ADCA in Annex XIV.

Proposed exempted (categories of) uses

ECHA did not propose any exemption of uses or categories of uses in their draft recommendation.

During the public consultation one environmental NGO supported ECHA´s recommendation not to allow any exemption. Two companies stated that they agree with ECHA that there is no specific Community legislation in force that would allow consideration of exemptions on the basis of Article 58(2).

Some companies requested that different uses of the substance should be exempted. They provided justification that appropriate substitutes do not exist and arguments on the absence of human health exposure risk.

One registrant requested exemption for some specific forms of ADCA (e.g. non- or low-dusting formats, master batches). Requests are submitted for general exemption of all industrial uses where exposure is properly managed by technical measures, as well as an exemption of all uses where ADCA is enclosed in a solid polymer matrix as the risk only exists for inhalation exposure.

MSC is of the opinion that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses.

PPORD exemptions

No PPORD exemption was proposed by ECHA in the draft recommendation.

There were no requests for PPORD exemption submitted during the public consultation.

MSC supports ECHA´s view that PPORD exemptions in Annex XIV are not warranted for ADCA.

Other issues

During the public consultation and MSC discussions, several MSC members expressed concern as to whether authorisation is the most appropriate risk management measure for ADCA and were of the opinion that other risk management options should also be considered (some MSC members suggested EU binding OEL as a more appropriate RMO). However, MSC recognises that RMO considerations are not in the scope of preparation of the recommendation for Annex XIV and such issues need to be addressed in other fora.

2.3. Aluminosilicate Refractory Ceramic Fibres (Al-RCF)

Justification for prioritisation

Aluminosilicate Refractory Ceramic Fibres (Al-RCF) are classified as carcinogen category 1B in Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008. Al-RCFs were identified as SVHC according to Article 57(a) of REACH. Those were included in the candidate list for authorisation on 19 December 2011, following ECHA's decision ED/77/2011 and ECHA's decision ED/95/2012 on consolidation of the entries in the Candidate list.

According to information provided in the registrations, Al-RCF is manufactured in the EU in a tonnage of more than 10 000 t/y. A lower amount is additionally imported. The exact total volume used within the scope of authorisation cannot be estimated but ECHA has concluded this tonnage to be the minimum as there might be more registrations falling under the Candidate List entry. ECHA has concluded that the entire volume is within the scope of authorisation.

The manufactured fibres are used as produced and/or further processed into several types of product. Blankets are often used directly (e.g. as a furnace insulation material), but they are also converted into modules used for furnace lining, gaskets and other products or articles. Al-RCF can also be used for textiles and mixed into cements and putties.

The main uses of Al-RCF are in high temperature processes in industry as insulation and for fire protection purposes (e.g. metal, glass and ceramic industry). The largest single use is furnace linings and related applications (about 67 %).

ECHA has concluded that the exact number of sites using the substance in the scope of authorisation is not known but based on the registration information on the types of uses a high number of sites is anticipated. According to information provided manufacturing sites are situated in three EU Member States. The registrations cover industrial as well as professional uses of the substance.

The exposure of workers may be controlled in most instances, but there may be potentially significant occupational exposure to fibre dust. Exposure may occur during all manufacturing processes such as production of fibres, mixing and forming processes, cutting or machining the material after fibre manufacture (finishing processes) and during processes where the fibres are combined or assembled with other material. Exposure may also occur during installation and end use processes (e.g. furnace maintenance). ECHA has considered the use of Al-RCF for insulation to be widespread.

Based on this, Aluminosilicate Refractory Ceramic Fibres (Al-RCF) meets the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation two MSCAs, one NGO and one Trade Union Organisation expressed their support for the prioritisation. One MSCA expressed its concerns over the description of substance identity given to the RCF in the Candidate list entry. The MSCA argued that the current entries use descriptions for RCF that differ from those fibres more commonly used in the EU. They also consider that there is a need for one description covering all RCF instead of two separate descriptions. The current situation could lead to misunderstandings to identify which RCF are actually subject to

authorisation. The MSCA pointed out that it is not clear whether manufactured RCF themselves are substances and whether the products made from RCF are substances or articles. Their concern centred on the fact that the interpretation will have great impact to the assessment of the priority (e.g. number of sites and wide dispersive use) - especially if the only use subject to authorisation would be the production of articles.

The main comments received from industry associations or trade associations, individual companies, individuals and one academic institution were arguments put forward for not prioritising Al-RCF. These arguments included reasons such as unclear description of substance identity, unclear substance vs. article status, overestimated priority, lack of alternatives and negative impacts on socioeconomics.

Most of the comments provided for RCFs in general relate to both Al-RCFs and Zr-RCFs (zirconium-aluminosilicate refractory ceramic fibres) and cover uses of RCFs in: metal, glass and ceramic industry; aerospace and defence industry (e.g. manufacture of turbine engines), electronic industry (e.g. manufacture of power semiconductor devices), gas industry's steam methane reforming units, automotive industry (e.g. catalytic converter systems), etc.

Several comments were received claiming that Al-RCFs are not substances and that fibres constitute an article as defined in the REACH regulation. It was emphasised that without clear understanding which physical forms of RCF should be considered as a substance or an article, there will be confusion on what shall be subject to authorisation. According to these comments, most of the RCFs are used as articles in the sense of REACH.

In several comments it was claimed that the given description of substance identity for RCF in the candidate list entry does not correspond in terms of chemical and physical description with all RCF materials currently sold in the EU. They argued that concentration ranges for "other oxide" content and physical dimensions in RCF commercial products do not match to descriptions given. Especially it was pointed out that the candidate list entries do not cover chromia aluminosilicate RCF where chromium is intentionally added in the fibre composition. In the absence of a clear description of substance identity and a common identifier (such as CAS number) there would be misunderstanding on which RCF`s require authorisation and which do not. According to industry associations different RCF can substitute each other for the same applications and the lack of clarity around the definition may lead to substitution with RCF forms with equal hazard properties. It is also requested to merge the candidate list entries for RCF into one entry and cover all variations of RCF to avoid misunderstandings.

Several industry associations challenged the prioritisation score for inherent properties, volume, and wide-dispersive use. It was stated that the priority score is overestimated. In many comments it was argued that the substance has a threshold for carcinogenic effects as concluded in the SCOEL recommendation for RCF from 2011. In the SCOEL recommendation substance identity is covered by one definition (as defined in Annex VI of the CLP Regulation) and it covers all RCF under one CAS number.

In several comments it was claimed that the total volume is overestimated because information in the joint registration dossier for RCF does not differentiate any volumes between Al-RCF and Zr-RCF. In addition, it is claimed that this volume includes other RCF than the ones covered by the current description for substance identity in the candidate list entry.

Several companies and industry association claimed that exposure is controlled in many uses because RCFs are used in controlled operational conditions and in closed systems that do not require frequent maintenance intervention. It was stated that exposure from the use of the substance is adequately controlled under existing occupational worker protection legislation. It was also pointed out that a binding occupational exposure limit value (BOELV) for RCF is under discussion at the EU Commission and is expected to be adopted by the end of 2014.

In many comments it was questioned whether authorisation is the most appropriate risk management measure for RCF. There were proposals to consider restriction instead of

authorisation and it was argued that the adoption of a BOELV at EU level would be a more efficient risk management option.

Several industry associations and companies claimed that there are no alternatives for the substance yet in many high temperature applications (especially applications above 900°C). In addition, it was stated in several comments that authorisation will have negative impact on EU business, the products are indispensable for meeting industry`s growing demand for resource, energy efficiency and the associated reduction of emission of CO_2.

Regarding the comments on the clarity of the substance identity, MSC agrees with the response provided in ECHA`s RCOM that the substance identity has been considered in the context of inclusion of the substance in the Candidate list and it is not relevant to the prioritisation phase. MSC appreciates ECHA's further clarification on substance identity provided in the RCOM.

MSC agrees with the ECHA`s response provided in the RCOM that there might be fibres on the market with potentially the same hazard properties and similar uses which are not covered by the current Candidate list entries.

Based on the agreed prioritisation approach, MSC acknowledges that ECHA does not assess at this stage of the process whether on the basis of the available scientific evidence it can be concluded that a non-effect level (threshold) for the carcinogenic effects of the RCFs exists. This is an issue to be addressed in the authorisation applications and in RAC when preparing its opinions on the authorisation applications.

Regarding the comments concerning overestimated volume, MSC notes that ECHA's estimation of volumes is based on information currently available in the registration dossiers and generally agrees with ECHA's view as expressed in the RCOMs that it is this information that the estimation should be based on, as opposed to external estimates of the volumes submitted during the public consultation. MSC further notes that RCF is registered as substances and the applications for authorisation should address all stages of the lifecycle including the use of Al-RCFs in articles.

Regarding the arguments provided by industry on the socio-economic benefits of using Al-RCFs and of the potential effect of authorisation on EU business, while MSC considers that these issues are very important and relevant, it generally agrees with the responses provided by ECHA in the RCOM document.

Regarding the comments on the clarity of whether products made from RCF (e.g. blanket, board, sheet, brick, module) are substances or articles, MSC agrees with the response provided in ECHA's RCOM that RCF products may be articles according to Art 3(3) and it is not always possible to conclude at which stage of the life cycle their status changes from substances to articles. The uses of articles do not require authorisation but the production of articles using RCFs requires authorisation.

MSC is of the opinion that the wide-dispersiveness of the uses of RCFs depends on the interpretation whether the products made from RCF (e.g. blanket, board and others) and used in the sites are considered substances or articles. For instance, it is uncertain whether installation of insulation material made from RCF such as blanket and end use processes such as maintenance of furnace are in the scope of authorisation. If the products made from RCF are considered to be articles it will have impact to the number of sites using the substance. However, based on the registration information on the types of uses (e.g. conversion bulk fibres into different types products, formulation of textiles, cements or putties, and use of bulk fibres as such for insulation), MSC agrees with the ECHA`s response provided in the RCOM, that a high number of sites using the substance and a high number of potentially exposed workers is anticipated even without considering end use processes such as installation of insulation material and furnace maintenance to be in the scope of authorisation.

During the MSC discussions, some members questioned the appropriateness of the release score related to wide-dispersive use. It was argued that the worker exposure is well controlled and the release score should be 1 (controlled) instead of 3 (significant), as concluded in the assessment of priority SVHC`s on the candidate list published in 2010.

MSC notes that the assessment in 2013 is mainly based on the registration information while the assessment in 2010 was done before the majority of registrations were submitted and all information available. Experience has also been built up in assessing the priority substances after 2010. While the exposure might be controlled in most instances, the MSC agrees with ECHA`s view that for some of the uses potentially significant exposure of workers cannot be excluded.

MSC is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of Al-RCFs for inclusion in Annex XIV.

Transitional arrangements: Latest application date and Sunset date

ECHA proposed the following transitional arrangements for Al-RCF:
(i) Latest application date: 21 months after entry into force of the Regulation
(ii) Sunset date: Latest application date + 18 months

During the public consultation one MSCA agreed to the dates. One NGO requested to set the latest application date to be maximum 24 months after entry into force.

Several comments were received indicating the need of longer transitional periods because of lack of suitable alternatives for the RCF. Several industry associations and individual companies proposed to extend the latest application date to at least 20 years. One metal industry association proposed to extend the latest application date to 30 months. One company from cement industry indicated the need to extend the latest application date over 30 years and one company from semiconductor industry proposed to extend the latest application date to 36 months.

One company from the aerospace industry indicated that there are no alternatives available yet and proposed to postpone inclusion of Al-RCF in Annex XIV by three years. Some specific supply chain arguments provided by aerospace industry stating that the supply chains are very complex. This creates substantial complexity in the process of authorisation, which is expected to take a substantial period to accomplish. One aerospace industry association requested to take into account the industry`s challenges as downstream users and establish application and sunset dates that are a minimum of five years after the authorisation dates for chromium substances.

In summary, extended latest application dates were proposed ranging from 30 months to 30 years, resulting a sunset date 2017 or later.

Regarding the point on the lack of suitable alternatives, MSC considers that information on alternatives should be provided as part of an application for authorisation and 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.

Regarding the requests for longer transitional periods in certain industry sectors based on the complexity of the supply chain, MSC considers that the required time for preparation of applications is partly a matter of co-operation, communication and organisation between actors in the supply chain. Applications for authorisation may be made for one or several uses and it is possible to submit joint applications by a group of duty-holders (manufacturer, importer and downstream user).

MSC is of the opinion that no new information was submitted during the public consultation that would support changes to the proposed transitional arrangements and therefore MSC agrees with ECHA`s recommendation for the transitional arrangements for Al-RCF.

Proposed review period for certain uses

No review period was suggested by ECHA.

During the public consultation, one NGO agreed that there is no need to allow any review periods. One industry association and several individual companies proposed review periods ranging from 10 to over 20 years. One semiconductor industry association proposed five years review period.

MSC is of the opinion that review periods are not warranted in the recommendation for inclusion of Al-RCF in Annex XIV.

Proposed exempted (categories of) uses

ECHA did not propose any exemption of uses or categories of uses in their draft recommendation.

During the public consultation one NGO agreed that there is no need to allow any exemptions.

Several companies and industry associations claimed that risks are adequately controlled under existing occupational worker protection legislation. In addition, in some comments it was pointed out that a BOELV for RCF`s is expected to be implemented in the near future. Taken together they consider the criteria for exemption of uses is met under article 58(2) of REACH. In many comments the lack of an alternative substance was one additional reason for requesting exemption of uses. In some of these comments it was specified to exempt uses in applications in high temperature processes at temperature higher than 900°C.

There were several proposals from aerospace industry to exempt uses in aerospace sector based on air safety considerations. One company proposed to consider restriction as a risk management route with derogations for aerospace and defence applications because of lack of suitable alternatives.

Regarding the point on the lack of suitable alternatives see transitional arrangements section above.

MSC considers that the arguments provided for the exemptions for the uses are not sufficient to justify an exemption under Article 58(2) of REACH.

MSC is of the opinion that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses.

PPORD exemptions

No exemptions for PPORD were suggested by ECHA in their draft recommendation.

There were no requests for PPORD exemptions submitted during the public consultation.

MSC supports ECHA's view that PPORD exemptions in Annex XIV are not warranted for Al-RCF.

Other issues

MSC noted that there is a need for additional guidance for duty-holders to further clarify the more exact coverage of the candidate list entries of Al-RCF, as well as the substance versus article status of the RCF products, if the substance is included in Annex XIV, to avoid misunderstanding when duty-holder is applying for an authorisation for the uses of the substance in question.

During the public consultation and MSC discussions, some MSC members expressed concern as to whether authorisation is the most appropriate risk management measure for the RCFs and were of the opinion that other risk management options should also be considered. However, MSC recognises that RMO considerations are not in the scope of preparation of the recommendation for Annex XIV and such issues need to be addressed in other fora.

2.4. Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF)

Justification for prioritisation

Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCFs) are classified as carcinogen category 1B and were identified as SVHC according to Article 57(a) of REACH. Those

were included in the candidate list for authorisation on 19 December 2011, following ECHA's decision ED/77/2011 and decision ED/95/2012 on consolidation of the entries in the Candidate list.

According to information provided in the registrations, Zr-RCF is manufactured/imported in the EU in high volumes (1000 to 10 000 t/y). The entire tonnage is allocated to uses within the scope of authorisation. Uses of the substance are considered to be widespread with a potential for significant worker exposure.

Based on this, Zr-RCFs meet the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

Two MSCAs specifically supported the proposal. One international NGO's and one Trade union expressed their support for the prioritisation. One MSCA expressed concerns related to the identification of Refractory Ceramic Fibres (RCF) as currently defined on the Candidate List. It was also noted that some suppliers might decide that the RCF-based products they place on the market are articles and further complications might arise as it can also be argued that, as with other man-made fibres, the RCF fibres themselves are articles.

Many general comments on the recommendation to include Zr-RCF in Annex XIV were received from industry or trade associations located in Europe; three comments were received from individuals located in Europe and one comment was received from individual located in US; one comment was received from academic institution and one comment was received from other contributors. The major arguments put forward in those comments included such points as:

- The current Candidate List entries fail to adequately and correctly describe the product as registered in the EU – leading to a high level of uncertainty for all stakeholders (industry as well as regulators / enforcers). The details given in the chemical composition ("other oxides"[8]) make it hard to know which RCF is covered. Lack of common identifier, such as an EINECS or CAS number makes it hard to track RCF uses.
- Score attributed to the volume criteria is largely overestimated with respect to the factual amounts of RCF's potentially concerned by Authorisation. Most of the RCF are used as articles in the sense of REACH. These materials are most often used in the industry in the form of articles (e.g. sheets, bricks, blankets, rolls, modules), for which the definition and exact status in a potential authorisation process is not clear for users.
- Intersubstitutability with RCF versions (with the same hazard profile) not covered by the present Candidate List entries has been demonstrated (for the most part the applications of Alumina-Silica-RCF, Zirconia-Alumina-Silica RCF and Chromia-Alumina-Silica-RCF's overlap and these products are "intersubstitutable", often competing with each other for the same applications).This leads to an unjustified different treatment of the listed materials.
- RCFs are covered by Directive 2001/41/EC on restrictions on the marketing and use of certain dangerous substances and preparations, as regards substances classified as carcinogens, mutagens or substances toxic to reproduction. This means that RCF cannot be placed on the market for use by the general public. The workplace risks associated with RCF dust exposures affect a small and declining cohort of professional workers who are adequately protected via applicable risk management measures. There are already occupational exposure limits for these RCF materials that are used to control the use and applications of these materials

[8] „Other oxides like potassium oxide (< 0.01 %), sodium oxide (< 0.3 %), magnesium oxide (0.01 %), calcium oxide (< 0.05 %), titanium oxide (0 04 %), iron oxide (< 0.05 %) and chromium oxide (< 0.01 %) are sometimes added to change the fibre properties". Reference: Annex XV report (2011) - Zirconia Aluminosilicate, Refractory Ceramic Fibres. Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. Submitted by Germany, August 2011. http://echa.europa.eu/documents/10162/1fe242c7-c234- 447d-89f1-5e71f87ca1ec.

in the workplace and authorisation process will give no advantage for workers safety but tremendous disadvantages for the environment and for the competitiveness of the European industry (REACH Art. 55 aims to ensure a.o. the good functioning of the internal market).

- Other statements for not including Zr-RCFs into Annex XIV are irreplaceability of Zr-RCFs in many high temperature applications, unavailability of substitutes with equivalent performance despite intensive searches, indispensability of RCFs for meeting energy and resource efficiency targets set out in the EU´s 2020 programme and industry´s growing demand for resource and energy efficiency and the associated reduction of CO_2, loss of competitiveness comparing to non EU counterparts.

Regarding the comments on unclear substance identity, MSC agrees with the response provided in ECHA's RCOM that the substance identity has been considered in the context of inclusion of the substance in the Candidate list and it is not relevant to the prioritisation phase. MSC appreciates ECHA's further clarification on substance identity provided in the RCOM.

MSC agrees with the ECHA's response provided in the RCOM that there might be fibres on the market with potentially the same hazard properties and similar uses which are not covered by the current Candidate list entries.

Based on the agreed prioritisation approach, MSC acknowledges that ECHA does not assess at *this stage of the process whether on the basis of the available scientific evidence it can be concluded that a non-effect level (threshold) for the carcinogenic effects of the RCFs exists. This is an issue to be addressed in the authorisation applications and in RAC when preparing its opinions on the authorisation applications.*

Regarding the comments concerning overestimated volume, MSC notes that ECHA's estimation of volumes is based on information currently available in the registration dossiers and generally agrees with ECHA's view as expressed in the RCOM that it is this information that the estimation should be based on, as opposed to external estimates of the volumes submitted during the public consultation. The MSC further notes that RCF is registered as substances and the applications for authorisation should address all stages of the lifecycle including the use of Zr-RCFs in articles.

Regarding the arguments provided by industry on the socio-economic benefits of using Al-RCFs and of the potential effect of authorisation on EU business, while the MSC considers that these issues are very important and relevant, it generally agrees with the responses provided by ECHA in the RCOM document.

Regarding the comments on the clarity of whether products made from RCF (e.g. blanket, board, sheet, brick, module) are substances or articles, MSC agrees with the response provided in ECHA`s RCOM that RCF products may be articles according to Art 3(3) and it is not always possible to conclude at which stage of the life cycle their status changes from substances to articles. The uses of articles do not require authorisation but the production of articles using RCFs requires authorisation.

MSC is of the opinion that the wide-dispersiveness of the uses of RCFs depends on the interpretation whether the products made from RCF (e.g. blanket, board and others) and used in the sites are considered substances or articles. For instance, it is uncertain whether installation of insulation material made from RCF such as blanket and end use processes such as maintenance of furnace are in the scope of authorisation. If the products made from RCF are considered to be articles it will have impact to the number of sites using the substance. However, based on the registration information on the types of uses (e.g. conversion bulk fibres into different types products, formulation of textiles, cements or putties and use of bulk fibres as such for insulation), MSC agrees with the ECHA`s response provided in the RCOM, that a high number of sites using the substance and a high number of potentially exposed workers is anticipated even without considering end use processes such as installation of insulation material and furnace maintenance to be in the scope of authorisation.

During the MSC discussions, some members questioned the appropriateness of the release score related to wide-dispersive use. It was argued that the worker exposure is well controlled and the release score should be 1 (controlled) instead of 3 (significant), as concluded in the assessment of priority SVHC`s on the candidate list published in 2010.

The MSC notes that the assessment in 2013 is mainly based on the registration information while the assessment in 2010 was done before the majority of registrations were submitted and all information available. Experience has also been built up in assessing the priority substances after 2010. While the exposure might be controlled in most instances, the MSC agrees with ECHA`s view that for some of the uses potentially significant exposure of workers cannot be excluded.

MSC is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of Zr-RCFs.

Transitional arrangements: Latest application date and Sunset date

ECHA proposed the following transitional arrangements for Zr-RCFs:

(iii) Application date: 21 months after entry into force of the Regulation
(iv) Sunset date: Latest application date + 18 months

During the public consultation, many comments were received related to the transitional arrangements. One Member State supported transitional arrangements proposed by ECHA. One NGO requested to shorten latest application and sunset dates.

Many requests from industry or trade organizations for longer transitional periods were based on socio-economic reasons, technical challenges, long service life times, lack of available alternatives, long periods of time required for approval of new safe alternatives (up to 10 years in aerospace industry), complex supply chains and organisational challenges that will be faced by many hundreds of operations of different types when trying to get organised in authorisation consortia. It is also claimed by industry that applying for authorisation would dilute resources currently focused on development of alternatives. Extensions of latest application and sunset dates are requested. Based on all the above arguments (with some differences in levels of argumentation), extended latest application dates ranging from 30 months to 30 years were proposed by industry, resulting in a sunset date in year 2017 or later.

Regarding the point on the lack of suitable alternatives, the MSC considers that information on alternatives should be provided as part of an application for authorisation and 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.

Regarding the requests for longer transitional periods in certain industry sectors based on the complexity of the supply chain, MSC considers that the required time for preparation of applications is partly a matter of co-operation, communication and organisation between actors in the supply chain. Applications for authorisation may be made for one or several uses and it is possible to submit joint applications by a group of duty-holders (manufacturer, importer and downstream user).

MSC is of the opinion that no new information was submitted during the public consultation that would support changes to the proposed transitional arrangements and therefore MSC agrees with ECHA`s recommendation for the transitional arrangements for Zr-RCF.

Proposed review period for certain uses

No review period was suggested by ECHA in its draft recommendation.

During the public consultation, one international NGO suggested that no review period should be included.

Proposals from industry were received to set a review period from 5 years up to more than 20 years (15 years is suggested for aerospace industry). However in the comments

made by industry it was also noted that due to the fact, that different applications have different operating conditions, it is very hard to provide generalised review period.

MSC is of the opinion that upfront specified review periods are not warranted in the recommendation for Annex XIV inclusion.

Proposed exempted (categories of) uses

ECHA did not propose any exemption of uses or categories of uses in its draft recommendation.

During the public consultation, one international NGO suggested that no uses should be exempted from the authorisation requirements.

General exemptions were requested for use of Zr-RCF in steel slab heating processes and in blast furnace hot stoves as well as in other furnaces of thermal threatment for lab or industrial applications (over 900°C) and are based on poor alternatives and complex technical factors. Exemptions were also asked for uses in the aerospace industry and are based among other reasons and on air safety considerations. Specific exemption was asked for use of RCFs as heat insulation material in fire protection applications (e.g. fire seals) in the oil & gas industry due there are no know suitable alternatives.

Several companies and industry associations claimed that the uses of RCF are already well regulated and the risks of RCF uses are adequately controlled under existing EU legislations. At first, a restriction applies under Directive 2001/41/EC, limiting the use to industrial applications only. Furthermore, National occupational emission limits (OELs) exist for RCF and a European binding OELV for RCF under the Carcinogens and Mutagens Directive is currently under discussion as part of the overall review of this Directive. A binding occupational exposure limit value (BOELV) is currently under discussion at EU Commission level and will be implemented in Annex III of Directive 2004/37/EC. A binding occupational exposure limit value for RCF is expected by the end of 2014, i.e. before authorisation would start. Taking into account all reasoning provided above industry considers that the criteria for exemption of uses is met under article 58(2) of REACH regulation.

Regarding the point on the lack of suitable alternatives see transitional arrangements section above.

MSC is of the opinion that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses.

PPORD exemptions

No exemptions for PPORD were suggested by ECHA.

There were no requests for PPORD exemption submitted during the public consultation.

MSC supports ECHA's view that PPORD exemptions in Annex XIV are not warranted.

Other issues

MSC noted that there is a need for additional guidance for duty-holders to further clarify the more exact coverage of the candidate list entries of Zr-RCF, as well as the substance versus article status of the RCF products, if the substance is included in Annex XIV, to avoid misunderstanding when duty-holder is applying for an authorisation for the uses of the substance in question.

During the public consultation and MSC discussions, some MSC members expressed concern as to whether authorisation is the most appropriate risk management measure for the RCFs and were of the opinion that other risk management options should also be considered. However, MSC recognises that RMO considerations are not in the scope of preparation of the recommendation for Annex XIV and such issues need to be addressed in other fora.

2.5. 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-Octylphenol ethoxylates) (4-tert-OPnEO)

Justification for prioritisation

4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues] (4-tert-OPnEO) have been identified as SVHC in accordance with Article 57(f) of Regulation (EC) 1907/2006 (REACH) as endocrine disruptors and were included in the Candidate List for authorisation on 19 December 2012, following ECHA's decision ED/169/2012.

The substance has not been registered under REACH as it is considered a polymer. Based on registration data for its precursor, 4-tert-octylphenol, ECHA has estimated the manufactured volume of 4-tert-OPnEO to be in the range of 1 000-10 000 tonnes per year. The substance is mainly used in formulation of paints, industrial end-use of paints, consumer and professional end-use of products (e.g. paints) and emulsion polymerisation and as an intermediate in the production of ether sulphates. Almost 50% of the volume is used as emulsifiers in emulsion polymerization.

Products containing 4-tert-OPnEO are used by industrial, professional and consumer end-users and, therefore, the use is considered as wide dispersive. Furthermore, due to the wide dispersive uses, widespread emissions to the environment are assumed.

Based on the above consideration, 4-tert-OPnEO meets the basic principles for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation, none of the MSCAs opposed the prioritisation of 4-tert-OPnEO for inclusion in Annex XIV. Two MSCAs, one Trade Union Organisation and one environmental NGO supported the proposal.

Two industry organisations representing manufacturers of alkylphenol and derivatives submitted joint comments in objection to the proposal to include 4-tert-OPnEO in Annex XIV. Furthermore, eight companies providing or using 4-tert-OPnEO for chemical analysis or medical in vitro diagnostics objected to the proposal to include the substance in Annex XIV. The comments and major concerns may be summarized as follows:

- Substance identity: As neither CAS nor EC number(s) are provided, it is difficult for industry to determine whether their substances are comprised by the inclusion in the Candidate List or Annex XIV. Some of the substances marketed under the Triton "X" trade names are likely to be comprised by the 4-tert-OPnEO.
- SVHC properties: 4-tert-OPnEO is not identified as a PBT or vPvB substance and, therefore, the substance should not be prioritised for Annex XIV. Furthermore, it is questioned whether 4-tert-OPnEO actually degrades to 4-tert-octylphenol and whether this degradation product possesses the same endocrine disruptive properties as nonylphenol.
- High volume: As 4-tert-OPnEO has not been registered (as it is considered a polymer), the volume is suggested to be in the lower half of the tonnage range of 1,000 – 10,000 tonnes per year estimated by ECHA.
- Use in formulation of paints: 4-tert-OPnEO is used predominantly in the formulation of paints and coating products; however, as it is used for emulsion polymerization it is expected to be bound in the paint polymer and not widely dispersed to the environment.
- Use in production of pharmaceutical products: 4-tert-OPnEO is used for viral inactivation in pharmaceutical products.
- Use for in vitro diagnostics: 4-tert-OPnEO is used in small volumes by a large number of SMEs for *in vitro* diagnostics medical devises. The total tonnage for this use is probably less than 33 tonnes per year.

- Use for chemical analysis: 4-tert-OPnEO is used for (bio)chemical analysis under strictly controlled conditions.
- Environmental monitoring: Analysis of almost 3,000 samples from European surface waters show concentration levels in 96% of the samples below 0.1 µg/L, which is the Annual Average Environment Quality Standard derived for 4-tert-octylphenol under the Water Framework Directive (no AA-EQS or PNEC has be derived for 4-tert-OPnEO).

MSC considers that as 4-tert-OPnEO is included in the candidate list, comments on the inclusion are of no relevance for the prioritisation for inclusion in Annex XIV.

MSC agrees with ECHA that information on topics such as 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, should be provided as part of the application for authorisation and will be taken into account by the Risk Assessment Committee and the Socio-Economic Analysis Committee when forming their opinions and by the Commission when taking the final decision, therefore not considered in the prioritisation for recommending substances for inclusion Annex XIV.

MSC notes the confirmation provided in the public consultation regarding the estimated volume of 4-tert-OPnEO in the EU being within the tonnage range as specified in ECHA's Background Document. Further, it is confirmed that the main use of 4-tert-OPnEO is for formulation of paints. Another use is the filling into containers for transport to downstream users. MSC considers that both of these uses are within the scope of authorisation. However, MSC considers that downstream uses in medicinal products (Article 2(5)(a)) are outside the scope of authorisation. Regarding the use 4-tert-OPnEO in medical diagnostics and chemical analysis, it may fall under the definition of Scientific Research & Development (Article 3(23): scientific analysis), which is outside the scope of the authorisation requirements (Article 56(3)).

Finally, the ubiquitous findings of the substance in surface water samples, although in low concentrations, in European waters confirm the wide dispersive use and release of 4-tert-OPnEO.

Based on the above considerations, the MSC is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritization of 4-tert-OPnEO for inclusion in Annex XIV.

Transitional arrangements: Latest application date and Sunset date

In its draft recommendation, ECHA propose the following transitional arrangements for 4-tert-OPnEO:

(i) Latest application date: Date of inclusion in Annex XIV plus 24 months

(ii) Sunset date: Latest application date plus 18 months

During the public consultation, one Member State and one environmental NGO supported the proposal for an application deadline of 2 years. The same organisation of medical diagnostics manufacturers and companies using 4-tert-OPnEO for *in vitro* diagnostics commented that 10 years would be required for identifying a suitable replacement substance.

MSC is of the opinion that no information has been provided during the public consultation that would challenge the suggested latest application date and sunset date.

Proposed review period for certain uses

No review period was suggested by ECHA in its draft recommendation.

During the public consultation, an environmental NGO suggested that no review period should be included, while an organisation of medical diagnostics manufacturers noted that 10 years would be required for identifying alternatives.

MSC is of the opinion that no information has been provided during the public consultation that would warrant specification of a review period.

Proposed exempted (categories of) uses

ECHA did not propose any exemption of uses or categories of uses in its draft recommendation.

During the public consultation, one Member State and one environmental NGO suggested that no uses should be exempted from the authorisation requirements. A chemicals provider of 4-tert-OPnEO to, a.o., manufacturers of medical in vitro diagnostics suggests that all uses including formulation, packaging and refilling of the substance and mixtures as well as uses for Scientific Research & Development and in medicinal products should be exempted from the authorisation requirements.

MSC is of the opinion that no information has been provided during the public consultation that would warrant any exemptions from the authorisation requirements.

PPORD exemptions

No exemptions for PPORD were proposed by ECHA.

The same organisation of medical diagnostics manufacturers suggested a general exemption for use for PPORD in quantities of up to 10 tonnes per year.

MSC is of the opinion that no information has been provided during the public consultation that would warrant a PPORD exemption.

Other issues

MSC noted that there is a need for additional guidance for duty-holders to clarify the relevant CAS numbers and other identifiers of the individual substances comprised by the general identifier 4-tert-OPnEO covering well-defined substances and UVCB substances, polymers and homologues.

Annex III

Draft 5th Recommendation of Priority Substances to be Included in Annex XIV of the REACH Regulation (List of Substances Subject to Authorisation)

Draft Annex XIV entries									
#	**Substance**	**EC number**	**CAS Number**	**SVHC-relevant intrinsic properties***	**Latest application date pursuant to REACH Art. 58 (1) (c) (ii)****	**Sunset date**	**Review periods**	**Exempted uses or categories of uses**	**Exemptions for PPORD**
1	N,N-dimethylformamide (DMF)	200-679-5	68-12-2	Art. 57 (c); Toxic for Reproduction 1B	Date of inclusion in Annex XIV plus 18 months [1)]	Latest application date plus 18 months	None	None	None
2	Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA)	204-650-8	123-77-3	Art. 57 (f); Equivalent level of concern having probable serious effects to human health	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None
3	Aluminosilicate Refractory Ceramic Fibres (Al-RCF) *are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil*	-	-	Art. 57 (a); Carcinogen 1B	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None

Draft Annex XIV entries									
#	**Substance**	**EC number**	**CAS Number**	**SVHC-relevant intrinsic properties***	**Latest application date pursuant to REACH Art. 58 (1) (c) (ii)****	**Sunset date**	**Review periods**	**Exempted uses or categories of uses**	**Exemptions for PPORD**
	the three following conditions: a) oxides of aluminium and silicon are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm) c) alkaline oxide and alkali earth oxide (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight								
4	Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF) *are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on*	-	-	Art. 57 (a); Carcinogen 1B	Date of inclusion in Annex XIV plus 21 months [2)]	Latest application date plus 18 months	None	None	None

Draft Annex XIV entries									
#	**Substance**	**EC number**	**CAS Number**	**SVHC-relevant intrinsic properties***	**Latest application date pursuant to REACH Art. 58 (1) (c) (ii)****	**Sunset date**	**Review periods**	**Exempted uses or categories of uses**	**Exemptions for PPORD**
	classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions: a) oxides of aluminium, silicon and zirconium are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm). c) alkaline oxide and alkali earth oxide (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight								
~~56~~	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated *[covering well-defined substances and UVCB substances, polymers and homologues]*	-	-	Art. 57 (f); Equivalent level of concern having probable serious effects to the environment	Date of inclusion in Annex XIV plus 24 months [3)]	Latest application date plus 18 months	None	None	None

* Reference is made to the identified SVHC properties in accordance with Article 57 of the REACH Regulation and to the corresponding classification in accordance with Annex VI, Table 3.1 (*List of harmonised classification and labelling of hazardous substances) of* REGULATION (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

** The standard Latest Application Date (LAD) of 18 months is used as the starting point and the dates for the five substances are spread in three lots over a period of 6 months (LADs 18, 21 or 24 months from entry into force) to distribute the workload in the authorisation application and decision phase more evenly.

In the first lot (substance 1) there is a substance that is similar in its inherent properties and its uses to a substance already recommended for inclusion in Annex XIV (N,N-dimethylacetamide; DMAC).

The second lot (substances 2 – 4) includes two substances with similar (to each other) inherent properties and uses (RCFs) plus ADCA. The remaining substance (5) was assigned to the last (third) lot.

1) 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 August 2016
2) 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
3) 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 February 2017