OPINION OF THE MEMBER STATE COMMITTEE

ON THE EIGHTH DRAFT RECOMMENDATION OF THE PRIORITY SUBSTANCES AND ANNEX XIV ENTRIES

Adopted on 11 December 2017

OPINION

This opinion of the Member State Committee (MSC) on the eighth draft recommendation of European Chemicals Agency (ECHA) concerning priority substances to be included in Annex XIV was adopted on 11 December 2017 in accordance with Article 58(3) of the REACH Regulation (EC) No 1907/2006[1].

PROCESS FOR ADOPTION OF THE OPINION

ECHA consulted MSC on its draft 8th Recommendation of priority substances for inclusion in Annex XIV of REACH, including the results of the prioritisation of the Substances of Very High Concern (SVHC) on the Candidate List and the proposed draft REACH Annex XIV entries for the priority substances. The Committee had a discussion about the proposed draft recommendation and draft REACH Annex XIV entries of the substances suggested for inclusion in the recommendation on 7-9 February 2017. After that, ECHA published its draft recommendation on 2 March 2017 on its website for public consultation.

MSC appointed a Rapporteur and a Co-Rapporteur for preparing its opinion on ECHA's draft recommendation for Annex XIV of REACH and, in addition, a Working Group to support the Rapporteur and Co-Rapporteur at its 52th meeting (7-9 February 2017).

For the preparation of its opinion the Committee was provided with the following documents:

- ECHA's priority setting approach[2] and its application to all substances on the candidate list not already included or recommended for inclusion in Annex XIV of REACH[3]
- General approach for defining the REACH 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 2 March 2017)[5]
- (Draft) Background documents for each substance summarising the available information used for priority setting and specification of draft REACH Annex XIV entries prepared by ECHA (published 2 March 2017 on the ECHA website in the context of the public consultation)

[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/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf
[3] https://echa.europa.eu/documents/10162/13640/prioritisation_results_CL_substances_march_2017_en.pdf
[4] http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf
[5] http://echa.europa.eu/documents/10162/13640/7th_recom_draft_axiv_entries_en.pdf

- Comments of the interested parties provided during the public consultation period that started on 2 March 2017 and closed on 2 June 2017
- Draft responses to comments provided by the ECHA Secretariat (by 12 October 2017 and in updated version by 30 November 2017).

The draft opinion provided to the Committee by the (Co-)Rapporteurs was finalised and adopted on 11 December 2017 after discussion at the 57th meeting of MSC. The support document for the MSC opinion is attached to this opinion (Annex I).

THE EIGHTH 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 opinion reviews whether the substances that ECHA has prioritised meet 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 Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV)[2] 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, if any, are included under the heading "Other issues" in the support document for the opinion of MSC (**Annex I** to this opinion).

The eighth 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

In its draft recommendation addressed in the public consultation, ECHA did not recommend any uses or categories of uses that should be exempted from authorisation pursuant to Article 58(2). Moreover, in its draft recommendation ECHA did not recommend any exemptions from the authorisation requirements for uses in product and process oriented research and development (PPORD), as provided for in Article 56(3).

ECHA's draft recommendation for Annex XIV that was addressed in the public consultation and was used while developing the opinion of MSC is attached to this opinion (**Annex II)**. The opinion of the Member State Committee focuses on this draft recommendation and the items of Annex XIV entries.

OPINION ON THE DRAFT RECOMMENDATION FOR PRIORITISATION OF SUBSTANCES

The members of the Member State Committee are of the opinion that all substances listed in the draft recommendation of ECHA, published on 2 March 2017, should be proposed for inclusion into Annex XIV. They agree that these following substances should be prioritised in accordance with Art. 58(3)

following application of approaches presented in the document on Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV)[2] and the document on General approach for Preparation of draft Annex XIV entries for substances to be included in Annex XIV[4].

- 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] (karanal group)
- 1-Methyl-2-pyrrolidone (NMP)
- 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)
- 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)
- 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)
- 2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)
- 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate]

REACH ANNEX XIV ENTRIES

Substance identities

#	Substance	EC number	CAS Number
1	5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] (karanal group)	-	-
2	1-Methyl-2-pyrrolidone (NMP)	212-828-1	872-50-4
3	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	247-384-8	25973-55-1
4	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	223-383-8	3864-99-1
5	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	253-037-1	36437-37-3
6	2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	223-346-6	3846-71-7
7	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5)	271-094-0, 272-013-1	68515-51-5, 68648-93-1

Intrinsic properties

The intrinsic properties are as outlined in the candidate list and further elaborated in the Support Document for each substance when identifying them as SVHCs.

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 REACH 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)(i) specifies that the sunset date(s) for uses of a substance should, where appropriate, take into account the production cycles specified for those uses, the Member State Committee is of the opinion that the currently available information does not provide sufficient basis to differentiate sunset dates by various uses of the prioritised substances.

Due to the information collected during the public consultation above assessing high number of industrial sites impacted, MSC is of the opinion that the proposed latest application date for NMP should be modified as follows:

- Application date: 24 months (instead of 18) after entry into force of the Regulation. The sunset date should remain as proposed by ECHA (latest application date plus 18 months).

Furthermore, 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 for the other substances presented in the ECHA's draft recommendation.

Review periods for certain uses

As the review period is closely connected to the use(s) for which the authorisation is requested and is set on a case-by-case basis when granting the authorisation, the MSC is of the opinion that upfront specified review periods are not warranted in the recommendation for REACH Annex XIV inclusion. The review periods should be set up in accordance with Article 60(8).

Uses or categories of uses exempted from the authorisation requirement

MSC is of the opinion that in order to benefit from an exemption under Article 58(2) for a particular use, the existing EU legislation must properly control the risk to human health and/or the environment from the use of the Substance specifically. Generally, the legislation should refer to the substance, either by naming it or referring to the group the substance belongs to. MSC emphasises that the existing EU legislation must impose minimum requirements for the control of risks for the use in question by defining the measures to be implemented by the users of the substance, covering all life cycle stages and these minimum requirements must be binding and enforceable.

After assessing the information provided during the public consultation, MSC is of the opinion that there are no grounds for exemptions from authorisation for any of the substances recommended by ECHA.

Furthermore, MSC is of the opinion that no information was submitted during the public consultation that would form the basis for inclusion of a specific exemption under Article 58(2) for a use or a category of use in Annex XIV for other substances presented in the ECHA's draft recommendation.

Exemptions for the use in product and process oriented research

ECHA in its draft recommendation did not propose PPORD exemptions for any of the substances. During the public consultation, no specific comments were received with regard to possible PPORD exemptions. Thus MSC supports the recommendation not to exempt uses in product and process oriented research.

Annex I: Support document for the opinion of MSC
Annex II: ECHA's draft recommendation for Annex XIV, as published on 2 March 2017

Annex I and II to the Member State Committee's opinion on

ECHA's 8th draft recommendation (adopted on 11 December 2017)

Annex I Support document for the opinion of MSC

Annex II Draft 8th Recommendation of Priority Substances to be included in Annex XIV of the REACH Regulation as submitted for public consultation on 2 March 2017

Support document for the opinion of MSC (Annex I)
on ECHA's 8th draft recommendation for inclusion of priority substances in the Authorisation List (adopted on 11 December 2017)

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 of REACH, i.e. more relevant substances are included before less relevant substances. The primary basis of the prioritisation is the Article 58(3) criteria. Further considerations on which substances are to be recommended for inclusion in Annex XIV take into account other substances already recommended or included in Annex XIV, in particular the potential interchangeability of substances in (some of) their uses. In order to avoid undesired interference between different regulatory actions other on-going regulatory risk management activities can also be considered when deciding on which substances to include in a specific recommendation. However, it should be stressed, that other potential risk management options and whether they could be more appropriate than the authorisation requirement are not analysed during the prioritisation step. Prioritisation is not the appropriate process for the assessment of the risks and/or exposure of a substance as a whole or, of the risks and/or exposure exerted by a particular use at a particular site/in a particular sector or, of the availability and suitability of alternatives or, of socio-economic considerations. Thus prioritisation of substances from the Candidate list for inclusion in Annex XIV is not based on 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 thus the assessment of priority is performed on a substance-specific basis. 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. The wide dispersiveness of uses is primarily assessed based on the types of actors which are relevant for the use of a substance (industrial (IND), professional (PROF) and consumer (CONS)) uses. However, the assessment of the wide dispersiveness of the uses is limited to a general evaluation of the use pattern and exposure potential that a substance may have.

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

In forming the opinion on the draft recommendation MSC took account of the information produced by ECHA (including background documents, prioritisation assessment results, setting latest application dates) and any relevant comments made during the three month public consultation period. In this consultation comments were received on only one of the substances, 1-methyl-2-pyrrolidone (NMP). These comments mostly addressed the prioritisation, exemptions of uses or groups of uses from the authorisation provisions and transitional arrangements. Some of these issues are summarised below, together with the views of MSC.

2.1 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] (karanal group)

Justification for prioritisation

5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] (karanal group)] was identified as a Substance of Very High Concern (SVHC) according to Article 57 (e) as it meets the criteria of a vPvB substance. The substance was therefore included in the Candidate List for authorisation on 15 June 2015, following ECHA's decision ED/39/2015.

One substance of this group entry had been notified under Directive 67/548/EEC (NONS) and is therefore considered registered under Regulation (EC) No 1907/2006 (REACH). As of 25 October 2015 no other registrations had been submitted.
A further substance covered by the group entry is pre-registered with an envisaged registration deadline of May 2018. This substance was commented on by a company during the public consultation on the proposal to identify this group of substances as SVHC indicating a volume used of < 10 t/y (RCOM, 2015). Based on the available information, the volume in the scope of authorisation is assumed to be > 1 t/y.

Based on public information sources the main use of the karanal group in the scope of authorisation is as fragrance ingredient in applications such as fine fragrances, soaps and detergents. It is assumed that these uses cover uses at industrial sites, uses by professional workers and consumer uses (IND, PROF and CONS).

Based on this information, 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] (karanal group)] meet the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation no comments were received.

MSC is of the opinion that 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] (karanal group)] meet the criteria for prioritisation for inclusion in Annex XIV.

Transitional arrangements: Latest application date and Sunset date

In its draft recommendation, ECHA proposed the following transitional arrangements5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] (karanal group)]:

(i) Latest application date: Date of inclusion in Annex XIV plus 18 months;
(ii) Sunset date: Latest application date plus 18 months.

There were no comments received during the public consultation requesting changes in the proposed transitional arrangements.

MSC is of the opinion that the suggested latest application date and sunset dates are appropriate.

Proposed review period for certain uses

No review period was suggested by ECHA in its draft recommendation. No requests for review periods were received during the public consultation.

As the review period is closely connected to the use(s) for which the authorisation is requested and is set on a case-by-case basis when granting the authorisation, MSC is of the opinion that upfront specified review periods are not warranted in the recommendation for inclusion of substances in Annex XIV.

Proposed exempted (categories of) uses

ECHA did not propose any exemption of uses or categories of uses in its draft recommendation. No requests for exemption of uses or categories of uses were received during the public consultation.

Overall, MSC is of the opinion that no exemption under Article 58(2) for a use or a category of use should be included in Annex XIV.

PPORD exemptions

No exemptions for PPORD were suggested by ECHA. No requests for exemptions for PPORD were received during the public consultation.

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

Other issues

No other issues were raised during public consultation with regard to 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] (karanal group)].

2.2 1-Methyl-2-pyrrolidone (NMP)

Justification for prioritisation

1-methyl-2-pyrrolidone (NMP) was identified as a Substance of Very High Concern (SVHC) according to Article 57 (c) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1B, H360D ("May damage the unborn child"), and was therefore included in the Candidate List for authorisation on 20 June 2011, following ECHA's decision ED/31/2011.

The amount of 1-methyl-2-pyrrolidone (NMP) manufactured and/or imported into the EU is, according to registration data (ECHA, 2016), in the range of 10,000 - 100,000 t/y. Some uses appear not to be in the scope of authorisation, such as in plant protection products and some of the uses in the manufacturing of pharmaceuticals. Based on an OECD study (2007) on the world market from 2005, the volume corresponding to those uses would be ~30 % of the total volume. The Annex XV report

(2011) assumes that a similar use distribution would apply for the European market. ECHA has no further information or indications that the situation regarding the share of uses outside the scope of authorisation on the European market has considerably changed since. Further minor uses in laboratories are also expected not to be in the scope of authorisation. In the absence of further information, the volume in the scope of authorisation is estimated to be in the range of 10,000 - 100,000 t/y (70 % of total volume).

Registered uses of NMP in the scope of authorisation include uses at industrial sites (formulation & (re)packing of substances and mixtures, in coatings, cleaning agents, oil field drilling and production operations, as binders and release agents, as functional fluids, polymer processing, water treatment), and uses by professional workers (in coatings, cleaning agents, oil field drilling and production operations, as binders and release agents, as functional fluids, road and construction applications, polymer processing). The majority of the volume in scope appears to be used in coatings, cleaning agents, as a solvent in the electronics sector and in petrochemical processing. The use in coatings and in cleaning agents seem to cover a wide range of mixtures in a high number of applications and sectors, having both industrial and professional users and including a number of SMEs. The supply chains for coating and cleaning products seem to be complex, with hundreds of formulators and thousands of industrial and professional end-users. In the 9th ATP which shall apply from 1 March 2018, the Specific Concentration Limit of 5% for Repr. 1B (H360D) was changed to the Generic Concentration Limit of 0.3% for NMP. This may have an impact on the number of industrial/professional users in the scope of authorisation.

Although the consumer use in ink is registered, a number of comments claimed this is outdated information due to the change in concentration limit.

ECHA did not recommend NMP in earlier rounds, despite it scoring relatively highly using their prioritisation approach, due to the ongoing assessment of the restriction proposal submitted by the Netherlands in August 2013 and the ongoing work on the OEL/DNEL determination. The proposed restriction when enters into force is not foreseen to have an impact on the volume in the scope of authorisation or the wide-dispersiveness of uses.

Additionally, NMP is a polar aprotic solvent that can be used (to some extent) in the same applications as DMF and DMAC both of which have been already recommended by ECHA for inclusion in Annex XIV, therefore also grouping considerations apply.

Based on this information, 1-methyl-2-pyrrolidone meets the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation a large number of comments were received from 56 companies, 22 industry/trade associations, 3 individuals and 1 MSCA. Over half the comments were against prioritisation, considering that the proposed restriction would sufficiently ensure risks were controlled (although a small number felt the proposed DNEL might be too low to be achievable for them). Most questioned the additional benefit of authorisation, some considering it disproportionate and a number of companies and industry/trade associations made very similar statements that the recommendation contradicted the RAC/SEAC opinion recommending the restriction as the most appropriate EU wide measure.

As noted above, ECHA considers that the restriction, when implemented, will not have an impact on the volume in scope of authorisation or the wide-dispersive use and therefore the priority score for

NMP will not change significantly and it meets the agreed criteria for recommendation. As noted in the introduction of this document, the prioritisation step considers use pattern and exposure potential in broad terms to rank potential substances but does not consider whether authorisation is the best risk management option. In this respect MSC considers that ECHA followed their procedures consistently in including NMP in its draft recommendation and this would bring all 3 aprotic solvents (NMP, DMAC and DMF) to the same step of the authorisation procedure, as noted by ECHA in their (draft) response to comments. Whilst the MSC supports the recommendation of NMP for the reasons given, it recognises that there are other ongoing activities that the Commission will need to consider in deciding whether NMP and other aprotic solvents should be subject to authorisation.

A large number of comments questioned the scores allocated by ECHA; firstly the WDU score of 12 was challenged, many providing information to show that NMP was not in the final articles produced and a number claiming that the only SiA notifications for NMP in PVC hoses are wrong assumptions. From the information provided it would seem that this additional score may not be warranted however this would only reduce the total score by 2 and the position of NMP in the prioritisation list would not change.

Many comments proposed that the scoring should be adapted; differentiating between industrial and professional uses or even calculating a score for each use separately. When considering industrial uses and professional uses separately they calculated reduced scores of 21 and 20 respectively. MSC notes that whilst a score of 21 would place NMP lower than a number of substances currently not prioritised, for a proper comparison, the splitting of industrial vs professional use tonnages would need to be done for all the substances and consequently the order of substances may not change.

ECHA have also taken grouping considerations into account stating that two other aprotic solvents, DMF and DMAC, have already been recommended. On this point there were opposing comments made; some argued that a robust category justification had not been made and the grouping considerations should be dropped, others, when considering alternatives, indicated other aprotic solvents were indeed possible substitutes for NMP. Others supported taking a common approach for the aprotic solvents, although as mentioned above preferred restriction alone. MSC considers that no new information was submitted indicating that NMP cannot be used as a substitute to DMAC or DMF, therefore, MSC concludes that the grouping approach is valid. This is an extra element supporting the prioritization of NMP which itself has a high priority score when applying the agreed criteria.

In considering the above, MSC is of the opinion that no new information has been submitted during the public consultation that would challenge the prioritisation of NMP.

Transitional arrangements: Latest application date and Sunset date

In its draft recommendation, ECHA proposed the following transitional arrangements for NMP:

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

During the public consultation, there were numerous comments from several organisations and companies requesting longer periods of transition for NMP. Comments covered the use in the production of fine chemicals, pharmaceuticals, medical devices, polymers, semiconductors, membranes, petrochemicals, electronic components, among others. Industry mainly supports restriction instead of authorisation, claiming that, due to restriction recommendation by RAC and SEAC in 2014, no authorisation preparation has been undertaken by them yet. Therefore, they consider that more time is needed for the submission of AfAs, requesting a LAD no shorter than 24 months. Nevertheless, taking also into account the total socio economic burden of its non-use as a process solvent, 36 months was proposed by industry as appropriate minimum LAD.

Full complexity of the supply chain for NMP, with many uses and applications and long R&D and investment cycles are frequently mentioned in the comments for the justification of 24-36 months LAD. Other mentioned aspects are high costs of investment for process adaptation, inexperience in the authorization process by small and medium sized companies and the existence of controlled conditions of use within industrial sites.

Lack of suitable alternatives for substitution and complex analysis of alternatives is also considered a reason for justifying a LAD of 24-36 months. However, ECHA does not consider the arguments on lack of alternatives as valid to lengthen the LAD, and MSC agrees.

This time slot of 18 months has initially been set in line with the ECHA document "Practical implementation of the Annex XIV entries approach" before ECHA had analysed the information received in the public consultation with regard to the complexity of the supply chain.

MSC notes that in the comments received complex supply chains and a high number of industrial uses of NMP have been reported. A large number of uses and occupational settings where NMP is used along the EU are also mentioned in the RAC opinion on NMP restriction. Applying the criteria established by ECHA longer application period would appear to be appropriate assuming more than 100 industrial use sites along EU.

Due to the mentioned considerations, MSC is of the opinion that the proposed latest application dates for NMP should be modified as follows:

- *Application date: 24 months (instead of 18) after entry into force of the regulation*

The sunset date should remain as proposed by ECHA (latest application date plus 18 months)

Proposed review period for certain uses

No review periods were suggested by ECHA in its draft recommendation.

Within the public consultation, several companies from the chemical and/or petrochemical industry noted their different point of view regarding ECHA proposal to not include in Annex XIV any review period. They consider this is in contradiction with Article 60 and 61 of REACH.

One pharmaceutical company claimed the strong need for very long review periods (>12 years) to guarantee the supply with lifesaving drugs.

MSC notes that the review period is closely connected to the use(s) for which an authorisation would be requested and therefore it is of the opinion that upfront specified review periods are not warranted in the recommendation for inclusion of substances in Annex XIV.

Proposed exempted (categories of) uses

In its draft recommendation ECHA did not propose any exemptions of uses or categories of uses for NMP.

During the public consultation period, exemptions were proposed by individual companies, industry and trade associations. These included a wide range of industry sector, such as producers of fine chemicals, polymers, plastics, semiconductors, coatings, winding wire, batteries, agrochemicals, medical devices or pharmaceutical products. Some arguments were shared among sectors, such us the absence of substance in the final product, the low worker exposure under controlled conditions and

low emissions. In that sense, Chemical Agents Directive (98/24/EC), Carcinogens and Mutagens Directive (2004/37/EC), Directive relating to Pregnant Workers (92/85/EEC), OSH "Framework Directive" (89/391/EEC), Directive 2009/161/EU, establishing an indicative occupational exposure limit value for NMP, EU Water Framework Directive (2000/60/EC) and Directive on industrial emissions (2010/75/EU) were mentioned. For the specific use as extraction agent of butadiene and benzene, producers of these carcinogenic substances argued that the application of their corresponding binding OEL (1ppm) implies an exposure limit significantly below to the current indicative occupational exposure limit value for NMP. MSC considers that the above mentioned Directives do not impose minimum requirements for controlling risks to human health and the environment. These Directives may not provide an adequate basis for an exemption under Article 58(2) REACH.

Regulations applied for the manufacturing of active pharmaceutical ingredients, including the use of GMP, were indicated by Pharmaceutical producers for their proposal of exemption. The application of Directive 93/42/EEC for the production of medical devices was also mentioned. A broader interpretation to also exempt the substances used only in the production process and not finally added to the medical device was requested. A similar approach was commented in relation to the application of the framework Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food. MSC agrees with ECHA's responses that industry have to examine themselves whether the specific uses of the substance can be regarded as uses where the general exemptions from authorisation can be applied. These exemptions can also cover the life-cycle steps preceding the incorporation of the substance into the end product, but only in volumes ending up in the exempted end-use.

Other general justifications for proposing exemptions in the public consultation included its use as a process solvent for the manufacture of intermediates, the lack of less hazardous alternatives or high socio-economic impact of an authorisation requirement. MSC agrees with ECHA´s view that these justifications are not considered within the prioritisation and they are taken into account in the application for authorisation phase.

Additionally, exemption of all NMP uses was suggested since the current NMP restriction proposal was considered, through many comments collected during the public consultation, as the best regulatory risk management option for an effective and efficient control of the potential NMP risks. MSC notes that actually there is an ongoing restriction process in the Commission. MSC is of the opinion that it belongs to the Commission at a future stage to decide giving consideration to address both REACH risk management processes can complement each other.

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

ECHA proposed not to recommend any exemptions for the use of NMP for PPORD in its draft recommendation.

During the public consultation, a comment on PPORD exemptions for the production of pharmaceuticals was received, but it did not include any specific PPORD request. According to ECHA's responses, no PPORD notifications were submitted by the end of public consultation.

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

Other issues

Many comments raised during the public consultation related to the socio-economic impacts of Authorisation, particularly the risk that companies might shut down or relocate outside the EU. Others provided tonnages and/or details on the risk management measures employed by their specific company/sector. A number of comments addressed alternatives; many noting the lack of alternatives for their specific use, the fact that possible substitutes were similarly hazardous or in the same regulatory position and in some sectors, for example the pharmaceutical industry, the long lead times needed for approval of alternatives.

MSC took note of these comments, but agrees with ECHAs responses that these are relevant for the parallel "call for information by the Commission" or for the authorisation applications but are not in the scope of either the draft recommendation or MSC's opinion on it.

Some of the comments noted that NMP was put on the candidate list without a Risk Management Option Analysis (RMOA) and the subsequent RMOA, agreed by MSs, considered restriction to be the best risk management measure for NMP. Reference was also made to the RMOA currently being produced by the Commission on three aprotic solvents, including NMP, and that the recommendation of NMP should at least await the outcome of this analysis.

MSC took note of these comments, but as noted in the introduction to this document other potential risk management options and whether they could be more appropriate than authorisation are not analysed during this prioritisation step.

Therefore MSC concludes that these other issues do not lead to a different opinion on the draft recommendation.

2.3 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328), 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327), 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) and 2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)

Justification for prioritisation

2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328) was identified as Substance of Very High Concern (SVHC) according to Article 57(d) and (e) of REACH as it meets the criteria of a PBT and vPvB substance. The substance was therefore included in the Candidate List for authorization on 17 December 2014, following ECHA's decision EC/108/2014.

The amount of UV-328 manufactured and/or imported into the EU is according to registration data in the range of 100 – 1000 tonnes per annum. All tonnage appears to be in the scope of authorization.

These uses include uses at industrial sites (e.g. formulation and use of preparations containing additives, formulation and use of master batches and compounds in the manufacture of plastic products, formulation and use of adhesives and sealants), uses by professional workers (e.g. use of additive resulting in inclusion into a matrix, including application in coatings, adhesives and plastics, use of polyurethane, use of adhesives or sealants) and uses by consumers (e.g. use of additive resulting in inclusion into a matrix, including application in coatings, adhesives and printing inks, use of polyurethane, use of adhesives or sealants). Furthermore, based on information from registrations and substance in article notifications the substance is used in articles (e.g. plastic articles).

2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320) was identified as Substance of Very High Concern (SVHC) according to Article 57(d) and (e) of REACH as it meets the criteria of a PBT and vPvB

substance. The substance was therefore included in the Candidate List for authorization on 17 December 2014, following ECHA's decision EC/108/2014.

There are no registrations for UV-320 under Regulation (EC) No 1907/2006 (REACH).

2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327) and 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) were identified as Substances of Very High Concern (SVHC) according to Article 57 (e) of REACH as they meet the criteria of a vPvB substance. The substances were therefore included in the Candidate List for authorization on 17 December 2015, following ECHA's decision ED/079/2015.

There are no registrations for UV-327 or UV-350 under Regulation (EC) No 1907/2006 (REACH). According to one substance in article notification, UV-327 is used in the scope of authorization in tonnages between 0 and 100 tonnes per annum. UV-327 is used at industrial sites and in plastic articles.

2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328) is the only registered substance from the group of phenolic benzotriazoles including UV-320, UV-327 and UV-350. Due to the structural similarities and similar physic-chemical properties it appears that the four phenolic benzotriazoles can be used as UV stabilisers in similar types of applications (e.g. in plastic articles coatings) indicating the potential to substitute each other in (some of) their uses.

Based on this information, 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328), 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327), 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) and 2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320) meet the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation no comments were received.

MSC *is of the opinion that 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328), 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327), 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) and 2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320) meet the criteria for prioritisation for inclusion in Annex XIV.*

Transitional arrangements: Latest application date and Sunset date

In its draft recommendation, ECHA proposed the following transitional arrangements for 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328), 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327), 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) and 2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320):

(i) Latest application date: Date of inclusion in Annex XIV plus 21 months;
(ii) Sunset date: Latest application date plus 18 months.

There were no comments received during the public consultation requesting changes in the proposed transitional arrangements.

MSC is of the opinion that the suggested latest application data and sunset dates are appropriate.

Proposed review period for certain uses

No review period was suggested by ECHA in its draft recommendation. No requests for review periods were received during the public consultation.

As the review period is closely connected to the use(s) for which the authorisation is requested and is set on a case-by-case basis when granting the authorisation, MSC is of the opinion that upfront specified review periods are not warranted in the recommendation for inclusion of substances in Annex XIV.

Proposed exempted (categories of) uses

ECHA did not propose any exemption of uses or categories of uses in its draft recommendation. No requests for exemption of uses or categories of uses were received during the public consultation.

Overall, MSC is of the opinion that no exemption under Article 58(2) for a use or a category of use should be included in Annex XIV.

PPORD exemptions

No exemptions for PPORD were suggested by ECHA. No requests for exemptions for PPORD were received during the public consultation.

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

Other issues

No other issues were raised during public consultation with regard to 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328), 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327), 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) or 2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320).

2.4 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5)

Justification for prioritisation

1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters (EC No. 271-094-0); 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters (EC No. 272-013-1) with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5) were identified as Substance of Very High Concern (SVHC) according to Article 57(c) of Regulation (EC) 1907/2006 (REACH) owing to their classification as Repr. 1B (*H360FD: May damage fertility. May damage the unborn child*). The substances are identified as SVHC only if they contain ≥ 0.3 % (wt/wt) of dihexyl phthalate (EC No. 201-559-5). This is due to the fact that dihexyl phthalate is covered by Index number 607-702-00-1 in part 3 of Annex VI to the Regulation (EC) No 1272/2008 (CLP), and that no specific concentration limits are set in Annex VI of the CLP Regulation and therefore the generic concentration limit is to be used for the purpose of determining the classification of substances (or mixtures) containing dihexyl phthalate. The substances were therefore included in the Candidate List for authorisation on 15 June 2015, following ECHA's decision ED/39/2015.

The amount of 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5)

manufactured and/or imported in the EU is, according to registration data, in the range of 100 - <1,000 t/y (ECHA, 2016). All tonnage appears to be in the scope of authorisation.

Substances have similarities in terms of structure or physico-chemical properties with other phthalates already included in Annex XIV. There are indications on the potential for using the substances in the same types of application (e.g. in adhesives).

Information about the uses is available only for the registered substance 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters (EC 271-094-0). Since 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters (EC 272-013-1) is not registered no information is available for that substance.

Registered uses of 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5) include uses at industrial sites (e.g. polymer processing - production of PVC compounds, formulation and use in coatings), uses by professional workers (e.g. use in adhesives, use in artist supply) and uses by consumers (e.g. lubricants and adhesives, building materials, artist supply). It should be noted that the supply of CMR substances to the general public is restricted pursuant to entries 28-30 of REACH Annex XVII, except for the use in artists' paint or the uses in mixtures in concentration lower than 0.3% and restriction for this substance applies from 1 January 2015. Therefore consumer uses in the EU, if still existing, should be limited to unrestricted uses. Furthermore, according to registration data the substance is used in articles (e.g. rubber and plastic articles, coated articles).

Based on this information, 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate meet the criteria for prioritisation for inclusion in Annex XIV.

Priority setting

During the public consultation no comments were received.

MSC *is of the opinion that 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate meet the criteria for prioritisation for inclusion in Annex XIV.*

Transitional arrangements: Latest application date and Sunset date

In its draft recommendation, ECHA proposed the following transitional arrangements for 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate:

(i) Latest application date: Date of inclusion in Annex XIV plus 24 months;
(ii) Sunset date: Latest application date plus 18 months.

MSC is of the opinion that the suggested latest application data and sunset dates are appropriate.

Proposed review period for certain uses

No review period was suggested by ECHA in its draft recommendation. No requests for review periods were received during the public consultation.

As the review period is closely connected to the use(s) for which the authorisation is requested and is set on a case-by-case basis when granting the authorisation, MSC is of the opinion that upfront

specified review periods are not warranted in the recommendation for inclusion of substances in Annex XIV.

Proposed exempted (categories of) uses

ECHA did not propose any exemption of uses or categories of uses in its draft recommendation. No requests for exemption of uses or categories of uses were received during the public consultation.

Overall, MSC is of the opinion that no exemption under Article 58(2) for a use or a category of use should be included in Annex XIV.

PPORD exemptions

No exemptions for PPORD were suggested by ECHA. No requests for exemptions for PPORD were received during the public consultation.

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

Other issues

No other issues were raised during public consultation with regard to 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate.

***Draft recommendation submitted for public consultation*, 2 March 2017**

Draft 8th Recommendation of Priority Substances to be included in Annex XIV of the REACH Regulation

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	5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] (karanal group)	-	-	vPvB	Date of inclusion in Annex XIV plus 18 months	Latest application date plus 18 months	None	None	None
2	1-Methyl-2-pyrrolidone (NMP)	212-828-1	872-50-4	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 18 months	Latest application date plus 18 months	None	None	None
3	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	247-384-8	25973-55-1	PBT, vPvB	Date of inclusion in Annex XIV plus 21 months	Latest application date plus 18 months	None	None	None
4	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	223-383-8	3864-99-1	vPvB	Date of inclusion in Annex XIV plus 21 months	Latest application date plus 18 months	None	None	None
5	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	253-037-1	36437-37-3	vPvB	Date of inclusion in Annex XIV plus 21 months	Latest application date plus 18 months	None	None	None

6	2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	223-346-6	3846-71-7	PBT, vPvB	Date of inclusion in Annex XIV plus 21 months	Latest application date plus 18 months	None	None	None
7	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5)	271-094-0, 272-013-1	68515-51-5, 68648-93-1	Toxic for Reproduction (category 1B)	Date of inclusion in Annex XIV plus 24 months	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 LADs were determined on the basis of the General approach for the preparation of draft Annex XIV entries for substances to be included in Annex XIV[6] and as further specified in the practical implementation document[7]. In particular the following considerations were made:

- The phenolic benzotriazoles are placed in the same slot since due to structural similarities group applications may be made.
- Application of the practical implementation method to the substances in this round resulted in the following order regarding the time estimated to prepare applications: karanal group < NMP < phenolic benzotriazoles < phthalate
- Three of the substances/substance group are expected to represent a relatively high workload for RAC, SEAC, ECHA-Secretariat, and the European Commission during the authorisation application and decision making phase and are therefore assigned to separate slots. These are NMP, the phthalate, and the group of four phenolic benzotriazoles. The karanal group on the other hand is expected to cause a relatively low processing workload and could therefore be allocated together with any one of the other substances/substance group in this recommendation round.

[6] General approach can be accessed at http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf
[7] Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_implementation_en.pdf/6fd729d4-4263-7d15-c2a2-13add8359b81