5 February 2018

# Response document

## Substance name: 1-methyl-2-pyrrolidone (NMP)

## EC-number: 212-828-1

## About this response document

The present document provides ECHA's responses to the comments received during the public consultation on its draft recommendation to include 1-methyl-2-pyrrolidone (NMP) in Annex XIV of the REACH regulation (list of substances subject to authorisation). The public consultation was held in the context of ECHA's draft 8th Annex XIV recommendation and took place from 2 March to 2 June 2017.

Although the responses aim to address individual comments, they have been compiled in a consolidated form structured by thematic block and level of information. This format intends to increase consistency and readability of responses and promote a better understanding of the authorisation process. In general, comments addressing same or similar issues have been assigned references to the same parts of the current document.

The responses to issues raised during the public consultation have been assigned to three thematic blocks, based on the following structure:

- **A. Priority and general issues**
  covers responses to issues related to the priority of the substances, including ECHA's prioritisation approach and its implementation in assigning priority scores and conclusions; also covers any other generic issue not covered by sections B and C;

- **B. Dates**
  covers responses to issues related to the latest application dates, sunset dates and review periods, including ECHA's approach for determining those timelines;

- **C. Exemptions**
  covers the responses to exemption requests, including ECHA's approach for evaluating those requests.



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Each thematic block (A, B, C) is further divided based on the level of information in the response, as follows:

1. **Process information**
   provides a summary of the principles applied by ECHA for its decision making relevant for each thematic block, as well as further information on aspects generally relevant (or non-relevant) for that decision. The process information has been developed based on the experience from previous recommendation rounds. It addresses issues commonly raised in comments submitted during the public consultation.

2. **Further responses relevant for the substance**
   provides responses to comments relevant for the substance not addressed in the process information.

The section headings in the process information and captions on the left of the responses provide a summary of the issue addressed per section / response. The headings and captions are also numbered (e.g. "A.1.2", "B.2.2"), to support the referencing to responses in the "Comments and references to responses document" and vice-versa; i.e. to allow tracking of the comment(s) the specific section/response in the current document refers to.



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# A. Priority and general issues

## A.1. Process information

### A.1.1. General, recommendation process

*1.ECHA's obligation to recommend/prioritise substances on the Candidate List*

As part of the authorisation process set out in Title VII of the REACH Regulation, ECHA has the obligation to recommend substances included in the Candidate List for inclusion in Annex XIV to the European Commission (Article 58 of REACH).

The prioritisation is the task of comparing those substances included in the Candidate List to determine which ones should be included first in Annex XIV. Substances not prioritised in one recommendation remain on the Candidate List and will be reassessed for priority in later recommendations together with the newly included substances in the Candidate List.

According to Article 58(3) and Recital (77), the number of substances included in each recommendation needs to reflect the capacity of ECHA and the Commission to handle applications in the time provided for as well as the workability and practicality for applicants preparing their applications for authorisation. The workability of the authorisation process necessitates a gradual inclusion of substances in Annex XIV.

*2.Legal basis for prioritisation*

According to Article 58(3), priority for inclusion into Annex XIV shall normally be given to substances with

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

Article 58(3) requires taking the mentioned three criteria 'normally' into account, but there is no provision how this should be done in practice. Moreover, the consideration of further aspects and criteria for priority setting is not excluded. Hence, Article 58(3) leaves discretion regarding the design of an approach used for prioritising Candidate List substances for inclusion in Annex XIV.

Information on the approach applied is provided below.



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*3.Prioritisation approach applied*

The prioritisation approach applied by ECHA was discussed with, and has been agreed by, the Member State Committee (MSC). Please refer to:
http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

It is noted that all priority setting approaches are conventions on how to systematically use the information chosen to be the basis for assessing the prioritisation criteria including how to weight and combine the criteria in qualitative and/or quantitative terms. To draw overall conclusions there is a need to integrate complex pieces of all relevant information. Therefore the assignment of weighting factors and scores remains to be done by expert judgement and by agreement amongst the users of the approach. In the case of the applied prioritisation approach this was done in the MSC.

The prioritisation is a comparative exercise supporting the conclusion on which substances to recommend first, i.e. the priority scores need to be considered in relation to each other and should not be seen in isolation.

The results of the priority assessment of all Candidate List substances using the prioritisation approach can be found at ECHA's website[1]. Further information on how the approach is applied in practice, especially on how the wide-dispersive use criterion is assessed, is provided in the "General approach for prioritisation of SVHCs: practical implementation examples"[2].

*4.Information taken into consideration for the draft recommendation*

For the purpose of its draft priority setting ECHA considers all relevant information available to it. The registration dossiers (including the CSRs) are the main source of information. It is the registrants' obligation to ensure that the information in the dossiers is clear, consistent and up-to-date. Further information e.g. from Annex XV SVHC dossiers and from SVHC public consultation is considered, where appropriate (see Section 4 of the prioritisation approach (linked in A.1.3)). Downstream user reports, PPORD and SiA notifications are used in addition when relevant.

*5.New information and next steps*

Relevant new information provided during the public consultation on the draft recommendation and in the registration dossiers (checked after closure of the public consultation), including any request for exemption, is taken into account (i) by the MSC when preparing its opinion on the draft recommendation and (ii) by ECHA when finalising its recommendation. ECHA also takes into account the MSC opinion when finalising its recommendation. The

[1] https://echa.europa.eu/documents/10162/13640/prioritisation_results_CL_substances_march_2017_en.pdf/391ae908-23f4-550d-94c9-090b922e50ec
[2] http://echa.europa.eu/documents/10162/13640/recom_general_prio_approach_implementation_examples_en.pdf



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*towards the final recommendation*

recommendation, together with MSC opinion, all comments received, and the responses to the comments, are submitted to the European Commission who makes the final decision on which substances to include in Annex XIV and on the details for the respective entries. All non-confidential information is also made available on ECHA's website.

New information provided during the public consultation on ECHA's recommendation is also used when finalising the substance specific background documents, if relevant, and according to its confidentiality status.

### A.1.2. Prioritisation: Volume

*1.Volume in the scope of authorisation*

The volume taken into consideration for priority setting is the volume for all uses in the scope of authorisation. That volume is derived based on data from the registration dossiers as provided in Section 3.2 and 3.5 of the IUCLID dossiers and/or in the CSRs, along with information presented in the Annex XV SVHC reports or information submitted during public consultation on SVHC identification of the substances. Where available, information on uses falling under the generic exemptions from authorisation[3] and on their related tonnage is assessed to estimate the volume relevant for the priority setting.

It is stressed, however, that the assessment of whether a use is in the scope of authorisation is done only for prioritisation purposes and it does not conclude or define the status of a use under the REACH Regulation (which is the responsibility of individual companies and subject to enforcement). In general, a realistic worst case approach is taken in cases where a clear conclusion on the intermediate status of the use or whether other exemptions apply is not possible on the basis of available data. The definition of intermediates as set out in Article 3(15) of the REACH Regulation, further elaborated and described in Appendix 4 of the 'Guidance on intermediates'[4] and in the 'Practical guide on intermediates'[5], is used to assess on the basis of available use descriptions (in the registrations incl. CSRs, the Annex XV SVHC reports and information received in SVHC public consultation) whether the identified uses are considered intermediate uses.

[3] A list of uses exempted from the authorisation requirement available at: http://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf
[4] https://www.echa.europa.eu/documents/10162/23036412/intermediates_en.pdf
[5] https://www.echa.europa.eu/documents/10162/23036412/pg16_intermediate_registration_en.pdf



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### A.1.3. Prioritisation: Wide-dispersiveness of uses

*1.Scope of the assessment of wide-dispersiveness of uses*

The wide-dispersiveness is assessed for the substance taking into account all uses within the scope of authorisation i.e. not only whether one use could be regarded as wide-dispersive or not wide-dispersive.

The assessment of wide dispersiveness of uses (WDU) comprises a general evaluation of the substance's use pattern, relying on basic indicators specified in the general prioritisation approach document (see A.1.3) – a methodology which ECHA has strived to apply in a consistent way for all substances assessed, driven by the comparative nature of the prioritisation process. It does not comprise an assessment of information such as detailed operational conditions, recommended/implemented RMM, exposure/risk assessment reported in CSR, or site-specific measurement data. Such assessment is beyond the scope of this step of the authorisation process.

More information can be found in Section 5.3 of the general prioritisation approach document[6] and in "General approach for prioritisation of SVHCs: practical implementation examples"[7]. Some of the main points are summarised below.

*2.Assignment of WDU score based on use types and their associated volumes*

In the prioritisation approach the wide-dispersiveness of uses is assessed based primarily on the types of actors which are relevant for the use of a substance. The underlying assumption is that, in general, when moving from consumer uses to professional uses to industrial uses, the expected control of releases increases (i.e. "dispersiveness" decreases) and the expected wide-spreadness (i.e. number/distribution of sites) decreases; thus the wide dispersiveness of uses decreases.

The full scores of higher WDU categories (professional and consumer uses) are assigned as long as the respective uses represented absolute volumes ≥ 10 t/y[8]. This is as consumer and professional uses can be regarded as having wide-dispersive pattern, regardless of how high the amount used at industrial sites is. In other words, the allocation of scores is based on the actual tonnage in different types of uses and not the share of the tonnage in different uses.

If there was reliable information indicating that the volume used by professionals or consumers was < 10 t/y, the WDU score is refined in a way that only half way up to the highest score category (professional or consumer) is assigned.

Furthermore, consumer uses for substances classified as Carc./Muta./Repr. 1A/B are not considered in the prioritisation score regardless of whether identified in registrations or not (as those are restricted[9] or, if in mixtures below the classification concentration limit, not in the scope of authorisation). For professional and industrial uses only the tonnage

[6] http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf
[7] http://echa.europa.eu/documents/10162/13640/recom_general_prio_approach_implementation_examples_en.pdf
[8] or unknown volumes, or ≥ 1t/y if the total volume in the scope of authorisation was < 10t/y
[9] Entries 28 to 30 of Annex XVII to REACH, unless the use is specifically derogated from this restriction



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above the relevant concentration limit is considered in those cases where this information is available in the registration dossiers or in other sufficiently reliable sources.

*3.Refinement of WDU score based on article service-life*

Although uses of articles containing a substance in the Authorisation List will not require authorisation, article service-life is still relevant in priority considerations. This is because in the authorisation-application phase the risks and benefits related to any article service-life subsequent to uses applied for need to be considered, too. The use of articles is usually widespread, with the exception of articles only intended for specific uses in industrial sites. The prioritisation approach explains how article service-life is taken into account in the assessment of priority.

Where registration data or other relevant information demonstrate that the substance ends up in articles, the initial WDU score (based on the use type) is refined upwards unless there is sufficiently reliable information that releases are unlikely during article service-life and waste phases.

It is stressed that no thorough assessment of exposure is done in this recommendation step of the authorisation process (see A.1.5.3). This applies also for the article service-life and waste phases of articles.

### A.1.4. Prioritisation: Further relevant considerations beyond Art.58(3) criteria

*1.Relevant further considerations*

The final conclusion on priority is drawn based on the assessment of the Article 58(3) criteria and consideration of additional aspects relevant for the recommendation. These additional aspects could be e.g. the grouping of substances (to take together SVHCs which could potentially replace prioritised or previously recommended SVHCs in some of their uses). There could be further considerations relevant for the prioritisation. It should also be noted that ECHA always aims to consider such additional aspects in a holistic way for the case at hand.

### A.1.5. Aspects not considered in ECHA's prioritisation

*1.Potential other regulatory actions*

In the process of recommending a Candidate List substance for inclusion in Annex XIV ECHA is not in the position to assess the pertinence of alternative regulatory risk management options to authorisation for the substance or some of its particular uses.

Any suggestion to address the concern raised by the substance via e.g. restriction of certain uses, or better enforcement of existing legislation for protection of workers, or the need to generate further information via substance evaluation



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prior to taking a decision on including the substance in Annex XIV are beyond the remit of ECHA in the recommendation process. The same applies for views that there is no need to initiate any further regulatory risk management action at this time.

Considerations on the most appropriate risk management options are usually discussed among authorities prior to proposing substances for inclusion in the Candidate List[10].

*2. Authorisation is disproportionate and/or means a ban*

The authorisation process aims at enhancing substitution when technically and economically viable alternatives are available. Until this is achieved the aim is to ensure proper control of risks.

Substances included on the Candidate List have been identified as substances of very high concern based on their hazardous properties. There is a societal interest to protect humans and/or the environment from risks potentially arising from the uses of these substances. At the same time, aspects such as the availability and suitability of alternatives, socio-economic, human health or environmental benefits of continuing a particular use or the (adverse) impacts of ceasing it[11], as well as information on the actual level of risk associated to a use of such substances are important. The authorisation process as a whole (inclusion in the Candidate List, inclusion in Annex XIV and application and granting the authorisations) takes into account and aims to balance these interests and aspects.

Authorisation does not ban the use of the substance. The use of substances included in Annex XIV can continue after their sunset date, provided a use-specific and applicant-specific authorisation is applied for and granted. It should be shown in the authorisation applications (and supported in the authorisation granting process) that either the risks arising from the use(s) applied for are adequately controlled or that there are no alternatives available and the socio-economic benefits outweigh the risks arising from the uses. Concomitantly, the obligation to apply for authorisation is a strong incentive (and duty) to search for and develop suitable alternatives.

*3.Use specific considerations*

The authorisation process foresees that the level of control of risks, the availability of and the time needed to transfer to suitable alternatives (e.g. due to need for established validation, safety requirements and/or performance standards) and socio-economic considerations such as the magnitude of benefits from continuing a certain use of an SVHC (i.e.

[10] The Public Activities Coordination Tool (PACT) lists the substances for which a Risk Management Option Analysis (RMOA) is either under development or has been completed since the implementation of the SVHC Roadmap commenced in February 2013. Available at: https://echa.europa.eu/pact

[11] These are impacts associated with the "non-use scenario" (e.g. the use of unsuitable alternatives), such as any acute/chronic effects, climate change impacts, cost of new equipment or production process, social security, employment etc.



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adverse impacts of ceasing a use) are not considered in the recommendation phase but are addressed at the application phase of the authorisation process. That is because it is this phase where the respective assessment can be done in an effective manner: based on structured input of information by the applicant, the foreseen dedicated public consultation for scrutinising the information on alternatives and the involvement of Committees having the respective expertise and mandate. Information on these aspects will be taken into account by the Committees for Risk Assessment and Socio-Economic Analysis (RAC and SEAC) when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.

*4.Control of risks*

ECHA considers that an assessment of the level of control or the level of exposure is not appropriate during the recommendation phase since it would shift the burden of proof back to authorities. Should a substance be included in the Authorisation List, such an assessment of exposure will be carried out by applicants for the uses they apply for as part of their authorisation application. The Risk Assessment Committee (RAC) will assess the appropriateness and effectiveness of the risk management measures as described in the application. There is also a possibility to specify in the authorisation decision further conditions, including monitoring requirements. This provides an additional level of scrutiny of the appropriateness of the control measures compared to the registration and downstream user obligations.

*5.Availability of suitable alternatives*

While for some uses in the short term there may not to be suitable alternatives, the authorisation title of REACH gives a long term incentive to find and deploy them when these alternatives are technically and economically feasible while enabling continued use where that is justified. Information on (lack of) availability of alternatives as well as on relevant research and development efforts is taken into account in the application and authorisation decision making phase.

*6.Socio-economic benefits of continued use*

Information about societal and economic benefits associated with a use is important in the application and authorisation decision making phase. In case risks are not demonstrated to be adequately controlled by an applicant or the authorisation can only be granted via the socio-economic route, the Socio-economic Analysis Committee (SEAC) compares the impacts to human health and/or the environment arising from the use of the substance with the benefits of the continued use. This is done when developing an opinion whether to grant an authorisation.



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*7.Potential competitive disadvantage*

Although subjecting the substance to authorisation may have an impact on individual companies in their capacity as manufacturers, importers, suppliers and/or users of the substance, these companies are generally not disadvantaged by this measure as it has the same impact on all other suppliers/users of the substance in the EU market, e.g. no matter whether a supplier is located outside or inside the EU. To the extent the substance may be present in imported articles, ECHA shall investigate after the sunset date if this poses a risk which is not adequately controlled. In that case it shall propose a restriction on these articles as per Article 69(2) of the REACH Regulation.

It is acknowledged that for certain production processes higher costs in comparison with competitors outside the EU may arise, if companies need an authorisation. These include for instance use of a substance as process chemical in the production of articles where the substance (or residues) does not end up in the article; or use in the formulation of mixtures having concentrations below the limit relevant for authorisation. Even though the use of the mixture is outside the scope of authorisation, still its formulation/production in the EU would require authorisation. The cost increase in these cases will apparently depend on the application fee and, in particular, on the costs of preparing the application. Its actual effect on the competitiveness of the respective industry in the EU will depend on the specific case (e.g. on the level of the overall production cost, including capital, raw material, and labour cost), but will often be relatively low.

Furthermore, it should be noted that not every actor on the market has to apply for authorisation of his use(s). This is because he can benefit from the authorisation granted to an actor up its supply chain[12]. It is further possible to submit joint applications by a group of actors.

*8.Uncertainty as to whether authorisation will be granted*

ECHA has made considerable effort to run the authorisation process in a transparent manner.

Commission, MSCAs, industry and ECHA have developed approaches and advice on how to prepare streamlined and fit-for-purpose applications.

ECHA has created a dedicated webpage "applying for authorisation" with the aim of guiding applicants in the preparation of their applications (http://echa.europa.eu/web/guest/applying-for-authorisation). This includes among others guidance documents, technical manuals, Q&As, and approaches agreed by the committees describing how applications are treated and evaluated.

[12] In accordance with Art. 62(1)(2) applications for authorisation may be made by the manufacturer(s), importer(s) and/or downstream users of a substance and for one or several uses. Applications may be made for the applicant's own uses and/or for uses for which he intends to place the substance on the market.



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The Risk Assessment Committee has been providing DNEL and dose-response relationships for almost all substances so far. This is a practice which it intends to continue, thus saving substantial time for the applicants and increasing the predictability of the process. Moreover, the Committee for Socio-economic Analysis has published an explanatory note providing clarifications on how it evaluates economic feasibility as part of applications for authorisation. Furthermore, the Committees have jointly agreed on the principle of the recommended length of the review period, which should increase predictability. ECHA informs on its website about the length of the review periods that its Socio-economic Analysis Committee proposes to the Commission in its opinion. This is normally seven years, but a long review period of e.g. 12 years is possible, too[13].

Further clarifications to potential applicants is provided via pre-submission information sessions with ECHA, in which future applicants for authorisation have the opportunity to ask case-specific questions regarding the regulatory and procedural aspects of the authorisation application process.

In addition, 'trialogues' are organised with applicants, Committee rapporteurs and interested parties during the opinion-making process. These activities are appreciated by applicants, as they have promoted efficient exchange of information during the process.

Seminars and workshops add to the support for applicants, in addition to the guidance and more formal documents that ECHA published.

As a result of these activities, the evaluation of applications for authorisation has become increasingly efficient and transparent.

By early 2018, over 120 applications for almost 200 uses from over 200 applicants have been submitted and are at various stages of processing[14]. They have been addressed in RAC and SEAC plenary meetings resulting in over 180 final opinions adopted and sent to the Commission for decision making. With the conclusions of each of those evaluations communicated at ECHA's website, predictability of the authorisation process should be less of an issue.

The level of support available and provided to involved companies (not only by ECHA, but also by many of its stakeholders) has been substantial and broadly acknowledged. ECHA will continue to develop its practices to provide fit-for-purpose support and increase predictability of the application for authorisation process even further.

[13] It should also be noted that an authorised use can be prolonged after the end of the review period. Authorisation holders have to submit a review report 18 months before the end the review period so that the authorised use could be prolonged.
[14] Up-to-date statistics on received applications at https://echa.europa.eu/received-applications



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## A.2 Further responses relevant for the substance

| Reference code | Issue raised in the comment(s) | Response |
|---|---|---|
| **A.2.1** | **Priority assessment: Unclarity on whether some uses in PPP and pharmaceuticals fall under the scope of authorisation** | Information available to ECHA indicates that NMP is used in the pharmaceutical sector and in the agricultural sector (plant protection) both as processing aid (e.g. as solvent in extraction, purification and/or crystallisation of substances) and as ingredient in the final formulations.<br><br>ECHA would like to clarify that<br><br>- Uses of NMP *as processing aid* fall in the scope of authorisation. Those uses and the related tonnage would need to be considered for the priority scoring (WDU and tonnage).<br><br>- Uses of NMP *in* pharmaceuticals and plant protection formulations appear to be outside the scope of authorisation. Those uses and the related tonnage would *not* be considered for the priority scoring.<br><br>However, to be able to take the above fully into account in the priority assessment, information on tonnage per use needs to be available (including the function of NMP) which was not the case. Therefore, estimations had to be made. Please refer to the final background document for further details.<br><br>In addition, you are invited to consult the final background document to the opinion by RAC and SEAC on the restriction proposal for additional information on uses of NMP in the agricultural and pharmaceutical sectors: https://echa.europa.eu/documents/10162/f6cd9c0f-47b0-48d0-abfa-8e4224b3620e. |
| **A.2.2** | **Priority assessment: Claim that ECHA used outdated information on uses (i.e. no reference to restriction report,** | As stated in the prioritisation approach (and further detailed in this response document), the registration data are the main source of information for the prioritisation assessment.<br><br>Registration data from 2016 was used for the priority assessment done for the 8th draft recommendation. Other sources of information were also used, among which the restriction report submitted by NL in 2013 (cited in Annex XIV background document as ECHA (2014) which is in fact an updated version of the restriction report). After closure of the public consultation, ECHA re-checked |



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| | **mentioning consumer use of printing inks)** | registration data for any updates submitted in the meantime and relevant for finalising the recommendation.<br><br>All registration information submitted to ECHA has to be kept up to date. It is the responsibility and the duty of registrants to update their registration information when needed without undue delay, e.g. in case of changes in use pattern. This is of particular relevance if you noted already some time ago that the registration information does not reflect the current situation.<br><br>The consumer use of printing inks is mentioned in registrations (see ECHA's dissemination website on registered substances (as of 2 June 2017): https://echa.europa.eu/search-for-chemicals). However, the consumer use of inks above the concentration limit resulting in the classification is banned from supply to the general public (as NMP is a reprotoxic substance). In accordance with the prioritisation approach that use was therefore not taken into account in the priority assessment (cf. also background document for NMP, Section 2.3).<br><br>The background document provided in the context of recommending substance for inclusion in Annex XIV aims to justify why a substance has been prioritised for recommendation. The uses are assessed with regard to their wide-dispersiveness (Section 2.3), however normally there is only a very brief use description. For some more details on specific uses of NMP, you are invited to consult the final background document to the opinion by RAC and SEAC on the restriction proposal https://echa.europa.eu/documents/10162/f6cd9c0f-47b0-48d0-abfa-8e4224b3620e.<br><br>In addition, the final Annex XIV background document makes the reference to the restriction report more clear. |
| **A.2.3** | **Priority assessment: Require ECHA to consider the lower priority of specific applications/uses** | Please note that the prioritisation approach (published on ECHA's website) is applied to prioritise and recommend substances from the Candidate List for inclusion in Annex XIV.<br><br>Within the priority assessment it is not intended to assess the risks arising from (specific) uses but to provide a very basic and general assessment of the use pattern and exposure potential a substance may have for humans (workers, consumers) or/and the environment, with the aim to compare it with other substances. The inclusion in Annex XIV is per substance and not per use (or installation). Therefore the priority score is derived considering all uses of a substance within the scope of authorisation. |



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| | | If the substance is included in Annex XIV the use and user specific conditions can be reflected in the authorisation application and they will be taken into account by ECHA's Committees when developing their opinions on the applications and by the Commission when taking the final decisions.<br><br>Please also refer to:<br><br>A.1.1.3 Prioritisation approach applied<br><br>A.1.2.1 Volume in the scope of authorisation<br><br>A.1.3.1 Scope of the assessment of wide-dispersiveness of uses<br><br>A.1.3.2 Assignment of WDU score based on use types and their associated volumes |
| **A.2.4** | **Priority assessment: Require ECHA to derive distinct scores for industrial and professional uses** | According to the prioritisation approach (published on ECHA's website), the criteria for volume and for WDU are assessed and scored separately.<br><br>The WDU score reflects whether the uses in the scope of authorisation are overall wide dispersive or not. If among the uses there are also professional applications, the substance is by default considered to have an overall wide dispersive pattern, provided that the professional uses represent absolute volumes > 10 t/y (or unknown volumes). This is because, as long as there are professional uses of not insignificant volumes, the substance may potentially lead to significant exposure to a considerable number of actors, regardless of how high the remaining amount used at industrial sites is.<br><br>It is acknowledged that all priority setting approaches are conventions on how to systematically use the information chosen to be the basis for assessing the prioritisation criteria, including an agreement how to weight and combine the criteria in qualitative and/or quantitative terms. The purpose of prioritisation is to define the order in which the substances on the Candidate List should be included in Annex XIV.<br><br>Use-type specific tonnage (i.e. tonnage per use and tonnage used in industrial, professional and consumer uses) is only rarely reported in registration dossiers. Therefore, it would be very difficult to use such information in the recommendation phase in a systematic manner.<br><br>Only the tonnage falling in the scope of authorisation is considered for the scoring.<br><br>Please also refer to A.1.1.3 Prioritisation approach applied |



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| **A.2.5** | **Priority assessment: Claim that the service-life is not relevant** | Producers and importers of articles must, under certain conditions, notify ECHA if any Candidate List substance (Substance of Very High Concern) is contained in their articles. Therefore, such notification is a legal obligation.<br><br>As can be seen on ECHA's website, a number of SiA notifications for NMP were received indicating its presence in articles.<br><br>In the public consultation a number of comment submitters, representing a significant share of the sectors where NMP can be used for the production of articles, pointed out that the substance is not or only in amounts <0.1% present in the final articles.<br><br>ECHA is not in the position to further verify or refute the information provided in the notifications of substances in articles which seem contradictory to the comments claiming non-presence of NMP in articles. Those comments did not either provide background documentation which would enable us to verify the information or enable us to conclude that these comments reflect the situation in the EU market.<br><br>To reflect this uncertainty a range of 0-2 is assigned for the article service life (instead of 2 in the draft recommendation) in the WDU assessment. This change is also reflected in the final background document where more information on the article service life of NMP can be found.<br><br>We would like to point out that even in case the WDU score was derived not accounting for any article service life, NMP is of high priority due to grouping considerations with DMF and DMAC.<br><br>For more information on Candidate List substances in articles and on their notification please refer to https://echa.europa.eu/information-on-chemicals/candidate-list-substances-in-articles-table<br><br>https://echa.europa.eu/regulations/reach/candidate-list-substances-in-articles/notification-of-substances-in-articles |
| **A.2.6** | **Priority assessment: Claim that more justification for grouping with DMF and DMAC is needed** | ECHA wants to highlight that the term "grouping" comprises different meanings in the two following consecutive steps of the authorisation process: prioritisation for Annex XIV recommendation and application for authorisation. |



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| | **(i.e. structural similarities, metabolism)** | Within the priority assessment, grouping can generally be applied for substances on the Candidate List for which the available information gives an indication that they could potentially replace other substances recommended or already included in Annex XIV, in (some of) their uses. This is described in Chapter 6 "Further considerations to be taken into account" of the prioritisation approach. https://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf/e18a6592-11a2-4092-bf95-97e77b2f9cc8<br><br>Grouping within the priority assessment is done with the aim to avoid replacing high-priority substances by low-priority substances in (some of) their uses. According to the prioritisation approach such grouping relates to the potential interchangeability of the substances in (some of) their uses.<br><br>The three polar aprotic solvents (DMAC, DMF, NMP) can be used (to some extent) interchangeably. This conclusion is based on registration information and has been confirmed by comments received in this public consultation.<br><br>In contrast to the grouping described above for the priority assessment, Article 62(3) REACH on applications for authorisation makes explicit reference to Section 1.5 of Annex XI of REACH. To apply for authorisation for a group of substances the definition of a group according to Section 1.5 of Annex XI needs to be met and structural similarity demonstrated. |
| **A.2.7** | **Priority assessment: Ask ECHA to reconsider the priority of NMP (based on the upcoming restriction)** | As part of the authorisation process set out in Title VII of the REACH Regulation, ECHA has the obligation to recommend substances included in the Candidate List for inclusion in Annex XIV to the European Commission (Article 58 of REACH).<br><br>To this end ECHA applies the prioritisation approach agreed (https://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf/e18a6592-11a2-4092-bf95-97e77b2f9cc8 ).<br><br>ECHA considers all legal requirements to which the substance may be subjected to when recommending substances for inclusion in Annex XIV, in particular with regards to the potential impacts on the uses and tonnage in the scope of authorisation (see Chapter 6 of prioritisation approach)<br><br>In 2013, the Netherlands submitted a restriction proposal for NMP, on which RAC and SEAC adopted their opinions in 2014. A decision on the restriction proposal by the European Commission is pending (more information can be found at: https://www.echa.europa.eu/web/guest/previous-consultations- |



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| | | on-restriction-proposals/-/substance-rev/1899/term). (See also response to issue A.2.10 Urging COM to proceed and finalise the restriction)<br><br>The suggested restriction proposes exposure limit values. The restriction, once it is implemented, may influence the level of control at industrial sites and professional settings. It needs to be seen, however, whether or to which extend the new limit values would have an impact on the volume in the scope of authorisation or the wide-dispersiveness of uses – factors which are taken into account in prioritisation. Nonetheless, grouping considerations with DMF and DMAC (both have already been recommended for inclusion in Annex XIV) apply.<br><br>Therefore, ECHA sees no reason to exclude NMP from the current Annex XIV recommendation based on its high priority. Both the decision on the Annex XIV inclusion and on the restriction is taken by the Commission. This enables the Commission to make sure that the next regulatory steps are taken in a complementary manner; the recommendation of the substance does not prevent or impede such complementary action.<br><br>See also responses:<br><br>A.1.5.1 Potential other regulatory actions<br><br>A.2.17 Request to regulate similar aprotic solvents (NMP, DMAC, DMF) in harmonised way<br><br>A.2.8 Perception that restriction and authorisation are alternative regulatory options / restriction preferred risk management option |
| **A.2.8** | **Perception that restriction and authorisation are alternative regulatory options / Restriction preferred risk management option** | Authorisation and restriction can be used in a complementary manner to ensure proper control of risk and provide an incentive to (continue to) develop alternatives (i.e. they do not exclude each other).<br><br>In the authorisation applications applicants should show for each use that the risks arising from the use(s) applied for are adequately controlled or that there are no alternatives available and the socio-economic benefits outweigh the risks arising from the uses. The authorisation process foresees that the availability of suitable alternatives and adequate control of risks for a use of an SVHC are addressed at the application for authorisation. It is this phase where the respective assessment can be done in an effective matter: use-specific scrutiny; based on structured input of information by the applicant; the foreseen dedicated public consultation for scrutinising this information; and the involvement of Committees having the respective expertise and mandate. |



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| | | The authorisation requirement provides the incentive for searching for alternatives and also the mechanism by which the outcome of an analysis of alternatives can be systematically documented and periodically reviewed by authorities.<br><br>It should be noted that in the process of recommending a substance for inclusion in Annex XIV ECHA is not in the position to assess the pertinence of alternative regulatory risk management options to authorisation for the substance or some of its particular uses. Therefore, any suggestion to address the concern raised by the substance via e.g. restriction of certain uses and whether this could be more appropriate than the authorisation requirement cannot be analysed by ECHA in the recommendation process. The same applies for views that there is no need to progress further with regulatory risk management actions at this point in time.<br><br>Please also refer to responses:<br><br>A.1.5.1 Potential other regulatory actions<br><br>A.2.7 Priority assessment: Ask ECHA to reconsider the priority of NMP (based on the upcoming restriction) and<br><br>A.2.17 Request to regulate similar aprotic solvents (NMP, DMAC, DMF) in harmonised way |
| **A.2.9** | **Claim that recommendation for Annex XIV inclusion contradicts the joint opinion of RAC and SEAC recommending restriction on NMP** | RAC and SEAC considered in their joint opinion that the proposed restriction is the most appropriate EU wide measure to address the identified risks but the committees did not consider if authorisation could be a complementary measure.<br><br>Please also refer to the response for:<br><br>A.2.8 Perception that restriction and authorisation are alternative regulatory options / restriction preferred risk management option,<br><br>A.1.1.1 on ECHA's obligation to recommend/prioritise substances on the Candidate List and<br><br>A.1.5.1 on potential other regulatory actions. |
| **A.2.10** | **Urging COM to proceed and finalise the restriction** | The compiled RAC and SEAC opinion on the NMP restriction proposal was submitted to COM in December 2014. After submission of the compiled RAC and SEAC opinion on a restriction proposal by ECHA to COM, the further actions and decision lie with COM and Member States. |



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| | | There has been further progress with regard to the restriction proposal. In the REACH Committee in October 2017 the Member States voted positively on the draft Annex XVII amendment prepared by COM that sets exposure limit values for workers. After scrutiny by the European Parliament and Council, the restriction could be adopted in the first half of 2018. Further details on the current status of the restriction proposal should be sought from the Commission. |
| **A.2.11** | **Claim that ECHA anticipates that the proposed restriction will not be implemented soon** | ECHA, when proposing NMP in its draft recommendation, did not consider the *timeline* of a possible adoption of the restriction proposal but rather its *impact* on the priority of the substance. The state of play of RAC and SCOEL joint work was provided as information only.<br><br>ECHA advices you to (re)consult the background document and the respective wording used therein.<br><br>Please refer also to:<br><br>A.2.10 Urging COM to proceed and finalise the restriction |
| **A.2.12** | **Claim that ECHA's Committees concluded that NMP is not replaceable in its existing uses, therefore authorisation inappropriate** | When evaluating the different RMOs presented in the restriction dossier, RAC and SEAC recognised that for some uses alternatives may be available (e.g. non-wire coating, professional cleaning, agrochemical formulation, construction materials). In general RAC and SEAC do not dispute the conclusion of the restriction dossier submitter concluding that technically equally good alternatives to NMP are available for some uses, but are lacking in other applications.<br><br>While in the short term there appear to be no alternatives for some of the uses, the authorisation title of REACH gives a long term incentive to find them and deploy them when these alternatives are technically and economically feasible.<br><br>The authorisation process foresees that the availability of suitable alternatives and adequate control of risks for a use of an SVHC are addressed at the application for authorisation. It is this phase where the respective assessment can be done in an effective matter: use-specific scrutiny; based on structured input of information by the applicant; the foreseen dedicated public consultation for scrutinising this information; and the involvement of Committees having the respective expertise and mandate.<br><br>The authorisation requirement provides the incentive for searching for alternatives and also the mechanism by which the outcome of an analysis of alternatives can be systematically documented and periodically reviewed by authorities. |



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| | | Please refer also to:<br><br>A.2.17 Request to regulate similar aprotic solvents (NMP, DMAC, DMF) in harmonised way |
| **A.2.13** | **Request harmonisation of OEL and DNEL by RAC and SCOEL** | As outcome of the restriction process RAC and SEAC recommended a harmonised DNEL via the inhalation route which differed from the iOEL established under Council Directive 98/24/EC5 following a scientific opinion of the Scientific Committee on Occupational Exposure Limits for chemical substances (SCOEL).<br><br>On becoming aware of the discrepancy, the Commission had asked RAC and SCOEL to work together to resolve the issue. As a result of this, on 30 November 2016 RAC proposed a modified DNEL for exposure of workers to NMP via the inhalation route.<br><br>There has been further progress with regard to the restriction proposal. In the REACH Committee in October 2017 the Member States voted positively on the draft Annex XVII amendment prepared by COM that sets exposure limit values for workers. After scrutiny by the European Parliament and Council, the restriction could be adopted in the first half of 2018. Further details on the current status of the restriction proposal should be sought from the Commission. |
| **A.2.14** | **Claiming RMOA as formal prerequisite to ECHA processes and referring to different conclusion made by NL** | The purpose of the RMO analysis is to support authorities in concluding whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern. We fully agree that preparing an RMO analysis early in the process (i.e. before initiating the SVHC identification process) promotes early discussion and helps to get a common understanding between authorities on the action pursued. However, it should be noted that preparing and discussing an RMO analysis is not a legally required step in REACH in general or during any phase of the authorisation process as defined in Title VII of REACH but is a voluntary action. It needs to be realised that the information and conclusions set out in an RMOA are those of the evaluating authority and do not necessarily reflect the position or opinion of other Member States or ECHA. Each Member State (or ECHA at request of the Commission) can decide on its own to propose a substance for inclusion in the Candidate List.<br><br>The RMO approach, as agreed in the SVHC roadmap, and the Public Activities Coordination Tool (PACT) that disseminates ongoing and concluded RMO analyses, were introduced in 2013. NMP was identified as SVHC and included in the Candidate List in June 2011.<br><br>But please also refer to responses: |



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| | | A.2.7 Priority assessment: Ask ECHA to reconsider the priority of NMP (based on the upcoming restriction)<br><br>A.2.8 Perception that restriction and authorisation are alternative regulatory options / restriction preferred risk management option<br><br>A.2.16 Claiming need for visibility and predictability of RMOA processes for industry<br><br>Find more information on ECHA's webpage on RMOA and consult the PACT:<br><br>https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/rmoa<br><br>https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact |
| **A.2.15** | **Claim that recommending NMP contradicts RMO Analysis and Member State expert opinion** | Representatives from Member State Competent Authorities, the European Commission and ECHA regularly convene in Risk Management Expert (RiME) meetings, which provide an informal platform to discuss and voluntarily coordinate activities related to regulatory risk management under REACH (see also https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/rime). Any suggestions, advice, common views and conclusions obtained at RiME are non-binding and only serve to support the work of the individual Member States and ECHA.<br><br>Please also refer to the response for:<br><br>A.2.14 Claiming RMOA as formal prerequisite to ECHA processes and referring to different conclusion made by NL<br><br>A.2.8 Perception that restriction and authorisation are alternative regulatory options / restriction preferred risk management option<br><br>A.1.1.1 on ECHA's obligation to recommend/prioritise substances on the Candidate List and<br><br>A.1.5.1 on potential other regulatory actions. |
| **A.2.16** | **Claiming need for visibility and predictability of** | ECHA has taken steps to improve transparency and predictability of its processes. ECHA's dissemination website (https://echa.europa.eu/search-for-chemicals) provides an overview under which REACH or CLP related process(es) a substance has been, currently is, or is intended to be |



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| | **RMOA processes for industry** | managed. In addition the so-called Public Activities Coordination Tool (PACT) (also available on ECHA Website: https://echa.europa.eu/pact) gives advance notice of the substances that are in the focus of authorities for exploring the potential need for regulatory risk management.<br><br>PACT lists the substances for which a risk management option analysis (RMOA) or an informal hazard assessment for PBT/vPvB (persistent, bioaccumulative, toxic / very persistent, very bioaccumulative) properties or endocrine disruptor (ED) properties is either under development or has been completed since the implementation of the SVHC Roadmap commenced in February 2013.<br><br>When available the conclusions of the RMOAs and outcomes of the informal PBT/ED assessments are made available.<br><br>ECHA is currently exploring the possibility to integrate further activities into the PACT e.g. evaluation processes.<br><br>Please also refer to the response for:<br><br>A.2.14 Claiming RMOA as formal prerequisite to ECHA processes and referring to different conclusion made by NL |
| **A.2.17** | **Request to regulate similar aprotic solvents (NMP, DMAC, DMF) in harmonised way** | DMAC and DMF were recommended previously for inclusion in Annex XIV. Recommending NMP will bring all three aprotic solvents at the same step in the authorisation procedure.<br><br>The Commission is developing a joint Risk Management Option Analysis (RMOA) to identify the best regulatory approach for the three aprotic solvents: Dimethylacetamide (DMAC), Dimethylformamide (DMF), methyl-2-pyrrolidone (NMP). This illustrates that the Commission is considering these three substances in a holistic manner. |
| **A.2.18** | **Claim that professional wide-dispersive uses will decrease due to lower concentration limit** | NMP is a reprotoxic substance. An authorisation requirement for the use of NMP in a mixture would apply if NMP is present above the concentration limit specified in the CLP Regulation, which result in the classification of the mixture as hazardous (Article 56(6)b of REACH).<br><br>The concentration limit for NMP (Repr. 1B) was recently lowered from 5 % to 0.3 % (9$^{th}$ ATP to CLP). There might be certain legislations/obligations (e.g. 94/33/EC) that could lead to a reduction in professional uses, e.g. because the use of certain mixtures previously allowed is now prohibited. |



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| | | However, it may also be possible that the number of industrial and/or professional users that fall under the authorisation requirement is higher when compared to the situation when the higher concentration limit was still in place.<br><br>Therefore, it is difficult to predict if and how the lower concentration limit will directly impact the professional wide-dispersive uses. |
| **A.2.19** | **Supplier informed that ECHA has included NMP in Annex XIV** | It needs to be clarified that, at this stage, NMP is not yet included in Annex XIV of the REACH Regulation. ECHA has the obligation to regularly recommend to the European Commission which substances from the Candidate List should be included in Annex XIV as a priority. The European Commission takes the final decision on which substances to include in Annex XIV and on the details of the respective entries.<br><br>Please refer to the following section of this response document for further information on ECHA's role in the recommendation process: A.1.1. General, recommendation process.<br><br>The list of substances recommended by ECHA for inclusion in Annex XIV can be found here https://echa.europa.eu/previous-recommendations (check the substance status).<br><br>The list of substances included in Annex XIV (authorisation list) following a decision of the European Commission can be found here https://echa.europa.eu/authorisation-list . |
| **A.2.20** | **Claiming risk of disruption of supply** | According to Article 55, the aim of the authorisation process is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable.<br><br>Authorisation does not ban the use of the substance. The use of substances included in Annex XIV can continue after their sunset date, provided a use-specific and applicant-specific authorisation is applied for and granted.<br><br>We strongly encourage all actors potentially impacted by the inclusion of NMP in Annex XIV to establish an active dialogue with the aim to (i) clarify the intention of the actors to continue the use/manufacture of the substance, (ii) identify/agree on who would apply for authorisation for certain use and (iii) define how the different actors can best contribute to the preparation of an application dossier. |



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| **A.2.21** | **Authorisation requirement impacts on companies not using the substance themselves** | It is acknowledged that the authorisation process for one substance may affect entire supply chain(s) including companies not using themselves the substance. Those companies are dependent on other companies to continue their use and cannot themselves apply for authorisation.<br><br>Communication, organisation and agreement between the relevant actors in the supply chain and efficient allocation of work are important aspects to consider by all actors involved, for allowing business decisions making for the time ahead and the management of the preparation of relevant applications. |
| **A.2.22** | **Claim that specific considerations for API manufacture are needed (as highly regulated, long approval processes, need for medication)** | We recognise that the manufacture of medicinal products must comply with specific requirements laid down by relevant regulations. This might involve e.g. certain product safety standards or approval procedures.<br><br>However, any such use-specific considerations cannot be taken into account in the recommendation phase but needs to be documented and substantiated in the application for authorisation.<br><br>Please see also:<br><br>A.1.5.2 Authorisation is disproportionate and/or means a ban<br><br>A.1.5.3 Use specific considerations<br><br>A.2.1 Priority assessment: Unclarity on whether some uses in PPP and pharmaceuticals fall under the scope of authorisation<br><br>C.2.4 Use as solvent in the manufacturing of active ingredients for medicinal products (API) |
| **A.2.23** | **Use as solvent for manufacture of polymers used in pharmaceutical industry and approved by government agencies (like EMEA or FDA)** | NMP used as a solvent in the manufacture of polymers falls within the scope of authorisation. If NMP was to be included in Annex XIV, an application for authorisation needs to be made to continue the use after the sunset date.<br><br>Polymers used in the pharmaceutical industry may need to comply with specific requirements laid down by relevant regulations. This might involve e.g. certain products safety standards or approval procedures. |



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| | | However, any such use-specific considerations cannot be taken into account in the recommendation phase but needs to be documented and substantiated in the application for authorisation and will be considered in the opinion and decision making phase.<br><br>Please see also:<br><br>A.1.5.2 Authorisation is disproportionate and/or means a ban<br><br>A.1.5.3 Use specific considerations<br><br>A.2.31 Claim that process aids/solvents (like NMP) are inadequately treated under REACH |
| **A.2.24** | **NMP crucial for planned new European battery production for electric vehicles** | When planning to introduce new manufacturing processes in the EU we encourage industry stakeholders to consider carefully all aspects before relying any new processes on substances of very high concern (SVHC). If after careful consideration of potential alternatives the use of an SVHC is deemed necessary, the work to identify potential alternatives and to define appropriate risk management measures and operational conditions to ensure the safe use of the SVHC in the process will provide a good basis for developing an application for authorisation.<br><br>ECHA and its Committees have experience in dealing with applications for authorisation for uses that are planned for the future and do not yet take place.<br><br>Please also refer to responses:<br><br>A.1.5.2 Authorisation is disproportionate and/or means a ban<br><br>A.1.5.3 Use specific considerations |
| **A.2.25** | **Burden of AfA for SMEs (some of which having niche applications)** | We take note of the concerns you raise in relation to SMEs.<br><br>Generally, such information is better placed in the call by the Commission for information on the possible socio-economic consequences of the inclusion of the substances in the Authorisation List.<br><br>Still, ECHA would like to note some observations based on the applications received by SMEs so far. During 2013-2016, 35 out of a total of 195 applications were made by SMEs. These showed that SMEs have been able to prepare and submit on their own applications for their niche uses. Other SMEs have formed a group of applicants (e.g. several Finnish platers for the use of chromium trioxide) |



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| | | SMEs can also be covered (without applying) under the umbrella of a more broadly defined use applied by upstream actors. If the authorisation is granted the SME downstream user company needs to notify ECHA free of charge about their use and ensure they comply with the conditions of the granted authorisation. |
| **A.2.26** | **Exposure is controlled since we work according to European/ international standards (e.g. BREFs, ISO 9001/14001, GMP)** | Please refer to A.1.5.4. Control of risks.<br><br>The authorisation system aims to improve (longer-term) substitution and increase the level of control of risk until substitution can happen. Whilst company-specific information on the control of exposure cannot be considered within the recommendation step, such information (e.g. on working techniques and quality management) can complement a potential future application since any risk management measures taken should be documented in AfA. For example, measured data generated in the context of other legislations could be used in an AfA to substantiate the appropriateness and effectiveness of RMMs in place as well as the assessments of exposures/emissions, risks or impacts. |
| **A.2.27** | **Applications where risk was not adequately controlled are already phased out** | According to Article 55, the aim of the authorisation process is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable.<br><br>From your comments we understand that an assessment has been performed in your value chain that has led to the phasing out of those applications where adequate risk control was sometimes not ensured. This is in line with the registration and downstream user obligations under REACH as well as with the aim of the authorisation process.<br><br>You have also indicated that the applications that have remained in service are those where the benefits of NMP are clear, justifying the continued use of NMP. This information is very valuable and should be provided in potential future AfA.<br><br>Substances of very high concern included in Annex XIV may normally be granted an authorisation if the applicant can show adequate control of risks (where applicable in accordance with Art. 60(3) of REACH) arising from the applied for uses or if there is no suitable alternative to the substance available and the socio-economic benefits of a use outweigh the associated risks for health and environment. |
| **A.2.28** | **Claim that substitution is not possible as** | The authorisation process aims to progressively replace all substances of very high concern (SVHC) by suitable alternatives as soon as technically and economically feasible, thereby reducing the overall |



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| | **alternatives are considered more hazardous or technically not feasible or are as well in regulatory focus** | risk arising from the use in question. Until substitution is achieved, the authorisation process aims to ensure proper control of risks.<br><br>Whether or not there are suitable alternatives available will be considered during the authorisation application and decision phase. Where there are no suitable alternatives available and the applicant wishes to continue the use after the sunset day, the applicant needs to demonstrate in its analysis of alternatives that this is the case. When assessing whether suitable alternatives are available, the Committees and the Commission take into account whether the transfer to alternatives would result in reduced overall risk as well as the technical and economic feasibility of the alternatives.<br><br>Please refer also to response A.1.5.2 Authorisation is disproportionate and/or means a ban. |
| **A.2.29** | **Substitution aspect adequately provided for by CAD, CMD, IED** | ECHA acknowledges that there is a body of EU legislative regimes in place addressing substances and/or uses that give some emphasis to substitution. However, considerations on the fact that the substance may be regulated in various EU legislative instruments are not taken into account in the priority setting but are addressed in the context of Art. 58 (2) exemption requests for which existing EU legislation is assessed case-by-case with regard to all the elements set out in that article. These pieces of legislation provide a broad framework generally addressing all actors and substances, and predate REACH, whose authorisation regime is more specific and can appropriately complement these pieces of legislation.<br><br>Please also refer to response A.1.5.1. on potential other regulatory actions. |
| **A.2.30** | **Claim that resources for innovation would be diverted to (possible) fruitless search for alternatives** | REACH is an EU Regulation aiming to ensure a high level of protection of human health and the environment while enhancing competitiveness and innovation. The obligation to apply for authorisation is to ensure that risks are adequately controlled or that socio-economic benefits are outweighing the risks, while concomitantly it is a strong incentive to search for and develop suitable alternatives. Substitution of an SVHC by suitable alternatives is seen as innovation. If a company cannot substitute an SVHC included in Annex XIV, it has to document it, justify and provide reasons for it in its application for authorisation. The overall aim is to facilitate a proportionate and efficient application process so that the exposure to humans and the environment relating to the use of substances of very high concern is minimised while maintaining the competitiveness of the EU industry.<br><br>Considering the search for alternatives for NMP that apparently has already happened, the additional work related to documenting the analysis of alternatives during the application for authorisation phase could be assumed to be relatively limited. It is stressed that the use of substances applied for can |



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| | | continue after the sunset date has expired, where the Commission has granted an authorisation, which is to be expected when applicants have a good case. |
| **A.2.31** | **Claim that process aids/solvents (like NMP) are inadequately treated under REACH** | There are currently no specific provisions under REACH for substances used as solvents or processing aids, similar to the provision existing for the substances used as intermediate. Therefore, ECHA has not ground to treat those substances differently. ECHA is not in a position to address any perceived shortcomings in the REACH regulation.<br><br>Information about societal and economic benefits associated with the use of a substance as process aid/solvent should be provided as part of an application for authorisation.<br><br>Authorisation will be granted if it is demonstrated that the risks are controlled or that socio-economic benefits outweigh the risks. |
| **A.2.32** | **Claim that through NMP authorisation requirement also production of non-SVHC substances and intermediates are affected by authorisation, which is contradicting REACH** | According to the REACH Regulation substances not identified as SVHC as well as intermediates cannot be subjected to the authorisation requirement.<br><br>ECHA recognises that the authorisation requirement of NMP could have an impact on the production of non-SVHC and substances used as intermediates.<br><br>However, the use of NMP raises concern, which can be addressed under authorisation. This is in line with the objective of REACH to improve the protection of human health and the environment.<br><br>The socio-economic impact of the authorisation requirement of NMP (including impact on the production of other substances) can be described in an application for authorisation and be addressed at that stage. The use of NMP can continue provided that an authorisation is applied for and granted.<br><br>Please also refer to A.1.5.6. on socio-economic benefits of continued use. |
| **A.2.33** | **Interpretation that the requirement for strictly controlled conditions is mandatory for intermediate use** | The requirement for strictly controlled conditions does not apply to all intermediate uses of a substance registered under REACH. Registrations according to Art. 10 of REACH can describe uses as intermediate when the substance is not handled under strictly controlled conditions. Strictly controlled conditions are only mandatory for intermediate uses of a substance registered according to Art. 17 or 18, requiring the registrant to provide less information on the substance.<br><br>Please also refer to response A.1.5.4 on control of risks. |



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| **A.2.34** | **Interpretation that 'advising use against' in registrations can be used as a tool by registrants to restrict uses in the supply chain** | Annex VI of REACH states that, where applicable an indication of the uses which the registrants advises against and why shall be provided. The uses advised against by a supplier are to be indicated in the SDS communicated down the supply chain.<br><br>However, it should be stressed that 'uses advised against' are non-statutory recommendations by the supplier: a use advised against is to be understood as a use that the registrant is aware of (either because it has been communicated by the downstream user or because of his own knowledge). He may have considered it unsafe after carrying out the CSA (or after concluding that insufficient information is available to consider the use safe). However, the use advised against can still be carried out in the EU, provided that a DU has assessed it to be safe in a DU CSA and has done the corresponding notification to ECHA according to Article 38.<br><br>Advising uses against should not be understood as a tool for registrants to impose use restriction in the supply chain. Furthermore, if not all registrants advice against the use, that use can still continue (also without a DU CSA).<br><br>For further information on Uses advised against please refer to p.34 of ECHA R12 guidance on use description. |
| **A.2.35** | **Asking to make comments available to the Commission** | Once the recommendation is finalised, all documentation including all comments received in the public consultation on the draft recommendation are sent to the Commission.<br><br>Note that during the public consultation, there is a parallel call for information by the European Commission on the possible socio-economic consequences of the inclusion of the substances in the Authorisation List. For reasons of transparency we would ask you in future to submit relevant information directly to that call if you wish to share it with the Commission.<br><br>Further information on the "call for information by the Commission" can be found here: https://echa.europa.eu/how-to-participate-in-the-parallel-call-for-information-by-the-european-commission |
| **A.2.36** | **Questionnaire on socio-economic consequences** | We note that you have submitted a filled-in questionnaire on "socio-economic consequences of including the substance in the Authorisation List" as part of your comment. This questionnaire seems to relate to the call for information by the Commission, which is parallel but different from ECHA's public consultation on the recommendation. Therefore your questionnaire has also been passed to the Commission for its consideration. |



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| | | Further information on the "call for information by the Commission" can be found here: https://echa.europa.eu/how-to-participate-in-the-parallel-call-for-information-by-the-european-commission<br><br>An overview of the types of information relevant to submit as part of ECHA's public consultation is available here: https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/public-consultation-in-the-authorisation-process. |
| **A.2.37** | **Estimated costs of an application for authorisation** | ECHA has systematically collected data on the costs of applications. Based on the information for 2013-2016, two findings are evident. Firstly, the application fees have been about 15-20 % of the total application cost and secondly, the total application effort has reduced by almost 50 % in 2016 compared to 2013. This is assumed to be due to, more expertise and better guidance provided on key information in the AfA as well as more consultants available.<br><br>The application effort – measured as the average cost of an application – is currently about EUR 140 000 in direct costs and the average number of internal staff months is just under 10 per use per applicant. However, there is considerable variability e.g. depending on whether it is an application made for an own niche use or whether it is an 'upstream' application intending to cover many downstream users.<br><br>The authorisation benefits not only the applicants but also their supply chain. This is in particular the case for 'upstream' applications. Another consideration is that the authorisations granted are valid for several years: the longer the length of the review period is, the lower the application cost per year. Given that the average length of the review is seven years, the average direct cost of an application per use and applicant is currently estimated to be about EUR 20 000 per annum.<br><br>For data until 2015 see: https://echa.europa.eu/documents/10162/13634/operation_reach_clp_2016_en.pdf (p.95). |



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# B. Dates

## B.1. Process information

### B.1.1. General principles for setting latest application dates / sunset dates

*1.Legal background*

Article 58(3) and Recital (77) of REACH provide that the latest application and sunset dates set for the substances included in Annex XIV shall take account of ECHA's capacity to handle applications in the time provided for as well as the workability and practicality for applicants preparing their applications for authorisation. Furthermore, the legal text specifies that the latest application date must be at least 18 months before the sunset date (Article 58(1)(c)(ii)) and the sunset date(s) for uses of a substance should where appropriate take into account the production cycles specified for those uses (Article 58(1)(c)(i)).

The document "General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV" describes how ECHA implements the above mentioned legal requirements in practice (available at: http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf.

*2.ECHA's proposal for sunset dates*

On the basis of the information available in the registration dossiers and submitted during public consultations on the draft recommendations, ECHA has so far not seen reasons or justification to deviate from the 18 months set out in the legal text or grounds to define criteria for such deviation(s) based on production cycles referred to in Article 58(1)(c)(i). Therefore, ECHA proposes a standard difference of 18 months between the application and sunset dates for all substances included in its draft recommendation.

*3.ECHA's proposal for latest application dates*

ECHA made its proposals for the latest application dates (LAD) on the basis of the earlier estimation that the time needed to prepare an authorisation application of sufficient quality might in standard cases require 18 months (roughly 12 months work-time for drafting the application and an additional buffer of 6 months for getting organised and consulting required external expertise). Based on discussions and experience on received applications so far, the applicants have not generally indicated that they have had difficulties with the stipulated time periods. Rather there had been problems for the first applicants preparing applications to have clarity on what information, analysis and justification was required in the applications. As over 160 opinions have already been given by RAC and SEAC, future applicants are in a better position than the first ones to prepare a fit-for-purpose application.

The work done and ongoing by the Commission, MSCAs, industry and ECHA to further develop approaches and advice on how to prepare a streamlined and fit-for-purpose application will also support the potential applicants concerned by substances in this recommendation. In this context, for example a step-by-step guide for applicants on how to apply



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for authorisation has been (December 2016) published on ECHA's website. Furthermore, there is ongoing work on applications for the specific cases of low volumes and legacy spare parts. It should also be noted that the requirements on communication of information down and up the supply chain (Title IV of REACH) as well as the downstream user obligations (Title V of REACH) have applied for some years. Implementation of and compliance with these requirements should as well support the organisation of the work within the supply chains related to the preparation of applications for authorisation.

Based on the above, establishing first LADs earlier than 18 months after inclusion in Annex XIV could even be considered. However, providing sufficient time to the applicants to get organised within sectors and prepare an application that provides a solid basis for the decision making is important. Therefore, it does not seem to be justified to propose shorter LADs.

On the other hand, ECHA further considered if the first LAD should be set later than 18 months after inclusion in Annex XIV. The complexity of the supply chain has been considered to be one, potentially the main, factor affecting how much time is needed in addition to the drafting of the different parts of an application. Structure and complexity of the supply chain has an impact on both the time needed to gather the information and on how to best organise the application (who will apply, which uses will be covered). Indeed, for substances with complex supply chains organisation, planning, and collection of information may require longer time than for short and simple supply chains, especially when applications will be made by actors high up in a complex supply chain. They may need to collect information from many layers of actors in the supply chain and these layers may not have clear contact points and co-ordinators. A longer time might also be needed in case many downstream users decide to make one joint application as this may require extensive communication with different actors to clarify who possesses the required information, who would actually apply and how to establish the knowledge and staff resources needed.

The complexity of the supply chain could potentially be assessed based on the number of different uses and affected industry sectors, the number of layers in the supply chain, the number and type of companies concerned, and the way potential future applications will be organised[15]. However, ECHA has currently insufficient information to define clearly enough the factors which it should take into account for this assessment. Furthermore, ECHA is currently unable to define precisely what type of information would be used to characterise the above-mentioned factors. Therefore, it is concluded that ECHA currently does not have enough information to justify a prolongation of the first LAD, i.e. the 18 months slot.

[15] E.g. existence of consortia and their experience, size and location; knowledge about if applications will be made mainly upstream and cover downstream uses, or if rather many downstream applications will be made.



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In sum, ECHA considers that a standard LAD of 18 months for the preparation of a well-documented application for authorisation is still valid.

The anticipated workload of ECHA's Committees and Secretariat to process authorisation applications is accounted for by grouping the proposed substances in slots, normally 3, and setting the application dates with 3 months intervals in between the slots. From the applicant's point of view it is beneficial to have these dates to coincide with (the last days of) the "submission windows" for submitting the applications.

The time differences between the LADs set out in a recommendation are relatively short, typically ranging from 3 to 6 months, compared to the total time reserved for the potential applicants to prepare their applications. ECHA proposes to allocate those substances to the "later" LAD slots for which the available information indicates a relatively high number of uses and/or complex supply chain(s). Furthermore, substances with no registration requirement are allocated to the later slots. ECHA has developed a practical implementation method to support a more consistent and transparent assessment of these criteria[16].

### B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates

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| *1.Extensive time needed in the supply chain to get organised for preparing application (e.g. due to high number of users)* | Based on ECHA's approach, substances with more complex supply chains and likely higher number of uses will normally be allocated to the "later" latest application date slots (i.e. 21 or more months after the inclusion in Annex XIV).<br><br>Communication, organisation and agreement between the relevant actors in the supply chains and efficient allocation of work are important aspects to get the application(s) ready in time. The standard period of 18 months considered by ECHA as the shortest application date already includes the time for getting organised and consulting external expertise.<br><br>The application for authorisation is the last step of a multi-step process where previous steps should already raise awareness about the substances under consideration for inclusion in the Authorisation List. It is also important to note that the application process is not anymore a "new" process but has been in place for some time now. |
| *2.Lack of alternatives, socio-economic aspects* | It is stressed that the present lack of alternatives to (some of) the uses of a substance, the time needed to transfer to alternatives (e.g. due to need for established validation, safety requirements and/or performance standards) as well as other socio-economic or practical considerations are not viable reasons for prolonging the latest application dates or sunset dates. |

[16] https://www.echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf



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Should ECHA know that there would not be technically and economically feasible alternative substances or techniques, this could be taken into account. If such evidence existed, the analysis of alternatives would be a straight forward exercise, and so would also the socio-economic analysis which would imply a relatively short LAD. However, ECHA does not normally have such information when preparing the recommendation as this becomes available only at the application stage. Thus, ECHA does not intend to use this as a criterion to shorten the LADs.

Socio-economic or practical considerations are no relevant reasons for prolonging or advancing the latest application dates or sunset dates as these considerations are normally use and sector or even case specific and difficult to take into account in the recommendation phase which considers all uses of the substance. Furthermore, such information would be very difficult to get at the prioritisation stage in a systematic manner. Therefore they are considered at the next phase of the authorisation process (application for authorisation and granting phase).

Authorisation, inter alia, aims to promote the development of alternatives. Article 55 explicitly stipulates that applicants for authorisation shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.

If a suitable alternative to a substance included in Annex XIV will be available before the foreseen sunset date, i.e. the date from which the placing on the market and the use of the substance is prohibited unless an authorisation is granted (Art. 58 (c) (i) of REACH), no application for authorisation of the current use of the substance would be required.

### B.1.3. Review periods

*1.Upfront review periods*

Setting 'upfront' review periods for any uses would require that ECHA had access to adequate information on different aspects relevant for a decision on the review period. So far such information was not available to ECHA at the recommendation step. Therefore, ECHA has not proposed any upfront specific review periods in its draft recommendations for inclusion in the Authorisation List. It is to be stressed that all authorisation decisions will include specific review periods which will be based on concrete case-specific information provided in the applications for



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authorisation. ECHA has published guidance on the type of information in an application for authorisation which may impact the review period when granting an authorisation[17].

## B.2 Further responses relevant for the substance

| Reference code | Issue raised in the comment(s) | Response |
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| **B.2.1** | **Questioning setting of LAD for NMP (which is reasoned by e.g. complexity of supply chain, lack of alternatives, time needed to change)** | ECHA is required to propose transitional arrangements as part of its recommendation for inclusion of substances in Annex XIV. The general approach for the preparation of draft Annex XIV entries describes how ECHA determines LADs in a particular round: https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf/2b80fc7f-fc40-4c1a-971f-023691baf702<br><br>Based on comments received in the past, ECHA has made efforts to further enhance the transparency on how LAD are assigned in one recommendation round. A practical implementation document for setting LAD was developed in preparation of the 8th draft recommendation: https://www.echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf<br><br>The document describes the factors considered to impact the time needed to prepare an AfA. In addition it reflects also on their systematic assessability, i.e. the possibility to use them in practice when assessing the time needed to prepare an application. It needs to be remembered that no detailed analysis of the factors considered (which are e.g. vertical and horizontal complexity of supply chain) is done but that the approach aims to roughly indicate the time needed to prepare applications in line with the main purpose of comparing a limited number of substances in one recommendation round for assigning them to LAD slots. Furthermore it should be noted that the actual allocation of substances |

[17] SEAC's approach for establishing the length of the review period (http://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf) and RAC's and SEAC's guidance paper on opinion trees for non-threshold substances (http://echa.europa.eu/documents/10162/13637/opinion_trees_non_treshold_subs_en.pdf)



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| | | to LAD slots needs to take also AfA processing-workload considerations for the Committees, ECHA-S and the Commission into account (for further details please refer to the implementation document).<br><br>ECHA normally sets latest application dates in three slots at 18, 21 and 24 months after inclusion in Annex XIV. Only in its 6th recommendation, which included 15 substances, an additional LAD slot at 27 months was proposed in order to distribute the workload more evenly.<br><br>Applying the criteria described in the implementation document the time required for the preparation of application(s) for authorisation for NMP was assumed to be relatively shorter than for other (groups of) substances included in the draft recommendation. During the public consultation comments by many sectors were received based on which the complexity of supply chain (horizontal, vertical and number of industrial use sites) was reassessed. That complexity seems relatively higher for NMP compared to the other substances in this recommendation round.<br><br>**Consequently, ECHA has reconsidered the LAD slots to be recommended (NMP changed from 18 to 24 months).**<br><br>As clarified in this response document (B.1.1.3 ECHA's proposal for latest application dates), the requirements on communication of information up and down the supply chain (Title IV of REACH) as well as the downstream user obligations (Title V of REACH) have applied for some years. Implementation of and compliance with these requirements should therefore support the organisation of the work within the supply chains related to the preparation of applications for authorisation, and are not considered a valid argument to lengthen the LAD.<br><br>Similarly, a present lack of alternatives and the claim that time is needed to transfer to alternatives cannot be used for lengthening the LAD. Respective information is assessed and fully taken into account in the application for authorisation phase.<br><br>ECHA welcomes all proposals and comments on the method to improve the LAD assignment in a consistent manner. However, for any changes of the method it needs to be kept in mind that the chosen assessment criteria (i.e. that factors considered) are assessable and available for ECHA at the recommendation step.<br><br>B.1.1.3 ECHA's proposal for latest application dates<br><br>B.1.2.2 Lack of alternatives, socio-economic aspects |



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| **B.2.2** | **Claim that SEA is difficult for process solvents and therefore minimum of 36 months LAD is appropriate** | The draft Annex XIV entries approach (https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf/2b80fc7f-fc40-4c1a-971f-023691baf702) details the grounds on which LAD slots are determined and how substances are allocated to these slots. The fact that a substance is used for a specific function therefore does not justify the prolongation of the LAD, i.e. the use of NMP as process solvent is in itself not relevant for allocating NMP to a specific slot. We would like to add that ECHA has no information indicating that in general preparing a SEA would be more complicated for process solvents than for other types of uses. The comment did not either provide further information supporting this claim.<br><br>Applying the criteria described in the implementation document the time required for the preparation of application(s) for authorisation for NMP was assumed to be relatively shorter than for other (groups of) substances included in the draft recommendation. During the public consultation comments by many sectors were received based on which the complexity of supply chain (horizontal, vertical and number of industrial use sites) was reassessed. That complexity seems relatively higher for NMP compared to the other substances in this recommendation round.<br><br>**Consequently, ECHA has reconsidered the LAD slots to be recommended (NMP changed from 18 to 24 months).**<br><br>It seems that you may consider the preparation of an upstream application that covers many uses of NMP. As this is one but not the only approach that can be taken when preparing an application, we recommend to start early on with assessing the advantages and disadvantages of the different types of AfA to identify the one that fits best your specific needs. Please refer to the practical guide on how to apply for authorisation (December 2016) which covers also submission strategies https://echa.europa.eu/documents/10162/13637/apply_for_authorisation_en.pdf/bd1c2842-4c90-7a1a-3e48-f5eaf3954676<br><br>Please also refer to:<br><br>B.1.1.3 ECHA's proposal for latest application dates<br><br>B.1.2.1 Extensive time needed in supply chain to get organised for preparing AfA<br><br>B.2.1: Questioning setting of LAD for NMP (which is reasoned by e.g. complexity of supply chain, lack of alternatives, time needed to change) |



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| **B.2.3** | **No preparations for authorisation were undertaken since industry awaited NMP restriction** | As further detailed in sections B.1.1.3 and B.1.2.1 of this response document, ECHA considers a time period of 18 months sufficient to prepare an application for authorisation of adequate quality. This is based on experience from previous applications and discussions with applicants.<br><br>The application for authorisation is the last step of a multi-step process where previous steps should already raise awareness about the substances under consideration for inclusion in the Authorisation List.<br><br>NMP was added to the Candidate List in June 2011.<br><br>Generally it can be said that the requirements for good-quality AfAs are better known compared to the earlier years. Industry as well as consultants have gained experience in preparing AfAs. Hence a time period of 18 months seems sufficient to prepare a fit-for-purpose AfA.<br><br>In the specific case of NMP, the restriction process should also have raised awareness about the concerns related to the substance. It can be assumed that actors impacted by the possible restriction have started collecting information that would also be relevant to prepare an application for Authorisation. B.1.1.3 ECHA's proposal for latest application dates<br><br>Please also refer to:<br><br>B.1.1.3 ECHA's proposal for latest application dates<br><br>B.1.2.1 Extensive time needed in supply chain to get organised for preparing AfA<br><br>B.2.1: Questioning setting of LAD for NMP (which is reasoned by e.g. complexity of supply chain, lack of alternatives, time needed to change) |
| **B.2.4** | **Claim that there has been a moratorium on regulatory action on NMP since 2014 which needs to be considered as "no time having passed"** | As further detailed in sections B.1.1.3 and B.1.2.1 of this response document, ECHA generally considers a time period of 18 months sufficient to prepare an application for authorisation of adequate quality. This is based on experience from previous applications and discussions with applicants. The recommended LAD begins at that point in time when the substance is included in Annex XIV by COM. Therefore, even with the shortest LAD of (normally) 18 months there should be sufficient time for preparation of an AfA. Nonetheless ECHA generally advises to start all preparatory work related to AfA as early as possible. |



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| | | The final decision to include substances in Annex XIV (Authorisation List) and in Annex XVII (List of restrictions) is taken by the COM (and MS).<br><br>Finally, ECHA would like to remind that the application for authorisation is the last step of a multi-step process where previous steps should already raise awareness about the substances under consideration for inclusion in the Authorisation List. NMP was added to the Candidate List in June 2011.<br><br>Please also refer to:<br><br>A.2.8 Perception that restriction and authorisation are alternative regulatory options / Restriction preferred risk management option<br><br>B.1.1.3 ECHA's proposal for latest application dates<br><br>B.1.2.1 Extensive time needed in supply chain to get organised for preparing AfA<br><br>B.2.1: Questioning setting of LAD for NMP (which is reasoned by e.g. complexity of supply chain, lack of alternatives, time needed to change) |
| **B.2.5** | **Claim that later LAD is required to have time to prepare a robust AfA (to support long review period)** | As further detailed in sections B.1.1.3 and B.1.2.1 of this response document, ECHA considers a time period of 18 months sufficient to prepare an application for authorisation of adequate quality. This is based on experience from previous applications and discussions with applicants.<br><br>An analysis of alternatives is required in all applications for authorisation according to Art. 62(4)(e) of REACH. Therefore, an applicant for authorisation must document an analysis of alternatives in his application. That analysis should comprise a description of all efforts made by the applicant in search for alternatives. The more specific the use applied for authorisation is, the easier it is to build a robust analysis of alternative. Long re-qualification/validation periods that are necessary to implement an alternative, if well explained and justified in the Analysis of Alternatives, can be very relevant to build a solid case for a long review period. Moreover, demonstration by applicant of adequate control as well as other SEA aspects can provide further arguments for long review periods.<br><br>It should also be noted that an authorised use can be prolonged after the end of the review period. Authorisation holders have to submit a review report 18 months before the end the review period so that the authorised use could be prolonged. |



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| | | Please refer also to:<br><br>B.1.2.2 Lack of alternatives, socio-economic aspects<br><br>B.2.1: Questioning setting of LAD for NMP (which is reasoned by e.g. complexity of supply chain, lack of alternatives, time needed to change)<br><br>B.1.3.1 on upfront review periods that includes also a link to the note by RAC and SEAC which explains how the length of the proposed review period is determined. |
| **B.2.6** | **Claim that later LAD is required due to inexperience with REACH** | As further detailed in sections B.1.1.3 and B.1.2.1 of this response document, ECHA considers a time period of 18 months sufficient to prepare an application for authorisation of adequate quality. This is based on experience from previous applications and discussions with applicants (many of them having applied for the first time, including companies from the pharmaceutical sector).<br><br>It is recognised that the preparation of an application is likely to be faster with an experienced (e.g. sectors with previous involvement in other REACH or CLP processes), well-organised consortium/company. By early 2018, over 120 applications for almost 200 uses from over 200 applicants have been submitted. A number of industry sectors and consultants have developed valuable experience which individual companies can benefit from.<br><br>ECHA cannot generically assess the readiness of an individual company.<br><br>Factors that can be considered or not in setting LAD are described in the practical implementation document:<br>https://www.echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf<br><br>Please also refer to:<br><br>B.2.1: Questioning setting of LAD for NMP (which is reasoned by e.g. complexity of supply chain, lack of alternatives, time needed to change) |
| **B.2.7** | **Claim that there is no argument justifying any shorter LAD than** | As described in ECHA's general approach for the preparation of draft Annex XIV entries and further detailed in B.1.1.3, ECHA considers 18 months as the standard latest application date. Normally three |



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| | **the standard LAD of 24 months** | slots are proposed with 3 months intervals in between the slots which normally correspond to 18, 21, 24 months after inclusion in Annex XIV.<br><br>ECHA considers a time period of 18 months generally sufficient to prepare an application for authorisation of adequate quality. This is based on experience from previous applications and discussions with applicants.<br><br>It should be noted that ECHA has made considerable effort to run the authorisation process in a transparent and efficient manner which should support industry in preparation of their applications. Commission, MSCAs, industry and ECHA have developed approaches and advice on how to prepare streamlined and fit-for-purpose applications (see also response A.1.5.8.) Industry as well as consultants have gained experience in preparing AfAs.<br><br>Draft Annex XIV entries approach:<br>https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf/2b80fc7f-fc40-4c1a-971f-023691baf702<br><br>Please also refer to:<br><br>B.1.1.3 ECHA's proposal for latest application dates<br><br>B.2.1: Questioning setting of LAD for NMP (which is reasoned by e.g. complexity of supply chain, lack of alternatives, time needed to change) |
| **B.2.8** | **Claim that proposing no review period is contradiction to Art. 60 and 61 of REACH** | In ECHA's draft Annex XIV entries approach (https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf/2b80fc7f-fc40-4c1a-971f-023691baf702) as well as in Section B.1.1.3 above, the reasons are given why ECHA has not proposed upfront review periods.<br><br>Article 60 on granting authorisations and Article 61 on reviewing authorisations relate to Commission's role in this part of the authorisation process, not to ECHA's role in recommending priority substances to be included in Annex XIV.<br><br>Please also refert to B.1.1.3 on ECHA's proposal for latest application dates. |



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| **B.2.9** | **Request long review period to guarantee supply with lifesaving drugs** | The decision on the length of the review period is taken by the Commission in the next step of the authorisation process based on the RAC and SEAC opinions, i.e. in the application for authorisation phase.<br><br>The current approach of ECHA's Committees is to recommend to the Commission review periods of four, seven or twelve years. RAC and SEAC have agreed on how the length of the review period they propose is determined: https://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf/c9010a99-0baf-4975-ba41-48c85ae64861.<br><br>Authorisation holders can submit a review report 18 months before the end the review period so that the authorised use could be prolonged.<br><br>We would like to remind that the applicant in his application should provide all information and arguments related to his specific circumstances which are relevant for setting the length of the review period.<br><br>Please also refer to B.1.3. Review periods. |
| **B.2.10** | **Claim that LAD and SSD for uses as extraction solvents are not acceptable due to safety reasons (exposure controlled, unsafe substitutes, delocalisation would increase risk for workers)** | Information on the level of control or level of exposure is not considered in the recommendation phase (see A.1.5.4 on control of risks). In particular, risks arising from the use of substances other than NMP (e.g. benzene and butadiene) cannot be considered when proposing latest application and sunset dates for NMP. This information should be included in a possible application for authorisation and will be considered in the decision phase.<br><br>Once a substance is included in Annex XIV, the latest application and sunset dates apply to all uses of this substance and normally no deviating dates for specific uses are defined.<br><br>Please also refer to B.1.2.2 on lack of alternatives, socio-economic aspects. |
| **B.2.11** | **Claim that substitution is not possible before sunset date** | Authorisation, inter alia, is a means to promote the development of alternatives. Article 55 explicitly stipulates that applicants for authorisation shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution (this has to be included in the analysis of alternatives to be submitted as part of the authorisation application in accordance with Art. 62 (4e)). Therefore, a present lack of alternatives to (some of) the uses of a substance as well as the |



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| | | need to complete R&D programmes and validation processes to get qualified alternatives are not viable reasons for postponing the subjection of a substance or some of its uses to authorisation.<br><br>Information regarding lack of suitable alternatives and the time needed for revalidation/requalification is however important information to be included in an authorisation application. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.<br><br>Please also refer to B.1.2.2 on lack of alternatives, socio-economic aspects. |



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# C. Exemptions

## C.1. Process information

### C.1.1. General principles for exemptions under Art. 58(2)

Uses (or categories of uses) can be exempted from the authorisation requirement on the basis of Article 58(2) of REACH. Furthermore certain uses fall under the generic exemptions from authorisation[18].
According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses '*provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled*'.

- The decision to grant an exemption from the authorisation requirement under Article 58(2) is taken by the Commission, taking into consideration ECHA's recommendation. The Commission enjoys discretion in deciding whether or not to provide exemptions from authorisations pursuant to Article 58(2) REACH within the limits of EU law, including the proportionality principle. https://echa.europa.eu/documents/10162/13640/8th_recom_draft_axiv_entries_en.pdf/d767eafc-53b9-3732-382d-b76f62716c2a

ECHA further recalls that it is apparent from the terms of Article 58(2) that:

(a) The obtaining of an exemption is a possibility and not an entitlement;

(b) The discretion afforded to the Commission only ever arises where there is specific minimum EU legislation in place imposing minimum requirements relating to the protection of human health or the environment for the use of the substance ensuring the risk is properly controlled; it should be noted that in the absence of existing specific EU legislation in force, the Commission is prohibited from granting an exemption on the basis of Article 58(2) in respect of the substance listed in Annex XIV of REACH; it is therefore not sufficient if there is national legislation governing such use or a Commission communication;

(c) Risk assessment and the question as to whether individual operators are able to control risks associated with the use of a substance of very high concern are not included among the criteria that may constitute a basis for the granting of exemptions of a use. In the absence of specific Union legislation the Commission has no discretion to grant an exemption under Article 58(2) of the REACH Regulation regardless of the outcome of risk assessment.

[18] http://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf



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In preparing its recommendation ECHA will consider the following elements in deciding whether to recommend an exemption of a use of a substance[19] (also described in the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV[20]):

- There is existing EU legislation (i.e., rules of law adopted by a European Union entity intended to produce binding effects) addressing the specific use (or categories of use) that is proposed to be exempted. Special attention has to be paid to the definition of use in the legislation in question compared to the REACH definition of use set out in Article 3(24) of REACH. Furthermore, the reasons for and effect of any exemptions from the requirements set out in the legislation have to be assessed;
- The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to a group of substances that is clearly distinct from other substances. A mere reference to carcinogenic, mutagenic or reprotoxic substances may be too general and requires case-by-case assessment;
- The existing EU legislation imposes minimum requirements for the control of risks of the use. The piece of legislation (i) has to define the minimum standard to be adopted in the interest of public health or the environment and (ii) allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in the EU legislation in question. Legislation setting only a general framework of requirements or the aim of imposing measures (e.g., EU legislation which provides Member States the possibility to impose less stringent requirements than that suggested by the EU legislation in question) or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

On the basis of the elements above:

(i) Only existing EU legislation is relevant in the context to be assessed (not national legislation).
(ii) Minimum requirements for controlling risks to human health and/or the environment need to be imposed in a way that they cover the life cycle stages that are exerting the risks resulting from the uses in question.
(iii) There need to be binding and enforceable minimum requirements in place for the substance(s) used.

[19] For further information, see the judgment of the General Court in Case T-360/13: *Verein zur Wahrung von Einsatz und Nutzung von Chromtrioxid und anderen Chrom-VI-verbindungen in der Oberflächentechnik eV (VECCO) and Others vs European Commission*.
[20] Available at: http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf



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### C.1.2. Generic exemptions

A list of uses exempted from the authorisation requirement according to the REACH Regulation can be found at http://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf. The scope of some of these generic exemptions is further clarified in ECHA's Q&A found at http://www.echa.europa.eu/qa-display/-/qadisplay/5s1R/view/ids/1027-1028-1029-1030-1031. It should be noted that if a use falls under the generic exemptions from authorisation, there is no need to propose an additional specific exemption.

It is the responsibility of companies to assess whether any of their uses complies with the requirements relevant for each of the exempted uses. Further information on such requirements can be found in the legislation listed at the above link, as well as in Article 3(23) REACH regarding scientific research and development, and in the ECHA Guidance on intermediates (http://www.echa.europa.eu/documents/10162/17224/intermediates_en.pdf).

### C.1.3. Aspects not justifying an exemption from authorisation

There are several generic exemptions from the authorisation requirement[18]. Furthermore, uses can be exempted from the authorisation requirement on the basis of Art 58(2) which depends on the provisions of existing EU legislation (See section C.1.1. General principles for exemptions under Art. 58(2)).

While information such as a low level of risk or low tonnage associated to a use, voluntary measures implemented by industry, availability and suitability of alternatives, socioeconomic benefits associated with continuing a use, is important, it cannot be used as basis for an Art. 58(2) exemption. Information regarding these topics needs to be provided as part of the application for authorisation in case the substance is included in Annex XIV. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.



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## C.2 Further responses relevant for the substance

| Reference code | Issue raised in the comment(s) | Response |
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| **C.2.1** | **Restriction interpreted as legal basis for Art. 58(2) exemption request** | NMP has been included in the Candidate List due to its toxicity to reproduction as confirmed by harmonised classification (Repro 1B) (human health concern). In addition, the EU is currently considering the adoption of a proposed restriction which sets down Derived No Effect Levels (DNELs) for exposure of workers to NMP via both the inhalation and the dermal routes. Therefore, for this particular life cycle stage and target population (workers), the requirements in relation to Article 58(2) REACH may potentially be met with the adoption of the restriction.<br><br>In assessing Article 58(2) exemption requests for the use of NMP, it is important to assess whether existing EU legislation imposes minimum requirements to properly control risks to human health via all relevant exposure routes and at all life-cycle stages of a particular use. Based on the information included in the registration dossiers and on the notifications submitted to ECHA under Article 7(2), it cannot be excluded that NMP is present in articles, which may be used by workers and consumers. In this respect, to cover potential risks of NMP arising from toxicity to reproduction, risks not only for workers dealing directly with this substance (as such or in a mixture) but also for the use of articles need to be considered. Regarding the service life stage of articles containing NMP, it appears that there is no specific EU legislation imposing minimum requirements relating to the protection of human health from the release of NMP from articles in order to ensure that the risk is properly controlled. Therefore, the uses of NMP that would result in the incorporation of NMP in articles might not merit an exemption under Art 58(2), even if the proposed restriction is adopted.<br><br>In addition, it should be noted that the proposed restriction may not be considered as a legislative measure which pushes for substitution in a similar manner to the authorisation requirement. Therefore in order not to limit the Commission's possibility to use authorisation as a complementary measure to the proposed restriction and as it appears that not all life cycle stages are subject to the proposed restriction, it may not be appropriate to recommend an exemption under Art 58(2).<br><br>As set out in C.1.1, ECHA considers the elements described in the 'General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV' when assessing exemption requests under Art 58(2). The European Commission will make its assessment of the exemption possibilities and include any exemptions the Commission regards as appropriate in its draft decision on Annex XIV inclusion which will be discussed in the REACH Comitology Committee. |



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| **C.2.2** | **Use in manufacture of medical and in vitro diagnostic (IVD) devices** | Issue: Use in medical devices<br><br>Medical Devices Directives (MDD, Directive 93/42/EEC) and the Directive on implantable medical devices (Directive 90/385/EEC) , which will be repealed by Regulation (EU) 2017/745 on medical devices; Directive on diagnostic in vitro medical devices (Directive 98/79/EC) which will be repealed by Regulation (EU) 2017/746 on in vitro diagnostic medical devices.<br><br>Response:<br><br>Please see C.1 Process information and in particular C.1.2. Generic exemptions which provides further information on generic exemptions from authorisation.<br><br>Regarding the use in medical devices, the Medical Devices Directives (MDD, Directive 93/42/EEC) and the Directive on implantable medical devices (Directive 90/385/EEC), which will be repealed by Regulation (EU) 2017/745 on medical devices, as well as the Directive on diagnostic in vitro medical devices (Directive 98/79/EC) , which will be repealed by Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices, are intended to harmonise the laws relating to medical devices within the EU. In relation to legislation relating to medical devices, ECHA refers to recital 18 of Commission Regulation (EU) No 143/2011 of 17 February 2011, amending Annex XIV to REACH for the first time:<br><br>'In accordance with Article 60(2) of the REACH Regulation, the Commission should not consider, when granting authorisations, the human health risks associated with the use of substances in medical devices regulated by Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, or Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. In addition, Article 62(6) of REACH Regulation provides 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 those Directives. It follows that an application for an authorisation should not be required for a substance used in medical devices regulated under Directives 90/385/EEC, 93/42/EEC, or 98/79/EC if such a substance has been identified in Annex XIV to REACH Regulation for human health concerns only. Therefore, 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'.<br><br>This is applicable when the substance is used in medical devices or for the uses and corresponding volumes of that substance upstream preceding this end-use (Q&A 1029 on ECHA's website (https://echa.europa.eu/support/qas-support/qas). |



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| | | Based on the above, ECHA would suggest that you examine whether the mentioned uses of your substance can be regarded as uses in medical devices in accordance with the Directives 90/385/EEC, 93/42/EEC, or 98/79/EC.<br><br>Please note that if this substance is used as a solvent in the manufacture of medical devices / IVDs, see response C.2.3 Use as solvent in production of membranes for medical devices. |
| **C.2.3** | **Use as solvent in production of membranes for medical devices** | Please see C.1.2. Generic exemptions which provides further information on generic exemptions from authorisation. Further clarification on the generic exemption for uses upstream preceding a use in a medical device, please refer to Q&A 1029 regarding the scope of that exemption on ECHA's website (https://echa.europa.eu/support/qas-support/qas).<br><br>This generic exemption is applicable when the substance has been identified in Annex XIV for human health concerns only and is used in medical devices regulated under the Medical Devices Directive (MDD, Directive 93/42/EEC) and the Directive on implantable medical devices (Directive 90/385/EEC) which will be repealed by Regulation (EU) 2017/745 on medical devices. The exemption also covers the use of a substance in upstream steps preceding the exempted end-use in medical devices, but only in the volumes ending up in this exempted end use.<br><br>Based on the information you have provided, it appears that the use of the substance as a solvent, in the production of membranes for medical devices, is not aimed at incorporating it into the medical device during the production process. Therefore, this use as solvent does not seem to be exempted from the authorisation requirement.<br><br>If the generic exemption under Articles 60(2) and 62(6) REACH, concerning hazards to human health, does not apply, it needs to be examined whether an exemption can be granted under Article 58(2) REACH. For the use of the substance in the production of medical devices, it appears that this specific legislation does not impose minimum requirements relating to the protection of human health and the environment in order to ensure that the risk is properly controlled. Therefore, it does not seem that this use would merit an exemption under Art 58(2) due to this legislation on its own. (See section C.1.1. General principles for exemptions under Art. 58(2) and see response to C.2.1 Restriction interpreted as legal basis for Art. 58(2) exemption request). |



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| **C.2.4** | **Use as solvent in the manufacturing of active ingredients for medicinal products (API)** | Issue: Use in medicinal products (as an excipient or as active ingredient)<br><br>Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use<br><br>Directive 2001/83/EC on the Community code relating to medicinal products for human use<br><br>Directive 2001/82/EC on the Community code relating to veterinary medicinal products<br><br>Response:<br><br>Please see C.1 Process information and in particular C.1.2. Generic exemptions which provides further information on generic exemptions from authorisation.<br><br>Regarding the use in medicinal products, Regulation (EC) No 726/2004 establishes the operation of European authorisation procedures for the placing of medicinal products on the market in the European Union (EU). Each application for authorisation must be accompanied by the particulars and documents referred to in Directive 2001/83/EC on the Community code relating to medicinal products for human use or in Directive 2001/82/EC relating to the production, placing on the market, labelling, distribution and advertising of veterinary medicinal products.<br><br>According to Art. 2(5) REACH, substances used in medicinal products for human and veterinary use within the scope of the relevant EU legislation are exempted from the authorisation process. We would suggest that you examine whether the use of your substance can be regarded as an excipient or an active ingredient and can fulfil the requirement of Article 2(5)(a) REACH. If you conclude that your uses of the mentioned substance fulfil the above requirement, the uses can benefit from the exemption from authorisation as set out in Article 2(5)(a) REACH and no authorisation would be required to continue the use after the sunset date. It should be noted that the exemption also covers the life-cycle steps preceding the incorporation of the substance into the medicinal products, but only in volumes ending up in the exempted end-use (Q&A 1027 on ECHA's website (https://echa.europa.eu/support/qas-support/qas)).<br><br>If the generic exemption under Article 2(5)(a) REACH does not apply, it needs to be examined whether an exemption can be granted under Article 58(2) REACH. For the use of the substance in the production of medicinal products, it appears that this specific EU legislation does not impose minimum requirements relating to the protection of human health and the environment in order to ensure that the risk is properly controlled. Therefore it does not appear that this use would merit an exemption under Art 58(2) due to this legislation on its own. (See section C.1.1. General principles |



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| | | for exemptions under Art. 58(2) and see response to C.2.1 Restriction interpreted as legal basis for Art. 58(2) exemption request). |
| **C.2.5** | **Claim that use in food contact material falls under generic exemption** | See C.1 Process information and in particular C.1.2. Generic exemptions which provides further information on generic exemptions from authorisation.<br><br>The framework Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food sets up general requirements for all food contact materials and articles to ensure that their constituents do not endanger human health and adversely affect the nature or quality of the food, via the transfer of substances, bringing an unacceptable change in the composition of the food or a deterioration in its organoleptic properties. Adhesives and plastics are groups of materials and articles, listed in Annex I, which may be covered by specific measures within the meaning of Article 5 of that Regulation.<br><br>For plastic materials and articles, there are specific measures which have been adopted at EU level by Regulation (EU) No 10/2011. This Regulation also apply to plastic multi-layer materials and articles held together by adhesives. NMP is included in the Union list of authorised substances set out in Annex I of this Regulation, which may be intentionally used as additive or polymer production aid (excluding as a solvent) in the manufacture of plastic layers in plastic materials and articles, under the specific migration limits set out in the Regulation. NMP as a solvent may be used in the manufacture of plastic layers in plastic materials and articles subject to national law of Member States.<br><br>We would suggest that you examine whether the use of your substance can be regarded as fulfilling the requirement of Article 56(5)(b) REACH. If you conclude that your uses of the mentioned substance fulfil the above requirement, the uses can benefit from the exemption from authorisation as set out in Article 56(5)(b) REACH and no authorisation would be required to continue the use after the sunset date. The exemption also covers the life-cycle steps preceding the incorporation of the substance into the food contact material, but only in volumes ending up in the exempted end-use (Q&A 1027 on ECHA's website (https://echa.europa.eu/support/qas-support/qas)). |
| **C.2.6** | **Claim that use as processing aid in fuel manufacture falls under generic** | Acc. to Art. 56(4)(c) and (d), the use as motor fuel and as fuel in combustion plants and closed systems is generically exempt from the authorisation requirement. These exemptions cover the incorporation of the substance into the product (i.e. the fuel) and also the life-cycle steps preceding |



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| | **exemptions of Art. 56(4)(c) and/or (d)** | the incorporation under the condition that the control of the risks – i.e. use in closed systems – is also pursued in the upstream life-cycle steps preceding the end-use as a fuel.<br><br>However, the exemption does not extend to the use of NMP as processing aid in the manufacture of fuel. If NMP was to be included in Annex XIV, an application for authorisation needs to be made to continue the use after the sunset date.<br><br>Section C.1.2 of this response document contains some more information and a list of uses generically exempted from authorisation.<br><br>Please refer also to Q&A #1027 and #1028 (https://echa.europa.eu/support/qas-support/browse) for further details. |
| **C.2.7** | **Claim that use in PPORD should generally be exempted** | REACH encourages innovation by foreseeing exemptions to some REACH obligations for substances used in scientific development. For details please refer to the respective guidance on SRD and PPORD available here: https://echa.europa.eu/documents/10162/23036412/ppord_en.pdf/22a12900-ad27-454c-aedd-82972ef2f675.<br><br>Regarding your request to generally exempt the use of NMP in PPORD, we would like to clarify that the use of an Annex XIV substance in PPORD generally requires authorisation unless that use is explicitly exempted in Annex XIV. ECHA can recommend exemptions due to PPORD; the decision on granting those lies with the COM. So far ECHA has not considered it appropriate to recommend exemptions for PPORD as the information available at this stage of the process is normally not sufficient/specific enough.<br><br>Actors can apply for a use of a substance included in Annex XIV for any PPORD activity. The application will be considered and scrutinised in the authorisation granting process in accordance with Article 60.<br><br>We would like to note that no specific PPORD requests have been received during the public consultation. No PPORD notifications had been submitted by the end of public consultation.<br><br>See also Section 5.2 of the general approach for the preparation of draft Annex XIV entries: https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf/2b80fc7f-fc40-4c1a-971f-023691baf702. |



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| **C.2.8** | **Compliance with Chemical Agents Directive and Carcinogens and Mutagens Directive** | Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (CAD) sets out a framework based on the determination and assessment of risk and general principles for the prevention of risk, associated with hazardous chemical agents. CAD (through Directive 2009/161/EU) establishes indicative occupational exposure limit values for NMP.<br><br>The Carcinogens or mutagens at work Directive 2004/37/EC (CMD) introduces a framework of general principles to protect workers against risks to their health (which includes prevention of risk) from exposure. The overriding principle is that the employer shall reduce the use of a carcinogen or mutagen (CM) at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, preparation or process which, under its condition of use, is not dangerous or is less dangerous to workers' health and safety. Where substitution is not possible, CMs should be used in closed systems, where technically possible. Furthermore, a hierarchy of measures shall be applied when a CM is used.<br><br>Both Directives outline a hierarchy of control and risk reduction measures (with substitution at the top), however, they leave the determination of the measures to be imposed to the employer and do not provide specific indicators to be used to assess whether a measure higher up in the hierarchy would have been technically possible. On this basis it is not considered that CAD or CMD impose minimum requirements for controlling risks to human health. Therefore, these Directives may not be regarded as a sufficient basis for exempting uses of NMP from authorisation in accordance with Article 58(2) REACH Regulation. In addition, it should be noted that NMP was included in the Candidate List due to its toxicity to reproduction (Repro 1B) and therefore the CMD does not apply to it. |
| **C.2.9** | **Compliance with occupational safety and health legislation** | Council Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work ('Framework Directive') aims at protecting the health and safety of workers at their workplace. This Framework Directive establishes basic rules on protecting the health and safety of workers with the objective of eliminating the risk factors for occupational diseases and accidents. It applies to all sectors of activity, both public and private, except where characteristics particular to certain specific public service activities, such as the armed forces, the police or certain civil protection service activities inevitably conflict with it. It lays down general principles concerning the prevention of risks and protection of workers against occupational accidents and diseases. On the basis of this Framework Directive a series of individual directives were adopted. The Framework Directive with its general principles continues to apply in full to all the areas covered by the individual directives, but where individual directives contain more stringent and/or specific provisions, these special provisions of individual directives prevail. |



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| | | Council Directive 89/654/EEC concerning the minimum safety and health requirements for the workplace supplements the general provisions of Directive 89/391/EEC on matters of health and safety at work. It includes obligations on the employer to ensure good technical maintenance of the workplace, equipment and devices, and the regular maintenance and checks of safety equipment to prevent and eliminate hazards. Workers and/or their representatives are informed of all measures to be taken in order to protect their health and safety and they are consulted on all issues and measures connected with this area.<br><br>While Council Directives 89/391/EEC and 89/654/EEC set out minimum requirements in relation to health and safety at work they do not appear to specifically define the measures to be imposed by the employer, particularly in relation to whether more stringent measures would be technically possible. Therefore, these Directives on their own do not seem to be a sufficient basis for exempting uses of NMP from authorisation in accordance with Article 58(2) REACH.<br><br>Please see also:<br><br>C.2.8 Compliance with Chemical Agents Directive and Carcinogens and Mutagens Directive<br><br>C.2.12 Compliance with Pregnant Workers Directive |
| **C.2.10** | **Compliance with Industrial Emissions Directive (and IPPC)** | Concerning the Directive 2010/75/EU on industrial emissions (IED), Annex II is an indicative list of the main polluting substances and includes large groups of substances. The directive does not specify how to identify polluting substances for which a permit for an installation needs to include an emission limit value. For these reasons the substances for which the minimum requirements set out in the Directive apply are not specified in a way that would allow the use of the IED Directive as a reason for exemption under Article 58(2) REACH. Whilst Commission Implementing Decisions may provide the basis for setting specific permit conditions these must be evaluated on a case-by-case basis, they can be derogated, they only apply to certain activities and they usually apply above defined capacity thresholds and therefore the minimum requirements are not set out in a way that would justify an exemption under Article 58(2) REACH.<br><br>It is further noted that pursuant to Article 62(5)(b)(i) REACH an applicant may justify in the authorisation application that emissions from an installation for which an IPPC permit has been granted do not need to be considered when deciding on an authorisation. This implies that a case specific consideration is needed to judge whether risks arising from IED installations are properly controlled. |



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| **C.2.11** | **Compliance with Water Framework Directive** | Concerning the Water Framework Directive 2000/60/EC (WFD) (and its daughter Directives 2006/118/EC, 2008/105/EC and 2013/39/EU), these Directives set environmental quality standards for certain substances in the aquatic environment, and a framework for control of emissions, discharges and losses of these substances into the aquatic environment. The WFD, *inter alia*, obliges Member States to protect, enhance and restore bodies of surface water with the aim of achieving good surface water status by 2015 (with certain derogations) and it also obliges Member States to implement the necessary measures with the aim of progressively reducing pollution from priority substances and ceasing or phasing out emissions, discharges and losses of priority hazardous substances (WFD Art 4).<br><br>However, the Directive does not establish specific emission limits for substances or define risk management measures required. These aspects would be covered e.g. in specific permits issued by national authorities. It is further noted that pursuant to Article 62(5)(b)(ii) REACH an applicant may justify in his authorisation application that discharges of a substance from a point source governed by the requirement for prior regulation referred to in Article 11(3)(g) of Directive 2000/60/EC and legislation adopted under Article 16 of that Directive do not need to be considered when deciding on an authorisation. (It can be noted that Article 61(5) of REACH envisages that the Commission may review authorisation applications if the environmental objectives as referred to in Article 4(1) of the WFD are not met.) This implies that a case specific consideration is needed to judge whether risks arising from such discharges are properly controlled. In addition, under Article 7a of Directive 2008/105/EC (as amended by Directive 2013/39/EU) it is foreseen that the REACH authorisation and restriction processes may be initiated by the Commission to achieve the objectives of that legislation[1]. Therefore, in order not to limit the Commission's possibility to take such action and considering the limitations of the WFD (e.g., no specific emission limits), it may not provide an appropriate basis for an exemption from the authorisation requirement. In conclusion, the WFD does not appear to be on its own sufficient for granting an exemption for the use under Article 58(2) REACH.<br><br>[1] See, in particular, Report from the Commission to the European Parliament and the Council on the outcome of the review of Annex X to Directive 2000/60/EC of the European Parliament and of the Council on priority substances in the field of water policy, COM (2011)0875, final, pages 5-6: "Since then, the legislation to control the authorisation and placing on the market of chemicals has been substantially expanded and improved, in particular with the adoption of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[6] and of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market. This and other existing EU legislation (e.g. biocides and veterinary medicines legislation) contains mechanisms suited to controlling the uses and emissions of most of the priority substances at EU level (e.g. evaluation, restriction, authorisation). These existing mechanisms should therefore be applied before others are developed and should in principle be sufficient to achieve the objectives of the WFD." |



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| | | See also Directive 2013/39/EU, recital 12: "The progressive reduction of pollution from priority substances and the cessation or phasing out of discharges, emissions and losses of priority hazardous substances, as required by Directive 2000/60/EC, may often be achieved most cost-effectively through Union substance-specific measures at source, for example pursuant to Regulations (EC) No 1907/2006…." and the Commission Staff Working Paper – Impact assessment accompanying the document "Proposal for a Directive of the European Parliament and of the Council amending Directive 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy SEC(2011) 1547 final |
| **C.2.12** | **Compliance with Pregnant Workers Directive** | The objective of Directive 92/85/EEC (Pregnant Workers Directive is to protect the health and safety of women in the workplace when pregnant or after they have recently given birth and women who are breastfeeding; thus, this aims to encourage improvements in health and safety at the workplace, and in this case, for a defined sensitive group, through the assessment of risks at the workplace. In case the results of this assessment reveal the existence of a risk to the safety or health of the female worker, provision must be made for the worker to be protected. In addition, pregnant workers and workers who are breastfeeding must not be engaged in activities which have been assessed as revealing a risk of exposure, jeopardizing safety and health, to certain particularly dangerous agents or working conditions.<br><br>Whilst the Directive identifies substances with R phrases relevant for reprotoxic potential for particular attention in an assessment, the Directive leaves the determination of the measures to be imposed to the employer. On this basis Directive 92/85/EEC does not seem to impose binding minimum requirements for controlling risks to human health in accordance with Article 58(2) of the REACH Regulation, as previously highlighted. Therefore, this Directive on its own seems not to be a sufficient basis for exempting uses of NMP from authorisation. |
| **C.2.13** | **Compliance with national legislation (e.g. GefahrstoffVO, BetriebssicherheitsVO, TA Luft, BImSchG)** | Please see C.1.1. General principles for exemptions under Art. 58(2), which states that national legislation governing a use is not sufficient for exempting uses from authorisation in accordance with Article 58(2) REACH. |



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