10 November 2016

Response document

Substance group: HHPA / MHHPA

Substance names and EC-numbers:

Substance name	EC number
Hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4] [The individual isomers [2], [3] and [4] (including their cis- and trans-stereo isomeric forms) and all possible combinations of the isomers [1] are covered by this entry] (MHHPA)	247-094-1 [1] 243-072-0 [2] 256-356-4 [3] 260-566-1 [4]
Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] and all possible combinations of the cis- and trans-isomers (HHPA)	201-604-9 [1] 236-086-3 [2] 238-009-9 [3]

About this response document

The present document provides ECHA's responses to the comments[1] received during the public consultation on its draft recommendation to include HHPA and MHHPA 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 7th Annex XIV recommendation and took place between 18 November 2015 and 18 February 2016.

[1] The compilation of comments received, along with references to responses , can be found at the following link(s):
https://echa.europa.eu/documents/10162/13640/7th_recom_comref_mhhpa_en.rtf
https://echa.europa.eu/documents/10162/13640/7th_recom_comref_hhpa_en.rtf

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Although the responses aim to address individual comments (submitted for individual substances), 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[1] 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.

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. The process information part is identical in all Response documents of the substances included in the draft 7th recommendation for public consultation.

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

The section headings in the process information and captions on the left of the substance/group-specific 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

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referencing to responses in the "Comments and references to responses document"[1] and vice-versa; i.e. to allow tracking of the comment(s) the specific section/response in the current document refers to.

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

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List substances for inclusion in Annex XIV.

Information on the approach applied is provided below.

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[2]. 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"[3].

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.1.1.3)). Downstream user reports, PPORD and SiA notifications are used in addition when relevant.

[2] https://echa.europa.eu/documents/10162/13640/prioritisation_results_CL_substances_nov_2015_en.pdf
[3] http://echa.europa.eu/documents/10162/13640/recom_general_prio_approach_implementation_examples_en.pdf

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5.New information and next steps towards the final recommendation

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 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[4] 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'[5] and in the 'Practical guide on intermediates'[6], 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

[4] A list of uses exempted from the authorisation requirement available at: http://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf
[5] http://echa.europa.eu/documents/10162/13632/intermediates_en.pdf
[6] http://echa.europa.eu/documents/10162/13655/pg16_intermediate_registration_en.pdf

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considered intermediate uses.

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.1.1.3) – 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[7] and in "General approach for prioritisation of SVHCs: practical implementation examples"[8]. 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[9]. 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.

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

[8] http://echa.europa.eu/documents/10162/13640/recom_general_prio_approach_implementation_examples_en.pdf

[9] or unknown volumes, or ≥ 1t/y if the total volume in the scope of authorisation was < 10t/y

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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[10] or, if in mixtures below the classification concentration limit, not in the scope of authorisation). For professional and industrial uses only the tonnage 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 demonstrates 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

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

[10] Entries 28 to 30 of Annex XVII to REACH, unless the use is specifically derogated from this restriction

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actions

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 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[11].

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[12], 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.

[11] 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: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact

[12] 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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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. 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.

7.Burden for industry and

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

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potential competitive disadvantage

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, the 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.

The overall impact of the authorisation requirement depends on the share of the application cost for the substance in the total production cost. In many cases the share of raw materials (in comparison to capital and labour costs) is relatively low. In such cases the overall cost increase would be relatively low and the effect on the competitiveness of the respective industry in the EU would be relatively low, too.

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[13]. It is further possible to submit joint applications by a group of actors.

Moreover, Commission, MSCAs, industry and ECHA have further developed / are further developing approaches and advice on how to prepare streamlined and fit-for-purpose applications. ECHA has already taken steps to help ensuring that the application process is predictable and proportionate, e.g. by giving information and guidance on its website (http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation/afa). This is to support the applicants to focus their applications and thus reduce the application costs.

The overall aim is to facilitate a streamlined 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.

[13] 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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A.2 Further responses relevant for the substances/substance group

Reference code	Issue raised in the comment(s)	Draft response
A.2.1	**Intermediate status of the use of HHPA/MHHPA in resins**	ECHA interprets Article 3(15) as explained in ECHA's Guidance on Intermediates (December 2010). See especially Appendix 4 of this guidance. According to the guidance, as soon as the main aim of the chemical process is not to transform a substance (A) into another substance (B), or when substance (A) is not used for this main aim but to achieve another function - either as part of the manufacturing of another substance (B) (e.g. as catalyst, processing agent, solvent), or as part of another activity (e.g. as an individual step in the production process of an article)- substance (A) used for this activity should not be regarded as an intermediate under REACH. Based on the information provided in the public consultation, HHPA and MHHPA are used as hardeners/curing agents for epoxy resins and also as a monomer in the synthesis of resin polymers. The use of HHPA and MHHPA as a monomer can be regarded as intermediate because the substances are used with the intention to manufacture another substance (i.e. the polymer). However, in the uses as hardeners/curing agents, the primary aim for the use of the substances is not to manufacture another substance, but rather to achieve another function. The chemical transformations are an integrated part of the process to manufacture articles. These uses appear therefore not to fulfil the intermediate definition. ECHA's interpretation on "definition of intermediate" appears to be in line with the European Court of Justice in its decision on the Case T-268/10 RENV of 24/9/2015. It is stressed that this prioritisation exercise is not taking a formal position whether certain uses of substances are regarded as uses as intermediates. It remains the responsibility of companies to assess whether any of their uses fulfils the intermediate definition and therefore is exempted from the authorisation requirement.
A.2.2	**Challenging the grouping approach**	Grouping considerations are applied to avoid undesired discrepancies in regulatory actions for similar substances to the benefit of stakeholders and authorities. The prioritisation approach gives the possibility to take further considerations into account when deciding on which substances to include in a

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		recommendation.
	(HHPA & MHHPA)	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 prioritised or already included in Annex XIV, for (some of) their uses. Based on registration information, both HHPA and MHHPA can be used as curing agents. It is in practice impossible and not necessary to provide positive evidence for the compatibility of the substances in all their particular uses as this would require knowledge about all the concrete processes and possible alternative processes, which appears impossible to achieve and not necessary at this stage of the authorisation process. In order to challenge the grouping concept in the case of HHPA and MHHPA, it is therefore deemed more appropriate that industry would document that it is technically not possible to replace HHPA with MHHPA, and vice versa.
A.2.3	**Challenging ELoC of the substance(s)** (HHPA & MHHPA)	The identification of HPPA/MHPPA as substances of very high concern (SVHCs) has already been agreed by the Member State Committee, based on the harmonised classification in force for this substance (Regulation (EC) No 1272/2008) and on the equivalent level of concern arguments put forward in the Annex XV dossier. This agreement cannot be changed via the recommendation process currently ongoing. This said we would like to note that it is clear from the wording of Article 57(f) that substances having endocrine disrupting properties or those having PBT/vPvB properties are merely examples of substances that can be identified as substances of equivalent level of concern to those listed in Article 57(a) to (e) (ELoC) ("*such as*"). Accordingly Article 57(f) can be used as a basis to identify substances with other properties (e.g., as a respiratory sensitiser) as ELoC. The criteria listed in the Guidance for the preparation of an Annex XV dossier (version 1) were followed for the identification of HHPA/MHHPA as SVHC(s). In accordance with this Guidance the following elements were considered in the identification process of HHPA/MHHPA as substances of very high concern: • The seriousness of the effect • Irreversibility of health effects • The consequences for society • Difficulty in performing concentration-based risk assessment • Other factors: Quality of life For further details please refer to the MSC support documents which provide detailed justification for the

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		agreement to identify HHPA and MHHPA as SVHC (ELoC), available on ECHA's website.
A.2.4.	**Challenging the prioritisation of HHPA and MHHPA with respect to both the volume and the wide dispersiveness of the uses**	Background information on the scope of the assessment of wide-dispersiveness of uses (WDU) as well as on the assignment of WDU score based on use types and their associated volumes can be found in **Section A.1.3** of this document. Assessment of the wide-dispersiveness of uses relies mainly on data from the registration dossiers as provided in Section 3.5 of the IUCLID dossiers and in the CSR. **WDU score** Registrations updates have been received (some of them after closure of public consultation). HHPA: Based on the comments submitted in this public consultation and the corresponding updates to the registration dossiers, there seems to be sufficient information to change the WDU score from the refined professional use score (WDU=7) to the industrial uses scores (WDU=5). Therefore the overall score for HHPA was revised to 18 (previously 20) meaning that there are other substances of similar priority not included in the 7th draft recommendation. **Volume score** The volume score was also challenged on the basis that almost all of the volume manufactured/ imported is for use as intermediate. ECHA has not sufficient information available in the registration dossiers regarding the intermediate status of some uses and the related volumes to merit lowering the score. In order to consider lowering the score it is necessary that key information to clarify the intermediate status of the substance(s) would be included in the registration dossiers, such as: • Information on the use allowing to conclude whether or not it is an intermediate use • The respective volume per use. More details on the type of information needed to clarify the intermediate status of the use of a substance can be found in ECHA's Practical Guide 16: *How to assess whether a substance is used as an intermediate under strictly controlled conditions and how to report the information for the intermediate registration in IUCLID* and in *ECHA's Guidance on intermediates.*

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A.2.5	**ECHA should not proceed with the recommendation of HHPA and MHHPA as there is a court case ongoing**	The Court Cases C-323/15 P (appealing T-134/13) and C-324/15 P (appealing case T-135/13) concern two actions brought by a number of companies for partial annulment of ECHA's decision ED/169/2012 concerning the identification, respectively, of hexahydrophthalic anhydride (HHPA) and methylhexahydrophthalic anhydride (MHHPA) as substances meeting the criteria set out in Article 57(f) REACH, in accordance with Article 59 REACH. As noted by the commenter, ECHA highlights that actions before the European Court of Justice have no suspensive effect. Therefore there is no reason to wait for the outcome of the Court's judgements.
A.2.6	**Socio-economic information and availability of alternatives should not play a role in the inclusion of substances in Annex XIV /** **Call on COM when and which socio-economic aspects to consider** (HHPA & MHHPA)	Regarding ECHA's work to prioritise substances for recommending them for inclusion in Annex XIV, we would like to refer to the prioritisation approach which explicitly states that the availability and suitability of alternatives or socio-economic considerations are not considered within the prioritisation but that these are taken into account in the application for authorisation phase. This approach is followed also in this recommendation round. We would also like to refer you to the document "ECHA's general responses on issues commonly raised in public consultations on draft recommendations" available on ECHA's website[14]. This document provides ECHA's general responses on a number of topics often commented on and – among other things – clarifies which type of information cannot be considered in this step of the authorisation process. Section **A.1.5. Aspects not considered in ECHA's prioritisation**, and in particular subsections 5. Availability of suitable alternatives, 6. Socio-economic benefits of continued use and 7. Burden for industry and potential competitive disadvantage specifically explain that socio-economic aspects are not taken into account for the prioritisation. Regarding the call by the Commission to submit information on possible economic, social, health and environmental impacts (cost and benefits) of the inclusion of the proposed substances in the Authorisation List, we would recommend to directly contact the Commission to learn more about how this information is used. As stated on ECHA's website, any submitted information in response to this call will neither be considered by the MSC nor by ECHA. This information has been directly passed on to the Commission.
A.2.7	**Request for a meeting to discuss**	We kindly ask you to refer to our reply sent on 21 January 2016 (reference number [A(2016)0140]) regarding your request for a meeting.

[14] There are common elements between ECHA's general response document on commonly raised issues available on ECHA's website and this document.

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	intermediate status during public consultation (HHPA & MHHPA)	As noted in that reply, in the interests of a fair and equitable treatment of all submitters, it is not our common practice to hold technical meetings on particular substances while the public consultation is running but rather prefer to receive any relevant new information via public consultation to allow all interested parties to take such into account. Any new information relevant for concluding on the type of uses should also be included in registration dossiers.
A.2.8	**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 relates 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 been passed to the Commission. Further information on the "call for information by the Commission" can be found here: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/call-for-information-by-the-commission An overview of the types of information relevant to submit as part of ECHA's public consultation is available here: (http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/public-consultation-in-the-authorisation-process).

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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 consultation on the draft recommendation, ECHA has 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 the 7th 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 60 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. It should also be noted that the requirements on communication

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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. Better insight into the matter might be available once the applications relating to the third recommendation will have been submitted and processed by ECHA and the Commission.

In sum, ECHA considers that a standard LAD of 18 months for the preparation of a well-documented application for

[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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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.

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

1.Extensive time needed in the supply chain to getting orga–nised 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).

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.

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.

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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 authorisation. ECHA has

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published guidance on the type of information in an application for authorisation which may impact the review period when granting an authorisation[16].

[16] 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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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[17].

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. It should however be recalled that the discretion to grant an exemption provided for in Article 58(2) of the REACH Regulation is an exception to the rule that the placing on the market and the use of substances of very high concern should be subject to authorisation, one of the purposes of which is to ensure they are phased out where economically and technically feasible (Article 55 of REACH).

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.

[17] 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[18] (also described in the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV[19]):

- 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.

[18] For further information, see the judgement 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) vs European Commission*.

[19] Available at: http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

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(iii) There need to be binding and enforceable minimum requirements in place for the substance(s) used.

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[17]. 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 substances/substance group

Reference code	Issue raised in the comment(s)	Draft response
C.2.1.	**Used in Quality Assurance testing system** (MHHPA)	Under Article 3(23) REACH, scientific research and development means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year. Thus, scientific research and development can cover analysis, and a substance may be exempted from authorisation under Article 56(3) REACH if used, on its own or in a mixture, in analytical activities such as monitoring and quality control. For instance, routine quality control or release tests in laboratory scale using the substance as extraction solvent or analytical standard fall into the definition of 'scientific research and development' under Article 3(23) REACH and in the scope of the exemption foreseen in Article 56(3) REACH, as long as the quality control or release tests are carried out under controlled conditions and in a volume not exceeding one tonne per year and per legal entity. Furthermore, we would like to add that the uses of a substance upstream preceding an exempted end-use in SRD are also exempted if used in quantities below 1 t/y (of substance ending up in the SRD use) and under controlled conditions. For further information you can also refer to Q&As 0585, 1030 and 1153 on ECHA's website.
C.2.2	**Use in scientific research and development (SRD)**	Please see **C.1 Process information** and in particular **C.1.2. Generic exemptions** which provides further information on generic exemptions from authorisation. ECHA would suggest that you examine whether the mentioned uses of your substance can be regarded as uses for scientific research and development in accordance with Article 3(23) and 56(3) of REACH.

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