12 April 2023

Response document

Substance name: Ethylenediamine

EC number: 203-468-6

About this response document

The present document provides ECHA's responses to the comments[1] received during the consultation on its draft recommendation to include ethylenediamine in Annex XIV of the REACH regulation (list of substances subject to authorisation). The consultation was held in the context of ECHA's draft 11th Annex XIV recommendation and took place between 2 February 2022 and 2 May 2022.

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 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**

[1] The compilation of comments received, along with references to responses, can be found at Recommendations for inclusion in the Authorisation List - ECHA (europa.eu)

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 consultation. The process information part is identical in all Response documents of the substances included in the draft 11th recommendation for consultation.

2. **Further responses relevant for the substances/substance group**
   Provides, if relevant, responses to comments 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.1.2.1", "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.

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.
3.Prioritisation approach applied	The prioritisation approach[2] applied by ECHA was discussed with, and has been agreed by, the Member State Committee (MSC).

[2] Available at Recommendations for inclusion in the Authorisation List - ECHA (europa.eu)

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"[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 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 towards the final recommendation

Relevant new information provided during the consultation on the draft recommendation and in the registration dossiers (checked after closure of the 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 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 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 consultation) whether the identified uses are 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.1.3) – 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.

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[3] A list of uses exempted from the authorisation requirement available at: Consultation on draft recommendation for inclusion in the Authorisation List - ECHA (europa.eu)

[4] See Guidance on REACH - ECHA (europa.eu)

[5] See Practical Guides - ECHA (europa.eu)

More information can be found in Section 5.3 of the general prioritisation approach document[2] and in "General approach for prioritisation of SVHCs: practical implementation examples"[2]. 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[6]. 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 halfway 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[7] 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 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.

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

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

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 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[8].

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

[8] 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

alternatives, socio-economic, human health or environmental benefits of continuing a particular use or the (adverse) impacts of ceasing it[9], 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. 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 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.

[9] 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.

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

[10] 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.

8.Uncertainty as to whether authorisation will be granted

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

Several seminars and workshops have been organised with the various stakeholders to explain and provide clarifications on all aspects of the application for authorisation process.

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 (https://echa.europa.eu/applying-for-authorisation). This includes among others guidance documents, technical manuals, Q&As, check-lists, and approaches agreed by the committees describing how applications are treated and evaluated.

So far the Risk Assessment Committee has been providing DNELs and dose-response relationships for almost all substances for which applications for authorisations have been submitted. 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 opinions. This is normally seven years, but review periods can also be shorter or longer than that[11,1717].

Further clarifications to potential applicants are provided during teleconference-based information sessions (TIS) 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.

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

[11] It should also be noted that i) a review period longer than 12 years can be granted (see criteria in the "Policy guidance for considering review periods for exceptional cases" available at https://echa.europa.eu/documents/10162/13580/ca_101_2017_criteria_longer_review_period_afa_en.pdf), and ii) 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.

Meanwhile, the Risk Assessment Committee (RAC) and the Socio-economic Committee (SEAC) have adopted final opinions and the Commission issued decisions for a significant number of applications received[12]. With the conclusions of each of those evaluations communicated at ECHA's website, predictability of the authorisation process should be less of an issue.

[12] Up-to-date statistics on received applications at https://echa.europa.eu/received-applications

A.2 Further responses relevant for the substance

Reference code	Issue title	Draft response
A.2.01	Questioning the priority of EDA, as it has the lowest intrinsic property score	When recommending substances for inclusion in Annex XIV, ECHA applies the following prioritisation approach, discussed and agreed with MSC: https://echa.europa.eu/documents/10162/17232/recom_gen_approach_svhc_prior_2020_en.pdf/fbbd748b-22dc-38c2-9b4c-58c6bc80c930?t=1643790475303. The priority of each substance is concluded considering the 3 following prioritisation criteria all together: inherent properties, volume in the scope of authorisation, and wide-dispersiveness of uses (WDU). Ethylenediamine as respiratory sensitiser identified as SVHC based on Art 57 (f) gets the lowest score among the possible scores for the inherent properties, however when considered together with the other criteria (scores for Volume and WDU) it is concluded as of relative high priority for inclusion in Annex XIV compared to other substances in the Candidate List. Please also refer to responses A.1.5.3 and A.1.5.4 for further explanation on when and how further information related to level of risk control of particular uses are considered in the authorisation process.
A.2.02	Volume in the scope of authorisation overestimated	When finalising its recommendation, ECHA took into consideration all relevant new information provided during the consultation on the draft recommendation and in the registration dossiers. All registration updates submitted as of 2 May 2022 have been considered. A number of registration updates have been received, leading to the revision of the volume score. The amount of ethylenediamine manufactured and/or imported into the EU is still according to registration data above 10,000 t/y. Part of the registered tonnage is related to monomer imported as part of polymers and is therefore not considered for priority assessment. Part of the tonnage is reported as directly exported outside the EU. Some uses appear not to be in the scope of authorisation, such as uses as intermediate (including use as monomer at industrial sites) and, to the extent the conditions for the generic exemption are met, uses in scientific research and development. Taking into account the information on the volume corresponding to those uses as provided in registrations, the volume in the scope of authorisation is estimated to be in the range 1.000-10,000 t/y. ECHA notes the comments from the Ethylene amines consortium assessing that the volume in the scope of authorisation is likely to be below 1.000 t/y. This could however not be confirmed based on information

		available in registration dossiers. For a number of registrations it is possible to conclude on the share of the tonnage outside the scope of authorisation, however, no information is available for a number of non-updated registration dossiers accounting all together for > 1.000 t/y. According to the prioritisation approach, worst case assumptions are applied in these cases. With regards to the comments asking to consider that the majority of the tonnage of EDA manufactured/imported in the EU is for uses falling outside the scope of authorisation, ECHA reminds that the allocation of priority scores takes into account only the uses/tonnage in the scope of authorisation and that the tonnage for those uses is considered in absolute terms (i.e. actual annual tonnage). The fact that the tonnage for those uses represent only a small share of the total tonnage of the substance manufactured/imported in the EU does not affect the priority conclusion.
A.2.03	BASF Volume in the scope of authorisation	ECHA has carefully assessed information on tonnage and uses provided in registrations. Where the information was available, ethylenediamine volumes not in scope of authorisation have been subtracted from the manufactured and imported volumes to achieve a proper prioritisation score. Volumes subtracted included: • Monomer volumes imported as polymer. • Volumes manufactured in the EU but directly exported for use outside the EU. • Intermediate uses including use as monomer in polymerisation reactions at industrial site. Following the assessment of the registration updates received by the end of the consultation (2 May 2022), none of the registered ethylenediamine volumes manufactured or imported by BASF's legal entities has been considered in the scope of the authorisation. It is stressed, however, that the assessment of whether a use is in the scope of authorisation was 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).
A.2.04	Use of the substance in specific application in low tonnage	When prioritising substances for inclusion in the authorisation list (i.e. recommendation process), ECHA applies the prioritisation approach discussed and agreed with MSC. See https://echa.europa.eu/documents/10162/17232/recom_gen_approach_svhc_prior_2020_en.pdf/fbbd748b-22dc-38c2-9b4c-58c6bc80c930?t=1643790475303.

		The wide-dispersiveness and volume are 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 or one use is of low or high tonnage. All uses and tonnage reported in registrations are considered for the assessment. Please also refer to response **A.1.5.3 – Use specific consideration** and **A.1.5.4. Control of risks** for further information on when and how information such as the level of risk control of a particular use is considered in the authorisation process.
A.2.05	WDU score overestimated	When assessing the substances priority ECHA applies the following prioritisation approach: https://echa.europa.eu/documents/10162/17232/recom_gen_approach_svhc_prior_2020_en.pdf. See also response A.1.3 – Prioritisation approach applied. Further explanation and exemplification on how the prioritisation approach is applied is available in the practical implementation document available at: https://echa.europa.eu/documents/10162/17232/recom_gen_approach_svhc_prior_impl_examples_2020_en.pdf/6af93451-5221-e0a5-c3dc-10bd760d2de2?t=1643790537588 The wide-dispersiveness of uses is assessed for the substance taking into account all uses within the scope of authorisation, i.e. not only whether one use from one company 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[13]. According to the prioritisation approach, the WDU score is assessed considering three use/actor types (industrial (IND), professional (PROF) and consumer (CONS)) that determine the score (5, 10, or 15 accordingly); with the highest applicable score assigned. The WDU score is refined if volume per use information allows this. In addition, if registration data or other relevant information demonstrates that the substance ends up in articles and that there is no reliable information that releases can be considered negligible during article service life and waste phase, the approach states that the presence in articles can as well be taken into account to refine the WDU score. In practice, the following two-steps approach is used to assign scores for WDU. *First*, an initial WDU score is derived taking into account the actors (IND / PROF / CONS) for which there is

[13] https://echa.europa.eu/documents/10162/2324909/r12_guidance_draft_for_committees_201507_en.pdf/a28688f2-d804-4526-a8d9-578f4383a031

		sufficiently reliable information that uses by the respective actors in the scope of authorisation occur in the EU (considered as 'confirmed'). However, the higher categories (PROF and CONS) are assigned in this first step only when the 'confirmed' use in this category is ≥10 t/y or where the volumes used by different types of actors are unknown. *At the second step*, the score is refined, where relevant, to take into consideration tonnage information indicating minor use, article service life, and uncertain uses. In case more than one refinement scenario is relevant, only that refinement is applied which leads to the higher score, i.e. only <u>one</u> refinement is considered. The refinement rules are further explained and exemplified in the practical implementation document linked above. Registration data are the main source of information for the prioritisation assessment. Industry is advised to provide all relevant data directly in registrations and to keep registrations up to date. Further sources of information are also considered and assessed according to their reliability. The reliability of such further information is assessed based on the following factors: - the actual source of the information, e.g. regulatory bodies, national registers, actors involved in supply chain - the degree of representativeness for the EU situation - the time period it reflects - the quality of the data, e.g. methodology used to generate the data. Considering all information available for ethylenediamine (including all registration updates submitted as of the last day of consultation 2 May 2022), ECHA concludes that a WDU score of 12 is justified. *At the first step* of assessment, an *initial* score of 10 is justified by the confirmed uses of the substances by industrial and professional users. Some registration dossiers have been updated during the period of the consultation. PROF uses have been removed in some registrations, but PROF uses are still reported in a number of registrations. At the second step of the assessment two further refinements can be considered relevant: 1. Refinement with an additional 2 points justified by the indication of the presence of the substance in articles. Some registrants do report article service-life in their registration dossiers, including in recently updated registrations.

		2. Refinement with an additional 2 points may be justified by uncertain consumer uses. Registration dossiers do not include consumer uses, and consumer use are now advised against in some active registrations. However, the substance has been reported every year for more than 15 years (last year disseminated: 2019) for use in consumer mixtures in the Nordic Product Registers (SPIN database). ECHA considers that a full score for CONS use (leading to a WDU of 15) in this case would not be justified. Instead, the uncertainty on the CONS use is reflected by assigning a half way score between PROF and CONS uses. As only one refinement is applied, a refined WDU score of 12 is deemed applicable. ECHA notes that ethylenediamine would still be concluded as high priority for inclusion in Annex XIV with a non-refined WDU score of 10 (i.e. assuming absence of article service-life and absence of consumer uses). See also response A.2.02 Volume in the scope of authorisation overestimated.
A.2.06	Question the information on the structure and complexity of supply chain reported in the background document	Section 2 of Annex I of the background document summarises the information available to ECHA to conclude on the structure and complexity of supply chains for the specific purpose of LAD setting. Information is derived from registration dossiers and is complemented with information from additional sources where available. Registration dossiers do include uses considered relevant in case of authorisation requirement under the following life-cycle stages: formulation, industrial use, professional use and service-life. Consumer use is not reported in registrations and is considered uncertain, as indicated in the background document. The substance is reported to be used in sectors such as automotive and electronics which in many cases consist of multilayers assembling chain. The following Product categories (PC), sector of use categories (SU) and Article categories (AC) are *explicitl*y reported in registrations dossiers: SU 8, SU 9, SU 20, SU 23, PC 1, PC 9a, PC 9b, PC 13, PC 16, PC 17, PC 20, PC 32, PC 37, AC 11, AC 13. ECHA was not in a position to conclude whether some of them may result from overreporting. The following additional SU/PC/AC categories have been considered relevant based on information received during consultation even though not explicitly reported in registrations: SU 16 Manufacture of computer, electronic and optical products, electrical equipment, SU 17 General manufacturing, e.g. machinery,

		equipment, vehicles, other transport equipment, AC1 Vehicles and AC2 Machinery, mechanical appliances, electrical/electronic articles. It is stressed that the use descriptors (life-cycle stages, PC, SU, AC) in this context are used to support a rough assessment of the horizontal and vertical complexity of the supply chain and the diversity of the "market sectors" possibly impacted by an authorisation requirement. Where a substance is used for the production of articles, ECHA normally takes into account a service-life and ACs, independent on whether the substance has reacted during the production process and how much it remains in the articles. This is as applicants in the context of an application for authorisation will be required to communicate with the users of the produced articles for their analysis of alternative. This may justify more time needed to prepare the application. Please refer to the practical implementation document for the Annex XIV entries approach for further details on the approach followed by ECHA for setting Latest Application dates.

B. Dates

B.1. Process information

B.1.1. General principles for setting latest application dates[14] / sunset dates[15]

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)).

[14] The latest application date is the latest date by which applications for authorisation must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date.

[15] The sunset date is the date from which the placing on the market and the use of that substance shall be prohibited unless an exemption applies, or an authorisation is granted, or an authorisation application has been submitted before the latest application date specified in Annex XIV, but the Commission decision on the application for authorisation has not yet been taken.

The document "General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV"[2] describes how ECHA implements the above mentioned legal requirements in practice.

2.ECHA's proposal for sunset dates

On the basis of the information available in the registration dossiers and submitted during 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 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 180 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 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[16]. 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.

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[2].

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

[16] 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.

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).

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.

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 straightforward 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 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 title	Draft response
B.2.01	Request LAD of 24 months'	In its draft recommendation, ECHA suggested the Latest application dates to be the date of inclusion in Annex XIV plus 18, 21 or 24 months. ECHA indicated that it will make the final LAD allocation when finalising the recommendation and will use all available relevant information including that received in the consultation. Having assessed all information received during the consultation, ECHA sees currently no reason to deviate from the three standard LAD slots mentioned above for ethylenediamine. 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.

[17] SEAC's approach for establishing the length of the review period and RAC's and SEAC's guidance paper on opinion trees for non-threshold substances (both available at Evaluating applications - ECHA (europa.eu))

		ECHA proposed 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). ECHA has developed a practical implementation method to support a consistent and transparent assessment of these criteria. The aim is to holistically compare a limited number of substances within one recommendation round. recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf (europa.eu) Based on the assessment performed, it seems that the supply chain of ethylenediamine can be concluded as being of relatively lower complexity compared to other substances foreseen to be included in the final recommendation. Therefore, a latest application date of 18 months is suggested. Please also refer to responses B.1.1.3 ECHA's proposal for latest application dates and B.1.2.2 Lack of alternatives, socio-economic aspects.

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[3].
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.

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 and/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 cannot grant an exemption on the basis of Article 58(2) of REACH in respect of the substance listed in Annex XIV of REACH; thus national legislation or non-binding EU acts addressing such use is not a sufficient ground for the Commission to grant such an exemption;
(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 REACH regardless of the outcome of risk assessment.

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[2]):

- 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 is too general and requires case-by-case assessment;
- The existing EU legislation imposes minimum requirements which properly control the 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) of REACH. Furthermore, it can be implied from the REACH Regulation

[18] 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*.

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.

C.1.2. Generic exemptions

A list of uses exempted from the authorisation requirement according to the REACH Regulation can be found at Consultation on draft recommendation for inclusion in the Authorisation List - ECHA (europa.eu). The scope of some of these generic exemptions is further clarified in ECHA's Q&A found at https://www.echa.europa.eu/web/guest/support/qas-support/qas (Q&As 1027, 1028, 1030 and 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[4].

C.1.3. Aspects not justifying an exemption from authorisation

There are several generic exemptions from the authorisation requirement[3]. 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.