12 April 2023

Response document

Substance name: glutaral

EC number: 203-856-5

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 glutaral 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**
  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.

[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).

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).

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].

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

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

[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)

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.

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.

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

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

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.

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

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

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 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.

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[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

[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.

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.
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.

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,

[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.

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.

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.

[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.

[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	Claiming uses in leather tanning and as cross-linking agent as intermediate	For the purpose of prioritisation ECHA did an initial assessment of the intermediate status of the use of glutaral in leather tanning and as cross-linker, based on the information available. ECHA interprets Article 3(15) as explained in ECHA's Guidance on Intermediates (version 3.1 published in January 2023)[4] which has been agreed by the relevant EU Authorities. See especially Appendix 4 of this guidance. According to the guidance three cumulative conditions are to be fulfilled for the use of substances to qualify as intermediates. The second of these conditions implies for example that another substance must be obtained from the intermediate via a chemical process (i.e. synthesis). This implies that a dedicated equipment must be used for that. In the case of glutaral as tanning agent this condition is not fulfilled, given that the other substance is not synthetised (i.e. obtained as a substance via a chemical process), but it is formed in the surface of the leather, as a result of the treatment process. The use of glutaral as cross-linking agent is described in the registration dossier as industrial use leading to inclusion into/onto an article. When a substance is used to produce an article or in the treatment process of an article, no synthesis takes place even though the substance reacts chemically. Indeed, the other substance is only obtained in the surface (or in the body) of an article during the treatment process (i.e. the starting and ending element of the process is always an article and not a substance). Based on the conclusions above, ECHA's assessment is that the three cumulative conditions are not met for the uses of glutaral as leather tanning agent and as cross-linking agent. ECHA considers therefore the uses in the scope of authorisation. Accordingly, the uses and the related volumes have been taken into account for prioritisation purposes. 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.2.02	Questioning the volume score assigned	The estimation of volumes in the scope of authorisation for priority setting relies mainly on data from the registration dossiers as provided in Section 3.2 and 3.5 of the IUCLID dossiers and in the CSR. Further information (especially on tonnages per uses) from SVHC Annex XV reports and consultations is also considered.

		The approach followed for volume scoring (including how uncertain information from registrations had been considered) is described in the final background document (section 2.2)[2]. ECHA's database was checked for registration updates at the end of consultation. All registration updates submitted as of 2 May 2022 have been considered. The priority assessment (including scoring) was reviewed in the light of all new information made available. Based on the registration data the volume of glutaral manufactured and/or imported in the EU appears to have decreased since the previous assessment and is now concluded to fall in the tonnage range of 1,000 - < 10.000 t/y. Part of this tonnage is reported to be exported after manufacture and is therefore not taken into account for prioritisation purposes. Some uses appear not to be in the scope of authorisation, such as uses as intermediate, and, to the extent they meet the conditions for the generic exemptions, uses as laboratory reagent in scientific research and development, use in medical devices and formulation of biocidal products. These uses of the substance and the related volumes, where provided, have not been taken into account for prioritisation purposes. Some companies commenting during the consultation and/or providing information in the registration dossiers claimed the use of glutaral in leather tanning and the use as cross-linker in polymer applications as being an intermediate use. ECHA considers however that such uses do not fulfil the intermediate definition. Please refer to response A.2.01 for more information). Those uses and their related volume have therefore been considered for prioritisation purposes. Uses in cleaning products are reported in some registrations. Based on information provided in registration updates, ECHA concludes that such uses may fall outside the scope of authorisation. Indeed, they appear to be either covered by the Biocidal Product Regulation (BPR) or by the Regulation (EU) 2017/745 on medical devices and would therefore be exempted from authorisation based on REACH Art. 56(4)(b), Art. 60(2) and 62(6)). The uses and the related volumes (when available) have not been taken into account for prioritisation purpose. Use of glutaral in X-ray developers is also reported in registrations. The use appears to be mainly in medical field and to a lesser extent in engineering applications. The use in the medical field may fall under the generic exemption on medical devices. Uncertainty remains on the remaining volume of the use in the other field, nevertheless overall the volume is very limited and potential exemptions would not have an impact on the priority of the substance. Based on the above-described assessment, the volume of glutaral in the scope of authorisation is estimated to be in the range of 1,000 - <10,000 t/, justifying a revised score of 12.

		It is stressed that this prioritisation exercise is not taking a formal position whether certain uses of substances are exempt from the authorisation requirement. It remains the responsibility of companies to assess whether any of their uses fulfils the conditions for such exemptions. Please also refer to: A.1.1.5 New information and next steps towards the final recommendation A.1.2.1 Volume in the scope of authorisation.
A.2.03	Questioning the WDU assessment	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 in particular how the wide-dispersive use (WDU) criteria is assessed- is available in the practical implementation document available at 6af93451-5221-e0a5-c3dc-10bd760d2de2 (europa.eu). The wide-dispersiveness of uses is assessed for the substance taking into account all uses considered to fall within the scope of authorisation. Please see response A.2.02 for information on how certain specific uses (e.g. use in leather tanning and as cross-linker, use in cleaning products, use in X-ray developers) have been considered in this regards based on all information available at the end of the consultation (2 May 2022). The assessment of wide dispersiveness of uses (WDU) comprises a general evaluation of the substance's use pattern, relying on basic indicators (IND, PROF, CONS). Score refinements are considered in case of article service life, minor uses (typically <10t/y), and uncertain uses. Based on the registration data available by the end of the consultation, industrial uses (IND) and professional uses (PROF) in the scope of authorisation in tonnage > 10t/y have been confirmed, justifying an *initial WDU score* of 10. Industrial uses considered for priority setting include leather tanning, X-ray film developers, as corrosion inhibitor, cross linking, as auxiliary for polymerisation reactions. Professional uses considered for priority setting include leather tanning, as hardener in X-ray film developers, as corrosion inhibitor, crosslinker and auxiliary for polymerisation reactions. The tonnage for professional uses is confirmed to be above 10t/y despite the uncertainty on the actual share of the tonnage for X-ray developer falling in the scope of authorisation.

		Registration data does not confirm the presence of the substance in articles (None of the active registrations have reported article service-life). Comments submitted during the consultation claim the absence of glutaral as such in articles or article matrices. The information on the absence of the substance in articles is however contradicted by non-negligeable number of submissions received for glutaral in ECHA's SCIP database. Notification in the database results from the requirement according to Article 9(1)(i) of the Waste Framework Directive 2008/98/EC to notify articles placed on the EU market containing substances of very high concern (SVHCs) on the Candidate List at a concentration above 0.1% weight by weight (w/w). Considering the above contradicting information, it is uncertain whether the substance is present in articles. The uncertainty on the presence in articles is reflected by assigning a range (or half-score) for the article service-life. Based on this a refined WDU score of 10-12 (or 11) appears justified. Should the representativeness and reliability of the information from the SCIP notifications be considered questionable, the WDU score could be revised to 10 (i.e. not applying an extra 1 point for uncertain article service-life). It is noted that the substance remains of high priority compared to other substances in the Candidate List whether or not a refinement for the article service-life is applied.
A.2.04	Presence as substance in articles is negligible	As stated in the final background document, there is uncertainty on the presence of glutaral in articles. There are indications that glutaral could remain in leather articles as a result of leather tanning. Those residual amounts would, however, be limited to concentrations below 0.1% if a proposed restriction on skin sensitisers in textiles will be adopted. Presence in articles may potentially result from other registered uses e.g use as crosslinker, use as auxiliary for polymerisation reactions and use in X-Ray film developer. The substance is expected to mainly react during the use, however there is uncertainty on potential residual unreacted amount. For further details, please refer to the substance specific background document (section 2.3 and section 1 of Annex I)[2].

B. Dates

B.1. Process information

B.1.1. General principles for setting latest application dates[13] / sunset dates[14]

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: https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_2020_en.pdf).

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.

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[13] 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.

[14] 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 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[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

[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.

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[16].

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

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.

[16] https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf

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 a 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 glutaral. 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 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 glutaral can be concluded as being of medium complexity compared to other substances included in the final recommendation. Therefore, a latest application date of 21 months is suggested. Please also refer to responses B.1.1.3 on ECHA's proposal for latest application dates and B.1.1.2 on ECHA's proposal for sunset dates.

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

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 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.

[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*.

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.

C.2 Further responses relevant for the substance

Reference code	Issue title	Draft response
C.2.01	Exemption for research and development, medical	As regards your request for exemption please note that uses (or categories of uses) can only be exempted from the authorisation requirement on the basis of Article 58(2) of REACH, unless they are already explicitly

	sector, medical devices	generically exempted from the authorisation requirement based on REACH Art. 2(5 or 8) or REACH Art. 56(3 – 6). According to the information provided it is not clear whether the uses of glutaral in scientific laboratories and in clinics applying electron microscopy for the purpose of research, diagnostics and in pathology, and the uses of glutaral in and for supply to industrial and scientific research laboratories and diagnostics fall under the generic exemptions from the authorisation requirement in accordance with Art. 56(3) for the use in scientific research and development or in accordance with Art. 2(5)(a) REACH for the use in medical devices. 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 (Section c) on Authorisation). If you conclude that your use(s) fall under the generic exemptions from authorisation, there is no need to propose an additional specific exemption under Art. 58(2). No authorisation would be required to continue the use after the sunset date. Note that the uses of the substance preceding the exempted end-use in scientific research and development (SRD) and in medical devices are also exempted from the authorisation requirement, for the volumes ending-up in the exempted end-uses. ECHA stresses, that as outlined under C.1.2, it is the responsibility of companies to assess whether any of their uses complies with the requirements relevant for each of the exempted uses. Would the above listed uses of glutaral not be covered by generic exemption from the authorisation requirement, ECHA is of the opinion that applications for authorisation would be needed to continue the use after the sunset date. Indeed, conditions for granting specific exemptions from the authorisation requirement under Art. 58(2) do not appear to be met. For further justification see response C.1.1 General principles for exemptions under Art 58(2) and response C.1.3 aspects not justifying an exemption from authorisation.
C.2.02	Request for exemption for tanning	As regards your request for exemption please note that uses (or categories of uses) can only be exempted from the authorisation requirement on the basis of Article 58(2) of REACH, unless they are already explicitly exempted in REACH Art. 2(5 or 8) or in Art. 56(3 – 6). Some companies have claimed the use in leather tanning as intermediate (intermediate uses qualify for generic exemption under art 2.8(b)). Please see response A.2.01 for ECHA's view on the intermediate status of that use.

		Would the above listed uses of glutaral not be covered by the generic exemption from the authorisation requirement, ECHA is of the opinion that applications for authorisation would be needed to continue the use after the sunset date. Indeed, conditions for granting specific exemptions from the authorisation requirement under Art. 58(2) do not appear to be met. For further justification see response C.1.1 General principles for exemptions under Art 58(2) and response C.1.3 aspects not justifying an exemption from authorisation. ECHA considers that the restriction proposal on the placing on the market of textile, leather, hide and fur articles containing skin sensitising substances (Registry of restriction intentions until outcome - ECHA (europa.eu)) is not a sufficient basis for granting exemption for the use of glutaral for tanning under Art. 58(2). Indeed, the restriction is not yet in force and therefore does not constitute an 'existing' community legislation. Furthermore, the restriction does not address the risks from the use of the substance arising from the intrinsic properties of the substance specified in Annex XIV. Glutaral is included in the Candidate list based on its respiratory sensitising properties. The proposed restriction addresses skin sensitising properties. Finally, the restriction does not cover all the life cycle stages that are exerting the risks. The restriction is targeted to the use of the substance in articles and does not cover risks from upstream uses.