01/07/2015

Response document

Group name: Coal stream substances

Substance names and EC-numbers:

Substance name	EC number
Anthracene oil (AO)	292-602-7
Pitch, coal tar, high temp. (CTPHT)	266-028-2

About this response document

The present document provides ECHA's responses to the comments[1] received during the public consultation on its draft recommendation to include the coal stream substances named on page 1 of the current document in Annex XIV of the REACH regulation. The public consultation was held in the context of ECHA's draft 6th Annex XIV recommendation and took place between 1 September and 1 December 2014.

Although the responses aim to address individual comments (submitted for individual substances), they have been compiled in a consolidated form structured by thematic block and level of information. This format intends to increase consistency and readability of responses and promote a better understanding of the authorisation process. In general, comments addressing same or similar issues have been assigned references[1] to the same parts of the current document.

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

[1] The compilation of comments received, along with references to responses , can be found at the following link(s):
http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_comref_anthracene_oil_en.pdf
http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_comref_CTPHT_en.pdf

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- **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. Timelines**
  covers responses to issues related to the latest application dates, sunset dates and review periods, including ECHA's approach for determining those timelines;
- **C. Exemptions**
  covers the responses to exemption requests, including ECHA's approach for evaluating those requests;

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

1. **Process information**
   provides a summary of the principles applied by ECHA for its decision making relevant for each thematic block, as well as further information on aspects generally relevant or non-relevant for that decision. The process information has been developed based on the experience from previous recommendation rounds. It addresses issues commonly raised in comments submitted during the public consultation. The process information part is identical in all Response documents of substances included in the draft 6th recommendation for public consultation.

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

The section headings in the process information and captions on the left of ECHA's responses provide a summary of the issue addressed per section/response. The headings and captions are also numbered (e.g. "A.1.2", "B.2.2"), to support references to responses in the "Comments and references to responses document"[1] and vice-versa; i.e. to allow tracking of the comment(s) the specific section/response in the current document refers to.

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A. Priority and general issues

A.1 Process information

A.1.1. General, recommendation process

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

ECHA has the obligation to recommend substances included in the Candidate List for inclusion in Annex XIV to the European Commission (Article 58 of the REACH Regulation).

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. Therefore, the workability of the authorisation process necessitates a gradual inclusion of substances in Annex XIV.

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 for this recommendation remain on the Candidate list and will be reassessed for priority in later recommendations together with the new substances included in the Candidate List.

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 3 criteria 'normally' into account, but there is no provision how this should be done in practise. Moreover, 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 currently applied is provided below.

3.Prioritisation approach applied

The prioritisation approach applied by ECHA to the current recommendation round (6th recommendation) was discussed with, and has been agreed by, the Member State Committee (MSC). Please refer to http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

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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 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 Annex 2 of the prioritisation results document.

4.Information taken into consideration for the draft recommendation

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

5.New information and next steps towards the final recommendation

Relevant new information provided during the public consultation on the draft recommendation and in the registration dossiers[3], including any request for exemption, is taken into account (i) by the MSC when preparing its opinion on the draft recommendation (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, will be submitted to the European Commission who makes the final decision on which substances to include in Annex XIV and on the details for the respective entries. All non-confidential information is also made available on ECHA's website.

New information provided during the public consultation on ECHA's Recommendation is also considered for inclusion in the background documents, if relevant, and according to its confidentiality status.

A.1.2. Prioritisation: Volume

1.Volume in the scope of

The volume taken into consideration for priority setting is the volume for all uses in the scope of authorisation. The estimation of volumes is based on data from the registration dossiers as provided in section 3.2 and 3.5 of the IUCLID

[2] http://echa.europa.eu/documents/10162/13640/prioritisation_results_6th_rec_en.pdf
[3] As of 1st December 2014 (end of public consultation)

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authorisation

dossiers and/or in the CSRs, along with information presented in the Annex XV SVHC reports or information submitted during public consultation on SVHC identification of the substances. Where available, information on uses falling under the scope of the generic exemptions from authorisation[4] and on their related tonnage is assessed to estimate the volume relevant for the priority setting.

It is stressed, however, that the assessment of whether a use is in the scope of authorisation is done only for prioritisation purpose 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, in the prioritisation phase of the authorisation process a conservative 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/described in Appendix 4 of the 'Guidance on intermediates[5]' and 'Practical guide on intermediates[6]' was used to assess on the basis of available use descriptions (in the registrations incl. CSRs, the Annex XV SVHC reports and information received in SVHC public consultation) whether the identified uses are in the scope of authorisation.

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.

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 – a methodology which ECHA has strived to apply in a consistent way for all substances assessed, driven by the comparative nature of the prioritisation process. It does not comprise an assessment of information such as detailed operational conditions, recommended/implemented RMM, exposure/risk assessment reported in CSR, or site-specific measurement data. Such assessment is beyond the scope of this step of the authorisation process.

More information can be found in Section 5.3 of the general prioritisation approach document[7] and Annex 2 of the prioritisation results document[2]. Some of the main points are also summarised below.

2.Assignment of WDU score based on use

In the current 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, when moving from consumer to professional to industrial uses, the expected control of releases increases (i.e. "dispersiveness" decreases) and the

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

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types and their associated volumes

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

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

Furthermore, consumer uses for substances classified as Carc./Repr./Mut. 1A/B were not considered in the prioritisation score regardless of whether identified in registrations or not (as those are restricted[9] or, if in mixtures below the classification concentration limit, not in the scope of authorisation). For professional and industrial uses only the tonnage above the relevant concentration limit was 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. Use of articles is usually widespread, with the exception of articles only intended for specific uses in industrial sites. The current prioritisation approach explains how article service-life is taken into account in the assessment of priority.

Where registration data or other relevant information demonstrated that the substance ends up in articles, the initial WDU score (based on the use type) was refined upwards unless there was 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

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 are i) grouping of substances to take

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

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

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considerations together SVHCs which could potentially replace prioritised/previously recommended SVHCs in some of their uses and ii) parallel on-going regulatory risk management activities to avoid undesired interference between different regulatory actions.

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 to the Candidate List[10].

2. Aim & proportionality of authorisation system - Authorisation is not a ban The authorisation process aims at enhancing substitution when technically and economically viable alternatives are available. Until this is achieved the aim is to ensure proper control of risks.

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

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

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

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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 (or duty) to search for and develop suitable alternatives.

3.Use specific scrutiny foreseen at application stage

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. That is because it is this phase where the respective assessment can be done in an effective manner: based on structured input of information by the applicant, the foreseen dedicated public consultation for scrutinising the information on alternatives and the involvement of Committees having the respective expertise and mandate. Information on these aspects will be taken into account by the 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.

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 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 them 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 are 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 compares the impacts to human health and/or the environment arising from the use of the substance with the benefits of the

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continued use. This is done when developing an opinion whether to grant an authorisation.

7.Burden for industry and 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 still be the case, 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 formulation of mixtures having concentrations below the limit relevant for authorisation. In these cases the use of the product is outside the scope of authorisation, still its 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.

It should also be kept in mind that the overall impact of the authorisation requirement depends on the share of the application cost for the substance in the total production cost. In many cases the share of raw materials (in comparison to capital and labour costs) is relatively low. Where this is the case, the overall cost increase would be relatively low and the effect on the competitiveness of the respective industry in the EU would be relatively low, too.

Regarding to the direct costs of the authorisation application process, it is however noted that not each actor on the market has to apply for authorisation of his use(s) because he can benefit from the authorisation granted to an actor up its supply chain. 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. It is further possible to submit joint applications by a group of actors.

Furthermore, ECHA has taken steps to help ensure that the application process is predictable and proportionate by giving information and guidance on its website (http://echa.europa.eu/web/guest/applying-for-authorisation). This is to support the applicants to focus their applications and thus reduce the application costs.

ECHA also informs on its website about the length of the review periods that its Socio-economic Analysis Committee proposes to the Commission in its opinion. This is normally seven years, but a long review period of e.g. 12 years is possible, too. Market certainty among potential applicants is thus increased.

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The overall aim is to facilitate a proportionate and efficient application process so that the exposure to humans and the environment relating to the use of substances of very high concern is minimised while maintaining the competitiveness of the EU industry.

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

Reference code	Issue raised in the comment(s)	Response
A.2.1.	Information on anthracene oil on uses and volumes per uses (potentially impacting the priority scores)	The information on uses and tonnage provided was analysed to determine whether the priority scores previously assigned should be revised. The volume in the scope of authorisation was reassessed taking into account indications that the use of anthracene oil in the production of electrodes may potentially fulfil the intermediate definition (Please refer to response with the title issue: "Claim the use of CTPHT/AO in the production of electrodes as intermediate"). Furthermore, new information submitted in this public consultation suggests that the uses of anthracene oil in the scope of authorisation are limited to the use as industrial solvent and the use as binder for solids in heavy-duty corrosion protection; other uses are listed which are claimed to be generically exempted from the authorisation requirement (e.g. intermediate use, use in fuel). The tonnage for the uses of anthracene oil in the scope of authorisation is stated to be < 10,000 t/y. Discrepancies exist however between the information provided in the public consultation and registrations. According to recent registration information (last update of the lead registrant dossier: 22 April 2014) the volume of anthracene oil used for these uses considered by all parties as being in the scope of authorisation is >10,000 t/y. Moreover, uses are listed in the registration dossiers that are difficult to track back to the information on use and tonnage provided during the public consultation and that are considered by ECHA as likely to fall under the scope of authorisation (e.g. use in refractories). Having correct volume and use information reported in the registrations is the responsibility of the registrants. Based on available information ECHA's current assumption is that the difference between the 2 tonnage estimations is due to the use in refractories (and the respective assessment of this use as

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		being within or outside of the scope of authorisation). Based on available information ECHA considers the use in refractories as non-intermediate use. Therefore the volume score remains 15. Would it be justified to change the volume score from 15 to 12-15 the substance would remain of high priority for inclusion on Annex XIV.
A.2.2.	Information on pitch, coal tar, high temp. on uses and volumes per uses / Volumes are lower than the ones reported in the Background document	New information submitted in the public consultation suggests that the production volume of CTPHT in the EU is lower than indicated in the draft Background document. It is stressed that the estimation of volumes in the scope of authorisation for priority setting mainly relies on data from the registration dossiers as provided in sections 3.2 and 3.5 of the IUCLID dossiers. Having the correct volumes reported in the registrations is the responsibility of the registrants. A guidance document on registration is available and can be directly downloaded from ECHA's website (http://echa.europa.eu/documents/10162/13632/registration_en.pdf. This guidance explains in detail how to report volumes in IUCLID so that multiple counting of volumes is prevented (see Section "2.2.6.3 Calculation of the total volume"). Other information such as information from the public consultation is also taken into consideration where its representativeness and reliability can be demonstrated. Any new information received during the public consultation is included in the background document, if relevant, and according to its confidentiality status. It is noted that for the purpose of prioritisation the tonnage considered is the tonnage for uses in the scope of authorisation. Based on the information available it is concluded that this tonnage remains above 10,000 t/y. This justifies the score 15 assigned to the volume criteria for this substance.
A.2.3.	Claim the use of CTPHT/AO in the production of electrodes as intermediate	New information provided during the public consultation gives further clarification on some uses of pitch, coal tar, high temp. (CTPHT) and anthracene oil (AO) in the manufacturing of Pitch Coke during the production of carbon and graphite electrodes used in aluminium industry. Based on the information available the use might potentially fulfil the definition of intermediate. The use as intermediate is exempted from the Authorisation requirement according to Article 2(8)(b). For the purpose of prioritisation, the use and the volume used in the manufacture/production of electrodes was not taken into account. It is recognised that the intermediate/non-intermediate status of this use is a complex issue, and stressed that this prioritisation exercise is not taking a formal position whether certain uses of substances are regarded as uses as intermediates in accordance with the definition in Article 3(15).

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		It is the responsibility of companies to assess whether any of their uses qualifies for an exemption.
A.2.4.	Scope of the Annex XIV entry for AO / SVHC properties may depend on the composition	Please note that the identification of the UVCB substance "anthracene oil" as Substance of Very High Concern has already been agreed by the Member State Committee, based on its composition range and the properties of its constituents (for more details see the relevant support document at: http://echa.europa.eu/documents/10162/6c7d6086-295c-4284-94c3-853fb16ad184). The substance has been included in the Candidate List due to its carcinogenicity, PBT and vPvB properties. The classification as Carc. 1B indeed does not apply if it can be shown that the substance contains less than 0.005 % (w/w) benzo[a]pyrene (EINECS No 200-028-5). However, even in the cases where classification as carcinogen does not apply, the substance is a substance of very high concern due to its PBT and vPvB properties. A CSR developed as a part of an application for authorisation need only to cover the risks to human health and/or the environment from the uses(s) of the substance arising from the relevant intrinsic properties of the substance.
A.2.5.	Disputing SVHC identification /classification of CTPHT	Your point in regard to the hazardous inherent properties of CTPHT is not relevant for this part of the authorisation process, as the identification of the substance as Substance of Very High Concern has already been agreed by the Member State Committee, based on the harmonised classification in force for this substance and listed in Annex VI of the CLP-Regulation (Regulation (EC) No 1272/2008) and based on the PBT and vPvB properties of some of its PAH-constituents. According to Article 37(6) of the CLP Regulation manufactures, importers and downstream users who have new information which may lead to a change of the harmonized classification and labelling elements of a substance in Annex VI shall submit a proposal […] to the competent authority in one of the member states in which the substance is placed on the market. The MSCA will then decide if it is appropriate to prepare a CLH dossier and submit it to the Agency in order to review/revise the existing harmonised classification.
A.2.6.	The text regarding the uses exempted from authorisation in the REACH legal text and in ECHA's Generic approach for	Regarding the use of CTPHT in the production of electrodes, please consider the response with the following title issue "Claim the use of CTPHT/AO in the production of electrodes as intermediate". Regarding the comment on the unclearness of the text on the exemptions, it is not clear from the comment whether it refers to the factors considered when assessing requests for an exemption from authorisation based on Art. 58(2) or to some of the generic exemptions. In case of the latter,

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	the preparation of draft Annex XIV entries is not clear	please see Section C.1.2 of this response document. In case of the former, the process can be summarised as follows. Interested parties are invited to provide comments during the public consultation on uses which should be exempted based on Art. 58(2), i.e. based on existing EU legislation that imposes minimum requirements for controlling the risks to human health and/or the environment of the use. ECHA assesses the information submitted in such proposals taking into account the considerations set out in Section 5.1. of the Generic approach for the preparation of draft A.XIV entries (http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf) when deciding whether to recommend an exemption based on Art. 58(2). Please note that the Commission makes the final decision on whether to grant an exemption for a use. Please see also section C.1.1. "General principles for exemptions under Art. 58(2)" of the current document.
A.2.7.	Substitution of SVHCs is already part of the company's policy. Inclusion in Annex XIV will delay substitution rather than enhancing it	As correctly stated in your comment authorisation aims at enhancing substitution when technically and economically viable alternatives are available. This aim appears to be in line with your company's policy. The inclusion of the substance in Annex XIV and the subsequent requirement to apply for authorisation are an opportunity to (re)assess the arguments that would justify continuing the use of a hazardous substance. Considering that this analysis is continuously performed by your company the additional work related to documenting the analysis of alternatives during the application for authorisation phase should be relatively limited. It is stressed that the use of substances applied for can continue after the set "sunset date" has expired, where the Commission has granted an authorisation, which is to be expected in cases where applicants have made a good business case. REACH is an EU Regulation aiming to ensure a high level of protection of human health and the environment while enhancing competitiveness and innovation. The obligation to apply for authorisation is to ensure that risks are adequately controlled or that socio-economic benefits are outweighing the risks, while concomitantly it is a strong incentive to search for and develop suitable alternatives. If a company cannot substitute an SVHC included in Annex XIV, it has to document it, justify and provide reasons for it in its application for authorisation. The overall aim is to facilitate a proportionate and efficient application process so that the exposure to humans and the environment relating to the use of substances of very high concern is minimised while maintaining the competitiveness of the EU industry.
A.2.8.	Authorisation process increases the	Although pitch, coal tar, high temp. is an important raw material in e.g. the production of aluminium, it is also classified as Carc. 1B and an identified PBT and vPvB substance. Hence there is

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	confusion over the viability of using substance in the medium to long term	as well a strong societal interest to protect humans, in particular workers handling the substance, from risks potentially arising from its uses. The obligation to apply for authorisation is an incentive to search for and develop suitable alternatives. On the concern expressed that the authorisation process increases the confusion over the viability of using substances in the medium to long term, ECHA stresses that there has been a significant effort to implement the application for authorisation process in a transparent manner, and to provide suitable support to companies to comply with their duties. ECHA's committees have so far adopted more than 60 opinions on applications for authorisation and the European Commission has granted the first authorisations to applicants. With the conclusions of each of those evaluations communicated at ECHA's website, predictability of the authorisation process should be less of an issue. ECHA has created a dedicated webpage "applying for authorisation" with the aim of guiding applicants in the preparation of their applications (http://echa.europa.eu/web/guest/applying-for-authorisation). This includes among others guidance documents, technical manuals, Q&As, and approaches agreed by the committees describing how applications are treated and evaluated. The Risk Assessment Committee has been providing, on a pilot basis, DNEL and dose-response relationships for almost all substances so far. This is a practice which it intends to continue, thus saving substantial time for the applicants and increasing the predictability of the process. Moreover, the Committee for Socio-economic Analysis has published an explanatory note providing clarifications on how it evaluates economic feasibility as part of applications for authorisation. Furthermore, the committees have jointly agreed on the principle of the recommended length of the review period, which should increase predictability. ECHA informs on its website about the length of the review periods that its Socio-economic Analysis Committee proposes to the Commission in its opinion. This is normally seven years, but a long review period of e.g. 12 years is possible, too. ECHA has also been updating formats and IT-tools to provide more clarity and to streamline the process further. Further clarifications to potential applicants is provided via pre-submission information sessions with ECHA, in which future applicants for authorisation have the opportunity to ask case-specific questions regarding the regulatory and procedural aspects of the authorisation application process. ECHA also regularly organises seminars and workshops to improve the understanding of the application process and share experiences. Beyond this, ECHA's authorisation teams maintain personal contact and interaction with the applicants through all the stages of the application

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		process. The level of support available and provided to involved companies (not only by ECHA, but also by many of its stakeholders) has been substantial and broadly acknowledged. ECHA will continue to develop its practices to provide fit-for-purpose support and increase predictability of the application for authorisation process even further. It is acknowledged that the authorisation process for one substance may affect entire supply chain(s) including companies not using themselves the substance. Communication, organisation and agreement between the relevant actors in the supply chain and efficient allocation of work are important aspects to consider by all actors involved, for allowing business decisions making for the time ahead and the management of the preparation of relevant applications.

B. Timelines

B.1 Process information

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

1.Legal background

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

The document "General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV" describes how ECHA implements the above mentioned legal requirements in practice (available at: http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf).

2.ECHA's proposal for sunset dates

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

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substances included in the 6th recommendation.

3.ECHA's proposal for latest application dates

ECHA made its proposals for the latest application dates (LAD) on the basis of the earlier estimation that the time needed to prepare an authorisation application of sufficient quality might in standard cases require 18 months (roughly 12 months work-time for drafting the application and an additional buffer of 6 months for getting organised and consulting required external expertise). Based on discussions and experience on received applications so far, the applicants have not generally indicated that they have had difficulties with the stipulated time periods. Rather there had been problems for the first applicants preparing applications to have clarity on what information, analysis and justification was required in the applications. As over 50 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. Furthermore, the registration deadline for all substance in this recommendation[12] was in 2010. 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 authorisation applications.

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

[12] Note that some members of the group "4-Nonylphenol, branched and linear, ethoxylated" (4-NPnEO) are expected to fulfil the REACH definition of polymers and are therefore exempt from registration.

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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, the number of layers in the supply chain, the number and type of companies concerned, and the way potential future applications will be organised[13]. However, ECHA has currently no sufficient information to define clearly enough the factors which it should take into account for this assessment nor is ECHA currently able 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. Better insight into the matter might be available once the applications relating to the third recommendation will have been submitted.

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 but more slots can be considered on a case-by-case basis, and setting the application dates with 3 months intervals in between the slots. From the applicant's point of view it would be 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. Furthermore, substances with no registration requirement are allocated to the later slots.

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

1.Extensive time needed in the supply chain to

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).

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

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getting orga–nised for preparing application (e.g. due to high number of users)	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 a time of about 6 months for getting organised and consulting external expertise. Therefore, the "later" LAD slots can be regarded as sufficiently long deadlines for complex-supply-chain cases.
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 straight forward exercise, and so would also the socio-economic analysis which would imply a relatively short LAD. However, ECHA does not normally have such information when preparing the recommendation as this becomes available only at the application stage. Thus, ECHA does not intend to use this as a criterion to shorten the LADs. Socio-economic or practical considerations are not 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. 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.

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B.1.3. Review periods

1.Upfront review periods

Setting 'upfront' review periods for any uses requires that the Agency has access to adequate information on different aspects relevant for a decision on the review period. ECHA currently assessed that the information available is not sufficient to conclude on upfront specific review periods. Therefore, ECHA did not propose such review periods in the draft recommendation. 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[14].

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[15].

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. The Commission enjoys discretion in deciding whether or not to provide exemptions from authorisations pursuant to Article 58(2) REACH. It should however be recalled that the discretion to grant an exemption provided for in Article 58(2) of the REACH Regulation is an exception to the rule that the placing on the market and the use of substances of very high concern should be subject to authorisation, one of the purposes of which is to ensure they are phased out where economically and technically feasible (Article 55 of REACH).

[14] RAC's and 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
[15] http://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf

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In preparing its recommendation and when assessing proposals for exemptions from the authorisation requirement in accordance with Article 58(2) that are submitted during the public consultation on the draft recommendation ECHA considers the following elements (also described in the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV[16]):

- There is existing EU legislation (i.e. Regulations and Directives adopted by the EU institutions) addressing the 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 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 considered.
- 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 cover the substance to be included in Annex XIV and address the concern related to its intrinsic properties. This can be the case e.g., where the legislation specifically refers to the substance to be included in Annex XIV either by naming the substance or by referring to the group the substance belongs to (e.g. by referring to the classification criteria or the Annex XIII criteria).
- The existing EU legislation imposes minimum requirements for the control of risks of the use. The piece of legislation has to define the measures to be implemented by the actors and to be enforced by authorities in a way that ensures the same minimum level of control of risks throughout the EU and that this level can be regarded as proper. This can include EU legislation that 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 the aim of imposing measures (e.g., EU legislation which provides Member States the possibility to impose less stringent requirements than that suggested by the EU legislation in question) or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

On the basis of the elements above:

(i) Only existing EU legislation is relevant in the context to be assessed (not national legislation).

(ii) Minimum requirements for controlling risks to human health or/and 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

[16] Available at: http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf

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

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

C.1.3. Aspects not justifying an exemption from authorisation

There are several generic exemptions from the authorisation requirement[15]. 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. While information such as a low level of risk or low tonnage associated to a use, voluntary measures implemented by industry, availability and suitability of alternatives, socioeconomic benefits associated with continuing a use, is important, it cannot be used as basis for an Art. 58(2) exemption. Information regarding these topics needs to be provided as part of the application for authorisation in case the substance is included in Annex XIV. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.

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C.2 Further responses relevant for the substances/substance group

Reference code	Issue raised in the comment(s)	Response
C.2.1.	Request for Art 58(2) exemption for use of CTPHT as binder in electrodes *Occupational Health legislation:* *Council Directive 98/24/EC (CAD)* *Carcinogens or mutagens at work Directive 2004/37/EC (CMD)* *Environmental legislation:* *Directive 2010/75/EU (IED)*	**Occupational Health legislation:** Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (CAD) sets out a framework based on the determination and assessment of risk and general principles for the prevention of risk, associated with hazardous chemical agents. The Carcinogens or mutagens at work Directive 2004/37/EC (CMD) introduces a framework of general principles to protect workers against risks to their health (which includes prevention of risk) from exposure. The overriding principle is that the employer shall reduce the use of a carcinogen or mutagen (CM) at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, preparation or process which, under its condition of use, is not dangerous or is less dangerous to workers' health and safety. Where substitution is not possible, CMs should be used in closed systems, where technically possible. Furthermore, a hierarchy of measures shall be applied when a CM is used. Both Directives outline a hierarchy of control and risk reduction measures (with substitution at the top), however, they leave the determination of the measures to be imposed to the employer and do not provide specific indicators to be used to assess whether a measure higher up in the hierarchy would have been technically possible. On this basis it is not considered that CAD or CMD impose minimum requirements for controlling risks to human health. Therefore, these Directives may not be regarded as a sufficient basis for exempting uses of CTPHT from authorisation in accordance with Article 58(2) REACH Regulation. **Environmental legislation:**

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	Water Framework Directive 2000/60/EC (WFD) (and its daughter Directives 2006/118/EC, 2008/105/EC and 2013/39/EU) *Council Directive 98/83/EC on the quality of water intended for human consumption* *Council Directive 2004/107/EC relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air* *Waste Framework Directive (2008/98/EC)* *REACH & CLP:* *Classification Labelling and Packaging (CLP) of Substances and Mixtures Regulation (EC) No 1272/2008*	In relation to Directive 2010/75/EU (IED), Annex II is an indicative list of the main polluting substances and includes large groups of substances. The directive does not specify how to identify polluting substances for which a permit for an installation needs to include an emission limit value. For these reasons the substances for which the minimum requirements set out in the directive apply are not specified in a way that would allow the use of the IED Directive as a reason for exemption under Article 58(2) REACH. It is further noted that pursuant to Article 62(5)(b)(i) REACH an applicant may justify in the authorisation application that emissions from an installation for which an IPPC permit has been granted do not need to be considered when deciding on an authorisation. This implies that a case specific consideration is needed to judge whether risks arising from IED installations are properly controlled. In relation to the Water Framework Directive 2000/60/EC (WFD) (and its daughter Directives 2006/118/EC, 2008/105/EC and 2013/39/EU), these Directives set environmental quality standards for certain substances in the aquatic environment (including for polyaromatic hydrocarbons in surface waters, which are identified as priority hazardous substances), and a framework for control of emissions, discharges and losses of these substances into the aquatic environment. The WFD, *inter alia*, obliges Member States to protect, enhance and restore bodies of surface water with the aim of achieving good surface water status by 2015 (with certain derogations) and it also obliges Member States to implement the necessary measures with the aim of progressively reducing pollution from priority substances and ceasing or phasing out emissions, discharges and losses of priority hazardous substances (WFD Art 4). However, the Directive does not establish specific emission limits for substances or define risk management measures required. These aspects would be covered e.g. in specific permits issued by national authorities. It is further noted that pursuant to Article 62(5)(b)(ii) REACH an applicant may justify in his authorisation application that discharges of a substance from a point source governed by the requirement for prior regulation referred to in Article 11(3)(g) of Directive 2000/60/EC and legislation adopted under Article 16 of that Directive do not need to be considered when deciding on an authorisation. (It can be noted that Article 61(5) of REACH envisages that the Commission may review authorisation applications if the environmental objectives as referred to in Article 4(1) of the WFD are not met.) This implies that a case specific consideration is needed to judge whether risks arising from such discharges are properly controlled. Under Article 7a of Directive 2008/105/EC (as amended by Directive 2013/39/EU) it is foreseen that the REACH authorisation and restriction processes may be initiated by the Commission to achieve the objectives of that legislation. Therefore, in order not to limit the Commission's possibility to take such action, it may not be appropriate to allow an exemption from the authorisation requirement on the basis of the WFD. In addition, and in any event, risks do not appear to be properly controlled at other life cycle stages (e.g. see above in relation to occupational health legislation). Therefore, the WFD does not appear to be on its own sufficient for granting an exemption for the use under Article 58(2) REACH.

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	REACH Regulation	Council Directive 98/83/EC on the quality of water intended for human consumption ('Drinking Water Directive') aims at protecting human health from adverse effects of any contamination of water intended for human consumption by ensuring that it is wholesome and clean. It applies to all water intended for human consumption apart from natural mineral waters and waters which are medicinal products. It sets essential quality standards for a range of parameters including benzo(a)pyrene, which must be monitored and tested regularly. The Directive states that '*without prejudice to their obligations under other Community provisions, Member States shall take the measures necessary to ensure that water intended for human consumption is wholesome and clean*'. The Directive does not establish specific emission limits for substances or define risk management measures required. These aspects would be covered e.g. in specific permits issued by national authorities. If the REACH risk management processes are necessary to achieve the objectives of this Directive, then the same considerations may apply as for the WFD. In addition, and in any event, risks to human health do not appear to be properly controlled at other life cycle stages (e.g. see above in relation to occupational health legislation). Therefore, on its own the Drinking Water Directive does not appear to be sufficient justification for granting an exemption for the use under Article 58(2) REACH. Council Directive 2004/107/EC relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air aims at minimising harmful effects on human health, paying particular attention to sensitive populations, and the environment as a whole, of airborne arsenic, cadmium and nickel and polycyclic aromatic hydrocarbons. It establishes target values (which are not to be considered as environmental quality standards as defined in Article 2(7) of Directive 96/61/EC and which, according to Article 10 of that Directive, require stricter conditions than those achievable by the use of BAT) for the concentration of certain pollutants in ambient air including benzo(a)pyrene, which is used as a marker for the carcinogenic risk of PAHs in ambient air. It ensures that good air quality is maintained and where necessary improved. It provides common methods and criteria for the assessment of concentrations of arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air and the deposition of the covered pollutants. It ensures that information on concentrations is adequately communicated with the public. The Directive requires that Member States shall take all necessary measures not entailing disproportionate costs to ensure that the concentrations of the covered pollutants, including benzo(a)pyrene, do not exceed the target values laid down in Annex I. The Directive does not establish specific emission limits for substances or define risk management measures required. These aspects would be covered e.g. in specific permits issued by national authorities. If the REACH risk management processes are necessary to achieve the objectives of this Directive, then the same considerations may apply as for the WFD. Given that the target values are not environmental quality standards this may reduce the protection afforded by the Directive. In addition, and in any event, risks do not appear to be properly controlled at other life cycle stages (e.g. see above in relation to occupational health legislation). For these reasons this Directive on its

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		own does not appear to be a sufficient basis to grant an exemption for the use under Article 58(2) REACH. The Waste Framework Directive (2008/98/EC) aims at, inter alia, protecting the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste (including hazardous waste). Wastes classified as hazardous are considered to display one or more of the properties listed in Annex III of the Directive - which includes CMR properties. Wastes classified as hazardous feature on the list established by Commission Decision 2000/532/EC. Wastes from industrial activities containing coal tar are listed as hazardous waste and need to be treated accordingly. The Waste Framework Directive in general contributes to environmental protection at the waste life cycle stage. Waste including coal tar is specifically listed as hazardous waste and therefore there appears to be minimum requirements related to the waste stage of this use. However, as outlined in the responses to other comments, risks do not appear to be properly controlled at other life cycle stages (e.g. see above in relation to occupational health legislation). Therefore, the Waste Framework Directive does not appear to be on its own sufficient for granting an exemption for the use under Article 58(2) REACH. **REACH & CLP:** In relation to the Classification Labelling and Packaging (CLP) of Substances and Mixtures Regulation (EC) No 1272/2008, this Regulation ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union through the classification and labelling of chemicals. According to Recital 10 CLP Regulation "the objective of this Regulation should be to determine which properties of substances and mixtures should lead to a classification as hazardous, in order for the hazards of substances and mixtures to be properly identified and communicated." The Regulation does not however impose sufficient measures to properly control the risks of such substances. Therefore, this Regulation is not a sufficient basis for exempting the uses of CTPHT from authorisation in accordance with Article 58(2) REACH Regulation. CTPHT is restricted in accordance with entry 28 of Annex XVII of the REACH Regulation. Pursuant to entry 28, substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 (CLP Regulation) classified as carcinogenic category 1A or 1B (Table 3.1 of Annex VI to CLP Regulation), shall not be placed on the market, or used, as substances, as constituents of other substances or in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than either the relevant specific concentration limit specified in Part 3 of Annex VI to the CLP Regulation, or the relevant concentration specified in Directive 1999/45/EC where no specific concentration limit is set out in Part 3 of the CLP Regulation.

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		Article 56(6)(b) of REACH provides that the authorisation requirement does not apply to the use of substances when they are present in mixtures below the lowest of the concentration limits specified in Directive 1999/45/EC or in Part 3 of Annex VI to the CLP Regulation. CTPHT was identified as a Substance of Very High Concern (SVHC) according to Article 57 (a) REACH as it is classified in Annex VI, Part 3, Table 3.1 of CLP Regulation as carcinogenic category 1B. (In addition, on the basis of the PBT and vPvB properties of some of its PAH-constituents, CTPHT fulfils the PBT and the vPvB criteria according to Article 57 d and e of the REACH Regulation and was identified as SVHC for these properties also.) CTPHT was therefore included in the Candidate List for authorisation on 13 January 2010, following ECHA's decision ED/68/2009. Table 3.1 in Part 3 of Annex VI to CLP Regulation does not set out a specific concentration limit; thus, the concentration limit specified in Directive 1999/45/EC applies. Accordingly, the concentration limits specified for CTPHT in Annex XVII of REACH are in fact the same as the concentration limits referred to in Article 56(6)(b) REACH. Therefore, the use of CTPHT below the concentration limits set out in Annex XVII of REACH does not need to be subject to an exemption from authorisation.
C.2.2.	Reference to *Carcinogens or Mutagens at Work Directive – (2004/37/EC)* with regard to use of anthracene oil and CTPHT.	The Carcinogens or Mutagens at Work Directive 2004/37/EC (CMD) introduces a framework of general principles to protect workers against risks to their health (which includes prevention of risk) from exposure. The overriding principle is that the employer shall reduce the use of a carcinogen or mutagen (CM) at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, preparation or process which, under its condition of use, is not dangerous or is less dangerous to workers' health and safety. Where substitution is not possible, CMs should be used in closed systems, where technically possible. Furthermore, a hierarchy of measures shall be applied when a CM is used. The Directive outlines a hierarchy of control and risk reduction measures (with substitution at the top), however, it leaves the determination of the measures to be imposed to the employer and does not provide specific indicators to be used to assess whether a measure higher up in the hierarchy would have been technically possible. On this basis it is not considered that CMD would impose minimum requirements for controlling risks to human health. Therefore, this Directive may not be regarded as a sufficient basis for exempting uses of anthracene oil or CTPHT from authorisation in accordance with Article 58(2) of the REACH Regulation.
C.2.3.	Exemption for use of anthracene oil as fuel and biocide	Please see process information C.1 and in particular C.1.2 which provides further information on generic exemptions from authorisation. In relation to use as fuel, we would suggest that you examine whether the use of your substance can be regarded as fulfilling the requirements of the relevant exemption as set out in Article 56(4)(d) REACH. If you conclude that your uses of the mentioned substance fulfil the above requirement, the uses can benefit

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		from the exemption from authorisation as set out in Article 56(4)(d) REACH and no authorisation application would be required to continue the use after the sunset date. In relation to use as biocide, the Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) includes a risk assessment and authorisation procedure for active substances and products containing these substances. Anthracene oil is not approved as an active substance under the Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) and based on the description of use it does not appear to be incorporated into the final product, therefore the exemption in Article 56(4)(b) REACH does not seem to apply. However, it is stated that anthracene oil is used for creosote manufacture (which is itself an approved substance under the BPR). Therefore, it appears that the use of Anthracene oil in this context may be an intermediate use within the meaning of Article 2(8) of the REACH Regulation pursuant to which certain intermediate uses of substances are exempt from the scope of authorisation.
C.2.4.	Request for an exemption for service parts of past models	Please see sections C.1.1 and C.1.3 of this document on the general principles for exemptions under Art. 58(2) and on aspects not justifying an exemption from authorisation. Please also note that for the cases of operators who need to continue using an Annex XIV substance in low volumes or for the production of legacy spare parts, the Commission has been considering establishing a streamlined and simplified authorisation process. A public consultation on the Commission's proposal for these cases ran between February and April 2015 (see http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8081&lang=en&title=REACH-Authorisation---Consultation-on-applications-for-low-volumes-and-on-extension-of-transitional-arrangements-for-uses-in-legacy-spare-parts-).

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