10 July 2019

Response document

Substance names and EC numbers:

Substance name	EC number
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0
Benzyl butyl phthalate (BBP)	201-622-7
Dibutyl phthalate (DBP)	201-557-4
Diisobutyl phthalate (DIBP)	201-553-2

About this response document

The present document provides ECHA's responses to the comments[1] received during the public consultation on the draft recommendation for amendment of Authorisation List entries of the above named phthalates (12 December 2018 to 12 March 2019) as well as the previous public consultation hosted on behalf of the Commission (5 June 2018 to 6 August 2018) on that issue.

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 to the same parts of the current document.

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

- **A. General issues**
  covers any generic issue not covered by sections B and C;

[1] The compilation of comments received, along with references to responses, can be found at the following link(s):
- DEHP: https://echa.europa.eu/documents/10162/13640/axiv_amend_recom_comref_dehp_en.rtf
- BBP: https://echa.europa.eu/documents/10162/13640/axiv_amend_recom_comref_bbp_en.rtf
- DBP: https://echa.europa.eu/documents/10162/13640/axiv_amend_recom_comref_dbp_en.rtf
- DIBP: https://echa.europa.eu/documents/10162/13640/axiv_amend_recom_comref_dibp_en.rtf

- **B. Latest Application Dates, Sunset Dates and review periods**
  covers responses to issues related to the latest application dates, sunset dates and review periods, including ECHA's approach for determining those timelines;
- **C. Uses that should be exempted from authorisation**
  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. Although the prioritisation of the substances was not relevant for this amendment recommendation as the substances are already listed in Annex XIV, the prioritisation related issues are still provided below as they are relevant as responses to some comments.

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

The section headings in the process information and captions on the left of the substance/group-specific responses provide a summary of the issue addressed per section / response. The headings and captions are also numbered (e.g. "A.1.2", "B.2.02"), 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. 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 applied by ECHA was discussed with, and has been agreed by, the Member State Committee (MSC). Please refer to: http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

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

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

The results of the priority assessment of all Candidate List substances using the prioritisation approach can be found at ECHA's website[2]. Further information on how the approach is applied in practice, especially on how the wide-dispersive use criterion is assessed, is provided in the "General approach for prioritisation of SVHCs: practical implementation examples"[3].

4.Information taken into consideration for the draft recommendation

For the purpose of its draft priority setting ECHA considers all relevant information available to it. The registration dossiers (including the CSRs) are the main source of information. It is the registrants' obligation to ensure that the information in the dossiers is clear, consistent and up-to-date. Further information e.g. from Annex XV SVHC dossiers and from SVHC public consultation is considered, where appropriate (see Section 4 of the prioritisation approach (linked in A.1.3)). 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 public consultation on the draft recommendation and in the registration dossiers (checked after closure of the public consultation), including any request for exemption, is taken into account (i) by the MSC when preparing its opinion on the draft recommendation and (ii) by ECHA when finalising its recommendation. ECHA also takes into account the MSC opinion when finalising its recommendation. The recommendation, together with MSC opinion, all comments received, and the responses to the comments, are submitted to the European Commission who makes the final decision on which substances to include in Annex XIV and on the details for the respective entries. All non-confidential information is also made available on ECHA's website.

[2] https://echa.europa.eu/documents/10162/13640/prioritisation_results_cl_substances_sept_2018_en.pdf

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

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

A.1.2. Prioritisation: Volume

1.Volume in the scope of authorisation

The volume taken into consideration for priority setting is the volume for all uses in the scope of authorisation. That volume is derived based on data from the registration dossiers as provided in Section 3.2 and 3.5 of the IUCLID dossiers and/or in the CSRs, along with information presented in the Annex XV SVHC reports or information submitted during public consultation on SVHC identification of the substances. Where available, information on uses falling under the generic exemptions from authorisation[4] and on their related tonnage is assessed to estimate the volume relevant for the priority setting.

It is stressed, however, that the assessment of whether a use is in the scope of authorisation is done only for prioritisation purposes and it does not conclude or define the status of a use under the REACH Regulation (which is the responsibility of individual companies and subject to enforcement). In general, a realistic worst case approach is taken in cases where a clear conclusion on the intermediate status of the use or whether other exemptions apply is not possible on the basis of available data. The definition of intermediates as set out in Article 3(15) of the REACH Regulation, further elaborated and described in Appendix 4 of the 'Guidance on intermediates'[5] and in the 'Practical guide on intermediates'[6], is used to assess on the basis of available use descriptions (in the registrations incl. CSRs, the Annex XV SVHC reports and information received in SVHC public consultation) whether the identified uses are 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)

[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] https://www.echa.europa.eu/documents/10162/23036412/intermediates_en.pdf
[6] https://www.echa.europa.eu/documents/10162/23036412/pg16_intermediate_registration_en.pdf

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

More information can be found in Section 5.3 of the general prioritisation approach document[7] and in "General approach for prioritisation of SVHCs: practical implementation examples"[8]. Some of the main points are summarised below.

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

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

The full scores of higher WDU categories (professional and consumer uses) are assigned as long as the respective uses represented absolute volumes ≥ 10 t/y[9]. This is as consumer and professional uses can be regarded as having wide-dispersive pattern, regardless of how high the amount used at industrial sites is. In other words, the allocation of scores is based on the actual tonnage in different types of uses and not the share of the tonnage in different uses.

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

Furthermore, consumer uses for substances classified as Carc./Muta./Repr. 1A/B are not considered in the prioritisation score regardless of whether identified in registrations or not (as those are restricted[10] or, if in mixtures below the classification concentration limit, not in the scope of authorisation). For professional and industrial uses only the tonnage above the relevant concentration limit is considered in those cases where this information is available in the registration dossiers or in other sufficiently reliable sources.

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

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

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

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

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

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

1.Relevant further considerations

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

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

1.Potential other regulatory actions

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

Any suggestion to address the concern raised by the substance via e.g. restriction of certain uses, or better enforcement of existing legislation for protection of workers, or the need to generate further information via substance evaluation prior to taking a decision on including the substance in Annex XIV are beyond the remit of ECHA in the recommendation process. The same applies for views that there is no need to initiate any further regulatory risk management action at this time.

Considerations on the most appropriate risk management options are usually discussed among authorities prior to proposing substances for inclusion in the Candidate List[11].

2. Authorisation is disproportionate and/or means a ban

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

Substances included on the Candidate List have been identified as substances of very high concern based on their hazardous properties. There is a societal interest to protect humans and/or the environment from risks potentially arising from the uses of these substances. At the same time, aspects such as the availability and suitability of alternatives, socio-economic, human health or environmental benefits of continuing a particular use or the (adverse) impacts of ceasing it[12], as well as information on the actual level of risk associated to a use of such substances are important. The authorisation process as a whole (inclusion in the Candidate List, inclusion in Annex XIV and application and granting the authorisations) takes into account and aims to balance these interests and aspects.

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

3.Use specific considerations

The authorisation process foresees that the level of control of risks, the availability of and the time needed to transfer to suitable alternatives (e.g. due to need for established validation, safety requirements and/or performance standards) and socio-economic considerations such as the magnitude of benefits from continuing a certain use of an SVHC (i.e. adverse impacts of ceasing a use) are not considered in the recommendation phase but are addressed at the application phase of the authorisation process. That is because it is this phase where the respective assessment can be done in an effective manner: based on structured input of information by the applicant, the foreseen dedicated public consultation for scrutinising the information on alternatives and the involvement of Committees having the respective expertise and mandate. Information on these aspects will be taken into account by the Committees for Risk Assessment

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

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

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

8.Uncertainty as to whether authorisation will be granted

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

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

ECHA has created a dedicated webpage "applying for authorisation" with the aim of guiding applicants in the preparation of their applications (https://echa.europa.eu/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 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

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

Commission in its opinion. This is normally seven years, but a long review period of e.g. 12 years is possible, too[14].

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

In addition, 'trialogues' are organised with applicants, Committee rapporteurs and interested parties during the opinion-making process. Seminars and workshops add to the support available for applicants.

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

By June 2019, >140 applications for >220 uses from >230 applicants have been submitted and are at various stages of processing[15]. The Risk Assessment Committee (RAC) and the Socio-economic Committee (SEAC) have adopted final opinions for a substantial number of uses (>200) and sent them to the Commission for decision making. With the conclusions of each of those evaluations communicated at ECHA's website, predictability of the authorisation process should be less of an issue.

A.2. Further responses relevant for the substance

Reference code	Issue raised in the comment(s)	Response
A.2.01	Draft amendment does not reflect comments submitted in previous consultation	ECHA hosted on behalf of the Commission a 2-months public consultation on the proposed amendment of Annex XIV entries of DEHP, BBP, DBP and DIBP from June to August 2018. After the end of the consultation ECHA was asked by the Commission to prepare a recommendation for the amendment of the Annex XIV entries according to Art. 58(3) and (4) of REACH. For the recommendation process another consultation on the same issue was required, but in this case running for three months (December 2018 to March 2019). As part of the second consultation it

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

		was communicated that comments received for both consultations are considered together when finalising ECHA's recommendation to amend the Authorisation List entries. Accordingly, comments received within the previous consultation were not analysed by ECHA before launching the second consultation in December 2018 and, hence, the transitional arrangements proposed in ECHA's draft recommendation were identical to those proposed by the Commission for the previous consultation. However, as mentioned all comments received for both consultations have been considered for finalising this amendment recommendation.
A.2.02	Claim that lower concentration limit will have negative impact on recycling rates of PVC	Annex XIV specifies for each substance, among others, the intrinsic properties referred to in Art. 57. In case the Candidate List is amended to identify a substance also due to additional intrinsic properties, the Annex XIV entry needs to be amended, too. ECHA acknowledges that the concentration limit for DEHP, BBP, DBP and DIBP, below which their presence in recycled PVC material would not trigger the need for authorisation, will be lower (0.1 % by weight). It should be noted that socio-economic considerations are not considered within the recommendation phase but are taken into account in the application for authorisation phase. Some actors in the supply chain have successfully applied for authorisation for uses of recycled soft PVC containing DEHP (see https://www.echa.europa.eu/applications-for-authorisation-previous-consultations).
A.2.03	Urging ECHA to set concentration limits below 0.1% for the four phthalates due to cumulative effects	ECHA acknowledges that combined exposure to these four phthalates was taken into account in the respective restriction proposal for these substances in articles under Article 69(2) (see https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1806e7a36). However, the specifications of each substance included in Annex XIV are provided in Art. 58(1) REACH. The regulation does not foresee the possibility for ECHA to set specific concentration limits for substances included in Annex XIV. Hence, the concentration limits as specified in Art.56, equal to or above which the use of a substance falls under the authorisation requirement (0.1 % (w/w) in case of the four substances), will apply once the Annex XIV entries have been amended.
A.2.04	Reminder that decisions by the Commission on some applications for	Thank you for your comment which we will make the Commission aware of. However, the fact that some applications for authorisation have not yet been decided on has no suspensive effect on this amendment recommendation process.

	authorisation for DEHP are still pending	
A.2.05	Request that ECHA should consider that BBP, DBP or DIBP could be used as regrettable substitutes for DEHP in food contact material (FCM)	Although the generic exemption for uses in food contact material from the authorisation requirement (Art. 56(5)(b) REACH) will not any more apply to DEHP once its endocrine disrupting properties for the environment have been added to the Annex XIV entry, the exemption will still cover those uses of BBP, DBP and DIBP, which were identified as substances of very high concern only because of hazards to human health. As noted in your comment it is the application for authorisation phase where the availability and suitability of alternatives are scrutinised for deciding on granting an authorisation for an applied for use.
A.2.06	Understanding that the Annex XIV amendment adds endocrine disrupting properties for the environment to entries of the four phthalates	Please note that only for the substance DEHP the Annex XIV entry will be amended to reflect the endocrine disrupting properties with effects both on human health and on the environment. For the substances BBP, DBP, DIBP only the endocrine disrupting properties with effects on human health will be added.
A.2.07	Questioning the endocrine disrupting properties	The substance has been added to the Candidate List on the basis of Article 57(f) due to its endocrine disrupting properties for human health and the environment. The reasoning for doing so is set out in the relevant support documents. Therefore, comments on the inherent properties of the substances are not relevant for this part of the authorisation process. Please refer to link below for relevant documents related to the Candidate Listing of DEHP: https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807d8dc8.
A.2.08	Questioning the reproductive toxicity	The substance has been added to the Candidate List based on its harmonised classification as toxic for reproduction, category 1B (Annex VI of the CLP-Regulation (Regulation (EC) No 1272/2008)). Therefore, comments on the inherent properties of the substances are not relevant for this part of the authorisation process.

B. Latest Application Dates, Sunset Dates and review periods

B.1. Process information

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

1.Legal background

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

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

2.ECHA's proposal for sunset dates

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

3.ECHA's proposal for latest application dates

ECHA made its proposals for the latest application dates (LAD) on the basis of the estimation that the time needed to prepare an authorisation application of sufficient quality might in standard cases require 18 months (roughly 12 months work-time for drafting the application and an additional buffer of 6 months for getting organised and consulting required external expertise). Based on discussions and experience on received applications so far, the applicants have not generally indicated that they have had difficulties with the stipulated time periods. Rather there had been problems for the first applicants preparing applications to have clarity on what information, analysis and justification was required in the applications. As over 180 opinions have already been given by RAC and SEAC, future applicants are in a better position than the first ones to prepare a fit-for-purpose application.

The work done and ongoing by the Commission, MSCAs, industry and ECHA to further develop approaches and advice on how to prepare a streamlined and fit-for-purpose application will also support the potential

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

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

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

The complexity of the supply chain could potentially be assessed based on the number of different uses and affected industry sectors, the number of layers in the supply chain, the number and type of companies concerned, and the way potential future applications will be organised[16]. However, ECHA has currently insufficient information to define clearly enough the factors which it should take into account for this assessment. Furthermore, ECHA is currently unable to define precisely what type of information would be used to characterise the above-mentioned factors. Therefore, it is concluded that ECHA currently does not have enough information to justify a prolongation of the first LAD, i.e. the 18 months slot.

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

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[17].

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.

[17] https://www.echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_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 straight forward exercise, and so would also the socio-economic analysis which would imply a relatively short LAD. However, ECHA does not normally have such information when preparing the recommendation as this becomes available only at the application stage. Thus, ECHA does not intend to use this as a criterion to shorten the LADs.

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

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

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

B.1.3. Review periods

1.Upfront review periods

Setting 'upfront' review periods for any uses would require that ECHA had access to adequate information on different aspects relevant for a decision on the review period. So far such information was not available

to ECHA at the recommendation step. Therefore, ECHA has not proposed any upfront specific review periods in its draft recommendations for inclusion in the Authorisation List. It is to be stressed that all authorisation decisions will include specific review periods which will be based on concrete case-specific information provided in the applications for authorisation. ECHA has published guidance on the type of information in an application for authorisation which may impact the review period when granting an authorisation[18].

B.2. Further responses relevant for the substance

Reference code	Issue raised in the comment(s)	Response
B.2.01	Request for later latest application date / sunset date	As described in ECHA's general approach for the preparation of draft Annex XIV entries and further detailed in B.1.1. (general principles for setting latest application dates / sunset dates) ECHA considers 18 months as the standard latest application date (LAD) and again 18 months as the standard sunset date. Based on the available information ECHA sees no ground to deviate from the standard transitional arrangements proposed in the draft recommendation. Accordingly, ECHA recommends for the affected uses of the four phthalates a latest application date 18 months after the amendment of Annex XIV and a sunset date 18 months after the LAD.
B.2.02	Request for later sunset date based on Art. 120 of the Medical Device Regulation (EU/2017/745)	ECHA's general approach for the preparation of draft Annex XIV entries and responses under B.1.1 describe that ECHA considers 18 months as the standard latest application date (LAD) as well as what aspects are considered when assigning the substances within a specific recommendation round to different LAD slots to even the workload. In addition, it is explained why ECHA usually recommends a standard difference of 18 months between the latest application and sunset dates. According to ECHA's recommendation the sunset date would be 36 months after the amendment of Annex XIV.

[18] 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)

		It should be noted that the final decision about transitional arrangements to be included in Annex XIV are taken by the Commission, who will ensure that timelines set in other legislation is taken into account where appropriate. Please also refer to responses A.1.5.2 (authorisation is disproportionate and/or means a ban), A.1.5.8 (uncertainty as to whether authorisation will be granted) and B.2.01 (request for later latest application date / sunset date).
B.2.03	Claim that proposed LAD overlaps with timelines of other EU legislation (e.g. MDR, RoHS) causing high regulatory burden and diverting resources away from innovation	The REACH Regulation aims to ensure a high level of protection of human health and the environment while enhancing competitiveness and innovation. The authorisation procedure aims to progressively replace substances of very high concern (SVHC) by suitable alternatives as soon as technically and economically feasible. As such it provides a strong incentive to search for and develop suitable alternatives. Until substitution is achieved authorisation aims to ensure the good functioning of the internal market while assuring that risks arising from SVHCs are properly controlled. In general, applications for authorisation have to cover not only human health but also environmental concerns for the entire lifecycle of a substance. ECHA's general approach for the preparation of draft Annex XIV entries and response B.1.1.3 describe that ECHA considers 18 months as the standard latest application date (LAD) as well as what aspects are considered when assessing within the recommendation process whether a prolonged LAD would be justified. It should be noted that the final decision about transitional arrangements to be included in Annex XIV are taken by the Commission, who will ensure that timelines set in other legislation are taken into account where appropriate.
B.2.04	LAD of 30 months was assigned when DEHP was included in Annex XIV	DEHP was included in Annex XIV within the very first amendment of Annex XIV in February 2011. Since then substantial experiences have been made in terms of preparing applications for authorisation. Please also refer to B.1.1.3. (ECHA's proposal for LADs), B.1.2 (Aspects not considered when proposing dates) and B.2.01 (Request for later latest application date / sunset date).
B.2.05	Claim that preparation time is shorter than for "standard" process of including	The phthalates DEHP, BBP, DBP and DIBP were initially identified as substances of very high concern (SVHC) due their toxicity to reproduction and included in Annex XIV in 2011 and 2012. DEHP was additionally identified as having endocrine disrupting properties with effects on the environment and the entry in the Candidate List of substances of very high concern for authorisation was updated already in 2014. At the same time the four phthalates were

	substances into Annex XIV	proposed to be identified also as having endocrine disrupting properties for human health. In 2017 the Candidate List entries of the four substances were amended to reflect their endocrine disrupting properties with effects on human health. We would like to point out that while there is no automatic update of the Annex XIV after an SVHC entry has been updated, any changes in the Candidate List of an SVHC triggers the need to amend the respective Annex XIV entry. The current recommendation process, including the public consultation ECHA carried out as a part of it, aims to ensure that the amendment is done in a transparent manner and the interested parties have a possibility to provide comments. As already noted in the comment the process for amending Annex XIV entries differs from the recommendation process to include substances in that Annex as the prioritisation step is not relevant for substances already included. The changes of intrinsic properties for these substances were communicated in a timely manner by updating the Candidate List entries in 2014 and 2017. Therefore the additional intrinsic property is relevant and ECHA sees no basis to recommend a prolonged latest application date for the substances.
B.2.06	Claim that inexperience with preparing applications for authorisation for endocrine disrupting substances further increases complexity	As further detailed in sections B.1.1.3 and B.1.2.1 of this response document, ECHA considers a time period of 18 months sufficient to prepare an application for authorisation of adequate quality. This is based on experience from previous applications and discussions with applicants. It should be noted that applications for authorisation have already been successfully submitted for similar (i.e. non-threshold) substances.
B.2.07	Request for earliest possible Latest Application and Sunset Date	The general approach for the preparation of draft Annex XIV entries describes how ECHA determines latest application and sunset dates in a particular round. Further details are provided in section B.1.1. on general principles for setting those dates. In section B.1.2. aspects are described that are not considered by ECHA when proposing latest application or sunset dates. Those aspects include the availability of alternatives. Similarly, biomonitoring data do not impact on the time required to prepare an application of authorisation and are therefore not considered for setting transitional arrangements. Please also refer to B.2.01 (request for later latest application date / sunset date).

B.2.08	Understanding that review period applies to exemption from authorisation requirement	It should be noted that review periods that according to Art. 58(1) of REACH could be included in Annex XIV relate to authorisations granted for a specific use of a substance. In contrast, review periods for exemptions from the authorisation requirement, as mentioned in the comment, are not foreseen in REACH. Please also refer to B.1.3.1. (review periods).

C. Uses that should be exempted from authorisation

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[19].
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 or the environment for the use of the substance ensuring the risk is properly controlled; it should be noted that in the absence of existing specific EU legislation in force, the Commission is prohibited from granting an exemption on the basis of Article 58(2) in respect of the substance

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

listed in Annex XIV of REACH; it is therefore not sufficient if there is national legislation governing such use or a Commission communication;

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

In preparing its recommendation ECHA will consider the following elements in deciding whether to recommend an exemption of a use of a substance[20] (also described in the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV[21]):

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

[20] 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*.

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

On the basis of the elements above:

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

(ii) Minimum requirements for controlling risks to human health and/or the environment need to be imposed in a way that they cover the life cycle stages that are exerting the risks resulting from the uses in question.

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

C.1.2. Generic exemptions

A list of uses exempted from the authorisation requirement according to the REACH Regulation can be found at 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 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 (https://www.echa.europa.eu/documents/10162/23036412/intermediates_en.pdf).

C.1.3. Aspects not justifying an exemption from authorisation

There are several generic exemptions from the authorisation requirement[19]. 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 raised in the comment(s)	Response
C.2.01	Use in medical sector, including (in vitro diagnostic) medical devices	**1. Use in medical devices - human health concern** Article 60(2) REACH establishes that the Commission should not consider, when granting authorisations, the human health risks associated with the use of substances in medical devices regulated by Council Directive **90/385/EEC** of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive **93/42/EEC** of 14 June 1993 concerning medical devices, or Directive **98/79/EC** of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. In addition, Article 62(6) REACH provides that applications for authorisation should not include the risks to human health arising from the use of a substance in a medical device regulated under those Directives. The same will apply once Regulations **2017/745** and **2017/746** become fully effective and repealing Directives **90/385/EEC**, **98/79/EC** and **93/42/EEC**. It follows that an application for authorisation should not be required for a substance used in medical devices regulated under the above-mentioned legislation ***if such a substance has been identified in Annex XIV to REACH for human concern only***. In these cases, an assessment as to whether the conditions for an exemption pursuant to Article 58(2) of REACH apply would not be necessary. **2. Blood Directive** Directive **2002/98/EC** applies to the collection and testing of human blood and blood components, whatever their intended purpose, and to their processing, storage, and distribution when intended for transfusion and aims at ensuring the quality and safety of whole blood and blood components in order to ensure a high level of human health protection. This piece of EU legislation does not provide minimum requirements specific to any specified substances (e.g. phthalates) based on which the risks to human health are properly controlled. Therefore, it may not be considered as a sufficient basis for exempting uses of phthalates from authorisation in accordance with Article 58(2) REACH.

		3. Guidelines, opinions and other similar documents: SCHEER, MEDDEV, Pharmacopoeia Guidelines, such as those under preparation by SCHEER, and SCENIHR opinions are not legally binding instruments and therefore cannot constitute 'specific EU legislation' within the meaning of Article 58(2) REACH. The same reasoning must be applied in relation to other referred documents, i.e. (MEDDEV 2.4/ Rev. 9 June 2010) and the European Pharmacopoeia 9.0. **4. Standards** ISO 3826-1:2013 and ISO 3826-4:2015 standards are international or European standards but not existing specific EU legislation imposing minimum requirements relating to the protection of human health and the environment for the use of the substance, based on which the risk is properly controlled. The existence of such standards is therefore not sufficient for exempting uses from authorisation in accordance with Article 58(2) REACH. **5. Immediate packaging of medicinal products – human health concern** We understand that the comment concerns immediate packaging of medicinal products. For DEHP, BBP and DBP, the Commission included the following exemption under Art 58 (2) in the current Authorisation list entries: Uses in the immediate packaging of medicinal products covered under Regulation (EC) No **726/2004**, Directive **2001/82/EC**, and/or Directive **2001/83/EC**. In the Regulation including DEHP, BBP and DBP in Annex XIV the Commission indicated that "that legislation of the Union provides for a framework to properly control risks of such immediate packaging materials by imposing requirements on the quality, stability, and safety of the immediate packaging materials". ECHA recommends that the exemption should no longer apply for DEHP as that substance has now also been identified for environmental hazards. ECHA would however invite the Commission to assess whether the exemption for immediate packaging in medicinal products should continue to apply to DBP and BBP in light of the new human health hazards for which these substances have been identified. Such assessment should also be done in accordance with the considerations on the application of Article 58(2) set

		out by the General Court and the European Court of Justice in their judgments in Cases T-360/13 and C-651/15 P Vecco and others v. Commission. **6. Environmental concern DEHP** Directive **2001/83/EC** on the Community code relating to medicinal products for human use applies to medicinal products for human use intended to be placed on the market in Member States. However, the directive does not set minimum requirements specific to DEHP and its use based on which the risk ***for the environment*** is properly controlled. Therefore, it may not be considered as a sufficient basis for exempting uses of DEHP from authorisation in accordance with Article 58(2) REACH. The same applies to Directive **2002/98/EC**, Directive **93/42/EEC** of 14 June 1993 concerning medical devices, or Directive **98/79/EC** of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices as well as Regulation **2017/745** and Regulation **2017/746**.
C.2.02	Use in electrical and electronic equipment	Directive **2011/65/EU** on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS), as amended by Commission Delegated Directive (EU) **2015/863** of 31 March 2015 set a maximum concentration value of 0,1 % tolerated by weight in homogeneous materials for DEHP, DIBP, BBP and DBP. This restriction shall apply to medical devices, including in vitro medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, from 22 July 2021. It could be argued that for the articles covered (and exempted) by the RoHS Directive, the requirements set out therein for the substances at issue could be seen as "minimum requirements for controlling risks to human health and the environment" resulting from the waste phase of the articles. However, the RoHS Directive does not contain requirements to minimise risks from use of substances in applications exempt from restriction throughout the whole life cycle of the substances (e.g. occupational exposure during the previous stages of the life-cycle of the substance). Thus, for these uses of the substances in question, the requirements in the RoHS Directive do not appear to constitute a sufficient justification for exemption under Art 58(2).
C.2.03	Claim that recommendation is	As described in detail in response C.2.01 to exemption requests for the 'use in (in vitro diagnostic) medical devices', applications for authorisation should not include the risks to

	duplicating or contradicting activities mandated under the Medical Device Regulation	human health arising from the use of a substance in a medical device regulated by the legislation mentioned in the response. In addition, those risks should not be considered by the Commission for granting authorisations under REACH. Accordingly, potential future applications for authorisation for uses of DEHP would need to demonstrate that risks ***for the environment*** are properly controlled or that there are no alternatives and the socio-economic benefits outweigh the risks. At the same time medical device specific legislation does not set minimum requirements to properly control risks for the environment resulting from the use of DEHP (see response referred to above). Therefore ECHA sees no duplication or contradiction in the assessment of uses of phthalates under the MDR and potential applications for authorisation for corresponding uses of DEHP under REACH.
C.2.04	Understanding that uses regulated under the RoHS Regulation are exempted from the authorisation requirement and request to apply the same logic to uses regulated under the Medical Device Regulation	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. For more details please refer to the following responses: • C.1.1. General principles for exemptions under Art. 58(2) • C.1.2. Generic exemptions Regarding the assessment of exemption requests according to Art. 58(2) based on RoHS or legislation specific to medical devices please refer to responses C.2.02 for use in electrical and electronic equipment and C.2.01 for use in (*in vitro diagnostic*) medical devices. It should be noted that there is no generic exemption from the authorisation requirement defined in REACH for uses in electrical and electronic equipment regulated under Directive 2011/65/EU (RoHS). Exemption requests for uses according to Art. 58(2) of REACH have to be assessed case by case (see responses referred to above).
C.2.05	Generic exemptions specific to certain intrinsic properties not clear	A REACH exemption cannot be extended to situations not covered by its scope. In this case, the exemption for medical devices is intended to avoid overlap with EU legislation on medical devices which addresses the risks for human health, not environmental risks. Therefore, the REACH exemption does not, by its terms, extend to environmental risks.