14 January 2009

Prioritisation of Substances of Very High Concern (SVHC) for Inclusion in the List of Substances Subject to Authorisation

Introduction

On 28 October 2008, ECHA published the first 'candidate list' which contains 15 Substances of Very High Concern. The inclusion of a substance in the candidate list is solely based on the specific intrinsic hazardous properties of the substance (as described by Article 57 of the Regulation (EC) No 1907/2006[1] (REACH)). In the next step of the authorisation process, ECHA has the obligation to make a recommendation of priority substances for inclusion in Annex XIV of REACH (the 'authorisation list'). The Member State Committee will issue an opinion on this draft proposal. By 1 June 2009, ECHA will have to send its final recommendation to the European Commission who will decide on which substances to include in Annex XIV through the regulatory Committee procedure with scrutiny.

Pursuant to Article 58(3) of REACH whenever a decision is taken to include substances referred to in Article 57 of REACH in Annex XIV, priority shall normally be given to substances with *PBT or vPvB properties, or wide dispersive use, or high volumes.* As indicated in recital 78 of REACH "*the Agency should provide advice on the prioritisation of substances to be made subject to the authorisation procedure, to ensure that decisions reflect the needs of society as well as scientific knowledge and developments*".

ECHA decided to use a pragmatic approach for the priority setting of the substances on the current 'candidate list', which mainly relies on the legal criteria provided for in Article 58(3) of REACH. The approach to assess the criteria is a qualitative, where possible semi-quantitative, evaluation resulting in an overall conclusion on the priority of a substance. The conclusion based on the criteria of Article 58(3) may, however, be superseded by additional considerations indicating that prioritisation of a

[1] Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006); amended by Council Regulation (EC) No 1354/2007 of 15 November 2007 adapting Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), by reason of the accession of Bulgaria and Romania (OJ L 304, 22.11.2007, p. 1).

substance for inclusion in Annex XIV would from a regulatory point of view either be appropriate or not be appropriate.

It should be noted that a conclusion to not give priority to the inclusion of a particular candidate substance in Annex XIV is only pertinent to the respective priority setting operation in which this conclusion has been drawn. In future priority setting operations, this substance may be re-considered for inclusion in Annex XIV together with all other substances on the candidate list which are not already included in Annex XIV.

Although the present low number of substances on the candidate list does not necessarily warrant an advanced priority setting mechanism capable of differentiating and prioritising among many substances on the basis of detailed information on properties, uses and volumes of a substance, the chosen approach is developed to ensure a coherent priority setting for substances taking into account the fact that the list will likely grow as a result of regular future updates. The approach, while it can be kept consistent with regard to the criteria applied, could be further enhanced and refined when more data on the individual substances becomes available (e.g. due to more elaborated Annex XV dossiers and/or the increasing availability of registration dossiers).

Section A of this document describes the general approach taken to prioritise substances from the present list of candidate substances for inclusion in Annex XIV. In Section B the results of the application of this approach are documented. It consists of the list of candidate substances extended with conclusions for each substance on its intrinsic properties, the nature of its uses, the volume supplied to uses covered by REACH Title VII and the resulting priority of the substance regarding its inclusion in the list of substances subject to authorisation. For each substance a background document is available that summarises the information that has been used to develop these conclusions on the priority setting as well as the information needed to develop the draft Annex XIV entries for those substances proposed for inclusion in Annex XIV. The general approach taken for developing the draft Annex XIV entries, the actual draft recommendation and the justification for the elements in Annex XIV for each substance are provided separately.

A Outline of the priority setting approach

The information used in accordance with the criteria of REACH Article 58(3) refers to (eco)toxicological properties (hazard), to potential for release and exposure as well as to volumes supplied. This information, in particular when assessed in combination could be seen as a proxy for potential risk to human health or the environment (i.e. the higher the hazard, the volume used and the potential for release of a substance, the higher its potential risk and thereby its priority). Hence the approach outlined in the following can be considered as risk-based. It should be noted that the actual assessment of the risks to human health and/or the environment should be included by the applicant when submitting the chemical safety report as part of the application dossier.

A.1 Prioritisation criteria and their parameterisation

According to Article 58(3) priority for inclusion in Annex XIV shall normally be given to substances with

a) PBT or vPvB properties; or
b) wide dispersive use; or
c) high volumes.

The term "normally" implies that the criteria mentioned in Article 58(3) do not need to be seen as exclusive, allowing other considerations to be taken into account which may warrant a higher or lower priority for a substance, in particular in relation to the regulatory effectiveness of selecting the substance.

Given that the listing of the criteria is connected by the term *'or'*, this means that meeting one criterion could in principle be sufficient to prioritise a substance for inclusion in Annex XIV. However, in order to allow further differentiation the approach actually followed for prioritising the candidate substances for inclusion in Annex XIV also considers how many of these three criteria are met by the candidate substance concerned and to what degree.

Therefore, it is necessary to consider the rationale of the criteria and to identify and select parameters by which the rationale of the criteria can be reflected. The following parameterisation of the above criteria *a), b) & c)* has been used for the present prioritisation.

a) PBT or vPvB properties

Substances that have been identified as having PBT or vPvB properties under Article 57 (d), (e) or (f) may be prioritised for inclusion in Annex XIV. However, substances not fulfilling criterion *a)* on *'PBT or vPvB properties'* does not preclude that CMR properties of substances meeting criteria *b) 'wide dispersive use'* and/or *c)'high volumes'* can be considered in the prioritisation[2].

b) Wide dispersive use

The term "wide dispersive use" is explained in Chapter R.16.2.1.6 of the Guidance on Information Requirements and Chemical Safety Assessment as follows: *"Wide dispersive use refers to many small point sources or diffuse release by for instance the public at large or sources like traffic. … Wide dispersive use can relate to both indoor and outdoor use"*. In the Technical Guidance Document for Risk Assessment of new and existing substances and biocides (2003, Chapter 5) this term is defined as follows: "*Wide dispersive use refers to activities which deliver uncontrolled exposure. Examples relevant for occupational exposure: Painting with paints; spraying of pesticides. Examples relevant for environmental/consumer exposure: Use of detergents, cosmetics, disinfectants, household paints."* In addition, the ECETOC Report No. 93 on Targeted Risk Assessment (Appendix B) states: *"A substance marketed for wide dispersive use is likely to reach consumers, and it can be assumed*

[2] If in future the candidate list will become substantially longer, it may be necessary to further differentiate between substances on the basis of their intrinsic properties (i.e. PBT or vPvB properties versus C, M or R properties) if a similar priority results from the degree of fulfilment of criteria *b)* and *c).*

that such a substance will be emitted into the environment for 100% during or after use."

Wide dispersive uses are hence characterised by use of a substance on its own, in a preparation or in an article at many places that may result in not insignificant releases and exposure to a considerable part of the population (workers, consumers, general public) or the environment. This means that uses taking place at many places, which however do not result in significant releases of a substance, may be considered only as 'widespread' but not as 'wide dispersive'.

In general, consumer use can be considered as wide dispersive if it can be reasonably assumed that this use results in non-negligible releases. Professional use can be wide dispersive as well if it takes place at many sites and is carried out by many workers and if it cannot be excluded that releases are negligible.

To assess the criterion '*wide dispersive use'*, it might be useful to consider also potential releases and exposure from uses other than 'wide dispersive', as not only wide dispersive uses may result in releases and contributions to exposure. However, for the current prioritisation no information was available allowing this aspect to be taken into account.

Depending on the information available, as many as possible of the following parameters are used as indicators to assess whether a use (and the resulting release) should be considered 'wide dispersive' and to get an at least qualitative indication on the degree of its 'dispersiveness':

- Tonnage going to the use.
- The complexity of the supply chain and the number of actors in the chain. In how many settings/locations does the use take place? What are the typical sizes of these settings?
- In which form is the substance placed on the market (e.g. as such, as part of a preparation, in/on an article)?
- Can the substance be released (and to which extent) during the service life of an article or a preparation (e.g. paints, adhesives, detergents) or is it transformed (thereby loosing its hazardous properties) or incorporated into a matrix (e.g. polymer) in a way preventing release?
- Information on operational conditions and risk management measures.
- Information on whether there is occupational exposure (quantitative or qualitative; e.g. approximate number of exposed workers, information on releases to the working environment, occupational exposure concentrations, health effects, OELs).
- Information whether there is consumer exposure (quantitative or qualitative; e.g. possibility of consumer use, information on consumer exposure, health effects, limit values).
- Releases to the environment (mainly for PBTs/vPvBs; e.g. t/y to the different compartments air, water, soil).
- Possibility of releases during the waste phase.

- Monitoring information for a substance in environmental compartments such as water, sediment, soil or in biota.

The parameters listed above are used in a weight of evidence approach. The priority of a substance increases with the portion of its uses (respectively the tonnage supplied to these uses) identified as wide-dispersive and the (estimated) released volumes from those wide dispersive uses. Likewise, no or lesser priority will be given when no significant releases occur from these uses or when the releases are comparatively low. As regards the releases, the focus is normally on environmental releases for substances with PBT properties and on releases leading to potential human exposure for CMR substances.

c) High volumes

The annual volume supplied in the EU to uses not exempted from the authorisation requirement[3] is taken as parameter for this criterion, i.e.:

Volume supplied = (Manufacture + Import) – (Export + supply to uses exempted from authorisation)

The total annual tonnages are considered as:

Low volumes, if	<10 t/y;
Relatively low volumes, if	10 - <100 t/y;
Relatively high volumes, if	100 - <1,000 t/y;
High volumes, if	1,000 - <10,000 t/y;
Very high volumes, if	>10,000 t/y.

Priority increases with increasing volume.

Note that the 'volume' criterion is considered not to be met if:

- There are no identified uses of the substance in the EU;
- There are no uses identified that are not exempted from the authorisation requirement.

No use or no use in the scope of Title VII of a substance implies logically that there cannot be 'wide dispersive use' of this substance.

Not prioritising a substance that has no identified uses in the EU will help to prevent developing Annex XIV into a list of obsolete substances.

A.2 Additional considerations for prioritising a candidate substance

In arriving at the overall conclusion on the priority of a substance, the 'regulatory effectiveness' of including the substance into the authorisation process should also be taken into account. Situations may for instance occur where inclusion in Annex XIV will only require regulatory efforts but most likely will not result in benefits for human health or the environment. For example:

[3] Annex 1 to this document provides a list of uses exempted from the authorisation requirement. Exemptions relevant in the context of the present prioritisation exercise are, for example, uses as on-site isolated intermediates or as transported intermediates, uses in biocidal products and uses in scientific research and development.

- All identified uses are subject to specific Community legislation imposing minimum requirements relating to the protection of human health or the environment ensuring that risks are properly controlled.
- All or most known uses can easily be replaced by another 'form' of the substance with a similar (or even worse) hazard profile, which is not on the candidate list (e.g. one metal salt on the candidate list can be replaced by another salt of the same metal with the same hazard profile, but this salt is not on the candidate list).
- Uses have been identified but the resulting releases are insignificant as such or insignificant compared to releases resulting from natural sources and/or uses not in the scope of authorisation.

In the first case, risks are already properly controlled by other Community legislation, and in the second case the authorisation requirement can easily be circumvented by replacement of the substance subjected to the authorisation requirement by the other 'form' of the substance not requiring authorisation.

Regarding the second case a grouping approach could be considered[4] in order to prevent simple replacement of a substance that will be subjected to authorisation by another 'form' of the substance.

A.3 Conclusion on the priority of a candidate substance

The three prioritisation criteria related to the intrinsic properties of a substance, the nature of its uses and its volume supplied to uses in the scope of Title VII are assessed together in a weight of evidence approach in a qualitative, where possible semi-quantitative manner, resulting in an overall conclusion on the priority of a substance. The more criteria are met and the higher the extent to which the criteria are fulfilled (i.e. the higher the rating of the intrinsic properties, the more wide dispersive the uses and the higher the volumes not exempted from Title VII), are important factors in deciding whether or not to prioritise a substance.

However, in arriving at the final conclusion on the priority of a substance the additional considerations outlined in section A.2 may also play an important role.

B Proposed prioritisation of candidate substances

In table B.1 below the conclusions on the inherent properties, volumes and wide 'dispersiveness' of uses are provided for the 15 substances that are currently included in the candidate list. In addition, the conclusion on whether priority should be given to these substances for their inclusion in Annex XIV is provided. These conclusions are based on information summarised in 'background reports' prepared by ECHA for

[4] Whether grouping of substances with similar properties is required in order to ensure efficacy of authorisation in terms of the aimed benefits for human health and the environment should already be considered during planning of Annex XV dossiers for identification of substances as SVHCs. A prerequisite for being able to group substances with the objective to subject them together to the authorisation requirement is their identification as SVHCs and their inclusion on the candidate list.

each of the substances on the candidate list and should therefore be read in conjunction with the supplementary information provided for in these reports.

Based on the information currently available, ECHA proposes to prioritise the following seven substances:

- 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene),
- Alkanes,C10-13,chloro (short chain chlorinated paraffins; SCCPs),
- Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified,
- 4,4'-Diamino diphenyl methane (MDA),
- Bis (2-ethylhexyl) phthalate (DEHP),
- Benzyl butyl phthalate (BBP), and
- Dibutyl phthalate (DBP).

It should be noted that the REACH Regulation (Article 58(3)) allows ECHA to adapt the number of substances recommended for inclusion in Annex XIV to its capacity to handle future applications in the time provided for. It was not necessary to apply this criterion for the present prioritisation as the number of substances prioritised for inclusion in the authorisation list does presumably not exceed the capacity of the Agency to handle the resulting authorisation applications.

Table B.1: Proposed prioritisation of candidate substances

	Conclusion on			
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	vPvB	No actual data on the volume of musk xylene used in the EU is available. Based on the decreasing trend observed in the recent past the volume currently used is estimated to approximately 25 tonnes/year.	Musk xylenes are mainly used in preparations for consumer use such as e.g. detergents, cleaning products, fabric softeners as well as in toiletries, colognes and shampoos. It can be assumed that these uses occur widespread all over the EU and that they will result in nearly 100% release of the substance. Hence, these uses are wide-dispersive.	Musk xylene is a vPvB and all its uses are wide dispersive, resulting in a nearly 100% release of the substance. Hence, although the volume used is presumably relatively low, **it is proposed to prioritise 5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene) for inclusion in Annex XIV**.
Alkanes,C10-13,chloro (short chain chlorinated paraffins; SCCPs)	PBT and vPvB	According to the available information the actual tonnage used in the EU is <1,000 t/y.	Formulation of preparations and manufacture of articles containing SCCPs appear to happen in a limited number of sites. However, all known uses of preparations and articles, i.e. use of rubber articles containing SCCPs, use of textiles with back coatings containing SCCPs, use of sealants, adhesives and paints containing SCCPs are likely to be widespread and associated with a high potential for release of the substance and therefore can be considered as wide dispersive. The same conclusion can be drawn for use of articles made from recycled rubber belts containing SCCPs.	Given the PBT and vPvB properties of the substance, the wide dispersive uses of the preparations and articles containing SCCPs and the relatively high volumes **it is proposed to prioritise Alkanes, C_{10-13}, chloro (SCCPs) for inclusion in Annex XIV**.
Anthracene	PBT	Current annual manufacture in the EU is less than 5,000 t/y. Most anthracene manufactured (>99,5%) is used as intermediate for the synthesis of anthraquinone. Anthracene supply for other uses is	Uses of anthracene other than as intermediate for anthraquinone synthesis include uses in pyrotechnic articles, as laboratory agent in scientific research, and for manufacture of pharmaceuticals (where the latter two uses are exempted from authorisation). Although use of pyrotechnics might be widespread, this use is not considered wide-dispersive because anthracene is transformed during end-use and therefore, and in consideration of the low volume	Anthracene is a PBT substance and the only known use not exempted from Title VII is use in pyrotechnics. This use is not considered wide-dispersive because releases thereof are considered negligible, in particular in relation to the amounts of Anthracene that may

	Conclusion on			
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**
		less than 2 t/y.	supplied to this use (<0.5 t/y), releases are considered negligible.	be unintentionally formed in combustion and other processes. **Consequently, it is proposed not to prioritise Anthracene for inclusion in Annex XIV.**
Bis (tributyl tin) oxide (TBTO)	PBT	The amount of TBTO manufactured for non intermediate use is assumed to be around 30 t/y, which are exported from the EU[5]. According to the information available, there is currently no known non-intermediate use of TBTO in the EU.	There are no known non-intermediate uses of TBTO in the EU.	TBTO is a PBT. However, as there are no known uses within the EU, **it is proposed not to prioritise Bis(tributyltin) oxide (TBTO) for inclusion in Annex XIV**.
Hexabromocyclo-dodecane (HBCDD) and all major diastereoisomers identified	PBT	The manufacturing volume of HBCDD is around 6,000 t/y and the total use in the EU in 2006 was ~12,000 tonnes with increasing tendency. The volume of HBCDD imported with articles is unknown, but believed to be considerable.	HBCDD is used as a flame retardant in polystyrene products (mainly insulation panels, packaging material and electronic/electric devices) and textile coatings, where the substance is uniformly incorporated into the polymer matrix. There are one manufacturing and about 50 main formulation sites in Europe; however there are thousands of professional users of articles containing HBCDD and nearly all end uses are widespread throughout Europe. Most uses are associated with a not insignificant release of HBCDD to the environment. Although release rates are relatively low, monitoring data show ubiquitous presence of HBCDD in the environment and in biota, even in arctic regions. A substantial proportion of articles containing HBCDD	Given the PBT properties of the substance, the wide dispersive uses of end products containing HBCDD, the very high volumes and the releases over the full life-cycle of articles and preparations, **it is proposed to prioritise Hexabromocyclododecane (HBCDD) and all its major diastereoisomers for inclusion in Annex XIV.**

[5] TBTO is restricted in accordance with REACH, Annex XVII

	Conclusion on			
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**
			will have very long service life duration (30+ years for typical building insulation) and environmental releases will continue for a long time into the future. Hence, all uses of HBCDD can be considered as wide dispersive.	
4;4'-Diamino diphenyl methane (MDA)	Carc. Cat. 2	According to information from industry the current production of MDA could amount to1,400,000 t/y. The volume of MDA used for non-intermediate uses is estimated to be minimally 350 t/y (In addition, there may be uses of MDA as hardener in adhesives. It is however not clear whether these are still actual uses and what amounts are supplied to these uses.)	The uses as hardener in epoxy resins and in adhesives are expected to potentially occur across the entire EU and are therefore considered to be widespread. Furthermore releases to the working environment and as a consequence exposure of workers in the skilled trade area cannot be excluded. The uses of MDA as hardener in epoxy resins and adhesives in the skilled trade area are therefore considered to be wide dispersive.	Given the relatively high volume of MDA supplied to uses and applications that must be considered as wide dispersive, **it is proposed to prioritise 4,4'-Diamino diphenyl methane for inclusion in Annex XIV.**
Benzyl butyl phthalate (BBP)	Repr. Cat. 2	BBP is manufactured in the EU in a volume of approximately 20,000 t/y. A net export of approximately 12,000 tonnes is estimated. Thus, the use in the EU is estimated to be approximately 8,000 t/y.	The formulation and processing of BBP into preparations and in particular into polymer (mainly PVC) products take place at relatively few sites in the EU. The articles and preparations produced are used throughout the EU. As BBP is not chemically bound in either preparations or articles, the potential for release and subsequent exposure is high. Consequently, there is a wide dispersive use of BBP and preparations and articles containing BBP.	Given the high volumes used and the wide dispersive uses of BBP in preparations and in articles, **it is proposed to prioritise BBP for inclusion in Annex XIV.**
Bis (2-ethylhexyl) phthalate (DEHP)	Repr. Cat 2	The volume of DEHP manufactured in the EU was approximately 340,000 tonnes in 2007. The use in	The formulation and processing of DEHP into preparations and in particular into polymer (mainly PVC) products take place at a large number of sites in the EU (assumed to be 500 to 1,000). DEHP is	Given the very high volumes used and the ubiquitous, wide dispersive uses of DEHP in preparations and in articles, **it is**

	Conclusion on			
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**
		the EU is estimated to approximately 280,000 tonnes in 2007.	used in a very large number of diverse articles and preparations. The articles and preparations produced are used ubiquitously in the EU. As DEHP is not chemically bound in either preparations or articles, the potential for release and subsequent exposure is high. Consequently, there is a wide dispersive use of preparations and articles containing DEHP.	**proposed to prioritise DEHP for inclusion in Annex XIV.**
Dibutyl phthalate (DBP)	Repr. Cat. 2	DBP is manufactured in the EU in a volume of less than 10,000 t/y (in 2007). Net export is estimated to approximately 2,000 tonnes. Thus, net use in the EU is estimated to be approximately 8,000 tonnes/year.	DBP is mainly used as a plasticiser in polymers (mainly PVC). Another main use is in formulation of a number of preparations (incl. adhesives and paints). The formulation and processing of DBP into preparations and into polymer products by major users take place at 50-100 sites in the EU. The end products are widely used in the EU. As DBP is not chemically bound in either preparations or articles, the potential for release and subsequent exposure is high. Consequently, there is a wide dispersive use of preparations and articles containing DBP.	Given the very high volumes used and the wide dispersive uses of DBP in preparations and in articles, **it is proposed to prioritise DBP for inclusion in Annex XIV.**
Cobalt dichloride	Carc. Cat. 2	The European production of cobalt dichloride amounted to 10,000 t in 2007. The quantity supplied to non-intermediate uses is <100 t/y.	More than 99% of the substance is thought to be used as intermediate in the synthesis of other cobalt compounds and vitamin B12. Non-intermediate uses of $CoCl_2$ may take place in electroplating, production of animal food and veterinary products. Confirmed are uses in humidity indicators and as agent to determine colours in liquids. Except of the uses for electroplating and humidity indicators, these uses are exempted from the authorisation requirement. As the humidity indicators are used in the military sector, this use may as well be exempted by Member States in the interest of defence. No consumer use has been identified for the substance. The uses covered by a potential authorisation requirement (electroplating and	The volume of cobalt dichloride supplied to non-intermediate uses is relatively low. The uses covered by a potential authorisation requirement are electroplating and humidity indicators. Whereas the use in humidity indicators is not considered wide dispersive, no conclusion on the nature of the release pattern of electroplating can be drawn without supplementary information. Nevertheless, the regulatory effectiveness of subjecting the

	Conclusion on			
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**
			humidity indicators) are specialised ones and therefore might take place at a limited (but unknown) number of sites. Because the tonnage used for the humidity indicators is very low and only a limited number of trained persons will come into contact (if at all) with these indicator cards, this use is not considered wide dispersive. As regards electroplating, no conclusion on the nature of this use can be drawn without supplementary information about releases and more precise information on the tonnage supplied to this use.	use of the dichloride salt alone to the authorisation requirement can be considered questionable because it might in many cases be easy to bypass the authorisation requirement by replacing the dichloride salt by another cobalt compound with a similar hazard potential. **Therefore, it is proposed to not prioritise cobalt dichloride for inclusion in Annex XIV.**
Diarsenic trioxide	Carc. Cat. 1	The total estimated volume used in the EU is around 3900 t/y. The volume of diarsenic trioxide used for non-intermediate uses is approximately 3,000 t/y.	The main uses of diarsenic trioxide are for lead alloys (especially in lead-acid batteries) and glass production. These processes result in incorporation of the substance into matrices and/or articles. For example, during use of articles made of glass consumers will not be exposed to the arsenate trioxide as it is not present (as the original compound) in the glass. Furthermore, because the arsenic is bound into the glass matrix, the potential for migration and exposure would be expected to be very low. A study into elemental migration from glass in contact with food found that, in general, accelerated migration testing did not result in detectable levels of various elements (including arsenic). For alloys, a similar assumption is made: because the arsenic is bound into an alloy, the potential for migration and exposure (to arsenic) would be expected to be very low. As regards recycling, it is unlikely that collection and sorting of glasses leads to significant exposure to arsenic. Similarly, 90% or more of car batteries are	The volumes of diarsenic trioxide supplied to non-intermediate uses are high and the uses can be considered as widespread. However, as releases from these uses and hence exposures of humans are expected to be (very) low, these uses are not considered wide-dispersive. The regulatory effectiveness of subjecting the use of diarsenic trioxide alone to the authorisation requirement can be questioned because it may in certain cases be easy to bypass the authorisation requirement by replacing this substance with other arsenic compounds with a similar hazard potential. **Therefore, it is proposed to not**

	Conclusion on			
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**
			recycled and it would be expected that most of the arsenic used in lead-acid batteries would be recovered for re-use. Although the use of arsenic containing glass and lead-acid batteries can be considered widespread, based upon available information, it is assumed that the release of arsenic compounds from those matrices/articles is most probably (very) low and hence not wide dispersive.	**prioritise Diarsenic trioxide for inclusion in Annex XIV.**
Diarsenic pentaoxide	Carc. Cat. 1	The volumes of diarsenic pentaoxide manufactured and used within the EU is <210 t/y. The volume supplied to non-intermediate uses is <110 t/y. However, the main part is used for biocidal products (wood protection), for which authorisation does not apply. A volume of <10 t/y is probably supplied to uses in the scope of authorisation.	The main use of diarsenic pentaoxide, which is relevant for the authorisation procedure under the REACH regulation, is for special glass production (<10 t/y). This conservative estimate is uncertain as the European glass industry trade association has suggested that the substance is not used within Europe for this purpose. Nonetheless, consumers will not be exposed to the arsenate trioxide as it is not present (as the original compound) in the glass (arsenic instead). Furthermore, because the arsenic is bound into the glass matrix, the potential for migration and exposure would be expected to be very low. A study into elemental migration from glass in contact with food found that, in general, accelerated migration testing did not result in detectable levels of various elements (including arsenic). Although the use of special glass articles can be considered widespread, based upon available information, it is assumed that the release of arsenic compounds from the glass matrix is most probably very low and hence not wide dispersive.	If there is any use of diarsenic pentaoxide covered by authorisation, then the volume supplied to this use (special glass and articles from this glass) is low. The use of articles made of special glass can be considered widespread. However, releases from these articles and hence exposure of humans can be considered very low and the use as not wide dispersive. The regulatory effectiveness of subjecting the use of diarsenic pentaoxide alone to the authorisation requirement can be questioned because it may in certain cases be easy to bypass the authorisation requirement by replacing this substance with other arsenic compounds with a similar hazard potential. **Therefore, ECHA proposes to**

	Conclusion on			
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**
				not prioritise Diarsenic pentaoxide for inclusion in Annex XIV.
Lead hydrogen arsenate	Carc. Cat. 1 Repr. Cat. 1	No manufacture or import of lead hydrogen arsenate has been identified in the EU.	There are no known uses of the substance in the EU.	As the substance is not used in the EU, **it is proposed to not prioritise Lead hydrogen arsenate for inclusion in Annex XIV.**
Triethyl arsenate	Carc. Cat. 1	There is no production of triethyl arsenate within the EU. Only very small quantities (less than 0.1 t/y) of the substance are imported in the EU. This volume is supplied to one use in which the substance is used as an intermediate.	Triethyl arsenate has been developed for use in specialised doping applications in semi-conductors. In manufacture of these semi-conductors triethyl arsenate is used as an intermediate.	No non-intermediate uses have been identified for this substance. **Therefore, it is proposed not to prioritise Triethyl arsenate for inclusion in Annex XIV.**
Sodium dichromate	C, M, R all Cat. 2	The volume used in the EU is <100,000 t/a, which is used almost exclusively as an intermediate.	Approximately 97% of the sodium dichromate supplied to the EU market is used as an intermediate for synthesis of chromium (III) compounds. Beside some minor non-intermediate uses (in total <<1%), the main non-intermediate use of $Na_2Cr_2O_7$ is for metal finishing in the aeronautics and metal packaging (canning) industry (~ 3%). This use takes place in a larger number of SMEs and in some industrial settings. The use of $Na_2Cr_2O_7$ in metal finishing can therefore be considered as widespread. However, as no information is available about releases from the use of $Na_2Cr_2O_7$ in metal finishing, a conclusion whether these uses must be considered as wide dispersive cannot be drawn without supplementary information becoming available.	The volume of sodium dichromate supplied to non-intermediate uses, predominantly metal finishing, is high but due to lack on information on releases, a decision as to whether these uses must be considered as wide dispersive cannot be drawn without supplementary information becoming available. Nevertheless, the regulatory effectiveness of subjecting the use of the sodium dichromate salt alone to the authorisation requirement can be considered

	Conclusion on			
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**
				questionable because it might in many cases be easy to bypass the authorisation requirement by replacing the sodium salt by another hexavalent chromium compound with a similar hazard potential. **Therefore, it is proposed to not prioritise Sodium dichromate for inclusion in Annex XIV.**

ANNEX 1: USES EXEMPTED FROM AUTHORISATION

On-site isolated intermediates and transported isolated intermediates {Art. 2(8b)}.
Use in medicinal products for human or veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC and Directive 2001/83/EC {Art. 2(5a)}.
Use in food or feedingstuffs according to Regulation (EC) No 178/2002 including use as a food additive in foodstuffs within the scope of Council Directive 89/107/EEC, as a flavouring in foodstuffs within the scope of Council Directive 88/388/EEC and Commission Decision 1999/217/EC or on foodstuffs drawn up in application of Regulation (EC) No 2232/96, as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003 and in animal nutrition within the scope of Council Directive 82/471/EEC {Art. 2(5b)}.
Use in scientific research and development {Art. 56(3)}.
Use on plant protection products within the scope of Council Directive 91/414/EEC {Art. 56(4a)}.
Use in biocidal products within the scope of Directive 98/8/EC {Art. 56(4b)}.
Use as motor fuels covered by Directive 98/70/EC {Art. 56(4c)}.
Use as fuel in mobile or fixed combustion plants of mineral oil products and use of fuels in closed systems {Art. 56(4d)}.
Use in cosmetic products within the scope of Council Directive 76/768/EEC (this exemption applies to substances listed on Annex XIV on the basis of their hazard to human health only) {Art. 56(5a)}.
Use in food contact materials within the scope of Regulation (EC) No 1935/2004 (this exemption applies to substances listed on Annex XIV on the basis of their hazard to human health only) {Art. 56(5b)}.
Use of substances when present in preparations below a concentration limit of 0.1% by weight. This applies only to substances listed in Annex XIV on the basis of being persistent, bioaccumulative and toxic (PBT) as defined by Art. 57(d), very persistent and very bioaccumulative (vPvB) as defined by Art. 57(e), or listed in Annex XIV on the basis that there is scientific evidence of probable serious effects to human health or the environment which give an equivalent level of concern to substances with PBT or vPvB properties, or an equivalent level of concern to substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1 and 2, as defined by Art. 57(f) {Art. 56(6a)}.
Use of substances when present in preparations below the lowest concentration limits specified in Directive 1999/45/EC or in Annex I to Council Directive 67/548/EEC which results in the classification of the preparation as dangerous. This applies only to substance listed in Annex XIV on the basis of their classification as CMR category 1 and 2 {Art. 56(6b)}.