

## **Results of the prioritisation of the SVHCs on the Candidate List with the objective to recommend priority substances for inclusion in Annex XIV**

The prioritisation results presented in this report have been obtained by applying ECHA's updated prioritisation approach as described in the document "*General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation*", version 28 May 2010.

In table 1 below ECHA's conclusions are provided with regard to the priority of the substances on the Candidate List<sup>1</sup> for inclusion in Annex XIV.

Both prioritisation approaches discussed and agreed with ECHA's Member State Committee, i.e.

- the new developed scoring approach, and
- the verbal-argumentative approach (already used for ECHA's first recommendation)

have been used.

The verbal description of the criteria "inherent properties", "volumes" and "wide dispersiveness of uses" as well as the scoring results are provided in the table along with the conclusions as to whether the substances should be prioritised for inclusion in Annex XIV, taking the regulatory effectiveness considerations into account.

Table 2 provides a ranking of the candidate substances on the basis of the scoring results and an overview on the results obtained with the scoring approach in comparison with the verbal-argumentative approach. The final conclusions regarding priority of the substances are the same for both approaches.

The information used for priority setting amongst the Candidate List substances is mainly drawn from the Annex XV dossiers of the substances, from the comments received during public consultation on the SVHC identification process in accordance with Article 59 of the REACH-Regulation, and from data collected either by consultants to ECHA or by ECHA itself on volumes of the substances on the European market, on their uses and on releases resulting from these uses.

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<sup>1</sup> Basis for the prioritisation presented in this report was the Candidate List in its version of 30 March 2010 (after inclusion of acrylamide). Due to their late inclusion date, the substances added to the Candidate List on 18 June 2010 could not be evaluated and considered for the current recommendation. Further, the substances already included in ECHA's first recommendation of 1 June 2009 were not considered. (Link: [http://echa.europa.eu/chem\\_data/authorisation\\_process/annex\\_xiv\\_rec\\_en.asp](http://echa.europa.eu/chem_data/authorisation_process/annex_xiv_rec_en.asp))

Based on the information available, ECHA has prioritised the following eight substances for its second draft recommendation of priority substances to be included in Annex XIV (list of substances subject to authorisation):

- **Diisobutyl phthalate (DIBP)**
- **Diarsenic trioxide**
- **Diarsenic pentaoxide**
- **Lead chromate**
- **Lead sulfochromate yellow (C.I Pigment Yellow 34)**
- **Lead chromate molybdate sulfate red (C.I Pigment Red 104)**
- **Tris (2-chloroethyl) phosphate (TCEP)**
- **2,4 – Dinitrotoluene (2,4-DNT)**

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 1: Prioritisation of the substances on the Candidate List. Results of the verbal-argumentative approach (VAA), the scoring approach (SCA) and final conclusions**

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
<b>Acrylamide (VAA)</b>	Carcinogen cat.2; Mutagen cat. 2	Total EU manufacture is estimated to be between 80,000 – 100,000 t/yr at the time of the risk assessment (RAR, 2002). Information on imports is not available. Acrylamide based grouting agents are imported because the only known EU manufacturer of these agents stopped production in 1997. In the Annex XV report it is stated that for the EU no information on current volumes of import or uses of acrylamide grouts is available. However, the Polyelectrolyte Producers Group (PPG) estimated a volume of approximately 100 t/yr to be used for grouting in the Netherlands and in Belgium in 2006. This figure can, however, not be confirmed by the Dutch authorities.	According to the Risk Assessment Report (RAR), the substance is manufactured by 3 companies in the EU. The RAR estimates that 99.9% of the acrylamide supplied in the EU is used as intermediate in the production of polyacrylamides (there are 7 main producers of polyacrylamide and a number of smaller ones throughout the EU) for a number of applications. Other uses are for on-site preparation of polyacrylamide gels (~0.1% ≈ 100 t/yr) and possibly as grouting agents. The polyacrylamide gels are used for electrophoresis in research establishments and thus fall under the exemption from authorisation of substances used in scientific research and development (Article 56(3)). Acrylamide based grouts are (suspected to be) used by a relatively small number of large civil engineering companies but also by a much larger number of small and medium sized enterprises in all Member States. There is no information available on the current volumes of import or uses of acrylamide grouts in the EU (but a decreasing trend is assumed because of the availability/use of alternatives).	Although there are uncertainties about the volume that is used for grouting applications, the potentially high volume, the wide dispersive use pattern and the available evidence that grouting applications can adversely affect human health and the environment would be sufficient to suggest prioritisation of acrylamide for inclusion in Annex XIV. On the basis of the prioritisation criteria, the substance qualifies for prioritisation.	On the basis of the prioritisation criteria, acrylamide qualifies for prioritisation. However, the Commission can in accordance with REACH Article 137(1) propose restrictions for all uses of acrylamide where a need for a restriction has been identified and agreed under Regulation (EEC) No 793/93. Use as grouting agent is one of the uses for which a need for limiting the risks has been identified and a need for a restriction was agreed. The only (potential) use falling in the scope of authorisation (i.e. use of acrylamide for grouting) will most likely be proposed for restriction. Therefore, there is at the moment no need to consider authorisation. <b>Hence, it has been concluded to not prioritise acrylamide for inclusion in Annex XIV.</b>
<b>Acrylamide (SCA)</b>	Non threshold CMR: 1 score	Assumption: Use as grout (the only known use in the scope of authorisation) ca. 100 t/yr in NL and BE. Extrapolation to EU level on the basis of population: in the range of 1,000 – 10,000 t/yr: 7	Use as grouting agent is wide dispersive use. The substance can be (is) used at many places and releases are diffuse and can be significant (as incidents show). Number of point sources high: 3 scores, releases diffuse and significant: 3 scores.	Total score: 17	The same considerations apply as brought forward under the verbal-argumentative approach.

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
		scores	Total score: 9		
<b>Anthracene (VAA)</b>	PBT	Current annual manufacture in the EU is less than 5,000 t/yr. Most anthracene manufactured (>99.5%) is used as intermediate for the synthesis of anthraquinone. Anthracene supply for other uses is less than 2 t/yr. Use for pyrotechnic mixtures, the only known use in the scope of authorisation, is less than 0.5 t/yr.	Uses of anthracene other than as intermediate for anthraquinone synthesis include uses in pyrotechnic articles (for special effects, i.e. black smoke for theatre and film productions), as laboratory agent in scientific research, and for manufacture of pharmaceuticals (the latter two uses are exempted from authorisation). Formulation of specialty "lack smoke" pyrotechnic mixtures in the EU takes place at a low number of sites and releases and worker exposure from formulation occur only from cleaning (only to wastewater) and in the worst case amount to 0.25%. Although the use of anthracene containing pyrotechnics may occur at a high number of sites, this use is not considered wide-dispersive because anthracene is transformed during the end-use and therefore, and in consideration of the low volume supplied to this use, releases are considered insignificant.	Anthracene is a PBT substance and the only known use not exempted from authorisation is use in pyrotechnics (<0.5 t/yr). Releases and potential worker exposure from formulation of anthracene containing pyrotechnic mixtures are very low. The end use is not wide-dispersive because anthracene is transformed. Based on the prioritisation criteria, the substance has a relatively low priority.	Based on the prioritisation criteria, anthracene has a relatively low priority. The only known use covered by the scope of authorisation is use in pyrotechnics. This use is not wide-dispersive because the releases are insignificant, in particular in relation to the amounts of anthracene that may be unintentionally formed in combustion and other processes. <b>Therefore, it has been concluded to not prioritise anthracene for inclusion in Annex XIV.</b>
<b>Anthracene (SCA)</b>	Score: 3	Low volume of uses in the scope of authorisation. Score: 1	Use at an unknown but potentially medium to high number of sites, score: 2 - 3. Releases insignificant, score: 0 (if number of sites is high: 1). Overall score: 0 or 3 (if site-# high)	Total score: 4 – 7	<b>The same considerations apply as brought forward under the verbal-argumentative approach</b>
<b>Aluminosilicate refractory ceramic fibres (Al-RCF) and</b>	Carcinogen cat.2	In 1999, RCF (Refractory Ceramic Fibres) were manufactured in the EU by 3 companies. EU manufacturing volume for RCF was 50,000 tonnes and decreased to 25,000	The information available is for RCF in general. RCF are high-temperature insulating fibres mainly used in industrial applications as insulation for industrial furnaces, pipes, ducts, and cables, as fire protection for buildings and industrial process equipment, as	Conclusion for both Al- RCF and Zr-Al-RCF: The volume of RCFs used in the EU is very high. There appears to be no uses where consumers could be exposed	Conclusion for both Al- RCF and Zr-Al-RCF: On the basis of the prioritisation criteria, the refractory ceramic fibres qualify for prioritisation.

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
<b>Zirconia aluminosilicate refractory ceramic fibres ((Zr-Al-RCF)</b>  (VAA)		tonnes in 2008.	<p>aircraft/aerospace heat shields, and in automotive uses, such as catalytic converters, metal reinforcements, heat shields, brake pads, and air bags (breakdown of uses by sector: industrial insulation (90% of which 66.7% for industrial furnaces, automotive (8%), fire protection (2%), others (&lt;1%).</p> <p>The European Association of the High Temperature Insulation Wool Industry (ECFIA) estimates that the exposed workforce dealing with RCF amounted to circa 25,000 employees in 1996 (ca. 750 in manufacture of RCF, the rest processing fibres and end use of processed articles) but that this figure may have decreased to recent approximate number of 1250. The processing of RCF into boards, felts, blankets, shapes, modules, gaskets etc., or its mixing into cements and putties is performed by numerous independent companies. Exposure of workers to fibres occurs during manufacture and use of the fibres, in particular during cutting and machining of RCF containing material and furnace related installation and deinstallation of RCF material.</p>	<p>but there is still a potentially high number of workers which is exposed to fibres during processing and handling. As this processing and handling occurs in industrial and professional environments it can be assumed that exposure at the workplace is normally controlled, however, there remains uncertainty whether exposure control is (in all cases) sufficient to render exposure insignificant. Therefore, on the basis of the prioritisation criteria, the refractory ceramic fibres qualify for prioritisation.</p>	<p>However, according to information provided by several industry associations representing manufacturers and users of RCFs on the European or national level, the current identification of Aluminosilicate RCF and Zirconia Aluminosilicate RCF on the Candidate List covers only a part of the RCFs on the European market. About 50% of the RCF on the market have different compositions (described in European Standard EN 1094-1 (2008)) compared to the ones defined in the Candidate List entries. All these RCFs are covered by index number 650-017-00-8 as Refractory Ceramic Fibres in Annex VI of the CLP Regulation. The use profiles are in principle the same. The chosen description of RCFs on the Candidate List provides therefore a loophole for RCF types that are not covered by the Candidate List entries.</p> <p><b>In order to avoid unjustified preferential treatment and market distortion in favour of RCF types not identified as SVHC, it has been concluded to refrain for the moment from prioritising the RCF types on the Candidate List for inclusion in Annex XIV until all RCFs falling under index number 650-017-00-8 of Annex VI of Regulation 1272/2008 are included in the Candidate List.</b></p>
<b>Aluminosilicate-</b>	Score: 1	Refractory ceramic fibres on EU market can be used	Use in very high volumes but only industrial/professional uses at a high number	Total Score: 13	<b>The same considerations apply as brought forward under the verbal-</b>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
<b>RCF And Zirconia aluminosilicate-RCF</b>  (SCA)		interchangeably. Therefore for both substances very high volume (>10,000 t/yr) assumed. Score: 9	of sites. Releases/expose of workers should normally be controlled but not clear whether exposure controls are in all cases sufficient to prevent health effects. Wide-dispersive use pattern. Scoring: number of sites: 3, releases:1; overall: 3		<b>argumentative approach.</b>
<b>Anthracene oil</b> (VAA)	Carcinogen cat.2; PBT and vPvB	8 manufacturers /importers listed in ESIS, HPV substance. 33 pre-registrations with a volume of 1,000+ t/yr. No actual information on manufacture, import and export for the European level as well as no information on shares supplied to different uses. From confidential information received during public commenting on the Annex XV report it can be inferred that the consumed volume is very high (well above the 100,000 t/yr range in 2009).	Contradicting information on uses. Anthracene oil is mainly used as an intermediate in the production of pure anthracene, which is used in the production of artificial dyes. Further main uses of anthracene oil, according to information provided by industry and cited in the Annex XV report, are: <ul style="list-style-type: none"> <li>- Component in technical tar oils (e.g. for production of carbon black, heating oils, bunker fuel)</li> <li>- Production of basic chemicals</li> <li>- Intermediate for phyto-pharmaceutical and human-pharmaceutical products.</li> <li>- Impregnation agent (mostly as wood preservative, sometimes for ropes and sailcloth)</li> <li>- Component in tar paints for special application (e.g. underwater corrosion protection)</li> <li>- Component of waterproof membranes for roofing and other sealing purposes</li> <li>- Component of asphalt used for road construction</li> <li>- Supplementary blast furnace reducing agent</li> </ul>	<b>All 5 anthracene oils:</b> The 5 Anthracene oils identified as SVHC are apparently all used in very high volumes (above 10,000 t/yr). The main amount appears to be used for synthesis of other substances. Other uses are however reported as well and at least some of these appear to be in the scope of authorisation. On these latter uses no specific information is available but considering their nature a wide-dispersive use pattern cannot be excluded as they imply use at a high number of sites, diffuse environmental releases and, at least for some of the uses, uncontrolled exposure at the workplace. Therefore, on the basis of the prioritisation criteria, the anthracene oils qualify for prioritisation.	On the basis of the prioritisation criteria, all anthracene oils on the Candidate List qualify for prioritisation. However, there is uncertainty about the nature (and volume) of uses falling in the scope of authorisation and as to whether authorisation would be appropriate from the regulatory efficiency point of view for these uses (one problem could e.g. be the enforcement of an authorisation requirement given that there are many similar substances coming from coal tar distillation processes, which could (and in fact appear to be) blended in various processing steps). <b>Therefore, it has been concluded to not prioritise the anthracene oil substances now but to wait with a decision on prioritisation until the registration dossiers, which have to be submitted by 1 December 2010, have been assessed with respect to the uses of these substances.</b> Moreover, as already mentioned with regard to a potential prioritisation of

Substance	Inherent properties	Conclusion on			Final conclusion, taking regulatory effectiveness considerations into account
		Volumes	Wide dispersiveness of uses	Priority	
			<p>- Industrial viscosity modifier</p> <p>However, during public consultation on the Annex XV report, a company (name confidential, RCOM) commented that anthracene oil is exclusively used for the manufacture of carbon black, which is mainly used in the rubber industry (annual European manufacture of carbon black 1.2 million t/yr from mineral oil and coal based feedstock; International Carbon Black Association, RCOM).</p> <p>From the information available it appears that most of the anthracene oil is used as intermediate in chemical synthesis. However, most of the other reported uses appear to be in the scope of authorisation. On these latter uses no specific information is available but considering their nature a wide-dispersive use pattern cannot be excluded as they imply use at a high number of sites, diffuse environmental releases and, at least for some of the uses, uncontrolled exposure at the workplace.</p>		pitch, coal tar, high temperature, it is noted that it would be useful to consider these PAH emissions in conjunction with more general objectives for reduction of PAH emissions from industry, incineration processes and other emission sources.
<b>Anthracene oil, anthracene paste</b>	Carcinogen cat.2; Mutagen cat.2; PBT and vPvB	5 manufacturers /importers listed in ESIS, HPV substance. 13 pre-registrations with a volume of 1,000+ t/yr. No actual information on volume marketed in Europe and on shares supplied to the different uses is available.	According to the Annex XV report the main uses of the substance are the same than reported for anthracene oil. No further information on specific uses of anthracene oil, anthracene paste is available.		
<b>Anthracene oil, anthracene-low</b>	Carcinogen cat.2; Mutagen cat.2; PBT and vPvB	4 manufacturers /importers listed in ESIS, HPVC. 27 pre-registrations with a volume of 1,000+ t/yr. No actual information on volume	According to the Annex XV report the main uses of the substance are the same than reported for anthracene oil. No further information on specific uses of anthracene oil, anthracene-low is available.		

Substance	Inherent properties	Conclusion on			Final conclusion, taking regulatory effectiveness considerations into account
		Volumes	Wide dispersiveness of uses	Priority	
		marketed in Europe and on shares supplied to the different uses is available.			
<b>Anthracene oil, anthracene paste, anthracene fraction</b>	Carcinogen cat.2; Mutagen cat.2; PBT and vPvB	1 manufacturer/importer listed in ESIS, HPVC. 10 pre-registrations with a volume of 1,000+ t/yr. No actual information on volume marketed in Europe and on shares supplied to the different uses is available.	According to the Annex XV report the main uses of the substance are the same than reported for anthracene oil. No further information on specific uses of anthracene oil, anthracene paste, anthracene fraction is available.		
<b>Anthracene oil, anthracene paste, distn. lights</b>	Carcinogen cat.2; Mutagen cat.2; PBT and vPvB	1 manufacturer/importer listed in ESIS, HPVC. 11 pre-registrations with a volume of 1,000+ t/yr. No actual information on volume marketed in Europe and on shares supplied to the different uses is available.	According to the Annex XV report the main uses of the substance are the same than reported for anthracene oil. No further information on specific uses of anthracene oil, anthracene paste, distn. lights is available.		
<b>All 5 Anthracene oil substances (SCA)</b>	Score: 4	Volume going to uses in the scope of authorisation not known. However, as the total volume used in the EU is presumably above several 100,000 tonnes per year, a very high volume (i.e. > 10,000 t/yr) in the scope of authorisation is assumed: 9 scores	There is no firm information on actual uses available except that the largest share of the anthracene oil substance is apparently used for synthesis of other substances such as pure anthracene and carbon black. However, there appear to be other uses of the substances such as <ul style="list-style-type: none"> <li>- Impregnation agent</li> <li>- Component in tar paints for special application</li> <li>- Component of waterproof membranes for roofing and other sealing purposes</li> <li>- Component of asphalt used for road construction</li> </ul> Therefore, a wide-dispersive use pattern cannot be excluded as the above mentioned	Total score: 22	<b>The same considerations apply as brought forward under the verbal-argumentative approach.</b>



Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			uses would imply uses at a high number of sites, diffuse environmental releases and, at least for some uses, uncontrolled exposure at the workplace. Scoring: number of sites: 3; releases: 3; overall score: 9		
<b>Bis (tributyl tin) oxide (TBTO) (VAA)</b>	PBT	The amount of TBTO manufactured for non intermediate use is assumed to be around 30 t/y, which are exported from the EU (TBTO is restricted in accordance with REACH, Annex XVII).	There are no known non-intermediate uses of TBTO in the EU.	TBTO is a PBT. However, there are no known uses in the EU. Therefore no priority on the basis of the prioritisation criteria.	No priority on the basis of the prioritisation criteria as there are no known uses of TBTO within the EU. No regulatory effectiveness considerations have been identified that would suggest prioritisation. <b>Therefore, it has been concluded to not prioritise bis(tributyltin) oxide for inclusion in Annex XIV.</b>
<b>Bis (tributyl tin) oxide (TBTO) (SCA)</b>	Score: 3	No supply of TBTO to uses in the scope of authorisation: 0 scores	No non-intermediate uses of TBTO in the EU. Overall score: 0	Total score: 3	<b>The same considerations apply as brought forward under the verbal-argumentative approach</b>
<b>Cobalt dichloride (VAA)</b>	Carcinogen 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 <sub>2</sub> 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	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. Based on the prioritisation	Based on the prioritisation criteria, cobalt dichloride has low priority for inclusion in Annex XIV. Further, the regulatory effectiveness of subjecting the 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 with another cobalt compound with a similar hazard potential. <b>Therefore, it has been concluded to not prioritise cobalt dichloride</b>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			<p>substance. The uses covered by a potential authorisation requirement (electroplating and 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 potential releases and more precise information on the tonnage supplied to this use. Worker exposure can be considered to be controlled as electroplating is carried out by specialised firms.</p>	<p>criteria, it appears that the substance has a relatively low priority as the volumes used are (relatively) low and exposure can be considered controlled.</p>	<p><b>now for inclusion in Annex XIV.</b></p>
<p><b>Cobalt dichloride (SCA)</b></p>	<p>Score: 1</p>	<p>Relatively low annual volume. Score: 3</p>	<p>The substance may be used at a medium number of sites. Occupational exposure is considered to be controlled. Environmental releases from indicator cards, due to the low amount used for this application, and the low potential for environmental exposure, are deemed insignificant. Environmental releases from electroplating should be low and are considered non-diffusive.</p> <p>Scoring: number of sites of releases medium: 2; occupational releases controlled and environmental releases non-diffusive: 1. Overall score 2</p>	<p>Total score: 6</p>	<p><b>The same considerations apply as brought forward under the verbal-argumentative approach.</b></p>
<p><b>Diarsenic pentaoxide (VAA)</b></p>	<p>Carcinogen cat.1</p>	<p>The volumes of diarsenic pentaoxide manufactured and used within the EU is &lt;210 t/y. The volume supplied to non-intermediate uses is &lt;110 t/y.</p>	<p>The main use of diarsenic pentaoxide, which is relevant for the authorisation procedure under the REACH regulation, is for special glass production (&lt;10 t/y). This conservative estimate is uncertain as the European glass</p>	<p>If there is any use of diarsenic pentaoxide covered by authorisation, then the volume supplied to this use (special glass and articles from this</p>	<p>On the basis of the prioritisation criteria, diarsenic pentaoxide can be considered as a borderline candidate for prioritisation. As it has been concluded to</p>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
		<p>However, the main part is used for biocidal products (wood protection), for which authorisation does not apply. A volume of &lt;10 t/y is probably supplied to uses in the scope of authorisation.</p>	<p>industry trade association has suggested that the substance is not used within Europe for this purpose. However, information provided by the Italian Competent Authority suggests that the substance may be used for manufacturing decorative glass for arts and crafts.</p> <p>Nonetheless, consumers will not be exposed to the diarsenate pentaoxide 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.</p> <p>The substance may be used for similar technical purposes than diarsenic trioxide in the small scale manufacture of art glass and therefore the same problems with the control of occupational exposure may occur (see information provided under "diarsenic trioxide above).</p>	<p>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.</p> <p>However, significant occupational exposure to diarsenic pentaoxide may occur if the substance is used for manufacturing of arsenic containing art glass (see diarsenic trioxide above).</p> <p>On the basis of the prioritisation criteria, diarsenic pentaoxide may be considered as a borderline candidate for prioritisation because of the low volume used, the low release potential from articles produced but the potentially significant exposure of workers during manufacture of As containing glass.</p>	<p>recommend a similar arsenic compound (diarsenic trioxide) for inclusion in Annex XIV, <b>it has been decided to prioritise diarsenic pentaoxide as well</b> because otherwise it may in certain cases be possible to bypass the authorisation requirement by substitution.</p>
<b>Diarsenic pentaoxide (SCA)</b>	Score: 1	Low volume used in the scope of authorisation: 1 score	The substance may be used at a presumably medium number of sites. Occupational exposure may be significant (see diarsenic trioxide above) Scoring: medium number of sites where the substance is used: 2; potentially significant exposure of workers but	Total score 8	<b>The same considerations apply as brought forward under the verbal-argumentative approach.</b>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			insignificant environmental releases: 3. Overall score: 6		
<b>Diarsenic trioxide (VAA)</b>	Carcinogen cat.1	<p>The total estimated volume used in the EU is around 3900 t/y.</p> <p>The volume of diarsenic trioxide supplied in the EU for non-intermediate uses is approximately 3,000 t/yr.</p> <p>The estimate for EU usage of diarsenic trioxide in glass processing is 1,000 t/yr and for vitrifiable enamels 200 t/yr (RPA, 2009).</p> <p>Lead/antimony grid alloys are used in acid batteries. A large number of 'standard' car batteries utilising the strengthened arsenic grids are still produced within the EU. It is estimated that around 1,350 t/yr arsenic is used for this purpose (RPA 2009).</p>	<p>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 insignificant. 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.</p> <p>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 recycled and it would be expected that most of the arsenic used in lead-acid batteries would be recovered for re-use. The waste management and occupational health requirements related to the production and waste management of lead-acid batteries are stringent because of the presence of lead.</p> <p>Although the use of arsenic containing glass and lead-acid batteries can be considered widespread, based upon available</p>	<p>The volumes of diarsenic trioxide supplied to non-intermediate uses are high. Consumer exposure via articles can be considered insignificant and exposure of humans via the environment as controlled.</p> <p>As regards occupational exposure there appear to exist problems with exposure control in (parts of the glass industry), in particular in manufacturing of art glass. Extrapolation of the data from Italy regarding numbers of factories and workers involved would suggest that a high number of workers could be exposed and that the use of As<sub>2</sub>O<sub>3</sub> for art glass manufacture should be considered as wide-dispersive.</p> <p>On the basis of the prioritisation criteria, diarsenic trioxide can be considered as a priority substance for being recommended for inclusion in Annex XIV although there is some uncertainty about the extent of the problem of insufficient exposure control</p>	<p>Based on the prioritisation criteria, diarsenic trioxide can be considered as a priority substance for being recommended for inclusion in Annex XIV although there is some uncertainty about the extent of the problem of insufficient exposure control for workers in the glass industry. <b>Therefore, it has been concluded to prioritise diarsenic trioxide for inclusion in Annex XIV.</b></p> <p>If diarsenic trioxide is included in Annex XIV it should be considered to include similar substances (e.g. As<sub>2</sub>O<sub>5</sub>) as well in order to prevent evasion of the authorisation requirement by replacing As<sub>2</sub>O<sub>3</sub> with other arsenic compounds with a similar hazard profile.</p>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			<p>information, it is assumed that the release of arsenic compounds from those matrices/articles is most probably (very) low and hence not wide dispersive.</p> <p>As regards occupational exposure, there seem to be problems with preventing such exposure in the manufacturing of hand-made decorative glass for arts and crafts, as can be inferred from information provided by the Italian CA. Biological monitoring of workers in glass manufactories in the Murano district, carried out through urinary arsenic measurement, revealed that workers employed in the mixture preparation and in the furnace work are still significantly exposed to arsenic despite the technical preventive measures adopted (mean concentrations of different As species in urine samples of workers are 2-3 times higher than the upper limit of reference for the non exposed population (Montagnani et al., 2006). Main problems are apparently the dustiness of As<sub>2</sub>O<sub>3</sub>, which is mixed with the other glass raw materials in form of fine powder and the high volatility of As<sub>2</sub>O<sub>3</sub> at the melting temperature (at least 20% loss of the As added), which lead to inhalative exposure. About 80 manufactories with ca. 800 – 1,000 workers are manufacturing As containing art glass. The annual consumption of As<sub>2</sub>O<sub>3</sub> for art glass manufacture is 8.2 t in the Murano district (estimate for entire Italy 12 t/yr).</p>	for workers in the glass industry.	
<b>Diarsenic trioxide (SCA)</b>	Score: 1	High annual volume: 7 scores	The substance is used at a presumably high number of sites. Occupational exposure is assumed to be controlled to a level that residual risks are low in the lead industry, because for this industry strict regulations apply. With regard to the glass industry the	Total score 17	<b>The same considerations apply as brought forward under the verbal-argumentative approach.</b>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			<p>situation is unclear. Whereas at the industrial scale of manufacture of As containing specialty glass occupational exposure may as well be sufficiently controlled this appears not to be the case for small scale manufacture of art glass in glass manufactories (However, there is no information available about the situation in other countries than Italy). There may be some releases to the environment from production sites (which should be controlled) but releases from articles are deemed to be insignificant because of fixation of arsenic in the glass matrix and the high recycling rate for lead batteries.</p> <p>Scoring: high number of sites where the substance is used: 3; controlled exposure of workers in the lead industry but significant exposure in (parts of) the glass industry: 3. Overall score: 9</p>		
<b>2,4 – Dinitrotoluene (2,4-DNT) (VAA)</b>	Carcinogen cat.2	<p>EU production: There are 5-6 manufacturing sites of dinitrotoluene (80% 2,4-DNT :20% 2,6-DNT) in the EU. From the data, EU manufacture of 2,4-dinitrotoluene could therefore range between 405000 and 648000 tonnes. This volume is reported to be exclusively used as non-isolated intermediate for synthesis of toluene diisocyanate (TDI), which is used for synthesis of polyurethane). In addition, one company manufactures 'pure' 2,4-DNT (95% 2,4-DNT content) as well as dinitrotoluene mixtures (containing 65 or 50% of 2,4-</p>	<p><u>Confirmed uses:</u> DNT is primarily used as intermediate in the synthesis of toluene diisocyanate. Other confirmed uses are: Manufacture of 'pure' 2,4-DNT and technical grade dinitrotoluene (2,4-DNT content 65% or 50%), use in explosives and ammunitions, in propellants for gun powders and use in the non ferrous metal industry as a cross linking binding agent.</p> <p>As regards uses in the scope of authorisation, exposure of workers during the formulation and use (mines/ quarries) of explosives is possible and of main concern. Professional contact with DNT in mines is envisaged via two routes:</p> <ul style="list-style-type: none"> <li>- <u>inhalation of fumes after explosion,</u></li> </ul>	<p>The volume used for applications in the scope of authorisation appears to be in the range of 100 - 1,000 t/yr. This relatively high amount is mainly used in explosives and ammunition and appears to fulfil the criteria of wide dispersive use. The end-use of explosives in mines, quarries and construction sites is expected to happen at a high number of sites with possibly uncontrolled exposure of workers when handling the explosives and (after detonation, particularly</p>	<p>On the basis of the prioritisation criteria, 2,4-DNT qualifies for prioritisation.</p> <p>No regulatory effectiveness considerations have been identified that would suggest to refrain from prioritisation.</p> <p><b>Therefore, it has been concluded to prioritise 2,4-DNT for inclusion in Annex XIV.</b></p>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
		DNT) in the range 100 – 1000 t/y each. Import into EU: Only data from one company available - imported volume of dinitrotoluene mixtures (50-55% of 2,4-DNT) in the 100-1000 t range for use as a binding agent in the non ferrous metal industry). Some further imports in relatively small amounts (1 -10 t/yr range) of propellants that contain technical grade dinitrotoluene of an unknown 2,4-DNT content.	- and <u>direct skin contact</u> during handling of DNT containing explosive sticks.	in mines and subterranean construction sites) to fumes containing residues of the substance.  There are further uses with potential for worker exposure (e.g. use in the non-ferrous metal industry or manufacture of explosive mixtures and articles).  On the basis of the prioritisation criteria, the substance qualifies for prioritisation.	
<b>2,4 – Dinitrotoluene (DNT) (SCA)</b>	Score: 1	Relatively high volume confirmed to be used for explosives and ammunition: 5 scores.	Use in explosives is confirmed. Formulation and packaging of explosives may take place at a medium number of sites and worker exposure may be controlled. However, the end-use of explosives in mines, quarries and construction sites happens at a high number of sites with possibly uncontrolled exposure of workers when handling the explosives and (after detonation, particularly in mines and subterranean construction sites) to fumes containing residues of the substance. Scoring: number of sites: 3; uncontrolled releases: 3. Overall score: 9, at least some uses wide-dispersive.	Total score: 15-	<b>The same considerations apply as brought forward under the verbal-argumentative approach.</b>
<b>Diisobutyl phthalate (DIBP) (VAA)</b>	Toxic to reproduction, cat.2	According to information in IUCLID (2000), the volume manufactured and/or used in the EU was in the range 10,000 to 50,000 t/y. There is no information on import/export available.	DIBP is used as a specialist plasticiser and frequently as a gelling aid in combination with other plasticisers. The substance is used as plasticiser in nitrocellulose, cellulose ether and polyacrylate and polyacetate dispersions. These are used in paints, lacquers, varnishes, paper, pulp and boards as adhesives,	Given the high volume used and the wide dispersive use pattern (confirmed by monitoring), the substance qualifies on the basis of the prioritisation criteria for prioritisation.	On the basis of the prioritisation criteria DIBP qualifies for prioritisation. Regulatory effectiveness considerations would further support a conclusion that the substance should be prioritised. Diisobutyl

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
		The globally used volume of both dibutyl phthalate and diisobutyl phthalate is about 450,000 t/yr (Annex XV Report, 2009). Volumes manufactured by two companies in Germany in 2002 are reported to be in the ranges of 1,000 – 5,000 t/yr and 10,000-50,000 t/yr, respectively.	bonding agents, softeners and viscosity adjusters. DIBP is also used in coatings and in epoxy repair mortars. As a plasticiser in dispersion glues and printing inks DIBP is used for paper articles and for packaging of food and water bottles. DIBP has been detected in many consumer products frequently used by children as well as in perfumes. Consumer exposure to DIBP can be inferred from its occurrence in house dust and in breast milk. As cited in the Annex XV report, the Nordic product register indicates that DIBP had wide spread uses for the period 2000-2006.		phthalate can be used to replace dibutyl phthalate and may as well be suitable to replace other phthalates already recommended for inclusion in Annex XIV. <b>Therefore, it has been concluded to give diisobutyl phthalate priority and recommend it for inclusion in Annex XIV.</b>
<b>Diisobutyl phthalate (DIBP)</b> (SCA)	Score: 0	Very high volume (range 10,000 to 50,000 t/y) supplied to uses in the scope of authorisation. Score: 9	Used as plasticiser at a high number of sites and in very many articles resulting in worker and consumer exposure. Diffuse environmental releases and uncontrolled consumer exposure (potentially as well uncontrolled worker exposure). Wide dispersive use confirmed by monitoring results. Scoring: number of sites: 3; releases: 3. Overall 9.	Total score: 18	<b>The same considerations apply as brought forward under the verbal-argumentative approach.</b>
<b>Lead chromate</b> (VAA)	Carcinogen cat. 2; Toxic to reproduction, cat.1	The only available information for manufacture in the EU refers to lead chromate produced in Slovenia (51t in 2008). No other information on manufacture is available, except that there is no manufacture anymore in France. Imports of lead chromate as a pigment in the range of 100 – 1,000 t/y were confirmed by a non-EU company.	According to the European colourants industry pure lead chromate was never of important technical use compared to the lead sulfochromate yellow and lead chromate molybdate red pigments. Furthermore, according to information provided by a non-EU manufacturer, lead chromate is not used as a pigment due to its poor colour stability. It may however often be confused with lead sulfochromate yellow. Information on uses of lead chromate	Relatively high annual volume. Uses widespread to wide dispersive. On the basis of the prioritisation criteria the substance qualifies for prioritisation.	On the basis of the prioritisation criteria lead chromate qualifies for prioritisation. Considering regulatory effectiveness, it further cannot be excluded on the basis of current knowledge that the substance could be used to replace lead sulfochromate yellow in some of its uses. <b>Therefore, it has been concluded to prioritise lead chromate for</b>



Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
		<p>The above reported volume of imported lead chromate pigment is consumed by masterbatch producers. In addition to this, the use of lead chromate in paints is estimated by the European Council of producers and importers of paints (CEPE) to roughly exceed 100 t/yr. Furthermore, data on consumption of lead chromate are available for some countries in Europe (France, Sweden, Denmark) with the respective volumes summing to less than 60 tonnes per year, and a trend to decrease.</p>	<p>suggests the following on-going uses:</p> <ul style="list-style-type: none"> <li>➤ manufacture of paints and varnishes (for vehicles, farming material, boat/ships, industrial paint products, civil engineering material, road sign and road painting, as well as quick dry enamels and floor paints)</li> <li>➤ manufacture of plastic masterbatches</li> <li>➤ manufacture of art conservation colours, use in conservation of arts</li> <li>➤ in leather finishing mixtures</li> <li>➤ manufacture of pyrotechnics (pyrotechnic delay compositions for ammunition, ignition compositions for ammunition, and delay detonators for the mining and demolition sectors)</li> </ul> <p>Downstream applications related to these uses, such as painting applications and use of pyrotechnics, were also confirmed.</p> <p>Other potential, but not confirmed uses, include: manufacture of other pigments, use in detergents, embalming products, tattoo inks, photosensitive materials, printing fabrics, and in decorating porcelain.</p> <p>Information that was made available covered the releases / exposure during painting applications, as well as during manufacture and use of pyrotechnics / explosives (RPA, 2010).</p> <p>According to provided information, exposure may occur mainly via dust (inhalation, skin contact and ingestion). Not always protective equipment is used in applications such as painting.</p> <p>Exposure to combustion products of lead chromate during use of ammunition may occur, although the amounts of lead chromate</p>		<p><b>inclusion in Annex XIV.</b></p>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			<p>in ammunition are small.</p> <p>According to information provided by industry, during the manufacture of pyrotechnics the entire amount is consumed in the manufacture process, with any waste generated being combusted, and the solid combustion products managed by specialized companies as toxic waste.</p>		
<b>Lead chromate (SCA)</b>	Score: 1	Relatively high volume (range 100 – 1000 t/yr) used in EU. Score: 5	<p>Uncontrolled exposure of professionals may occur in applications such as, for example, painting, use in restoration, or use of pyrotechnics. Releases to the environment may occur especially after the end of the service life of articles (coated articles, plastics). The reported uses of the substance are widespread to wide dispersive.</p> <p>Scoring: Number of sites of use potentially high: 3; environmental releases may be considered diffuse whereas releases to the working environment, respectively worker exposure, may in most instances be controlled. However, for some uses uncontrolled exposure of professionals as well as consumers cannot be excluded: 3. Overall score: 9</p>	Total score: 15	<b>The same considerations apply as brought forward under the verbal-argumentative approach.</b>
<b>Lead Sulfochromate yellow (C.I pigment Yellow 34)</b> and <b>Lead chromate molybdate sulfate red (C.I pigment red 104)</b>	Carcinogen cat.2; Toxic to reproduction, cat.1	<p>Estimated global production of both pigments CI 34 &amp; 104 is 50 kt/yr (info by a non-EU manufacturer).</p> <p>Volume manufactured in the EU (in 2008) of CI 34 &amp; C.I 104 was 30,000 tons (EMLC). However, a non-EU manufacturer estimates EU manufacture at 10,000 t/yr. Import to EU:</p>	<p>According to information provided by a non-EU manufacturer, the uses of pigments CI 34 yellow and CI 104 red are mostly industrial, apart from some coatings used in applications by professionals. There is no use of the pigments in applications for consumers</p> <p>Current uses in the EU: ➤ Coloration of plastics (~60% of the EU</p>	<p>Conclusion for both pigments C.I. 34 Yellow and C.I. 104 Red: Both substances are used in high volumes and at a high number of sites and may be released (presumably in relatively low amounts) at very many sites from articles during service life or (in</p>	<p>Conclusion for both pigments C.I. 34 Yellow and C.I. 104 red: On the basis of the prioritisation criteria, both pigments qualify for prioritisation. No regulatory effectiveness considerations have been identified that would suggest to refrain from prioritisation. <b>Therefore, it has been concluded</b></p>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
(VAA)		<p>Import volume (in 2008) - CI 34 yellow: range 1,000 – 10,000 t (&gt;80% non encapsulated ["coated"], &lt;20 % encapsulated); CI pigment 104 red: range 100 – 1000 t (&gt;80% non encapsulated ["coated"], &lt;20 % encapsulated). These figures may not cover all imports to the EU.</p> <p>Consumption in EU: According to EMLC, consumption of lead chromate pigments in Europe from European production was much lower in 2008 than the volume produced in Europe (range 1,000 – 10,000 t, 65% CI 34 yellow, 35% CI 104 red). According to EMLC, all lead chromate pigments placed on the EU market by their members are coated. It is unclear if this figure includes fully encapsulated forms as well.</p> <p>Adding the share of EU manufacture that is consumed in the EU and the (known) volumes imported, an EU consumption in the range of &gt;5000 to &lt; 10,000 t/yr can be assumed as the minimum (due to uncertainties regarding imports) for the lead chromate pigments. Of this volume pigment CI 34 yellow holds a share of approximately 67% and pigment CI 104 red 33%.</p>	<p>market for the pigments, EMLC 2009)</p> <p>This use concerns each type of plastic material/composite (polyolefins, polyvinyl chloride and nylon) as well as each process of modelling (injection, extrusion, etc)</p> <p>Applications in this sector include industrial carpet fibres, automotive interiors, non-food packaging, rust resistant furniture and electronic housings. Examples of finished products include trash bags, industrial packaging, piping and tubing, PVC profiles, tarpaulins (DCC). Nevertheless, DCC (personal communication) declined the use in trash bags for consumer use].</p> <p>➤ Paints [Varnishes/Coatings] (~40% of the EU market, EMLC 2009)</p> <p>These pigments are used in a variety of industrial coatings. Applications in this sector include:</p> <ul style="list-style-type: none"> <li>- Vehicles not covered by the end of live vehicles directive (trucks, buses, commercial vehicles, vintage cars)</li> <li>- Agricultural equipment</li> <li>- Civil engineering material</li> <li>- Boats / Ships</li> <li>- Road sign and road painting / Thermoplastic road marking / Airport horizontal painting</li> <li>- General industrial [Skips, plant and machinery; industrial doors, pumps, machinery; large steel structures; gas cylinders; off shore steel structures (e.g. drilling rigs); camouflage / ammunition, interior coatings for</li> </ul>	<p>potentially higher but unknown and uncontrolled amounts) after the end of the life cycle in the waste state or during recycling. Releases to the working environment and worker exposure during formulation and coating steps appear to be controlled but potentially uncontrolled exposure during repair/refurbishing of coated surfaces (e.g. sanding / high pressure blasting). At least widespread and in some applications wide dispersive use.</p> <p>On the basis of the prioritisation criteria, both pigments qualify for prioritisation.</p>	<p><b>to prioritise the two pigments C.I. 34 Yellow and C.I. 104 Red for inclusion in Annex XIV.</b></p>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			<p>military equipment]</p> <ul style="list-style-type: none"> <li>- Aeronautics</li> <li>- Coil coating</li> <li>- Coating of plastic material (PVC, PP, ABS edge bands)</li> <li>- GRP constructions (boats, auto parts, silos)</li> <li>- Thermochromic paint</li> </ul> <p>➤ Other potential, but not confirmed uses, include:</p> <ul style="list-style-type: none"> <li>- Textile printing / Leather finishing / Printing inks (e.g. outer surface of food packaging)</li> <li>- Tattoo inks</li> <li>- Artists paints</li> <li>- Mastics</li> <li>- Paper</li> <li>- Linoleum / Flooring compounds / Colouring of rubber / Wall covering</li> </ul> <p>In order to be stable under environmental conditions, lead the pigments are normally modified with small amounts oxides of Lanthanides, Al, Ce, Sb, Si, Sn, Ti, Zn, Zr, or Fluorine salts . Various combinations of these stabilising modifiers are used to produce different grades of so called "coated" crystals, which is often referred to as (partial) encapsulation, but these stabilised pigments are not truly fully encapsulated.</p> <p>Fully encapsulated pigments are coated with up to 20% amorphous silica, which forms a glass shell around the pigment particle. Encapsulation increases weather, heat, acid and alkalis resistance of the pigments and also bioavailability. Nevertheless, there are also some uncertainties regarding the extent</p>		

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			<p>to which bioavailability is reduced.</p> <p>According to a non-EU manufacturer, "Fully encapsulated" forms of the lead pigments are not manufactured in Europe , with their share on the exports to EU being &lt;20%.</p> <p>Encapsulated forms of the pigments are mainly used (&gt;90%) for coatings (e.g. coil coatings and signage). Encapsulated forms can be used in all applications whereas non-encapsulated forms cannot.</p> <p>Potential exposure of workers during manufacture of pigments and during formulation of paints and colour master batches (emptying pigment bags into the formulation matrix). According to industry, appropriate RMMs are available / in place to control exposure in these areas.</p> <p>Not clear which RMMs are in place/observed to prevent exposure during professional applications (e.g. coating but as well repair manipulation of coated surfaces (exposure to dust from sanding, high pressure particle-blasting of surfaces).</p> <p>Releases from coloured or coated articles during service life may be low but there may be releases from the waste phase or during recycling (no separate collection or particular treatment of lead chromate pigment treated items).</p>		
<p><b>Both pigments C.I. 34 Yellow &amp; C.I. 104 Red</b></p> <p>(SCA)</p>	Score: 1	Both substances are used in high annual volumes. Both score: 7	Both substances are used at a high number of sites and may be released (presumably in relatively low amounts) at very many sites from articles during service life or (in potentially higher but unknown and uncontrolled amounts) after the end of the service life in the waste state or during recycling. Releases to the working	Total score: 17	<b>The same considerations apply as brought forward under the verbal-argumentative approach.</b>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			<p>environment and worker exposure during formulation and coating steps appear to be generally controlled but potentially uncontrolled exposure during repair/refurbishing of coated surfaces (e.g.sanding / high pressure blasting).</p> <p>Use and release at potentially a high number of sites – score: 3; Environmental releases diffuse and for some uses uncontrolled occupational exposure cannot be excluded whereas for other uses occupational exposures seem to be controlled – score: 3. Overall score: 9</p>		
<b>Lead hydrogen arsenate (VAA)</b>	Carcinogen cat.1; Toxic to reproduction, 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.	No use in the EU, therefore no priority on the basis of the criteria.	<p>No priority on the basis of the prioritisation criteria (as lead hydrogen arsenate is not used in the EU).</p> <p>No regulatory effectiveness considerations have been identified that would suggest prioritisation.</p> <p><b>Therefore, it has been concluded to not prioritise lead hydrogen arsenate for inclusion in Annex XIV.</b></p>
<b>Lead hydrogen arsenate (SCA)</b>	Score: 1	No manufacture in the EU and no import: 0 scores	No known uses. Overall score: 0	Total score: 1	<b>The same considerations apply as brought forward under the verbal-argumentative approach.</b>
<b>Pitch, coal tar, high temperature (CTPHT) (VAA)</b>	Carcinogen cat.2; PBT and vPvB	EU manufacture approximately one million tonnes per year. Overall EU consumption 750,000 t/yr of which more than 95% are supplied to uses in the scope of	Main uses (650,000 t/yr) are as binding agent in the manufacture of anodes/electrodes for the production of primary metals (aluminium), ferro-alloys, non-ferrous metals, metal alloys, calcium carbide and silicon carbide. Further	The substance is used in very high volumes and nearly all uses can be considered wide dispersive, although the main use (~87% of the total	<p>On the basis of the prioritisation criteria, pitch, coal tar, high temperature (CTPHT) qualifies for prioritisation.</p> <p>However, while the Risk Reduction</p>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
		authorisation.	<p>uses as binding agent in refractories (37.5 kt/yr), briquettes (6.8 kt/yr), clay-targets (6 kt/yr), roofing (5.3 kt/yr) and (specialty) paving (1.5 kt/yr). Anti-corrosion agent in (specialty) coatings and paints (7.5 kt/yr), starting material/binder for manufacture of active carbon and carbon fibres (12.8 kt/yr), and some other applications.</p> <p>Given the amount used for anode/electrode manufacture, the number of sites where electrodes are manufactured and taking account of the PAH emissions resulting from the baking of anodes/electrodes, this use is considered wide dispersive. The same applies, for the potential number of sites of use/ worker exposure or (un)controlled releases from uses in refractories, paints and coatings, briquettes, clay-targets, paving and roofing.</p>	<p>amount) happens in (very) large industrial installations. Therefore, on the basis of the prioritisation criteria, the substance qualifies for prioritisation.</p>	<p>Strategy (RRS) prepared as a part of the transitional dossier under Article 136(3) of REACH and the assessment carried out using the information gathered when preparing and agreeing on the Annex XV SVHC dossier came to some extent to different conclusions on the most appropriate measures to be taken, neither of them supported the authorisation process. In particular, PAH emissions resulting from the use of CTPHT in the production of electrodes and refractories (~92 % of the total use) and their use in metal industry, should be looked at in a holistic way together with other metal industry sources of PAH emissions to ensure that an overall reduction of PAH emissions is achieved.</p> <p>Furthermore, it is noted that it would be useful to consider these PAH emissions from the metal industry and their reduction objectives in conjunction with more general objectives for reduction of PAH emissions from industry, incineration processes and other emission sources.</p> <p><b>Therefore, it has been concluded to not prioritise pitch, coal tar, high temperature (CTPHT) now for inclusion in Annex XIV.</b></p>
<b>Pitch, coal tar, high temperature (CTPHT) (SCA)</b>	Score: 4	Very high volume in the scope of authorisation: 9 scores	<p>Many uses with emissions occurring at a high number of sites. Releases are diffuse and they might be significant. Scoring: number of sites: 3; releases: 3,</p>	Total score: 22	<b>The same considerations apply as brought forward under the verbal-argumentative approach.</b>

Substance	Inherent properties	Conclusion on			Final conclusion, taking regulatory effectiveness considerations into account
		Volumes	Wide dispersiveness of uses	Priority	
			overall: 9		
<b>Sodium dichromate (VAA)</b>	Carcinogen cat.2; Mutagen cat.2; Toxic to reproduction, cat.2	The volume used in the EU is <100,000 t/a, which is used almost exclusively as an intermediate.	<p>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 &lt;&lt;1%), the main non-intermediate use of Na<sub>2</sub>Cr<sub>2</sub>O<sub>7</sub> 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<sub>2</sub>Cr<sub>2</sub>O<sub>7</sub> in metal finishing can therefore be considered as widespread. However, as no information is available about releases from the use of Na<sub>2</sub>Cr<sub>2</sub>O<sub>7</sub> in metal finishing, a conclusion whether these uses must be considered as wide dispersive cannot be drawn without supplementary information becoming available.</p> <p>A small portion (&lt;&lt; 1% of EU volume) of sodium dichromate is used in the textile industry for dyeing of protein fibres. According to information provided by the Associazione Tessile e Salute (Italy), no dichromate remains in the textiles and, due to operational conditions and risk management measures in place the worker exposure is low (as shown by sampling results at the workplace).</p>	<p>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.</p> <p>On the basis of the prioritisation criteria, sodium dichromate can be considered as a borderline candidate for prioritisation because on the one hand the volume used is high but on the other hand occupational exposure appears to be controlled.</p>	<p>On the basis of the prioritisation criteria, sodium dichromate can be considered as a borderline candidate for prioritisation. Nevertheless, the regulatory effectiveness of subjecting the sodium dichromate salt alone to the authorisation requirement can be considered questionable because it might in many cases be possible to evade the authorisation requirement by replacing the sodium salt by another hexavalent chromium compound with a similar hazard potential.</p> <p><b>Therefore, it has been concluded to not prioritise sodium dichromate now for inclusion in Annex XIV.</b></p>
<b>Sodium dichromate (SCA)</b>	Score: 1	High annual volume in the scope of authorisation: 7 scores	<p>Non intermediate uses of sodium dichromate may occur in a high number of sites. However, releases and exposure to workers will presumably be controlled.</p> <p>Scoring: number of sites: 3; releases: 1. Overall score: 3</p>	Total score: 11	<b>The same considerations apply as brought forward under the verbal-argumentative approach.</b>



Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
<b>Triethyl arsenate (VAA)</b>	Carcinogen 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 for specialised doping applications in semi-conductors.	<p>Triethyl arsenate has been developed for use in specialised doping applications in semi-conductors.</p> <p>If the doping process is a step in the production process of electronic components (such as semiconductor devices), than triethyl arsenate is considered as a substance used for the production of articles because the shape and design of the built-in integrated circuits determine the function to a greater degree than does the chemical composition (Art. 3(3) of the REACH Regulation).</p> <p>When instead the doping process takes place in the manufacture of silicon for use in special applications, e.g. for the production of semi-conductors, solar cells and other electronic devices, the triethyl arsenate can be considered as an intermediate, because the outcome of this doping process, doped silicon ingots, is a new substance of its own, which is not regarded the same as the silicon substance fed into that process.</p> <p>All doping processes are performed in closed chambers where the electronic components or the silicon material is put in contact with the substance in vapour form inside the process chamber. By-products of the reaction and non reacted chemicals are discharged from the chamber via vacuum pumps connected to abatement devices (thermal or wet scrubber). Therefore, exposure of workers to the substance or releases to the environment can be considered insignificant. The uses of triethyl arsenate are not considered as wide-dispersive.</p>	<p>The volume used is very low and there is neither worker nor environmental exposure resulting from the use of triethyl arsenate.</p> <p>On the basis of the prioritisation criteria, the substance has only a very low priority for inclusion in Annex XIV.</p>	<p>On the basis of the prioritisation criteria, triethyl arsenate has only a very low priority for inclusion in Annex XIV.</p> <p>No regulatory effectiveness considerations have been identified that would suggest prioritisation.</p> <p><b>Therefore, it has been concluded to not prioritise triethyl arsenate for inclusion in Annex XIV.</b></p>
<b>Triethyl arsenate (SCA)</b>	Score: 1	Low annual volume: 1 score.	The substance is only used for doping applications in the semiconductor industry	Total score: 2	<b>The same considerations apply as brought forward under the verbal-</b>

Substance	Inherent properties	Conclusion on			Final conclusion, taking regulatory effectiveness considerations into account
		Volumes	Wide dispersiveness of uses	Priority	
			under strictly controlled conditions. This may occur at a medium number of sites. Scoring: number of sites: 2; insignificant worker exposure and environmental releases: 0. Overall score: 0.		argumentative approach.
<b>Tris (2-chloroethyl) phosphate (TCEP)</b> (VAA)	Toxic to reproduction, cat.2	The volume of TCEP currently manufactured, imported, exported or used in the EU is difficult to estimate from the data available. EU manufacture 2000 t/yr in 1998 (RAR 2009, for EU 15). However, according to information obtained from industry the substance is not manufactured anymore in the EU (European countries before May 2004). In the RAR the amount used in the EU is estimated to be 1007 t/a. However, this estimate does not take account of manufacture in Poland for 2004, which is estimated to amount to 300 - 500 t/yr, of which 300 to 400 t are exported from the EU). So, under consideration of data from Poland, EU consumption may have been 1000 – 1200 tonnes in 2004.	Main uses of TCEP are as an additive plasticiser and viscosity regulator with flame retarding properties in polyurethane, polyesters, polyvinyl chloride and other polymers. Nowadays it is mainly used in the production of unsaturated polyester resins (~80%). Other fields of application are acrylic resins, adhesives and coatings. The main industrial branches to use TCEP as a flame retardant plasticiser are the furniture, the textile and the building industry (roof insulation), it is also used in the manufacture of cars, railways and aircrafts. Specific information on fields of application is available for 44% of the total tonnage: 1% is supplied for use in paints, 5% is used as intermediate of wax additives, 94% in the polymer industry. There is no information to which uses the remaining 56% of the supply are allocated. TCEP is not bound to the polymer matrix. Therefore, TCEP can migrate to the surface and releases can be expected to occur during service life and after disposal of products containing TCEP. Data suitable to quantify releases are not available, but as TCEP is in liquid state at room temperature, its migration potential might be high. However, as the vapour pressure of the TCEP is very low at room temperature, releases and exposure are mainly expected to occur due to abrasion	From the data available on manufacture, import and uses it is assumed that a high volume (range 1,000 – 10,000 t/yr) is supplied in the EU to uses which are in the scope of REACH. As TCEP is not bound to the polymer matrix and therefore can be released during service life and after disposal of products containing it, many of its uses have to be considered wide-dispersive. Wide dispersive use is further confirmed by monitoring results of dust and water samples. On the basis of the prioritisation criteria the substance qualifies for prioritisation.	On the basis of the prioritisation criteria TCEP qualifies for prioritisation. No regulatory effectiveness considerations have been identified that would suggest to refrain from prioritisation. <b>Therefore, it has been concluded to give tris (2-chloro-ethyl) phosphate priority and recommend it for inclusion in Annex XIV.</b>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			<p>from the polymer matrix (dust) unless the polymers are heated (may be relevant for formulation of polymers and production of articles). The substance leaches from immersed polymers to water.</p> <p>In the RAR it has been concluded that there is a need to limit the risks from occupational exposure (inhalative and dermal route) of workers and consumers (babies, significant exposure could occur due to sucking at toys containing TCEP).</p> <p>TCEP is very persistent (vP: DT50 in soil = 167 d, non biodegradable in surface water), but not liable to bioaccumulate (BCF = 5). The substance has been monitored in house dust and in the environment (water and sediment).</p>		
<b>Tris (2-chloroethyl) phosphate (TCEP) (SCA)</b>	Score: 0	From the data available on manufacture, import and uses it is assumed that a high volume (1,000 – 10,000 t/yr) is supplied in the EU to uses which are in the scope of REACH. Score : high volume: 7	From the data available on manufacture, import and uses it is assumed that a high volume (range 1,000 – 10,000 t/yr) is supplied in the EU to uses which are in the scope of REACH. Scoring: Use at potentially a high number of sites – score 3; releases are diffuse – score: 3. Overall score: 9	Total score: 16	<b>The same considerations apply as brought forward under the verbal-argumentative approach.</b>

**Table 2: Ranking of the SVHCs on the Candidate List on the basis of the scoring approach\* and comparison of the scoring results with the prioritisation results of the verbal-argumentative approach.**

\* 
$$\text{Score}_{\text{Total}} = \text{Score}_{\text{Inherent properties}} + \text{Score}_{\text{Volume}} + \text{Score}_{\text{Wide-dispersive use}}$$
 Score (min/max): (0/22), (0/4) (0/9) (0/9)

Total Score	Substance	Inherent properties	Volumes	Wide dispersive use	Verbal-argumentative #	Final conclusion, taking regulatory effectiveness into account #
22	<b>Anthracene oils</b>	4	9	9	All anthracene oils on the Candidate List qualify for prioritisation.	Because there is uncertainty about the nature (and volume) of uses falling in the scope of authorisation and as to whether authorisation would be the appropriate instrument for these uses, <b>it has been concluded to not prioritise the anthracene oil substances now</b> but to wait with a decision on prioritisation until the registration dossiers have been assessed with respect to the uses of these substances. Moreover, as mentioned for CTPHT, it should be considered to look at the PAH emissions in a wider context.
22	<b>Pitch, coal tar, high temperature (CTPHT)</b>	4	9	9	Substance qualifies for prioritisation.	<b>Conclusion to not prioritise CTPHT</b> because authorisation may not be the optimal instrument (conclusion Transitional Dossier by NL and analysis by ECHA). In particular, PAH emissions resulting from the use of CTPHT in the production of electrodes and refractories (~92 % of the total use) and their use in metal industry, should be looked at in a holistic way together with other metal industry sources of PAH emissions to ensure that an overall reduction of PAH emissions is achieved. Furthermore, it is noted that it would be useful to consider these PAH emissions from metal industry and their reduction objectives in conjunction with more general objectives for reduction of PAH emissions from industry, incineration processes and other emission sources. For some smaller applications of CTPHT (and other PAH containing compounds) restriction under REACH could be used if an urgent need to phase out these uses is deemed necessary.
18	<b>Diisobutyl phthalate (DIBP)</b>	0	9	9	Substance qualifies for prioritisation.	Regulatory effectiveness considerations further support prioritisation: Diisobutyl phthalate can be used to replace dibutyl phthalate and may as well be suitable to replace other phthalates already recommended for inclusion in Annex XIV. <b>Conclusion to prioritise DIBP.</b>
17	<b>Acrylamide</b>	1	7	9	Substance qualifies for prioritisation.	<b>Conclusion to not prioritise acrylamide</b> as the only use in the scope of authorisation (grouting) will likely be covered by a restriction proposal of the Commission.
17	<b>Diarsenic trioxide</b>	1	7	9	Substance qualifies for prioritisation.	There is some uncertainty about the extent of the problem of insufficient exposure control for workers in the glass industry. <b>However, conclusion to prioritise diarsenic trioxide.</b>

Total Score	Substance	Inherent properties	Volumes	Wide dispersive use	Verbal-argumentative #	Final conclusion, taking regulatory effectiveness into account #
17	<b>Lead sulfochromate yellow (C.I pigment Yellow 34)</b>	1	7	9	Substance qualifies for prioritisation.	No regulatory effectiveness considerations have been identified that would suggest to refrain from prioritisation. <b>Conclusion to prioritise lead sulfochromate yellow.</b>
17	<b>Lead chromate molybdate sulfate red Lead chromate molybdate sulfate red</b>	1	7	9	Substance qualifies for prioritisation.	No regulatory effectiveness considerations have been identified that would suggest to refrain from prioritisation. <b>Conclusion to prioritise lead chromate molybdate sulfate red.</b>
16	<b>Tris (2-chloroethyl) phosphate (TCEP)</b>	0	7	9	Substance qualifies for prioritisation.	No regulatory effectiveness considerations have been identified that would suggest to refrain from prioritisation. <b>Conclusion to prioritise TCEP.</b>
15	<b>2,4 – Dinitrotoluene (2,4-DNT)</b>	1	5	9	Substance qualifies for prioritisation.	No regulatory effectiveness considerations have been identified that would suggest to refrain from prioritisation. <b>Conclusion to prioritise 2,4-DNT.</b>
15	<b>Lead chromate</b>	1	5	9	Substance qualifies for prioritisation.	Considering regulatory effectiveness, it further cannot be excluded on the basis of current knowledge that the substance could be used to replace Pigment C.I. Yellow 34 in some of its uses. <b>Conclusion to prioritise lead chromate.</b>
13	<b>Aluminum silicate refractory ceramic fibres (Al-RCF)</b>  and 13 <b>Zirconia aluminium silicate refractory ceramic fibres Zr-Al-RCF)</b>	1	9	3	Substances qualify for prioritisation.	According to information provided by several industry associations, the current identification of Al-RCF and Zr-Al-RCF on the Candidate List covers only a part of the RCFs on the European market (about 50%). <b>Conclusion to not prioritise Al-RCF and Zr-Al-RCF now</b> in order to avoid unjustified preferential treatment and market distortion in favour of RCF types not yet identified as SVHC. Suggestion to wait with prioritisation until all RCF types falling under index number 650-017-00-8 of Annex VI of Regulation (EC) No. 1272/2008 are included in the Candidate List.
11	<b>Sodium dichromate</b>	1	7	3	Substance can be considered as a borderline candidate for prioritisation.	The regulatory effectiveness of subjecting the sodium dichromate salt alone to the authorisation requirement can be considered questionable because it might be possible to evade the authorisation requirement by replacing the sodium salt by another hexavalent chromium compound with a similar hazard potential. <b>Conclusion to not prioritise sodium dichromate now.</b>
8	<b>Diarsenic pentaoxide</b>	1	1	6	Substance can be considered as a	As it has been concluded to prioritise diarsenic trioxide, diarsenic pentaoxide should be prioritised as well because otherwise it may be used to bypass the authorisation requirement by substitution.

Total Score	Substance	Inherent properties	Volumes	Wide dispersive use	Verbal-argumentative #	Final conclusion, taking regulatory effectiveness into account #
					borderline candidate for prioritisation.	<b>Conclusion to prioritise diarsenic pentaoxide.</b>
6	<b>Cobalt dichloride</b>	1	3	2	The substance has relatively low priority.	Further, the regulatory effectiveness of subjecting the use of the dichloride salt alone to the authorisation requirement can be considered questionable because it might be easy to bypass the authorisation requirement by replacing the dichloride salt with another cobalt compound with a similar hazard profile. <b>Conclusion to not prioritise cobalt dichloride now.</b>
4-7	<b>Anthracene</b>	3	1	0 - 3	Anthracene has a relatively low priority	The only known use not exempted from authorisation is use in pyrotechnics. This use is not wide-dispersive because the releases are insignificant. <b>Conclusion to not prioritise anthracene.</b>
3	<b>Bis (tributyl tin) oxide</b>	3	0	0	No uses of the substance in the EU in the scope of authorisation. Therefore no priority.	There are no known uses in the EU within the scope of authorisation. <b>Conclusion to not prioritise TBTO.</b>
2	<b>Triethyl arsenate</b>	1	1	0	The substance has only very low priority (no exposure).	Uses do not result in exposure. Therefore low priority. No regulatory effectiveness considerations have been identified that would suggest prioritisation. <b>Conclusion to not prioritise triethyl arsenate.</b>
1	<b>Lead hydrogen arsenate</b>	1	0	0	No uses in the EU. Therefore no priority.	No uses in the EU. <b>Conclusion to not prioritise lead hydrogen arsenate.</b>

# Table 2 contains only abridged summaries with regard to information taken into account and the conclusions drawn. See table 1 for more comprehensive information on lines of reasoning.