20 June 2012

Draft results of the 4th 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[1].

In table 1 below ECHA's conclusions are provided with regard to the priority of the substances on the Candidate List for inclusion in Annex XIV. Basis for the prioritisation presented in this report was the Candidate List as updated on 19 December 2011. All substances on the Candidate List except those already included in one of ECHA's previous Recommendations and the group of the Refractory Ceramic Fibre entries have been considered. However, the substances that were already assessed for priority in the context of the 3rd Recommendation but not prioritised for inclusion in Annex XIV in 2011 or before were not re-assessed during the current prioritisation exercise, as a survey of registration-updates received for these substances[2] revealed that, with one exemption (acrylamide, see below), no new information regarding e.g. volumes and uses was included in these updates that would have an influence on the previously drawn conclusions with regard to the priority of these substances for inclusion in Annex XIV.

The candidate list of 19 December 2011, including indication as to which of the listed substances have been considered in the current prioritisation exercise, is provided in Annex 1.

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

- the verbal-argumentative approach and
- the scoring approach

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.

The information used for priority setting amongst the Candidate List substances is primarily based on information provided in the registration dossiers on quantities on the European market and on identified uses. In addition, information from the Annex XV dossiers of the substances, or received during public consultation on the SVHC identification in accordance with Article 59 of the REACH Regulation has also been taken into account, where relevant. Finally, data collected either by consultants to ECHA or by

[1] http://echa.europa.eu/documents/10162/17232/axiv_prioritysetting_general_approach_20100701_en.pdf

[2] Registrations and registration-updates submitted to ECHA between April 2011 and March 2012 were considered in this survey. Registrations and updates received before April 2011 were already taken into consideration in the previous prioritisation for the 3rd Recommendation.

ECHA itself on volumes of the substances on the European market, on their uses and on releases resulting from these uses have been considered.

Based on the information available and the justifications provided in Table 1, ECHA proposes to prioritise the following substances for its fourth recommendation of priority substances for inclusion in Annex XIV (list of substances subject to authorisation):

Substance name	EC
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	500-036-1
Arsenic Acid	231-901-9
Dichromium tris(chromate)	246-356-2
Strontium chromate	232-142-6
Potassium hydroxyoctaoxodizincatedichromate	234-329-8
Pentazinc chromate octahydroxide	256-418-0
Bis(2-methoxyethyl) ether (Diglyme)	203-924-4
N,N-Dimethylacetamide (DMAC)	204-826-4
1,2-Dichloroethane (EDC)	203-458-1
2,2'-dichloro-4,4'-methylenedianiline (MOCA)	202-918-9

Refractory Ceramic Fibres:

With the latest update of 19 December 2011 two new entries for Aluminosilicate refractory ceramic fibres (Al-RCF) and Zirconia-aluminosilicate refractory ceramic fibres (Zr-Al-RCF) were included in the Candidate List so that there were, with the two older entries for these substances dating from January 2010, in total four entries for RCFs on the list. During agreement seeking by the Member State Committee on the SVHC identification of the new proposals it had been agreed that ECHA should investigate whether the new Al-RCF and Zr-Al-RCF entries cover the older ones with the same substance names. This investigation was still ongoing when the prioritisation of the substances on the Candidate List was carried out. Therefore, priority of the refractory ceramic fibres for inclusion in Annex XIV was not assessed in the current prioritisation exercise.

In the meantime ECHA's investigation regarding options for consolidation of the RCF entries has been finalised. Conclusion was that the RCF entries from 2010 are indeed entirely covered by the ones included in the Candidate List in December 2011 and that it therefore was possible to remove the entries from 2010 without any impact on the range of the fibre types/compositions covered (i.e. the remaining two RCF entries cover the same fibre types/compositions than the original four entries). The consolidation of the RCF entries took place on 18 June 2012.

Acrylamide:

For acrylamide three new uses have been identified in registration updates. These regard the uses by professional workers for in-situ polymerisation for: water shut-off, salt-damp remediation, and concrete repair. Those uses, which had already been described in the A.XV Dossier[3], appear not to be uses of the substance as an intermediate (and therefore are in the scope of authorisation).

Nevertheless, it is noted that Commission Regulation (EU) No 366/2011 of 14 April 2011 prohibits the placing on the market of acrylamide for grouting applications (as a substance or constituent of mixtures in a concentration, equal to or greater than 0,1 % by weight) after 5 November 2012 (entry 60 of Annex XVII of the REACH Regulation). As a consequence, the newly identified uses of acrylamide do not seem to have an influence on the previously drawn conclusions with regard to the priority of this substance for inclusion in Annex XIV, as they are restricted from 5 November 2012 on. It should though be mentioned that there is a pending action for annulment concerning the referred to acrylamide restriction (case T-368/11: Polyelectrolyte Producers Group and others/Commission).

[3] The A.XV Dossier for acrylamide (the Netherlands, 2009) had reflected that "there is very little information on the tonnage of acrylamide-base grouts used within the EU either at present or historically, although it is known that this use has decreased significantly compared with the past (because of moving to alternatives) and that when used, acrylamide grouts are now only used for extreme conditions".

Table 1: Prioritisation of the substances on the Candidate List (as updated on 19 December 2011; substances already included in a previous recommendation have not been considered anymore)

Prioritisation results of the verbal-argumentative approach (VAA) and of the scoring approach (SCA) are provided as well as the final conclusions on the priority of the substances for inclusion in Annex XIV after regulatory effectiveness considerations have been taken into account. The description of the prioritisation approach, including how the wide dispersiveness of uses has been assessed and how scores on inherent properties (0-4), volumes (0-9) and wide dispersiveness of uses (0-9) has been derived, is presented in the general approach document available at: http://echa.europa.eu/documents/10162/17232/axiv_prioritysetting_general_approach_20100701_en.pdf.

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
Formaldehyde, oligomeric reaction products with aniline (technical MDA) *(VAA)*	Art. 57(a); Carcinogen 1B	Most of the volume (> 500,000 t/y) of technical MDA is registered as intermediate mainly for the manufacture of methylene diphenyl diiscyanate (MDI). A relatively high amount (100 – 1000 t/y) is registered for uses in the scope of authorisation (see ECHA's dissemination website): • Manufacture of rolls with composite cover • Filament winding • Closed mould application of aromatic amines In the Annex XV dossier it is stated that technical MDA is known to be used as a curing agent for epoxy resins or as a hardener in adhesives. These uses are sometimes	The main constituent of technical MDA is MDA (about 60 %). Both, MDA and technical MDA, have the same functions as curing agent for polymers and hardener in epoxy resins and adhesives, which are in the scope of authorisation. Full registration dossiers for technical MDA (similarly to the registrations of MDA), advise against the use of the substance by professionals or consumers. No conclusive information is available regarding the supply chain structure and the conditions of uses in the scope of authorisation. However, as regards the structure of the supply chain, the Annex XV dossier on technical MDA assumes a similar supply chain as for MDA. The use of MDA as hardener in epoxy resins and adhesives is expected to take place in the entire EU and to result in exposure of workers, in particular in smaller companies.	The substance is used in (relatively) high volumes in the scope of authorisation. Most uses appear to have a high potential for significant exposure of workers and seem to take place at many sites. Thus they can be considered wide dispersive. On the basis of the criteria the substance has high priority.	On the basis of the prioritisation criteria, Formaldehyde, oligomeric reaction products with aniline (technical MDA) gets high priority for inclusion in Annex XIV. Furthermore, a very similar substance with similar uses, namely MDA (main constituent of technical MDA), is already included in Annex XIV. Considering regulatory effectiveness (i.e. that technical MDA could at least in some uses replace MDA) further supports the prioritisation of this substance. Additionally, technical MDA should be seen as a potential alternative to MOCA, even though it might not be suitable to replace this substance in all its applications. **Therefore, it is proposed to**

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
		interpreted as intermediate uses, however it seems that they are rather end uses providing desired properties and functions to the resin or adhesive mixtures. Therefore, it is possible that some registrants erroneously deemed their use of the substance as curing agent or hardener covered by their registration of technical MDA as intermediate. Therefore, a (likely small) part of the overall tonnage registered as intermediate might in fact be allocated to uses in the scope of authorisation. Therefore, similar to the approach taken for MDA (see MDA background document), the volume of 100 – 1000 t/y in the scope of authorisation should be regarded as the minimum whereas a higher volume cannot be excluded.	The EU Risk Assessment Report (RAR) on MDA (which sometimes refers also to technical MDA), describes tens of different formulations containing MDA in one-component and two-component mixtures, in liquid, paste, granular or powder form and containing MDA in concentrations between 0.1 - 60 %. Formulations containing MDA/technical MDA seem to be prepared in big industrial settings and then further distributed to downstream users (RAR, technical report on MDA). This suggests a similar structure of the supply chain for MDA/technical MDA as for MOCA (for similar uses and applications), where information available is indicating the existence of tens of formulator sites and hundreds of use sites. Therefore it appears reasonable to assume that technical MDA is also used at a high number of sites. Some specific uses appear to be highly automated and contained (e.g. ion exchange resins in nuclear power plants). Whereas other uses include process steps like dipping and pouring, transfer at non-dedicated facilities and others that seem to have high potential for exposure of workers (see ECHA's dissemination website). In conclusion it is assumed that the uses of technical MDA in the scope of authorisation bear a high potential for significant exposure at a high number of		**prioritise formaldehyde, oligomeric reaction products with aniline (technical MDA) for inclusion in Annex XIV.**

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			sites in the EU.		
Formaldehyde, oligomeric reaction products with aniline (technical MDA) *(SCA)*	Score: 1	'Relatively high' to 'high' volume used in the scope of authorisation. Score: 5 - 7	Expected to be used at a high number of sites in the EU. Score: 3 Potential for significant exposure of workers. Score: 3 Overall score: 9	Total score: 15 - 17	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Arsenic acid *(VAA)*	Art. 57(a); Carcinogen 1A	The substance is imported in a tonnage of 100-1000 t/y, partly as aqueous solution in 2010. No manufacture. Main use in EU is as fining agent in the manufacture of speciality glass for removing bubbles from the glass melt. This use of the substance appears to be use as "processing agent", similar to the use of As_2O_3 in glass making (Background document for As_2O_3, 2010; Annex XV). The second known use is in the production of copper foil for printed circuit boards (electronic components	Special glass tends to be produced in a few large facilities (Annex XV dossier). According to industry referenced in Annex XV dossier arsenic is used by a limited number of industrial glass manufacturers in EU. However, it is known that special glass containing arsenic (compounds), e.g. artisan glass, is also manufactured by many smaller manufactories. There are several glass manufacturing facilities across the EU, each with arsenic emissions to the environment in the range from 0.1 to 0.7 t/y. The sources are various arsenic compounds used in the glass making, e.g. arsenic acid and diarsenic trioxide (and possibly others). No consumer exposure is expected	Relatively high volume within scope of authorisation. Consumer exposure via articles resulting from the uses considered to be insignificant but potentially significant occupational exposure. On the basis of the criteria arsenic acid has a relatively high priority.	On the basis of the prioritisation criteria, arsenic acid gets relatively high priority for inclusion in Annex XIV. Arsenic acid can be used to replace As_2O_3 in some of its applications. As_2O_3 has already been included in Annex XIV. This further supports recommending arsenic acid for inclusion in Annex XIV. **Therefore, it is proposed to prioritise arsenic acid for inclusion in Annex XIV.**

[4] In the Murano region, about 80 manufactories with ca. 800 – 1,000 workers manufacture arsenic-containing art glass. Extrapolation from Italian data to EU suggests that a considerable number of workers could be exposed and that the use of As_2O_3 for art glass should be considered wide-dispersive.

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
		sector). No further information was available. Both uses are considered to be in the scope of authorisation.	since the arsenic acid is not present as original compound in the glass (chemical speciation changes during manufacturing process). Furthermore the arsenic is bound into the glass matrix (i.e. possible migration insignificant). Similarly, potential for exposure of consumers to arsenic on the printed circuit boards is considered insignificant as the final boards are lacquered. About 97 % of the total tonnage is used as fining agent in the manufacture of speciality glass for removing bubbles from the glass melt (Annex XV, 2011). Arsenic acid is used in the industrial special glass sector, in particular in the manufacture of black and white ceramic glass. The available registration data indicate closed processes for the use in glass making), but also include transfer processes where potential for exposure is given. In glass production arsenic acid has the same function as diarsenic trioxide (As_2O_3), i.e. fining agent. Both substances can and appear to be used interchangeably in the glass sector. For As_2O_3, of which about 150 t/y As_2O_3 are used in the glass sector, it was concluded that there seem to be problems regarding occupational exposure control in (parts of) the glass industry although there is uncertainty		

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			about the extent (ECHA, 2010)[4]. Although no specific information indicating the use of arsenic acid in the artisanal glass sector has been obtained, such use cannot be excluded given the interchangeability of the substances for use as fining agent. Therefore, the same conclusion is drawn for arsenic acid as for As_2O_3 since both substances are used interchangeably in the glass sector.		
Arsenic acid *(SCA)*	Score: 1	Relatively high volume in the scope of authorisation. Score: 5	The number of sites at which arsenic acid is used is unknown. The substance is used in similar amounts as As_2O_3 for the same use, therefore the same conclusions are drawn: Presumably used at a high number of sites. Score: 3 Potential for significant occupational exposure in (parts of) the glass industry (in particular if arsenic acid is used as replacement for As_2O_3 in the art glass sector). Score: 3 Overall score: 9	Total score: 15	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Dichromium tris(chromate)	Art. 57 (a); Carcinogen 1B	According to registration information the amount of the substance used in the EU	As reported in the Annex XV dossier, dichromium tris(chromate) is mainly used for surface treatment of metals	The volume of the substance supplied to uses in the scope of	On the basis of the prioritisation criteria dichromium tris(chromate) gets moderate

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
(VAA)		is in the range 10 – 100 t/y. Almost all the tonnage used is allocated to uses in the scope of authorisation.	due to its corrosion inhibiting properties (the substance reacts on contact with the metal surface to form a thin metal oxide conversion layer on the surface of the treated metal). According to information provided in the registrations and the Annex XV dossier, applications of the substance in the scope of authorisation are: - formulation of metal treatment products and - industrial surface treatment of metals with reactive anti-corrosion primer for steel and aluminium (e.g. in the construction and the aeronautic sectors). As a further minor application identified in the registration dossiers, dichromium tris(chromate) is used as a laboratory reagent for quality control purposes. Occupational exposure cannot be excluded and its extent depends on the operational conditions and risk management measures in place. According to information provided in the registrations and in the Annex XV dossier the substance is applied for surface treatment of metals by dipping, brushing, roller application or manual spraying. Aerosols generated during the mentioned applications bear a high potential for exposure of workers.	authorisation is relatively low. The uses of the substance are considered to be widespread with a potential for significant worker exposure. On the basis of the criteria, the substance has moderate priority.	priority for inclusion in Annex XIV. There are other chromium (VI) compounds already recommended for inclusion in Annex XIV such as sodium dichromate and potassium dichromate which potentially could be replaced by dichromium tris(chromate) in surface treatment. **Therefore, it is proposed to recommend dichromium tris(chromate) for inclusion in Annex XIV.**

[5] The exposure values provided in tables 7 – 19 of the Annex XV dossier for chromium trioxide are expressed in µg CrO_3/m^3 air (and not as µg $CrVI/m^3$ as erroneously stated in the dossier).

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			In the Annex XV dossier recent monitoring results regarding exposure to chromium (VI) via air at the workplace in different metal working sectors in France, among them the "metal treatment and surface finishing" sector, are reported. The data indicate that French workers in the metal treatment and surface finishing sector are exposed via the respiratory route to non-negligible concentrations of chromium (VI) compounds. Furthermore, recent exposure information reported in the Annex XV dossier for chromium trioxide prepared by Germany shows that also German workers are exposed to significant concentrations of chromium (VI)[5] in workplace air in sectors such as "formulation of metal treatment products" and "surface treatment". Based on this recent information on exposure of French and German workers to Cr(VI) resulting from uses and processes in which also dichromium tris (chromate) is used it can be assumed that other European workers are also likely to be exposed to non-negligible concentrations of Cr(VI) compounds, among them dichromium tris(chromate). The exact number of sites of use of dichromium tris(chromate) in the EU is		

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			unknown. In the registrations it is reported that several sites are involved whereas in the Annex XV dossier it is stated that a high number of enterprises are involved in surface treatment activities (mainly small or medium size enterprises). Information received during the public consultation on the SVHC identification of the substance (RCOM, 2011) indicates use at a small number of industrial sites with a well-defined supply chain (passivation-coil coating). Due to these uncertainties regarding the number of industrial sites a medium to high number of sites is assumed.		
Dichromium tris(chromate) *(SCA)*	Score: 1	Relatively low volume allocated to uses in the scope of authorisation. Score: 3	Uses of the substance in the scope of authorisation may take place at a medium to high number of industrial sites. Score: 2-3. Releases and exposure to workers might be controlled in most instances, however some of the uses have a potential for significant worker exposure. Score: 3. Overall score: 6-9	Total score: 10-13	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Strontium chromate *(VAA)*	Art. 57 (a); Carcinogen 1B	According to information provided in the registrations the amount of the substance	As reported in the Annex XV and registration dossiers, the main application of strontium chromate is in	The volume of strontium chromate supplied to uses in the scope of	On the basis of the prioritisation criteria, strontium chromate gets high priority for inclusion in

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
		used in the EU is in the range of 1,000 – 10,000 t/y. The entire amount is allocated to uses in the scope of authorisation.	coil coated galvanised steel (for the protection of steel and zinc). It is also used in much lower quantities in primers for aerospace applications (for the protection of aluminium) but also in anti-corrosion primers, in fillers and sealants for the construction and maintenance of vehicles (such as heavy duty vehicles and trucks, military vehicles and agricultural equipment (excluding personal vehicles)). Applications of the substance in the scope of authorisation are: - formulation of coatings and sealants and - industrial use of coatings in: • coil coating sector, • aerospace sector and • vehicle coating sector. - industrial use of sealants in: • aerospace sector In addition, it seems that strontium chromate can be used in artist paints; however, the quantities involved are expected to be very low. Occupational exposure cannot be excluded and its extent depends on the operational conditions and risk management measures in place. Information provided in the registrations and the Annex XV dossier	authorisation is high. The uses of the substance are considered to be widespread with a potential for significant worker exposure. On the basis of the criteria, the substance has high priority.	Annex XIV. There are other chromium (VI) compounds on the Candidate List, such as potassium hydroxy-octaoxodizincatedichromate and pentazinc chromate octahydroxide, which could be replaced by strontium chromate in (some of) their uses (and vice versa). **Therefore, it is proposed to recommend strontium chromate for inclusion in Annex XIV.**

[6] The exposure values provided in tables 7 – 19 of the Annex XV dossier for chromium trioxide are expressed in µg CrO_3/m^3 air (and not as µg $CrVI/m^3$ as erroneously stated in the dossier).

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			indicates that potential for exposure is given in uses or process steps such as: - raw material handling (during charging/mixing/dispersing of strontium chromate (as powder) in liquids), - mixing or blending for formulation of preparations, - application of coatings or sealants to the support (by dipping, brushing, roller application and manual spraying, which can generate aerosols) and - manual stripping of coatings/sealants with abrasive techniques (e.g. sanding during maintenance activities of aircrafts and vehicles). In the Annex XV dossier recent monitoring results regarding exposure to chromium (VI) via air at the workplace in different metal working sectors in France, among them the "metal treatment and surface finishing" sector, are reported. The data indicate that French workers in the metal treatment and surface finishing sector are exposed via the respiratory route to non-negligible concentrations of chromium (VI) compounds. Furthermore, recent exposure information reported in the Annex XV dossier for chromium trioxide prepared by Germany shows that also German		

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			workers are exposed to significant concentrations of chromium (VI)[6] in workplace air in sectors such as "formulation of metal treatment products" and "surface treatment". Based on this recent information on exposure of French and German workers to Cr(VI) resulting from uses and processes in which also strontium chromate is used, it can be assumed that other European workers are also likely to be exposed to non-negligible concentrations of Cr(VI) compounds, among them strontium chromate. As reported in the registrations, the formulation of strontium chromate containing coatings / sealants is carried out at a medium number (10 - 100) of sites. Coil coating takes place in large industrial installations at presumably < 100 sites. As regards the other uses, information is less clear. However, it seems that many industrial sites are involved in surface treatment activities (coating) supplying the aerospace sector. Indeed, the Annex XV dossier (2011) suggests a supply chain which horizontally involves a high number of small and medium size enterprises. Comments received during public consultation on the SVHC identification of the substance appear to confirm the information available on the supply chain structure in the aerospace industry (RCOM, 2011). Regarding		

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			vehicle coating, including repair/refurbishment of coating, it can be expected that the surface treatment itself is performed at a high number of sites in the EU (in larger industrial installations but also in small workshops).		
Strontium chromate *(SCA)*	Score: 1	High volume allocated to uses in the scope of authorisation. Score: 7	Uses of the substance in the scope of authorisation take place at a high number of industrial sites. Score: 3. Although exposure of workers might be controlled in most industrial applications there is potential for significant worker exposure, in particular during repair and refurbishing activities. Score: 3. Overall score: 9	Total score: 17	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Potassium hydroxyocta-oxodizincate-dichromate *(VAA)*	Art. 57 (a); Carcinogen 1A	According to information provided in the registration the amount of the substance used in the EU is in the range of 100 – 1,000 t/y. The entire amount is allocated to uses in the scope of authorisation.	Based on information provided in the Annex XV dossier, the substance is used as an anti-corrosion agent for the formulation of primers and it is further used in jointing compounds (sealants). As reported in the registration and the Annex XV dossier, applications of the substance in the scope of authorisation are: - formulation of coatings and sealants,	The volume of the substance supplied to uses in the scope of authorisation is relatively high. The uses of the substance are considered to be widespread with a potential for significant worker exposure. On the basis of the	On the basis of the prioritisation criteria potassium hydroxyocta-oxodizincatedichromate gets relatively high priority for inclusion in Annex XIV. Furthermore, there are other chromium (VI) compounds on the Candidate List, such as pentazinc chromate octahydroxide and strontium chromate, which could be

[7] The exposure values provided in tables 7 – 19 of the Annex XV dossier for chromium trioxide are expressed in µg CrO_3/m^3 air (and not as µg $CrVI/m^3$ as erroneously stated in the dossier).

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	

			- industrial use of sealants and
			- industrial use of coatings in:
			  - aerospace sector and
			  - vehicle sector.
			
			Applications in the vehicle sector include: fleet and commercial vehicles, heavy duty vehicles and trucks, military vehicles and agricultural equipment (excluding personal vehicles).
			
			Occupational exposure cannot be excluded and its extent depends on the operational conditions and risk management measures in place. Information provided in the registration and the Annex XV dossier indicates that potential for exposure is given in uses or process steps such as:
			- raw material handling (during charging/mixing/dispersing of potassium hydroxyoctaoxodizincatedichromate (as powder) in liquids),
			- application of coatings or sealants to the support (by dipping, brushing, roller application and manual spraying, which can generate aerosols) and
			- manual stripping of coatings/sealants with abrasive techniques (e.g. sanding during maintenance activities of aircrafts and vehicles).
				criteria, the substance has relatively high priority.	replaced by potassium hydroxy-octaoxodizincatedichromate in (some of) their uses (and vice versa).
					
					Therefore, it is proposed to recommend potassium hydroxyoctaoxodizincate-dichromate for inclusion in Annex XIV.

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			In the Annex XV dossier recent monitoring results regarding exposure to chromium (VI) via air at the workplace in different metal working sectors in France, among them the "metal treatment and surface finishing" sector, are reported. The data indicate that French workers in the metal treatment and surface finishing sector are exposed via the respiratory route to non-negligible concentrations of chromium (VI) compounds. Furthermore, recent exposure information reported in the Annex XV dossier for chromium trioxide prepared by Germany shows that also German workers are exposed to significant concentrations of chromium (VI)[7] in workplace air in sectors such as "formulation of metal treatment products" and "surface treatment". Based on this recent information on exposure of French and German workers to Cr(VI) resulting from uses and processes in which also potassium hydroxyoctaoxodizincatedichromate is used, it can be assumed that other European workers are also likely to be exposed to non-negligible concentrations of Cr(VI) compounds, among them potassium hydroxyocta-oxodizincatedichromate. The number of sites of use is not known except for the formulation stage for		

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			which an estimation of less than 10 formulators in the EU is provided in the Annex XV dossier and confirmed by registration information. For the other uses, there is no clear picture. However, there seems to be a high number of sites involved in surface treatment activities (coating) of aircraft parts, be it as supplier of articles to the aerospace sector or carrying out maintenance and repair of aircrafts. In the commercial vehicle and agricultural equipment sector it is expected that the same applies. In particular during repair and refurbishment of coatings of vehicles and agricultural equipment in workshops it may come to significant exposure of workers sanding or sand-blasting off old coatings.		
Potassium hydroxyocta-oxodizincate-dichromate *(SCA)*	Score: 1	Relatively high volume allocated to uses in the scope of authorisation. Score: 5	Uses of the substance in the scope of authorisation take place at a high number of industrial sites. Score: 3. Although exposure of workers might be controlled in most industrial applications, there is potential for significant exposure, in particular during repair and refurbishing activities. Score: 3. Overall score: 9	Total score: 15	**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	
Pentazinc chromate octahydroxide *(VAA)*	Art. 57 (a); Carcinogen 1A	The amount registered for use in the EU is in the range 100 – 1,000 t/y. The entire amount is allocated to uses in the scope of authorisation. Indeed, according to the Annex XV dossier, it is assumed that the total tonnage of the substance is used to formulate coatings.	As reported in the Annex XV dossier the substance is used in the aerospace sector as an anti-corrosion agent for the formulation of primers and jointing compounds (sealants). It is also used in anti-corrosion primers, in fillers and sealants for the construction and maintenance of vehicles. Applications of the substance in the scope of authorisation are (Registrations & Annex XV dossier): - formulation of coatings and - industrial use of coatings in: • aerospace sector and • vehicle sector Applications in the vehicle sector include: fleet and commercial vehicles, heavy duty vehicles and trucks, military vehicles and agricultural equipment (excluding personal vehicles). Occupational exposure cannot be excluded and its extent depends on the operational conditions and risk management measures in place. Information provided in the registration and the Annex XV dossier indicates that potential for exposure is given in uses or process steps such as - raw material handling (during charging/mixing/dispersing of	The volume of the substance supplied to uses in the scope of authorisation is relatively high. The uses of the substance are considered to be widespread with a potential for significant worker exposure. On the basis of the criteria, the substance has relatively high priority.	On the basis of the prioritisation criteria, pentazinc chromate octahydroxide gets relatively high priority for inclusion in Annex XIV. There are other chromium (VI) compounds on the Candidate List, such as strontium chromate and potassium hydroxyoctaoxodizincate-dichromate, which could be replaced by pentazinc chromate octahydroxide in (some of) their uses (and vice versa). **Therefore, it is proposed to recommend pentazinc chromate octahydroxide for inclusion in Annex XIV.**

[8] The exposure values provided in tables 7 – 19 of the Annex XV dossier for chromium trioxide are expressed in µg CrO_3/m^3 air (and not as µg $CrVI/m^3$ as erroneously stated in the dossier).

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			pentazinc chromate octahydroxide (as powder) in liquids), - application of coatings or sealants to the support (by dipping, brushing, roller application and manual spraying, which can generate aerosols) and - manual stripping of coatings/sealants with abrasive techniques (e.g. sanding during maintenance activities of aircrafts and vehicles). In the Annex XV dossier (2011) recent monitoring results regarding exposure to chromium (VI) via air at the workplace in different metal working sectors in France, among them the "metal treatment and surface finishing" sector, are reported. The data indicate that French workers in the metal treatment and surface finishing sector are exposed via the respiratory route to non-negligible concentrations of chromium (VI) compounds. Furthermore, recent exposure information reported in the Annex XV dossier for chromium trioxide prepared by Germany shows that also German workers are exposed to significant concentrations of chromium (VI)[8] in workplace air in sectors such as "formulation of metal treatment products" and "surface treatment".		

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			Based on this recent information on exposure of French and German workers to Cr(VI) resulting from uses and processes in which also pentazinc chromate octahydroxide is used it can be assumed that other European workers are also likely to be exposed to non-negligible concentrations of Cr(VI) compounds, among them pentazinc chromate octahydroxide. The number of sites of use is not known except for the formulation sector for which an estimation of less than 5 formulators in the EU is provided in the Annex XV dossier and confirmed by information given in the registrations. As regards the other uses, there is no clear picture. However, there seems to be a high number of sites involved in surface treatment activities (coating) of aircraft parts, be it as supplier of articles to the aerospace sector or carrying out maintenance and repair of aircrafts. In the commercial vehicle and agricultural equipment sector it is expected that repair and refurbishment of coatings of vehicles and agricultural equipment is carried out in very many workshops and that these activities may result in significant exposure of workers who are sanding or sand-blasting off old coatings.		
Pentazinc chromate octahydroxide	Score: 1	Relatively high volume allocated to uses in the scope of authorisation.	Uses of the substance in the scope of authorisation take place at a high number of industrial sites.	Total score: 15	**The same considerations apply as brought forward under the verbal-**

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
(SCA)		Score: 5	Score: 3. Although exposure of workers might be controlled in most industrial applications, there is potential for significant exposure, in particular during repair and refurbishing activities. Score: 3. Overall score: 9		**argumentative approach.**
Bis(2-meth-oxyethyl) ether (Diglyme) *(VAA)*	Art. 57(c); Toxic for Repr.1B	The amount manufactured and/or imported into the EU is according to registration data in the range of 100 – 1000 t/y. No information on exports is available. Practically the complete amount in the EU is used as solvent in applications in the scope of authorisation. Uses not in the scope of authorisation appear to be minor, such as laboratory uses for SRD, or in medicinal products exempted according to Art. 2(5a) of REACH).	According to registration information the substance is used at industrial sites as a "**solvent** or **process chemical** and **distribution of substance"**. The substance is used in a variety of applications (information from Registration complemented by information in the Annex XV dossier), including for example as solvent for many syntheses (of chemicals and pharmaceuticals), extraction, distillation, purification. It is also used in the production of plastic and potentially other materials (such as binding agents, rubber, fabricated metal materials, and – according to the public consultation - syntactic foam for filling composite materials); as well as in sealed batteries as solvent of electrolytes. During the public consultation, further uses of diglyme were mentioned, such as in PTFE etchant solutions, in rain	The substance is used in relatively high volume in the scope of authorisation. The number of use sites is unknown. Significant dermal or even inhalation exposure may occur in occupational activities during maintenance/ cleaning/sampling/transfer operations, in particular in less modern facilities. There is also uncertainty regarding potential exposure during some of the applications as solvent / process chemical, as the overall information on actual applications taking place in the EU is somewhat vague. On the basis of the criteria, Bis(2-methoxyethyl) ether has	On the basis of the prioritisation criteria bis(2-methoxyethyl) ether (Diglyme) gets moderate to relatively high priority for inclusion in Annex XIV. The substance is used in a relatively high volume and apparently many applications. It appears that some of the process steps taking place during the uses have a potential for significant occupational exposure and that this exposure is difficult to control, as risk characterisation ratios close to risk (even for the suggested operational conditions) indicate. **Therefore, it is proposed to recommend bis(2-methoxyethyl) ether (Diglyme) for inclusion in Annex XIV.**

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			erosion coatings (i.e. coatings used to protect e.g. aircrafts from raindrops hitting the surface at high speeds), in electronic coatings as specialty thinner, and in adhesives. It is so far not clear whether those uses take place also in the EU or only outside the EU, potentially resulting in the incorporation of diglyme in imported articles, such as aerospace and defence products. Further information on potential applications is available from reports in the literature, including the use in the manufacture of semiconductor chips, in mixtures such as paints (and maybe sealants, adhesives, automotive care products, lacquers, diesel fuels etc.), as well as for photolithography, etc. (Annex XV dossier). It is noted that the substance has been registered only for industrial uses, with uses in any consumer product (apart from sealed batteries) advised against. During the public consultation, industry claimed that uses of mixtures intended for consumers are rather historic, due to the current REACH restriction (entry 30). There is no conclusive information available about the allocation of the EU tonnage per use. Furthermore, no information on use sites in the EU is available. For most of its uses (see above) the	moderate to relatively high priority.	

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			substance is expected to be used in closed systems. The PROC categories in registration dossiers indicate closed processes, but also include processes where opportunity for exposure arises (PROC 4), as well as transfer processes (PROCs 8,9). No distinction is made between the various applications as solvent / process chemical, but rather a generic exposure scenario has been developed. The most significant potential for occupational exposure is probably associated with cleaning, maintenance, sampling, and transfer operations (mainly dermal – it is noted that diglyme penetrates many glove materials). Exposure via inhalation can also not be excluded, although the substance has low volatility, at least at ambient temperature (Diglyme's boiling point and stability allow also for reactions at high temperature, which would rather be assumed to occur in closed systems). Exposure during cleaning, maintenance, sampling, and transfer seems to be difficult to control as even with the suggested operational conditions the RCRs are close to indicate risk. Furthermore, as there is some uncertainty on the exact sectors and applications in which the substance is used as a solvent / process chemical,		

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			there may be other processes in non closed-loop applications with significant potential for exposure. Finally, to the extent uses of mixtures such as paints/coatings (professional or industrial) containing diglyme take place in the EU, workers could be exposed , for example during painting/coating operations. (However, such uses appear not to be covered by the registrations, based on the PROCs in registrations and the absence of identified professional uses). The substance is moderately persistent in the environment, while it significantly adsorbs to activated sludge. Monitoring data in river water, ground water, and outflow of STP indicate that the risk for man via the aquatic environment is probably low.		
Bis(2-meth-oxyethyl) ether (Diglyme) *(SCA)*	Score: 0	Relatively high volume in the scope of authorisation. Score: 5	Use at an unknown, but presumably at least medium number of sites. Score = 2-3. Exposure to workers may be controlled in many instances but may be significant for example during maintenance, cleaning, sampling, and transfer operations. Score = 3. Overall score = 6-9	Total score = 11-14	**The same considerations apply as brought forward under the verbal-argumentative approach**
N,N-	Art. 57(c);	The amount used in the EU is	According to information provided by	The substance is used in	On the basis of the prioritisation

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
Dimethylacetamide (DMAC) *(VAA)*	Toxic for Repr.1B	in the range of 11,000-19,000 t/y. Most of the amount in the EU seems to be used in applications in the scope of authorisation, except from uses such as intermediate in synthesis or uses in medicinal products (exempted according to Art. 2(5a) of REACH).	the registrants, the use in the EU is allocated as follows: * **65-70%** of tonnage: use as **solvent, and to some (unknown) extent as intermediate in the manufacture of agrochemicals, pharmaceuticals and fine chemicals**. * **20-25%**: **spinning solvent in the production of fibres** of various polymers including acrylic, polyurethane-polyurea copolymer and meta-aramid (mainly for clothing, but also for technical textiles, e.g. for reinforcement of composite plastic materials). ***3-5%**: as **solvent in coatings for industrial use** (e.g. in polyamide-imide (PAI) enamels used for electrical wire insulation); * **<2%**: a **solvent for production of films of polyimide** (for consumer electronics, solar photovoltaic and wind energy, aerospace, automotive and industrial applications) **and possibly other resins**. * **smaller amounts** in other uses such as **paint strippers** (mainly for use in industrial settings, but to some extent also for professional users)**, ink removers** (< 0.01t in eraser pens, to be ceased by mid 2012)**, petrochemical applications, sealants, laboratory use, putty, adhesives, and potentially in the production of cellulose fibres such as cellophane.**	very high quantities in the scope of authorisation. DMAC has widespread uses and at least some uses have a high likelihood for releases and exposure. On the basis of the criteria, DMAC is of high priority.	criteria, DMAC gets high priority for inclusion in Annex XIV. **Therefore, it is proposed to recommend DMAC for inclusion in Annex XIV.**

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			The substance is used in very many industrial sites, as well as at sites at which work by professionals is carried out (but uses by professionals appear predominantly to comprise mixtures below the SCL, mainly in paint strippers). Based on the available information, it appears that, in particular for uses in the scope of authorisation, a medium number of EU manufacturers and importers, and a very high number of downstream users are involved in the supply chain. Worker exposure (dermal and by inhalation) during the main industrial uses of DMAC is highly variable reflecting a wide range in the scale of processes and degree of enclosure and other risk management measures applied. The highest levels of exposure are likely to occur during mixing and blending of DMAC in batch formulation processes where workers may have multiple and/or significant contact with DMAC; or during not enclosed or partially enclosed operations during uses such as fibre spinning or applying coatings by spraying / roller / brushing / pouring / dipping. Industrial and in some cases professional workers might also be exposed to lower amounts of DMAC found as residues in fibres (up to 3%,		

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			mostly removed during further processing), or in polyimide films (<1%) or in coatings. After its use DMAC will ultimately end up in waste, in emissions to air, and as residue in products. The major releases to the environment may be associated with the production and use of fibres and secondarily with the release of residues from various products (mainly fibres). As DMAC is reported to be readily biodegradable the risk for exposure of man via the environment appears to be low.		
N,N-Dimethylacetamide (DMAC) *(SCA)*	Score: 0	Very high volume in the scope of authorisation. Score: 9	Uses in industrial settings at a very high number of sites. Score: 3. Significant occupational exposure may occur during formulation processes or non-enclosed or partially enclosed operations. Score: 3. Overall score: 9	Total score: 18	**The same considerations apply as brought forward under the verbal-argumentative approach.**
1,2-Dichloro-ethane (Ethylene dichloride - EDC) *(VAA)*	Art. 57(a); Carcinogen 1B	According to registration information, the total annual volume of EDC currently manufactured in the EU is in the range between 1,000,000 and 10,000,000 t/y, and	Information on solvent use of EDC in the registrations is very limited. According to the Annex XV dossier, releases resulting in occupational exposure in the order of magnitude of	The substance is used in high to very high volumes in the scope of authorisation and is used in a wide variety of applications with potential	On the basis of the prioritisation criteria, 1,2-Dichloroethane gets high priority for inclusion in Annex XIV. **Therefore, it is proposed to**

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
		between 10,000 and 50,000 t/y are imported. The substance is mainly used in the synthesis of vinyl chloride monomer (VCM). The use as an intermediate on site represents more than 95 %, use as an (transported) intermediate for VCM synthesis represents more than 4 % of the total amount of the substance. The substance is also used as an intermediate in fine chemical synthesis. Therefore, > 99% of the total tonnage appears to be used as intermediate in the synthesis of other substances. About 0.2 % of the total tonnage of EDC (Annex XV dossier) is used as a process solvent in the chemical and pharmaceutical industries. This use is in the scope of authorisation (apart from any use in medicinal products exempted according to Art. 2(5a) of REACH) and corresponds to a tonnage of 2,000 to 20,000 t/y. The volumes confirmed to be used as process solvent in the registration dossiers are	established OELs are reported from the manufacture of the substance. Moreover, an exposure survey covering the synthesis of VCM in 2006/7) indicated significant exposure. According to registration information, manufacture takes always place in closed systems at dedicated sites, where either no or only controlled exposure can occur. However, this can not always be assumed for the use of the substance as a solvent. The registration dossiers include some activities that take place at non-dedicated facilities (PROC 8a) where opportunity for exposure arises (PROC 4). Considering the already significant exposure from the closed systems in which manufacture of EDC takes place, significant exposure cannot be excluded from the apparently less closed systems in which uses of the substance appear to take place. Taking into account the relatively high volatility of the substance, it can be assumed that significant releases with a high potential for exposure of workers might occur. Information from the Annex XV dossier and the RCOM indicates that EDC is used as a solvent in several different applications, such as processing aid in fine chemicals manufacture, solvent in the preparation of different mixtures for biochemical applications (e.g. liquid media and cell cultures), in the	for significant exposure of workers. On the basis of the criteria the substance has high priority.	**prioritise 1,2-Dichloroethane for inclusion in Annex XIV.**

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
		in the range of 1000 -10,000 t/y, however there are further registrations reporting use as process solvent but do not indicate the volumes dedicated to this use. Therefore, the total volume in the scope of authorisation cannot be estimated with certainty. Only a lower limit can be estimated and is assumed to be in the range of 1,000 t/y to > 10,000 t/y.	production of rubber, or the formulation of degreasing solvents and adhesives. During data gathering for the Annex XV dossier several MS informed about imports of EDC to their countries, in small quantities by several distributors, not likely to be used for PVC manufacture. From this information it can be concluded that there are more than 10 distributors in the EU. Given the number of distributors and the variety of applications, it can be reasonably assumed that EDC is used as a solvent at a high number of sites.		
1,2-Dichloro-ethane (Ethylene dichloride - EDC) *(SCA)*	Score: 1	High to very high volume used in the scope of authorisation: Score: 7-9	Substance used at a high number of sites; Score = 3 Significant potential for worker exposure from uses as solvent. Score = 3 Overall score: 9	Total score: 17-19	**The same considerations apply as brought forward under the verbal-argumentative approach.**
2,2'-dichloro-4,4'-methyl-enedianiline (MOCA) *(VAA)*	Art. 57(a); Carcinogen 1B	According to the Annex XV dossier, MOCA is not manufactured in Europe. The import of the substance ranges between 1,000 – 10,000 t/y. Less than 100 t/y are exported. In conclusion, a high volume of MOCA (1,000 – 10,000 t/y) is considered to be used	The main use of MOCA in the scope of authorisation is as curing agent in the manufacture of polyurethane (Annex XV dossier). MOCA is used to provide specific properties, such as high abrasion resistance, heat, fuel and solvent resistance, high load-bearing and good mechanical and dynamic properties (Annex XV dossier) to articles (e.g. industrial rollers, wheels and mining equipment; see RCOM)	The substance is used in high quantities in the scope of authorisation. These uses are widespread and are likely to bear a significant potential for exposure of workers. On the basis of the criteria the substance has high	On the basis of the prioritisation criteria, 2,2'-dichloro-4,4'-methylenedianiline (MOCA) gets high priority for inclusion in Annex XIV. In addition, regulatory effectiveness considerations support the inclusion of MOCA in Annex XIV since it could be used

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
		in the scope of authorisation.	containing the substance. As transformation of MOCA takes place during the so called "in mould" phase where (part of an) article is produced (Annex XV dossier, RCOM), this use is an end use giving the article its desired properties and not manufacture of a new substance. A further minor use is as a monomer in the manufacture of a pre-polymer. This may be a use of MOCA as an intermediate, as the outcome is pre-polymer flakes without defined shape and further additives determine the properties of the final polymer. Based on information from industry (Annex XV dossier), the supply chain consists of importers, distributors and industrial users with a total of more than 200 use sites within the EU. Therefore it can be concluded that MOCA is used at a high number of sites. The registration information indicates several activities, particularly for the uses as curing agent in the manufacture of polyurethane, where significant exposure to the substance is likely (e.g. mixing or blending, or use in batch and other processes where opportunity of exposure arises). The major exposure route for MOCA is the dermal route. Some studies have monitored urinary levels of workers	priority.	as an alternative to MDA and technical MDA (and vice versa) in uses as curing agent. The substance MDA is already included in Annex XIV whereas technical MDA is on the Candidate List. **Therefore, it is proposed to prioritise 2,2'-dichloro-4,4'-methylenedianiline (MOCA) for inclusion in Annex XIV.**

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			using MOCA in the polyurethane sector or residues of MOCA at workplace surfaces. Those studies have shown that there is a potential for significant occupational exposure. Non-reacted MOCA may be present in the final articles (up to 4 % reported by literature cited in the Annex XV dossier), which could lead to exposure of recipients of articles, including consumers. However, there are technical means in place at industrial sites to minimise the content of free MOCA (<< 0.1 %, Annex XV dossier, RCOM). Professional uses have not been indicated in the registration dossiers, however the substance is available to professionals in bi-component resins (resins + hardener) that are known to be used in construction and arts applications (Annex XV dossier). The Annex XV dossier does not provide information on releases from these applications; however there is potential for significant exposure to MOCA during preparation of the final component mix by professional workers and due to release of non-reacted MOCA residues from the resin. In conclusion, significant releases of MOCA with high potential for worker exposure from a range of processes and applications may take place at a high		

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			number of sites.		
2,2'-dichloro-4,4'-methyl-enedianiline (MOCA) *(SCA)*	Score: 1	High volume used in the scope of authorisation. Score: 7	Use of the substance takes place at a high number of sites. Score: 3 Releases to be expected from a number of uses and processes with potential for significant exposure of workers. Score: 3. Overall Score: 9	Total score: 17	**The same considerations apply as brought forward under the verbal-argumentative approach.**
1-Methyl-2-pyrrolidone (NMP) *(VAA)*	Art. 57(c); Toxic for Repr.1B	According to information provided in the registrations NMP is used in the EU in very high volumes, between 10,000 – 50,000 t/y. All uses seem to fall in the scope of authorisation with the exception of the use in plant protection products and some uses in the pharmaceutical industry. Use in plant protection products and in the pharmaceutical industry may account for 30% of the volume used in the EU. Therefore, it can be concluded, that a very high volume (> 10,000 t/y), at	According to information provided in the Annex XV dossier (no use-specific information in the registrations) NMP is used in the following applications: - Coatings (20 %, e.g. in industrial and professional paints and lacquers), - Cleaners (20 %, e.g. industrial and professional cleaners, graffiti removers), - Electronics (20 %, e.g. in production of semiconductor devices, insulation of magnet wires and as photo-resistant stripper to remove resist from wafers and photo masks during semiconductor manufacturing) - Petrochemical processing (10 %, mainly as solvent in extractive distillation of hydrocarbons).	The substance is used in very high quantities in the scope of authorisation. The uses can be considered widespread and some uses have a high potential for releases and worker exposure. On the basis of the criteria the substance has high priority.	On the basis of the prioritisation criteria, 1-methyl-2-pyrrolidone gets high priority for inclusion in Annex XIV. However, a dossier in accordance with Annex XV REACH, proposing to impose restrictions on certain uses of 1-methyl-2-pyrrolidone is currently under preparation[9] (expected date of submission: 19/04/2013). Therefore, ECHA suggests to refrain from recommending the inclusion of NMP in Annex XIV now. This is because after the inclusion of the substance in Annex XIV it would not anymore be possible to impose new restrictions on NMP because of risks arising

[9] For further details on the restriction proposal, please consult: http://echa.europa.eu/web/guest/registry-of-current-restriction-proposal-intentions

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
		least 70 % of the total imported/manufactured volume, is used in the scope of authorisation.	- Agrochemicals (15 %, mainly as part of pesticide formulations - in the scope of the PPP Regulation) - Pharmaceutical industry (15 %, e.g. as aprotic solvent in extraction processes, or as penetration enhancer in pharmaceutical products) Further minor uses described in the registration dossiers are in functional fluids or in polymer processing. Additional uses have been described in the RCOM (2011), such as processing aid in the production of poly-aromatic polymers or meta-aramid fibres. Several uses of NMP, such as coating (e.g. construction and road paints, parquet lacquers), cleaners (e.g. paint or graffiti remover, cleaning solvent), functional fluids, polymer processing or petrochemical processing are registered for both, industrial and professional users. Information in the Annex XV dossier suggests that concentrations of NMP in paints are typically in the range of 1-10 %, while cleaning products can contain up to 25 % and therefore are above the specific concentration limit of 5 %. Some uses seem to take place mainly under controlled conditions in closed processes or systems, e.g. in the semiconductor industry. However,		from the SVHC properties for which it had been included in the authorisation list. **Therefore, it is proposed <u>not</u> to prioritise 1-Methyl-2-pyrrolidone for inclusion in Annex XIV now.**

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			exposure from those uses still could occur during transfer, cleaning and maintenance activities (Annex XV dossier, registration information). Moreover, as can be inferred from the respective information provided in the registrations, some of the industrial/professional processes in which NMP is used have a high potential for exposure, e.g. roller application or brushing, non-industrial spraying, dipping and pouring or hand-mixing with direct contact and only PPE available. Also other applications of NMP such as in coatings and paint strippers bear high potential for significant exposure of workers. The substance is easily absorbed by the skin (used as penetration enhancer in pharmaceuticals), therefore also this exposure route is likely. NMP is used at a very high number of industrial sites and by many industrial and professional workers. Even though some uses (e.g. in semiconductor industry) seem to take place under controlled conditions with no potential for significant exposure, this cannot be assumed for most other uses, which on the contrary appear to have a potential for significant exposure of workers (e.g. application of coatings and use of paint strippers).		

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			According to industry information provided in the Annex XV dossier, several hundreds of industrial companies and thousands of professional users are involved in the supply chains of coatings and cleaners.		
1-Methyl-2-pyrrolidone (NMP) *(SCA)*	Score: 0	Very high volume used in the scope of authorisation. Score: 9	Uses in industrial settings and by professionals at a high number of sites. Score: 3. No significant release potential expected to arise from some uses. However, other applications such as e.g. coatings and paint stripping bear high potential for significant exposure of workers. Score: 3. Overall score: 9	Total score: 18	**The same considerations apply as brought forward under the verbal-argumentative approach.**
4-(1,1,3,3-tetramethyl-butyl)phenol, (4-tert-octyl-phenol) *(VAA)*	Art. 57 (f); Equivalent level of concern having probable serious effects to the environment	Based on information from registration dossiers uses of 4-tert-octylphenol are: • As a monomer for polymer preparations • As an intermediate for manufacture of ethoxylates, which to some extent will be a component of products (e.g. paints) used by industry, professional users and consumers. • As an intermediate for production of ether	There is no information on uses of the substance in the scope of authorisation.	There is no information on uses of this substance in the scope of authorisation. On the basis of the criteria, the substance has very low priority.	On the basis of the prioritisation criteria 4-tert-octylphenol gets very low priority for inclusion in Annex XIV. **Therefore, it is proposed <u>not</u> to prioritise 4-(1,1,3,3-tetramethylbutyl)phenol (4-tert-octylphenol) for inclusion in Annex XIV.**

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
		sulphates. • As a monomer that is chemically reacted with formaldehyde and possibly other reactants to form 4-tert-OP based phenolic resins. These resins are used in the formulation of adhesives, coatings, printing inks etc. which are used by industry, professional users and consumers. The phenolic resins are also used as a tackifier for the manufacture of tyres and rubber products. Therefore all uses appear to be intermediate and therefore outside the scope of authorisation.			
4-(1,1,3,3-tetramethyl-butyl)phenol, (4-tert-octyl-phenol) *(SCA)*	Score: 0	All uses are intermediate and therefore outside the scope of authorisation. Score: 0	There is no information on uses of the substance in the scope of authorisation. Overall score wide-dispersiveness of uses: 0	Total score: 0	**The same considerations apply as brought forward under the verbal-argumentative approach.**
1,2-Benzenedicarboxylic acid, di-C6-8-branched	Art. 57(c); Toxic for Repr.1B	No registrations submitted for this substance.	There is no information on uses which would be in the scope of authorisation.	There is no information on uses which would be in the scope of authorisation. On the basis of the criteria, the substance has	On the basis of the prioritisation criteria 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich gets very low priority for inclusion in Annex

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
alkyl esters, C7-rich *(VAA)*				very low priority.	XIV. **Therefore, it is proposed <u>not</u> to prioritise 1,2-Benzene-dicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich for inclusion in Annex XIV.**
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich *(SCA)*	Score: 0	No volume registered. Score: 0	Overall score wide-dispersiveness of uses: 0	Total score: 0	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Bis(2-methoxyethyl) phthalate *(VAA)*	Art. 57(c); Toxic for Repr.1B	No registrations submitted for this substance.	There is no information on uses which would be in the scope of authorisation.	There is no information on uses which would be in the scope of authorisation. On the basis of the criteria, the substance has very low priority.	On the basis of the prioritisation criteria Bis(2-methoxyethyl) phthalate gets very low priority for inclusion in Annex XIV. **Therefore, it is proposed <u>not</u> to prioritise Bis(2-methoxyethyl) phthalate for inclusion in Annex XIV.**
Bis(2-methoxyethyl) phthalate *(SCA)*	Score: 0	No volume registered. Score: 0	Overall score wide-dispersiveness of uses: 0	Total score: 0	**The same considerations apply as brought forward under the verbal-argumentative approach.**
1,2-Benzenedicarboxylic acid,	Art. 57(c); Toxic for	No registrations submitted for this substance. No known manufacture or import.	There is no confirmed information on uses which would be in the scope of authorisation.	No registration for the substance has been submitted and there is no	On the basis of the prioritisation criteria, 1,2-Benzenedicarboxylic acid, di-C7-11-branched and

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
di-C7-11-branched and linear alkyl esters (DHNUP) *(VAA)*	Repr.1B	According to the Annex XV dossier there is one cable producer who reported the use of **100 - 700 t/y** (year not given but likely ~2010). This tonnage seems to come from stock bought in previous years by the cable producer (quantity of that stock not known) as all its suppliers (indicated as three EU based plasticiser producers) responded to consultation that they currently do not manufacture DHNUP. When enquired by ECHA from the dossier submitter, it was not possible to identify the source of the information regarding the existence of such cable producer nor the size of its stock of DHNUP. The assessment is therefore based on registration information.		confirmed information on uses which would be in the scope of authorisation. On the basis of the criteria DHNUP has very low priority.	linear alkyl esters (DHNUP) gets very low priority for inclusion in Annex XIV. **Therefore, it is proposed <u>not</u> to prioritise 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP) for inclusion in Annex XIV.**
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)	Score: 0	No volume registered. Score: 0	No confirmed information on uses which would be in the scope of authorisation. Overall score: 0	Total score: 0	**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	
(SCA)					
1,2,3-Trichloropro-pane *(VAA)*	Art. 57(a) and (c); Carcinogen 1B Toxic for Repr.1B	According to registration information the total EU tonnage (manufactured and used) is estimated to be 10,000 – 50,000 t/y. 90 % use as intermediate in production of chlorinated solvents and agricultural products. 5 % used as monomer in polymer production (polysulfides, hexafluoro-propylene for manufacture of sealing compounds. No TCP present.) 5% incinerated on site No use in articles or preparations. There is no evidence for direct use of 1,2,3-Trichloropropane as solvent as it was done in the past.	According to registration information the substance is used as intermediate for synthesis of other substances and as monomer. There is no information on uses in the scope of authorisation	Although total tonnage used in the EU is very high, there is no information on uses in the scope of authorisation. On the basis of the criteria 1,2,3-TCP has very low priority.	On the basis of the prioritisation criteria, 1,2,3-Trichloropropane gets very low priority for inclusion in Annex XIV. **Therefore, it is proposed <u>not</u> to prioritise 1,2,3-Trichloropropane for inclusion in Annex XIV.**
1,2,3-Trichloropro-pane *(SCA)*	Score: 1	No volume in the scope of authorisation. Score: 0	There is no information on uses in the scope of authorisation. Overall score: 0	Total score: 1	**The same considerations apply as brought forward under the verbal-argumentative approach.**

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
Phenolphthalein *(VAA)*	Art. 57(a); Carcinogen 1B	According to registration information a volume of 10 – 100 t/y is imported, however consultation with industry resulted in an imported tonnage of 1-10 t/y. As the consultation (2011) was carried out after the registrations were submitted (2010) and includes all registrants as well as further companies importing/ exporting phenolphthalein, the latter tonnage is considered relevant for prioritisation. There is currently no manufacture in the EU. Minor amounts are exported. Almost the complete tonnage is used in the formulation of mixtures which are used in the laboratory. Further uses are in formulation of pharmaceuticals and in specialist applications, e.g. disappearing inks and laboratory indicator paper, both of these in the kg/y range. The volume used in applications in the scope of authorisation (formulation of	Consultation suggests that formulations are prepared by < 10 companies. The substance in powdered form is mixed with alcohol and water. Laboratory scale batches (1-10 l) are made by professionals handling small amounts of phenolphthalein at a time (<250 g). The mixtures are made in batch operation (less than once a month) and distributed to a large number of customers (> 1000). The handling of powders (and solutions) presents potential for occupational exposure. Given the small amounts of substance used and the low frequency of use the workplace exposure levels during formulation are likely to be low. The quantity of mixture (typical concentration between 0.5 and 2 %) used on each occasion is extremely small (<0.5 ml). In conclusion, it is assumed that occupational exposure during use of phenolphthalein is controlled and there is no significant risk of exposure of man via the environment.	Low volume in the scope of authorisation and insignificant releases. On the basis of the criteria phenolphthalein has very low priority.	On the basis of the prioritisation criteria, phenolphthalein gets very low priority for inclusion in Annex XIV. **Therefore, it is proposed <u>not</u> to prioritise phenolphthalein for inclusion in Annex XIV.**

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
		mixtures) is 1-10 t/y.			
Phenolphthalein *(SCA)*	Score: 1	Low volume in scope of authorisation Score: 1	Small number of formulation sites. (Laboratory use sites are assumed to fall under scientific research and development and thus not in the scope of authorisation) Score: 1 Release of substance likely to be controlled. Score: 1 Overall score: 1	Total score: 3	**The same considerations apply as brought forward under the verbal-argumentative approach.**
2-Methoxy-aniline; o-Anisidine *(VAA)*	Art. 57(a); Carcinogen 1B	According to the Annex XV dossier, the total volume manufactured/imported is between 1,000 and 10,000 t/y. However, on the basis of the registrations it is not possible to confirm the quantity because not in all registrations indicate the tonnage covered. Only uses as intermediate are registered, mainly for the manufacture of fine chemicals, such as azo dyes and pigments (registration information and Annex XV dossier). Therefore, no volume in the	There is no information on uses of this substance in the scope of authorisation.	There is no information on uses of this substance in the scope of authorisation. On the basis of the criteria, the substance has very low priority.	On the basis of the prioritisation criteria 2-Methoxyaniline gets very low priority for inclusion in Annex XIV. **Therefore, it is proposed <u>not</u> to prioritise 2-Methoxyaniline for inclusion in Annex XIV.**

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
		scope of authorisation.			
2-Methoxyaniline; o-Anisidine *(SCA)*	Score: 1	No volume in the scope of authorisation. Score: 0	Overall score wide dispersiveness of uses: 0	Total score: 1	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Hydrazine *(VAA)*	Art. 57(a); Carcinogen 1B	According to the registration information the total volume used in the EU is in the range of 10,000 – 50,000 t/y. A tonnage in the range of 1,000-10,000 t/y is allocated to uses in the scope of authorisation.	Hydrazine is used as hydrazine hydrate (HH) and anhydrous hydrazine (AH). According to the information from registration dossiers, most of the hydrazine supplied to the EU market is used as intermediate for synthesis and as a monomer (e.g. pharmaceuticals, agrochemicals, chemical blowing agents, coatings). These uses are outside the scope of authorisation. The main non-intermediate use of hydrazine hydrate (HH) is as a corrosion inhibitor. Hydrazine hydrate is used in the treatment of water in nuclear and fossil fired power plants. It is used to scavenge oxygen from water used in boiler feeds, which keeps corrosion low. This use is expected to take place at a high number of sites. Hydrazine hydrate is also used as a reducing agent in the recovery of precious metals and in the production of basic metals (industrial closed system). A further use is as a reducing agent in the refining of chemicals. However these uses account for lower tonnages	The volume of hydrazine supplied to uses in the scope of authorisation is high. The use of hydrazine in corrosion inhibition is considered to be widespread. However, potential for worker exposure and release to the environment appear to be low and controlled across all uses. On the basis of the criteria, hydrazine has moderate priority.	On the basis of the prioritisation criteria hydrazine gets moderate priority for inclusion in Annex XIV. **Therefore, it is proposed <u>not</u> to prioritise hydrazine for inclusion in Annex XIV.**

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			in comparison to the main use therefore the number of sites where these uses take place is expected to be much lower than for the main non-intermediate use as a corrosion inhibitor. The Annex XV dossier also mentions the possible use of hydrazine hydrate in electroplating and electroless plating, however it seems that such techniques are only driven by research rather than by application, and commercial uses of such techniques are likely to be limited (Annex XV dossier). There are no registrations covering this use. Therefore, this use is not further considered for prioritisation. The main non-intermediate use of anhydrous hydrazine (AH) is as propellant in aerospace industry and areas of defence. In the context of the aerospace industry, the Annex XV dossier indicates that hydrazine is the fuel used as a monopropellant when decomposed by a suitable solid catalyst. It can also be used as a bipropellant when injected simultaneously with an oxidiser. In the context of defence, hydrazine fuel is used to allow aircraft to maintain electrical and hydraulic power during periods of engine shutdown. The tonnage dedicated to this specialised use is relatively low (1-10 t/y AH) and release and exposure to workers is expected to be low.		

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			Regarding workers and the use of hydrazine hydrate in water treatment, exposure may occur during pumping and tank transfer associated with the preparation and dosing of the hydrazine hydrate. However, dilute solutions of hydrazine hydrate are used in closed systems and therefore exposure potential and possible exposure levels seem to be low. During the use of hydrazine hydrate solutions in the production of basic metals e.g. in the removal of selenium from process effluents, the hydrazine hydrate solutions are stored in small plastic vessels in a dedicated room. The solution is fed into the process by pump directly from the storage vessel to the reactor tank. The vessel and pump are located in a separate ventilated room. From this, it is expected that the worker exposure to hydrazine in the production of precious metals and basic metals is low.		
Hydrazine *(SCA)*	Score = 1	High volume in the scope of authorisation. Score = 7	Substance used at a high number of sites. Score = 3 Releases appear to be controlled and potential for exposure of workers low. Score = 1 Overall score = 3	Total score = 11	**The same considerations apply as brought forward under the verbal-argumentative approach.**

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
Lead diazide, Lead azide *(VAA)*	Art. 57(c); Toxic for Repr. 1A	According to the registration information the total volume used in the EU is in the range of 10-100 t/y. All of this tonnage is allocated to uses in the scope of authorisation.	According to the information from registration dossiers, most of the lead diazide supplied to the EU market is used as a primary explosive in detonators used for both civilian and military uses. Other uses (pyrotechnic devices used in military munitions (fuzes) and space shuttles/satellites) account for very small tonnages. The Annex XV dossier indicates that lead diazide is either used on its own or added to mixtures (primers) and subsequently used to fabricate detonators at the same sites where lead diazide is manufactured (small number of sites). The use of detonators containing lead diazide is then likely to happen at a high number of different sites. Regarding the use of lead diazide in the manufacture of explosives, workplace hygiene is (required to be) very high, therefore worker exposure is likely to be limited. Risk management measures (e.g. barricaded rooms and/or automated systems) are in place to reduce exposure to workers. There is potential for exposure during equipment maintenance and cleaning operations, however these are carried out under 'wet conditions' and the amount of lead diazide handled is low, therefore the potential for exposure is likely to be controlled. The same operational conditions and RMMs are applied during	The volume of lead diazide supplied to uses in the scope of authorisation is relatively low. The use of lead diazide in detonators is considered to be widespread. Worker exposure to lead diazide during manufacture of detonators appears to be controlled due to the necessary safety measures for handling this explosive substance. Furthermore, exposure of humans and the environment (per site) to lead compounds during use of detonators seems normally also to be low. Lead diazide decomposes when it explodes, leading to release of lead and other lead compounds (e.g. lead oxide) into the environment. This contributes to the overall environmental release and human exposure to lead (compounds) which needs to be considered in the light of the EU objective to reduce all releases of lead. However, the contribution from using lead primary	On the basis of the prioritisation criteria lead diazide gets low priority for inclusion in Annex XIV. It is noted that lead diazide is included in the Candidate List due to its toxicity to reproduction (and not due to the concern related to its decomposition products lead and lead compounds to the environment). The environmental release caused by the use of lead diazide should be considered in the context of an overall reduction strategy covering releases resulting from intentional use of lead and its compounds. **Therefore, it is proposed <u>not</u> to prioritise lead diazide for inclusion in Annex XIV now.** Due to its properties as primary explosive it might be possible to use lead diazide as a replacement for other primary explosives classified as toxic for reproduction such as lead styphnate and lead dipicrate. Therefore grouping of these substances should be considered when a decision is taken to recommend any of them for

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			production of detonators, which is performed at the same site. Exposure to and release of lead diazide itself during the use of detonators is considered to be insignificant, as the substance is enclosed in the detonator and lead diazide decomposes when it explodes. The end use of detonators can therefore lead to release of combustion products (lead oxides, nitrogen oxides and nitrogen), however per unit (e.g. detonator) emission of lead will be very small, at the milligram level. Workers working in firing ranges, quarries, construction and demolition and military personnel may be exposed to these combustion products during the use of detonators containing lead diazide. During the public consultation it was communicated that lead and nitrogen oxides are produced in infinitesimal amount due to the fact that the quantity of lead is lower than a gram by blast hole. These few grams of oxides are emitted to air and disseminated within the tons of blasted rocks.	explosives (lead diazide, lead styphnate and potentially lead picrate) appears to be low compared to the total lead releases resulting from the uses of lead compounds in the EU. On the basis of the criteria, lead diazide has low priority.	inclusion in Annex XIV.
Lead diazide, Lead azide *(SCA)*	Score = 0	Relatively low volume in the scope of authorisation. Score = 3	Substance used in the manufacture of detonators at a small number of sites. Detonators containing lead diazide are used at a high number of sites. Score = 3 Exposure of lead diazide to workers appears to be controlled and release to	Score = 6	**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	
			the environment of lead containing decomposition products insignificant. Score = 1 Overall score = 3		
Lead styphnate *(VAA)*	Art. 57(c); Toxic for Repr.1A	According to the registration information the total volume used in the EU is in the range of 10-100 t/y. All of this tonnage is allocated to uses with in the scope of authorisation.	According to the information from registration dossiers, most of the lead styphnate supplied to the EU market is used as a primary explosive in firearm ammunition (with sport/hunting ammunition representing the significant majority. Other uses (military/security ammunition, detonators for civilian use, powder actuated cartridges, automotive pyrotechnics, detonators for munitions) account for smaller tonnages. The Annex XV dossier reports that the majority of companies known to manufacture lead styphnate use the substance in-house in the preparation of primers for ammunition (small number of sites). There are also EU-based companies which purchase primer caps that already contain lead styphnate and use these in manufacturing of the final ammunition cartridges, from EU manufactures of primer caps. The use of ammunition containing lead styphnate happens at a high number of different sites. Regarding the use of lead styphnate in the manufacture of primers for ammunition, the required workplace	The volume of lead styphnate supplied to uses in the scope of authorisation is relatively low. The use of lead styphnate in ammunition is considered to be widespread. Worker exposure to lead styphnate during manufacture of primers appears to be controlled due to the necessary safety measures for handling this explosive substance. Furthermore, exposure of humans and the environment (per site) to lead compounds during use of the ammunition seems also to be low. Lead styphnate decomposes when it explodes, leading to release of lead and other lead compounds (e.g. lead oxide) into the environment. This	On the basis of the prioritisation criteria lead styphnate gets low priority for inclusion in Annex XIV. It is noted that lead styphnate is included in the Candidate List due to its toxicity to reproduction (and not due to the concern related to its decomposition products lead and lead compounds to the environment). The environmental release caused by the use of lead styphnate should be considered in the context of an overall reduction strategy covering releases resulting from intentional use of lead and its compounds. **Therefore, it is proposed <u>not</u> to prioritise lead styphnate for inclusion in Annex XIV now.** Due to its properties as primary explosive it might be possible to use lead styphnate as a

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			hygiene for safe handling of this explosive is very high and therefore worker exposure is likely to be limited. Risk management measures are in place to minimise exposure. The substance is primarily used in 'wet' form. Automated procedures are used where possible (for activities such as filtering, washing, drying, weighing, mixing, sieving and pressing) and workers are omitted from several of the fabrication steps as these are undertaken in closed reinforced spaces. Therefore the potential for worker exposure is likely to be low. Exposure to and release of lead styphnate itself, during the use of ammunition is considered insignificant, as the substance is enclosed in the ammunition. However lead styphnate decomposes when it explodes. The end use of ammunition can therefore lead to release of lead containing combustion products (e.g. lead monoxide, lead carbonate) of lead styphnate to the environment. However, per unit emission of lead will be very small, at the milligram level. Workers working in firing ranges and civilians or military personnel practising there may be exposed to these lead containing combustion products.	contributes to the overall environmental release and human exposure to lead (compounds) which needs to be considered in the light of the EU objective to reduce all releases of lead. However, the contribution from using lead primary explosives (lead diazide, lead styphnate and potentially lead picrate) appears to be low compared to the total lead releases resulting from the uses of lead compounds in the EU. On the basis of the criteria, lead styphnate has low priority.	replacement for other primary explosives such as lead diazide and lead dipicrate. Therefore grouping of these substances should be considered when a decision is taken to recommend any of them for inclusion in Annex XIV.
Lead styphnate *(SCA)*	Score = 0	Relatively low volume in the scope of authorisation. Score = 3	Substance used in manufacture of ammunition at a small number of sites. Ammunition containing lead styphnate	Total Score = 6	**The same considerations apply as brought forward under the verbal-**

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			is used at a high number of sites. Score = 3 Exposure of lead styphnate to workers appears to be controlled and release to the environment of lead containing decomposition products insignificant. Score = 1 Overall score = 3		**argumentative approach.**
Lead dipicrate *(VAA)*	Art. 57(c); Toxic for Repr.1A	No registrations submitted for this substance. According to the Annex XV dossier small amounts of the substance (below registration threshold of 1 t/y) are manufactured in the EU and allocated to uses in the scope of authorisation.	It appears that the substance is used in small amounts in uses the scope of authorisation. Lead dipicrate has explosive properties, similar to that of lead diazide and lead styphnate. During the public consultation various parties indicated that the substance is used as a primary explosive in the EU in small quantities. As the explosive properties of lead dipicrate are similar to that of lead diazide and lead styphnate and because the uses as primary explosive appear to be similar as well, it can be concluded with reasonable certainty that the potential for exposure of workers and for releases of the substance/its combustion products to the environment are in principle the same (albeit the amounts released are smaller due to the lower volume used).	The volume of lead dipicrate supplied to uses in the scope of authorisation is very low. Worker exposure to lead dipicrate during production of primers and pyrotechnic devices can be considered controlled due to the necessary safety measures for handling this explosive substance. Furthermore, exposure of humans and the environment (per site) to lead compounds during use of the products seems also to be low. Lead dipicrate decomposes when it explodes, leading to release of lead and other lead compounds (e.g. lead	On the basis of the prioritisation criteria lead dipicrate gets very low priority for inclusion in Annex XIV. It is noted that lead dipicrate is included in the Candidate List due to its toxicity to reproduction (and not due to the concern related to its decomposition products lead and lead compounds to the environment). The environmental release caused by the use of lead dipicrate should be considered in the context of an overall reduction strategy covering releases resulting from intentional use of lead and its compounds. **Therefore, it is proposed <u>not</u> to prioritise lead dipicrate for inclusion in Annex XIV now.**

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
				oxide) into the environment. This contributes to the overall environmental release and human exposure to lead (compounds) which needs to be considered in the light of the EU objective to reduce all releases of lead. However, the contribution from using lead primary explosives (lead diazide, lead styphnate and potentially lead picrate) appears to be low compared to the total lead releases resulting from the uses of lead compounds in the EU. On the basis of the criteria, lead dipicrate has very low priority.	Due to its properties as primary explosive it might be possible to use lead dipicrate as a replacement for other primary explosives such as lead diazide and lead styphnate. Therefore grouping of these substances should be considered when a decision is taken to recommend any of them for inclusion in Annex XIV.
Lead dipicrate *(SCA)*	Score = 0	Substance not registered. However, low volume appears to be allocated to uses in the scope of authorisation. Score = 1	Substance used in the production of specialty pyrotechnic devices and primers at a low number of sites. Number of sites at which the devices and primers are used not known but potentially high number. Score = 1 - 3 Exposure of lead dipicrate to workers presumably controlled and release to the environment of lead containing decomposition products insignificant. Score = 1	Total score = 2 - 4	**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	
			Overall score = 1 - 3		
Calcium arsenate *(VAA)*	Art. 57(a); Carcinogen 1A	According to registration information, the tonnage of calcium arsenate manufactured and imported is in range of 100 – 1,000 t/y, registered as transported isolated intermediate. The two uses mentioned in the Annex XV dossier, i.e. • Use as precipitating agent in copper smelting (Use #1) and • Use for manufacturing of diarsenic trioxide (As_2O_3) (Use #2), are parts of the same integrated metallurgical cycle. Currently the information on the processes and the function of the substance is too limited to be able to draw firm conclusions on the intermediate or non-intermediate nature of the uses of the substance. The relevant volume possibly	There is no information available on how many of the copper smelters in the EU use calcium arsenate as precipitating agent (Use #1). There are a number of registrations for copper. As_2O_3 (Use #2) is manufactured in metallurgical processes. The number of smelters in the EU at which the respective processes take place is unknown. The VRAR on lead and lead compounds from 2008 lists 32 production plants in the EU with a lead production of >1000 t/y (in 2002). Even when considering the high uncertainties, the substance is probably used at a medium number (>10 - <100) of sites. No data on environmental emissions or occupational exposure are available. Measured arsenic at smelters cannot be attributed to calcium arsenate alone. Calcium arsenate is not used by professionals or in any consumer products. Registration information regarding the use of calcium arsenate gives conflicting process descriptors for the same use (PROC 3 "closed batch process", PROC 4 "opportunity of exposure arises" and PROC 22 "potentially closed processing operations with mineral/metals at	Relatively high volume in the scope of authorisation. No consumer exposure expected. There is no indication of significant exposure that could be related to calcium arsenate. On the basis of the criteria calcium arsenate has low priority.	On the basis of the prioritisation criteria and the limited information currently available, calcium arsenate gets a low priority for inclusion in Annex XIV. More information on the processes in which the substance is used and its specific function in these is needed to allow assessment on whether the uses fall in the scope of authorisation. More information is also required to assess whether further regulatory effectiveness considerations, such as suitability of calcium arsenate to replace other arsenic compounds, need to be taken into account before reaching a final conclusion on the priority of calcium arsenate. **Therefore, it is proposed <u>not</u> to prioritise calcium arsenate for inclusion in Annex XIV now.**

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
		in the scope of authorisation is assumed to be in the range of 100 – 1000 t/y.	elevated temperature") thereby not allowing a conclusion regarding potential for releases during use. It is not possible to draw conclusions on the potential exposure of workers due to the presence of the calcium arsenate in the raw materials and its circulation in the metallurgical process. However, taking all available information into account, there is no indication of significant exposure that could be related to calcium arsenate.		
Calcium arsenate *(SCA)*	Score: 1	Based on the current information the volume in the scope of authorisation is between none and relatively high Score: 0-5	Use at a medium number of sites. Score: 2 No indication of significant exposure in the metallurgical sector that could be specifically related to calcium arsenate. Score: 1 Overall score: 2	Total score: 3-8	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Trilead diarsenate (TLDA) *(VAA)*	Art. 57(a) and (c); Carcinogen 1A Toxic for Repr. 1A	The manufactured and imported tonnage in the EU (registered as transported isolated intermediate) is in the range of 10 -100 t/y. According to the Annex XV, TLDA is present in complex raw materials, i.e. by-	Currently it is assumed that there are no uses in the scope of authorisation.	There is no information on uses in the scope of authorisation. On the basis of the criteria trilead diarsenate has a very low priority.	On the basis of the prioritisation criteria, trilead diarsenate gets very low priority for inclusion in Annex XIV. Further information on the process is needed to assess the function of trilead diarsenate in the metallurgical process which

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
		products from smelting and refining of non-ferrous metals. These raw materials are partly imported and are used in refining of copper, lead and a range of precious metals. There is not enough information on the process available to conclude on the use of TLDA. For the time being it is considered that there is no volume in the scope of authorisation. However, more information is sought after to clarify the exact function of TLDA in the process which might lead to a re-assessment of the volume considered in the scope of authorisation.			might lead to a re-assessment of the current conclusion. **Therefore, it is proposed <u>not</u> to prioritise trilead diarsenate for inclusion in Annex XIV.**
Trilead diarsenate *(SCA)*	Score: 1	No volume in the scope of authorisation. Scope: 0	Overall score: 0	Total score: 1	**The same considerations apply as brought forward under the verbal-argumentative approach.**
2-Ethoxyethyl acetate *(VAA)*	Art. 57(c); Toxic for Repr.1B	No registrations submitted.	There is no information on uses which would be in the scope of authorisation.	There is no information on uses which would be in the scope of authorisation. On the basis of the criteria, the substance has very low priority.	On the basis of the prioritisation criteria 2-Ethoxyethyl acetate gets very low priority for inclusion in Annex XIV. **Therefore, it is proposed <u>not</u> to prioritise 2-Ethoxyethyl acetate for inclusion in Annex XIV.**

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
2-Ethoxyethyl acetate *(SCA)*	Score: 0	No volume registered. Score: 0	Overall score wide-dispersiveness of uses: 0	Total score: 0	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Below this line: Substances included in the Candidate List before 2011, which had already been assessed during previous prioritisation exercises, but had not been recommended for inclusion into Annex XIV.					
Disodium tetraborate *(VAA)*	Art. 57 (c) Toxic for reproduction 1B	The registered volume is in the range of 100,000 to 500,000 t/y. According to EBA (in the Annex XV dossier, 2010), the total use in the EU in 2008 was 266,000t (anhydrous equivalent), which was almost exclusively imported. Although a firm estimate on the amount of the substance allocated to uses in the scope of authorisation cannot be given on the basis of the information available, it still can be concluded that this volume is >10000 t/y. Uses in the scope of authorisation mainly include formulation of mixtures (in most mixtures in concentrations below the specific concentration limit	About 20% of the registered tonnage of disodium tetraborate is used (apparently as intermediate) in the manufacture of sodium metaborate and sodium perborate. However, the formulation of these other borate compounds into detergents seems to decrease and be phased out in Western Europe (EBA, in the Annex XV dossier, 2010). As regards the sectors off glass / glass fibres (~55% of tonnage) and ceramic (frits, , glazes, enamels; ~15%), there is for some of the uses uncertainty as to whether they are uses as intermediate or not, i.e. whether the nature of these uses meets the definition in Article 3(15). Uses of disodium tetraborate include (according to information from the Registrations, the European Borates Association (EBA) and the RCOM 2010):	Disodium tetraborate is used in very high volumes for several uses in the scope of authorisation and at very many sites. In conclusion, the uses of the substance can be considered wide dispersive. Based on the criteria, the substance has high priority.	When assessed against the general prioritisation criteria it is noted that a very high tonnage is dedicated to uses in the scope of authorisation and that many of these (end) uses must be considered as wide dispersive. This is the case even if the uncertainties on whether certain uses would actually benefit of the generic exemptions from the authorisation requirement are taken into account. Hence, disodium tetraborate and boric acid fulfil these general criteria for prioritisation. If further grouping considerations are taken into account - to avoid potential replacement of the mentioned boron compounds with another one having a similar hazard potential - this conclusion can as well be drawn for tetraboron disodium heptaoxide, hydrate.

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
		for classification; SCL), repackaging, incorporation into some articles (mainly as flame retardants), uses in metallurgy and other applications.	*(Tonnage information provided by EBA, relating to 2008 and expressed here as anhydrous tonnage equivalent. References: Annex XV dossier, 2010; personal communication with EBA)* - production of insulation and textile **glass fibres** (~100,000 t) - production of **glass** (~45,000 t) - manufacture of **perborate** (~47,000 t) - manufacture of **ceramics** (glazes, enamels, frits) (~40,000 t) - use in **adhesives** (~5,000 t) - as **flame retardant** (for cellulose insulation material, mattresses (phasing out), wood or paper products, ~5,000 t) - in **fertilisers** (~11,000 t), - in **industrial fluids** (lubricants, antifreeze agents, metal working fluid, etc., ~ 2,500 t), - in **buffering / chemical reagents** (~5,000 t), - in **metallurgy** (steel & non-ferrous metal production, metal surface refining, ~2,000 t;.an additional volume of 2,000 t is used in steel slag stabilisation,) - in liquid / laundry **detergents** (as stabiliser, ~850t) - in **refractories** (~100 t) and **other applications (**up to 1,400 t, including production of paints and inks, production of construction materials such as plasterboards and wood-based boards, as well in abrasives, cement,		From the grouping perspective, it should further be noted that there are some additional boron compounds which are classified as toxic for reproduction (cat 1B) which are not on the Candidate List. The boron compounds currently on the Candidate List are listed in Annex VI to Regulation EC No. 1272/2008 (CLP Regulation) as Repr. 1B with specific concentration limits (SCLs) of more than one order of magnitude above the generic limit of 0.3% (i.e. SCLs are in the range of 4.5% - 8.5% weight by weight). Also SCLs of those boron compounds that as yet have not been identified as SVHCs and placed on the Candidate List but for which uses have been registered are at the same range (i.e. Diboron trioxide, EC 215-540-4; Perboric acid, sodium salt, tetrahydrate, EC 234-390-0). Pursuant to Article 56(6)(b) the authorisation requirement does not apply to the use of substances in mixtures below the concentration limits specified in Annex VI. This new classification in Annex VI took effect on 1 December 2010. Currently the Commission is proposing a restriction for

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			leather tanning, photographic chemicals, photolithography, fireworks, igniters, plasticisers, manufacture of B_2O_3 containing catalysts, in medical devices, in biocides, analytical reagents, pharmaceuticals, etc; Annex XV dossier, 2010, RCOM 2010**)**. The substance seems to be used in mixtures (mainly below the specifc concentration limit for classification) at a high number of sites in each of the following industrial sectors: Metallurgy (also by professionals), production of industrial liquids, adhesives (also DU and professionals), agriculture (also by professionals), reagent chemicals (also by professionals), other uses as mentioned above (also by professionals). At least at a medium number of sites the substance is use as flame retardant in the formulation of cellulose insulation material and the production of mattresses and similar furniture articles and probably in the formulation of detergents. As regards workers, there is evidence from the Transitional Dossier (Austria 2008) that a presumably very high number of industrial workers and professionals may be exposed while using the substance. The most relevant exposure routes identified are inhalation and dermal uptake due to activities		consumer use as such and in mixtures above the specific concentration limit. The authorisation requirement would not result in further reduction of the availability of boron compounds on their own or in mixtures to the consumers as the same specific concentration limit on substances in mixtures is used for restriction and authorisation. Furthermore, the registrants have to ensure that their registration dossiers, including the CSA with the appropriate ES/RMMs, follow the classification and labelling of the substance. From the available information it can be concluded that boron compounds are, apart from uses in the synthesis of other substances or in manufacture of glass and ceramics, mainly used for the formulation of mixtures. High share of the mixtures for industrial and professional uses currently formulated appear to contain boron compounds below the SCLs. There appear to be some cases where mixtures for the industrial/professional market are supplied as concentrates and require dilution by the industrial /professional users to render them ready for use. From this follows that if the

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			such as sweeping, discharging, loading/unloading and packing. These activities are relevant across most of the sectors mentioned above. The borate concentration in mixtures for supply to consumers will be limited to the specific concentration limits for classification applicable for boron compounds by a restriction, which presumably will enter into force in autumn 2011.		boron compounds on the Candidate List were included in the Authorisation List (Annex XIV), the authorisation requirement would mainly apply for the formulation of mixtures but not to the actual uses of these mixtures. **Therefore, it is proposed to not prioritise the boron compounds on the Candidate List now for inclusion in Annex XIV but to first wait for the impacts of the new restriction on consumer uses and of the registrations in accordance with the classification of the substances as "Repr. 1B" on use patterns and resulting worker exposure.**
Disodium tetraborate *(SCA)*	Score: 0	Very high volume used in the scope of authorisation. Score: 9	Uses in industrial settings and by professionals at a high number of sites (widespread use). Score: 3. Releases may be controlled for most uses, but potentially significant exposure of workers in industrial settings and of professionals cannot be excluded (dispersive use). Score: 3. Overall score: 9	Total score: 18	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Tetraboron disodium heptaoxide,	Art. 57 (c) Toxic for reproduction	No registrations submitted for this substance.	No registration, it can be concluded that the substance is not used in significant amounts in the EU.	No registration for the substance submitted. Therefore very low	No registration for the substance has been submitted. Therefore, based on the prioritisation

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
hydrate *(VAA)*	1B		In principle the substance could be used for the same applications than disodium tetraborate (overlapping in substance identity).	priority.	criteria, the substance gets very low priority for inclusion in Annex XIV**.** However, as the substance could be used to replace the other boron compounds on the Candidate List, tetraboron disodium heptaoxide, hydrate should be grouped with these substances. ***For the overall conclusions on the priority of the boron compounds for inclusion in Annex XIV please refer to Disodium tetraborate.***
Tetraboron disodium heptaoxide, hydrate *(SCA)*	Score: 0	No registration: Score: 0	No registration: Score: 0	Total score: 0	**The same considerations apply as brought under the verbal-argumentative approach.**
Boric acid *(VAA)*	Art. 57 (c) Toxic for reproduction 1B	The registered volume is in the range of 100,000 – 500,000 t/y. According to EBA (personal communication), the total use in the EU in 2008 was 192,000t. Several thousand tonnes of boric acid are used in the manufacture of other boron substances or for uses exempted from authorisation,	As regards the sectors off glass / glass fibres (~55% of tonnage) and ceramic (frits, , glazes, enamels; ~15%), there is for some of the uses uncertainty as to whether they are uses as intermediate or not, i.e. whether the nature of these uses meets the definition in Article 3(15). Uses of boric acid (according to information from the Registrations, the European Borates Association (EBA) and the RCOM 2010):	Boric acid is used in very high volumes for several uses in the scope of authorisation and at very many sites. In conclusion, the uses of the substance can be considered wide dispersive. Based on the criteria, the substance has high	On the basis of the generic prioritisation criteria boric acid gets high priority for inclusion in Annex XIV. As there are other boron compounds on the Candidate List that could replace the substance in at least some of its uses, these other boron compounds should be grouped with boric acid. ***For the overall conclusions***

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
		such as in biocides, cosmetics, and pharmaceuticals. A firm estimate on the amount of the substance allocated to uses in the scope of authorisation cannot however not be given on the basis of the information available, Nevertheless, it still can be concluded that this volume is >10000 t/y. Uses in the scope of authorisation mainly include formulation of mixtures (in most mixtures in cocentrations below the specific concentration limit for classification; SCL), repackaging, incorporation into some articles (mainly as flame retardants), uses in metallurgy and other applications.	*(Tonnage information provided by EBA is relating to 2008. References: Annex XV dossier, 2010; personal communication with EBA)* - production of insulation and textile **glass fibre** (~25,000 t) - production of **glass** (~25,000 t) - manufacture of **ceramics** (glazes, enamels, frits) (~32,000 t) - use in **adhesives** (~3,000 t) - as **flame retardant** (for cellulose insulation material, mattresses (use is phasing out), wood or paper products, epoxy coatings, etc. ~15,000 t) - in **fertilisers** (~12,000 t), - in **industrial fluids** (lubricants, brake fluids, metal working fluid, etc., ~12,000 t; a significant portion of the tonnage allocated to this area of application relates to the manufacture of other boron substances before formulation of the fluids), - in **buffering / chemical reagents** and the **manufacture of other boron substances** (~33,000 t), - in **metallurgy** (steel & non-ferrous metal production, metal surface refining, ~5,000 t) - in liquid / laundry **detergents** (as stabiliser, ~10,000t), - in **refractories** (~1,000 t) - in **nuclear application** (at least 1,000t according to data form registration) - **manufacture of nylon** (2,000 t)	priority.	***on the priority of the boron compounds for inclusion in Annex XIV please refer to Disodium tetraborate.***

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			- **biocides** (~5,000 t) - **ceramic pigments** (~1,500 t) - **production of plasterboards and wallboards** (~2,500 t) - and **other applications** (~4,000 t, including cosmetics ~700t - , pharmaceuticals – ~500t - as well as production of paints and inks, cement, photolithography, manufacture of B_2O_3 containing catalysts, in medical devices, analytical reagents, etc.). Very similar to disodium tetraborate, boric acid seems to be used at a high number of sites in many different industrial sectors. As regards workers, there is evidence from the Transitional Dossier (Austria 2008) that a presumably very high number of industrial workers and professionals may be exposed while using the substance. The most relevant exposure routes identified are inhalation and dermal uptake due to activities such as sweeping, discharging, loading/unloading and packing. These activities are relevant across most of the sectors mentioned above. The borate concentration in mixtures for supply to consumers will be limited to the specific concentration limits for classification applicable for boron compounds by a restriction, which presumably will enter into force in autumn 2011.		

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
Boric acid	Score: 0	Supplied in very high amounts to uses in the scope of authorisation: Score: 9	Uses in industrial settings and by professionals at a high number of sites (widespread use). Score: 3. Releases may be controlled for most uses, but potentially significant exposure of workers in industrial settings and of professionals cannot be excluded (dispersive use). Score 3. Overall Score: 9.	Total score: 18	**The same considerations apply as brought forward under the verbal-argumentative approach.**
2-Methoxyethanol *(VAA)*	Art. 57 (c) Toxic for Reproduction 1B	According to registration information 2-methoxyethanol is used in Europe in the range of 1000 – 10000 t/y. The tonnage allocated to uses in the scope of authorisation is lower than the total volumes but is still within the above given tonnage range.	According to registration information and supplementary data submitted by the European manufacturers of the substance, the larger part of the tonnage used in the EU is allocated to the manufacture of other substances (e.g. silanes; RCOM 2010) and as such not in the scope of authorisation. A further identified use as laboratory agent is most likely as well exempted from authorisation (Art. 56(3)). Main uses in the scope of authorisation from manufacturer's regostrations are as processing aid and as extraction agent. These uses appear to take place in few industrial sectors and a limited number of industrial settings in closed systems. In cases in which the substance is used as processing aid and extraction agent it seems not to remain in the end-products. The potential for any significant exposure of workers from these uses appears to be low.	2-methoxyethanol is supplied in a high volume to uses in the scope of authorisation. However, on the basis of the information available, it appears that the main volume of these uses take place in few industry sectors and a limited number of industrial settings in closed systems. Only a very low volume of the substance appears to end up in products available to consumers or professionals. In conclusion: the substance is used in high volumes, but it appears that releases and exposures are either controlled or only a few sites are affected.	Based on the criteria, 2-methoxyethanol has moderate priority for inclusion in Annex XIV. **Therefore, it is proposed to not recommend 2-methoxyethanol for inclusion in Annex XIV.**

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
		Additionally there are less than 10 t/y imported by several other companies. These importers describe uses as solvents, formulation preparation and professional uses.	This is backed by the OSPA Charter on Glycolethers which does not support inappropriate end-use applications by the OSPA member companies (downstream users confirm controlled conditions and no product containing methoxyethanol is placed on the market). The importers (all 1-10 t/y, not providing a CSR), give uses as solvent, formulation of preparations and professional uses. These uses might correspond to the uses described earlier, such as solvent in paints, varnishes, colours, glues and adhesives. These uses of the substance may lead to uncontrolled exposure of industrial or professional workers. These uses may lead to uncontrolled exposure of industrial or professional workers.	On the basis of the criteria, the substance has moderate priority.	
2-Methoxyethanol *(SCA)*	Score: 0	Based on the information available a high volume is allocated to uses in the scope of authorisation. High volume. Score: 7	Manufcturers: The substance seem to be used at a medium number of sites. Score: 2 Exposure of workers appears to be controlled. Score: 1 Overall score: 2 Importers: From the available information it is difficult to assess the wide-	Total score: 9-13	**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	
			dispersiveness of the uses. However, given the low tonnage we can either expect uncontrolled releases (score:3) from a medium number of sites (score: 2); or we can expect controlled releases (score: 1) on a high number of sites (score: 3). Total score for wide-dispersiveness would then be: 3 * 2 = 6 1 * 3 = 3		
2-Ethoxyethanol *(VAA)*	Toxic for Reproduction 1B	According to registration information an amount ranging between 1000 and 10000 t/y of 2-ethoxyethanol is used in the EU. Only a low volume (< 10 t) is allocated to uses in the scope of authorisation.	According to registration information, nearly the complete volume supplied in the EU is used for the manufacture of other substances. A low volume of <10 t/y is allocated to the remaining (industrial) uses, which are formulation of mixtures, as a solvent and as a laboratory chemical (the latter use also by professionals). Uses as laboratory agent do presumably fall under the exemption of uses of substances for scientific research and development from authorisation (Art. 56.3). The remaining uses for mixtures and as solvent bear a potential risk for exposure of workers. However, as the tonnage allocated to these uses is so low, it can be assumed that they will be carried out at a small number of industrial sites and apparently in closed	The volume of the substance allocated to uses in the scope of authorisation is low. Because of the low volume, and because the uses appear exclusively to be carried out in industrial settings, it is concluded that the uses are not widespread. They should normally be controlled, however, potential exposure of workers cannot be ruled out. Based on the criteria, the substance has very low priority.	Based on the criteria, 2-ethoxyethanol has very low priority for inclusion in Annex. **Therefore, it is proposed to not recommend 2-ethoxyethanol for inclusion in Annex XIV.**

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			systems (professionals are not involved in these uses, according to the information provided in the registrations). The uses are not widespread and exposure should normally be controlled.		
2-Ethoxyethanol *(SCA)*	Score: 0	Low volume. Score: 1	Small number of sites. Score: 1 Uses take place in industrial settings and releases and exposure appear to be controlled. Score: 1 Overall score: 1	Total score: 2	**The same considerations apply as brought forward under the verbal-argumentative approach**
Aluminosilicate-RCF and Zirconia aluminosilicate-RCF*)*					Before proceeding there is a need for further clarity on the composition / identity of the compounds that shall be covered by the refractory ceramic fibres entry (or entries).
Pitch, coal tar, high temperature (CTPHT) *(VAA)*	Art. 57 (a), (d) & (e); Carcinogen 1B; PBT and vPvB	According to registration information the total tonnage used in the EU is i >500000 t/y. Most of this tonnage is allocated to uses in the scope of authorisation.	Main uses according to registration information are in the metal industry (aluminium, metallurgic smelting, electro steel), the carbon and graphite industry, for refractories, and for activated carbon, CTPHT containing coatings, waterproofing materials, sealings and adhesives, and for clay pigeons. Further uses as fuel in industrial heavy diesel engines, as fuel for industrial energy generation, and as intermediate for the synthesis of other substances. Technical functions of the substance are according to information included in the Annex XV dossier as binding agent in	The substance is used in very high volumes and nearly all uses can be considered wide dispersive, although the main use takes place in (very) large industrial installations. On the basis of the prioritisation criteria, the substance has very high priority.	On the basis of the prioritisation criteria, pitch, coal tar, high temperature (CTPHT) gets very high priority for inclusion in Annex XIV. However, while the Risk Reduction 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

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			the manufacture of anodes/electrodes in the metal industry and in refractories and as anti-corrosion agent in (specialty) coatings and paints, starting material for active carbon and carbon fibres. From the registrations it cannot be determined whether uses indicated in the consultation (Background document 2009, Annex XV dossier 2009) such as binder for briquettes, material for roofing and for (specialty) paving are still continued. The use-information provided in the registrations is to a large extent consistent with the information previously obtained from the Annex XV dossier (2009) and (public) consultation (RCOM 2009, Background document, 2009). Given the very high volume 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, clay-targets and potentially briquettes, paving and roofing.		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 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 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. **Therefore, it is proposed to not prioritise pitch, coal tar, high temperature (CTPHT) now for inclusion in Annex XIV.**
Pitch, coal tar, high	Score: 4	Very high volume in the scope of authorisation.	Many uses with emissions occurring at a high number of sites. Score: 3.	Total score: 22	**The same considerations apply as brought forward**

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
temperature (CTPHT) *(SCA)*		Score: 9	Releases are diffuse and might result in significant exposure of workers and the environment. Score: 3. Overall score: 9		**under the verbal-argumentative approach.**
Anthracene oil *(VAA)*	Carcinogen 1B; PBT and vPvB	Full registrations and registrations as transported isolated intermediate are available, tonnage band > 1000 t/a. The registrations seem to confirm the information received during public commenting on the Annex XV report that the volume on the European market is very high (well above 100,000 t/y). A complete overview on volumes used in the scope of authorisation cannot be established from the information provided in the registrations. However, the largest amounts seem to be assigned to uses of the substance as an intermediate but the amounts dedicated to non-intermediate uses still seem to be very high (> 10000vt/y).	In the registrations it is indicated that anthracene oil, in mixtures with other substances of the coal or petroleum stream, is used as intermediate for the manufacture of other substances, as reducing agent for iron production in blast furnaces, and as fuel for industrial energy generation. Further applications comprise uses, as absorbent for industrial gas cleaning and as industrial solvent. The substance is used in the carbon and graphite industry, in the metallurgic smelting, aluminium and electro steel industry, for refractories, coatings, paints, waterproofing materials and sealants. From the information available it appears that most of the anthracene oil is used as intermediate for the manufacture of other substances. 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 and their similarity to the applications of coal tar high temperature, 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, significant	Anthracene oil is supplied in very high volumes to uses in the scope of authorisation. On the uses in the scope of authorisation no specific information is available but considering their nature and similarity to the fields of application of coal tar high temperature a wide-dispersive use pattern cannot be excluded. On the basis of the criteria, the substance has very high priority.	On the basis of the prioritisation criteria anthracene oil gets very high priority for inclusion in Annex XIV. However, there is uncertainty as to whether authorisation would be appropriate from the regulatory efficiency point of view (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). Moreover, as already mentioned with regard to a potential prioritisation of 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. **Therefore, it is proposed to**

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			exposure at the workplace.		**not prioritise anthracene oil now** (and the other anthracene oil substances on the Candidate List by applying the grouping approach).
Anthracene oil *(SCA)*	Score: 4	Very high volumes (> 10000 t/y) seem to be allocated to uses in the scope of authorisation: 9 scores	Many uses that can be considered wide dispersive (with emissions occurring at a high number of sites with diffuse releases that might be significant and not always controlled). Scoring: number of sites: 3; releases: 3, overall: 9	Total score: 22	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Anthracene oil, anthracene paste *(VAA)*	Carcinogen 1B; Mutagen 1B; PBT and vPvB	Registration as transported isolated intermediate, tonnage band > 1000 t/a. No complete information on the tonnages used in the EU provided but presumably > 10000 t/y.	According to information provided in the registrations the substance is used as intermediate in the synthesis of other substances, for manufacture of pure substances and for the production of technical oils. There is not enough information available to assess the nature of all these uses as to whether they meet the definition in Article 3(15).	According to registration information the substance has no uses in the scope of authorisation. However, this appears not to be certain and further investigation may be necessary.	Further investigation may be necessary before a firm conclusion on priority based on the generic criteria can be taken. However, there is in any case uncertainty as to whether authorisation would be appropriate from the regulatory efficiency point of view. (Please refer for further details to the conclusions on anthracene oil.) **Therefore, it is proposed to not prioritise anthracene oil, anthracene paste now** (and the other anthracene oil substances on the Candidate List by applying the grouping approach).
Anthracene	Score: 4	No clarity on the volumes	No clarity on the nature of the uses	Total score:	**The same considerations**

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
oil, anthracene paste *(SCA)*		supplied to uses in the scope of authorisation			**apply as brought forward under the verbal-argumentative approach.**
Anthracene oil, anthracene-low *(VAA)*	Carcinogen 1B; Mutagen 1B; PBT and vPvB	Registration as transported isolated intermediate. Tonnage band >1000 t/y.	According to registration information the substance is used as intermediate in the manufacture of pure substances, synthesis of substances and as reduction agent in iron production. There is not enough information available to assess the nature of all these uses as to whether they meet the definition in Article 3(15).	According to registration information the substance has no uses in the scope of authorisation. However, this appears not to be certain and further investigation may be necessary.	Further investigation may be necessary before a firm conclusion on priority based on the generic criteria can be taken. However, there is in any case uncertainty as to whether authorisation would be appropriate from the regulatory efficiency point of view. (Please refer for further details to the conclusions on anthracene oil.) **Therefore, it is proposed to not prioritise anthracene oil, anthracene low now** (and the other anthracene oil substances on the Candidate List by applying the grouping approach).
Anthracene oil, anthracene low *(SCA)*	Score: 4	No clarity on the volumes supplied to uses in the scope of authorisation	No clarity on the nature of the uses	Total score:	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Anthracene oil, anthracene	Carcinogen 1B; Mutagen1B; PBT and vPvB	No registration has been submitted for this substance.	No registration submitted.	No registration for the substance submitted. Therefore low priority.	On the basis of the criteria, anthracene oil, anthracene paste, anthracene fraction gets

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
paste, anthracene fraction *(VAA)*					low priority for inclusion in Annex XIV. However, the substance should be grouped with the other anthracene oil substances on the Candidate List in case these are recommended for inclusion in Annex XIV.
Anthracene oil, anthracene paste, anthracene fraction *(SCA)*	Score: 4	No registration: Score: 0	No registration: Score: 0	Total score: 4	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Anthracene oil, anthracene paste, distn. lights *(VAA)*	Carcinogen 1B; Mutagen 1B; PBT and vPvB	Registration as transported isolated intermediate, tonnage band >1000 t/y (no further information on quantities given).	Use as intermediate in the synthesis of other substances, for manufacture of pure substances and in the laboratory.	According to registration information the substance has not uses in the scope of authorisation. Therefore low priority.	On the basis of the criteria, anthracene oil, anthracene paste, distn. lights gets low priority for inclusion in Annex XIV. However, the substance should be grouped with the other anthracene oil substances on the Candidate List in case these are recommended for inclusion in Annex XIV.
Anthracene oil, anthracene paste, distn. lights *(SCA)*	Score: 4	No substance supplied to uses in the scope of authorisation. Score: 0	No uses in the scope of authorisation. Score: 0	Total score: 4	**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	
Anthracene *(VAA)*	PBT	Only registrations as isolated transported intermediate. Tonnage band >1000t/y, no further information on volumes provided in the registrations. According to information received during public consultation on the proposal to identify anthracene as SVHC (RCOM 2008) the 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 other substances. Anthracene supply for other uses was reported to be less than 2 t/y. Use for pyrotechnic mixtures, the only known use in the scope of authorisation, was assumed to be far less than 0.5 t/y.	The only use identified in the registrations is as intermediate for synthesis of other substances. According to information received during public consultation on the proposal to identify the substance as SVHC (RCOM 2008) anthracene is used for the synthesis of anthraquinone. In the registrations no indication could be found that the substance is still used, as ireported during public consultation (RCOM, 2008), 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 would be exempted from authorisation). If formulation of specialty "black smoke" pyrotechnic mixtures still takes place in the EU, this may happen at a low number of sites and releases and worker exposure from formulation might occur only from cleaning (only to wastewater) and in the worst case amount to 0.25% (RCOM, 2008). 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, however without identified uses in the scope of authorisation in the registrations. Based on the criteria, the substance has a very low priority.	Based on the prioritisation criteria, anthracene gets very low priority for inclusion in Annex XIV. **Therefore, it is proposed to not prioritise anthracene for inclusion in Annex XIV.**

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
Anthracene *(SCA)*	Score: 3	No volume of the substance in the scope of authorisation. Score: 0	No uses in the scope of authorisation. Score = 0	Total score: 3	**The same considerations apply as brought forward under the verbal-argumentative approach**
Bis (tributyl tin) oxide (TBTO) *(VAA)*	PBT	Registration as on site isolated intermediate, tonnage band > 1 – 10 t/y.	According to registration information the substance is used as intermediate for the synthesis of other substances under strictly controlled conditions as defined by the Regulation. TBTO is restricted in accordance with REACH, Annex XVII .	TBTO is a PBT. However, there are no known uses in the scope of authorisation in the EU. Therefore very low priority.	On the basis of the prioritisation criteria TBTO gets very low priority for inclusion in Annex XIV. **Therefore, it is proposed to not prioritise bis(tributyltin) oxide for inclusion in Annex XIV**.
Bis (tributyl tin) oxide (TBTO) *(SCA)*	Score: 3	No registered supply of TBTO to uses in the scope of authorisation. Score 0.	No registered uses in the scope of authorisation. Overall score: 0	Total score: 3	**The same considerations apply as brought forward under the verbal-argumentative approach**
Triethyl arsenate *(VAA)*	Carcinogen 1A	No registrations have been submitted for this substance. According to available information (Background document 2009), triethyl arsenate is not manufactured 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.	Triethyl arsenate has been developed for use in specialised doping applications in semi-conductors. 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). When instead the doping process takes place in the manufacture of silicon for use in special applications, e.g. for the	The volume used is very low and there is neither worker nor environmental exposure resulting from the use of triethyl arsenate. On the basis of the criteria, the substance has very low priority**.**	On the basis of the prioritisation criteria, triethyl arsenate gets very low priority for inclusion in Annex XIV**.** **Therefore, it is proposed to not prioritise triethyl arsenate for inclusion in Annex XIV.**

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
			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. 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.		
Triethyl arsenate *(SCA)*	Score: 1	Low annual volume. Score: 1.	The substance is only used for doping applications in the semiconductor industry 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.	Total score: 2	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Lead hydrogen	Carcinogen 1A; Toxic for	No registration for this substance submitted.	No registration and no known uses of the substance in the EU.	No use in the EU, therefore very low priority	On the basis of the prioritisation criteria lead hydrogen arsenate

	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
arsenate *(VAA)*	reproduction 1A	That is consistent with previous findings in which no manufacture or import of lead hydrogen arsenate has been identified in the EU (Background document 2009).		on the basis of the criteria.	gets very low priority for inclusion in Annex XIV. **Therefore, it is suggested to not prioritise lead hydrogen arsenate for inclusion in Annex XIV.**
Lead hydrogen arsenate *(SCA)*	Score: 1	No registration submitted. Score: 0.	No known uses. Overall score: 0	Total score: 1	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Acrylamide (VAA)	Carcinogen 1B Mutagen 1B	According to registration information the substance is manufactured in or imported to the EU in a tonnage range of 100000 – 500000 t/y. Registrations are exclusively as a monomer or the identified uses are as intermediate in the synthesis of other substances,	No uses in the scope of authorisation identified.	No use in the scope of authorisation in the EU identified, therefore very low priority on the basis of the criteria.	On the basis of the prioritisation criteria acylamide gets very low priority for inclusion in Annex XIV. **Therefore, it is suggested to not prioritise acrylamide for inclusion in Annex XIV.**
Acrylamide (SCA)	1	No volume in the scope of authorisation. Score: 0	No uses in the scope of authorisation. Overall score: 0	Total score: 1	**The same considerations apply as brought forward under the verbal-argumentative approach.**

Annex 1

Candidate List of Substances of Very High Concern for Authorisation (as updated on 19 December 2011)

Light grey background highlights substances already prioritised and included in previous Recommendations, which therefore were not considered anymore in the current prioritisation exercise. White (i.e. no) background highlights the substances that were included in the Candidate List until 15 December 2010 and assessed for priority in the context of the 3rd and previous recommendations but were not recommended for inclusion in Annex XIV yet. Light blue background highlights new substances included in the Candidate List during 2011, which are assessed for the first time in the present prioritisation exercise.

Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
1,2,3-Trichloropropane	202-486-1	96-18-4	20/06/2011	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)	ED/31/2011
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	276-158-1	71888-89-6	20/06/2011	Toxic for reproduction (article 57c)	ED/31/2011
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	271-084-6	68515-42-4	20/06/2011	Toxic for reproduction (article 57c)	ED/31/2011
1,2-dichloroethane	203-458-1	107-06-2	19/12/2011	Carcinogenic (article 57 a)	ED/77/2011
1-Methyl-2-pyrrolidone	212-828-1	872-50-4	20/06/2011	Toxic for reproduction (article 57c)	ED/31/2011
2,2'-dichloro-4,4'-methylenedianiline	202-918-9	101-14-4	19/12/2011	Carcinogenic (article 57 a)	ED/77/2011
2,4-Dinitrotoluene	204-450-0	121-14-2	13/01/2010	Carcinogenic (article 57a)	ED/68/2009
2-Ethoxyethanol	203-804-1	110-80-5	15/12/2010	Toxic for reproduction (article 57c)	ED/95/2010
2-Ethoxyethyl acetate	203-839-2	111-15-9	20/06/2011	Toxic for reproduction (article 57c)	ED/31/2011
2-Methoxyaniline; o-Anisidine	201-963-1	90-04-0	19/12/2011	Carcinogenic (article 57 a)	ED/77/2011
2-Methoxyethanol	203-713-7	109-86-4	15/12/2010	Toxic for reproduction	ED/95/2010

Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
				(article 57c)	
4-(1,1,3,3-tetramethylbutyl)phenol	205-426-2	140-66-9	19/12/2011	Equivalent level of concern having probable serious effects to the environment (article 57 f)	ED/77/2011
4,4'- Diaminodiphenylmethane (MDA)	202-974-4	101-77-9	28/10/2008	Carcinogenic (article 57a)	ED/67/2008
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	201-329-4	81-15-2	28/10/2008	vPvB (article 57e)	ED/67/2008
Acids generated from chromium trioxide and their oligomers. Group containing: Chromic acid, Dichromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid	231-801-5, 236-881-5	7738-94-5, 13530-68-2	15/12/2010	Carcinogenic (article 57a)	ED/95/2010
Acrylamide	201-173-7	79-06-1	30/03/2010	Carcinogenic and mutagenic (articles 57 a and 57 b)	ED/68/2009
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	287-476-5	85535-84-8	28/10/2008	PBT and vPvB (articles 57 d and 57 e)	ED/67/2008
Aluminosilicate Refractory Ceramic Fibres *are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the two following conditions: a) Al2O3 and SiO2 are present within the following concentration ranges:Al2O3: 43.5 – 47 % w/w, and SiO2: 49.5 – 53.5 % w/w,orAl2O3: 45.5 – 50.5 % w/w, and SiO2: 48.5 – 54 % w/w,b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm).*	-	Extracted from Index no. 650-017-00-8	13/01/2010	Carcinogenic (article 57a)	ED/68/2009
Aluminosilicate Refractory Ceramic Fibres	-	-	19/12/2011	Carcinogenic (article 57	ED/77/2011

Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions: a) oxides of aluminium and silicon are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (μm) c) alkaline oxide and alkali earth oxide (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight				a)	
Ammonium dichromate	232-143-1	7789-09-5	18/06/2010	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)	ED/30/2010
Anthracene	204-371-1	120-12-7	28/10/2008	PBT (article 57d)	ED/67/2008
Anthracene oil	292-602-7	90640-80-5	13/01/2010	Carcinogenic [1], PBT and vPvB (articles 57a, 57d and 57e)	ED/68/2009
Anthracene oil, anthracene paste	292-603-2	90640-81-6	13/01/2010	Carcinogenic [2], mutagenic [3], PBT and vPvB (articles 57a, 57b, 57d and 57e)	ED/68/2009
Anthracene oil, anthracene paste, anthracene fraction	295-275-9	91995-15-2	13/01/2010	Carcinogenic [2], mutagenic [3], PBT and vPvB (articles 57a, 57b,	ED/68/2009

Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
				57d and 57e)	
Anthracene oil, anthracene paste,distn. lights	295-278-5	91995-17-4	13/01/2010	Carcinogenic [2], mutagenic [3], PBT and vPvB (articles 57a, 57b, 57d and 57e)	ED/68/2009
Anthracene oil, anthracene-low	292-604-8	90640-82-7	13/01/2010	Carcinogenic [2], mutagenic[3], PBT and vPvB (articles 57a, 57b, 57d and 57e)	ED/68/2009
Arsenic acid	231-901-9	7778-39-4	19/12/2011	Carcinogenic (article 57 a)	ED/77/2011
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7	28/10/2008	Toxic for reproduction (article 57c)	ED/67/2008
Bis (2-ethylhexyl)phthalate (DEHP)	204-211-0	117-81-7	28/10/2008	Toxic for reproduction (article 57c)	ED/67/2008
Bis(2-methoxyethyl) ether	203-924-4	111-96-6	19/12/2011	Toxic for reproduction (article 57 c)	ED/77/2011
Bis(2-methoxyethyl) phthalate	204-212-6	117-82-8	19/12/2011	Toxic for reproduction (article 57 c)	ED/77/2011
Bis(tributyltin)oxide (TBTO)	200-268-0	56-35-9	28/10/2008	PBT (article 57d)	ED/67/2008
Boric acid	233-139-2 / 234-343-4	10043-35-3 / 11113-50-1	18/06/2010	Toxic for reproduction (article 57 c)	ED/30/2010
Calcium arsenate	231-904-5	7778-44-1	19/12/2011	Carcinogenic (article 57 a)	ED/77/2011
Chromium trioxide	215-607-8	1333-82-0	15/12/2010	Carcinogenic and mutagenic (articles 57 a and 57 b)	ED/95/2010
Cobalt dichloride	231-589-4	7646-79-9	28/10/2008	Carcinogenic (article 57a)	ED/67/2008
Cobalt(II) carbonate	208-169-4	513-79-1	15/12/2010	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)	ED/95/2010
Cobalt(II) diacetate	200-755-8	71-48-7	15/12/2010	Carcinogenic and toxic for	ED/95/2010

Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
				reproduction (articles 57 a and 57 c)	
Cobalt(II) dinitrate	233-402-1	10141-05-6	15/12/2010	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)	ED/95/2010
Cobalt(II) sulphate	233-334-2	10124-43-3	15/12/2010	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)	ED/95/2010
Diarsenic pentaoxide	215-116-9	1303-28-2	28/10/2008	Carcinogenic (article 57a)	ED/67/2008
Diarsenic trioxide	215-481-4	1327-53-3	28/10/2008	Carcinogenic (article 57a)	ED/67/2008
Dibutyl phthalate (DBP)	201-557-4	84-74-2	28/10/2008	Toxic for reproduction (article 57c)	ED/67/2008
Dichromium tris(chromate)	246-356-2	24613-89-6	19/12/2011	Carcinogenic (article 57 a)	ED/77/2011
Diisobutyl phthalate	201-553-2	84-69-5	13/01/2010	Toxic for reproduction (article 57c)	ED/68/2009
Disodium tetraborate, anhydrous	215-540-4	1303-96-4/ 1330-43-4/ 12179-04-3	18/06/2010	Toxic for reproduction (article 57 c)	ED/30/2010
Formaldehyde, oligomeric reaction products with aniline	500-036-1	25214-70-4	19/12/2011	Carcinogenic (article 57 a)	ED/77/2011
Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified: Alpha-hexabromocyclododecane Beta-hexabromocyclododecane Gamma-hexabromocyclododecane	247-148-4 & 221-695-9	25637-99-4 3194-55-6 (134237-50-6) (134237-51-7) (134237-52-8)	28/10/2008	PBT (article 57d)	ED/67/2008
Hydrazine	206-114-9	302-01-2, 7803-57-8	20/06/2011	Carcinogenic (article 57a)	ED/31/2011
Lead chromate	231-846-0	7758-97-6	13/01/2010	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)	ED/68/2009

Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9	12656-85-8	13/01/2010	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)	ED/68/2009
Lead diazide, Lead azide	236-542-1	13424-46-9	19/12/2011	Toxic for reproduction (article 57 c),	ED/77/2011
Lead dipicrate	229-335-2	6477-64-1	19/12/2011	Toxic for reproduction (article 57 c)	ED/77/2011
Lead hydrogen arsenate	232-064-2	7784-40-9	28/10/2008	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)	ED/67/2008
Lead styphnate	239-290-0	15245-44-0	19/12/2011	Toxic for reproduction (article 57 c)	ED/77/2011
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	1344-37-2	13/01/2010	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)	ED/68/2009
N,N-dimethylacetamide	204-826-4	127-19-5	19/12/2011	Toxic for reproduction (article 57 c)	ED/77/2011
Pentazinc chromate octahydroxide	256-418-0	49663-84-5	19/12/2011	Carcinogenic (article 57 a)	ED/77/2011
Phenolphthalein	201-004-7	77-09-8	19/12/2011	Carcinogenic (article 57 a)	ED/77/2011
Pitch, coal tar, high temp.	266-028-2	65996-93-2	13/01/2010	Carcinogenic, PBT and vPvB (articles 57a, 57d and 57e)	ED/68/2009
Potassium chromate	232-140-5	7789-00-6	18/06/2010	Carcinogenic and mutagenic (articles 57 a and 57 b).	ED/30/2010
Potassium dichromate	231-906-6	7778-50-9	18/06/2010	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)	ED/30/2010

Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
Potassium hydroxyoctaoxodizincatedichromate	234-329-8	11103-86-9	19/12/2011	Carcinogenic (article 57 a)	ED/77/2011
Sodium chromate	231-889-5	7775-11-3	18/06/2010	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)	ED/30/2010
Sodium dichromate	234-190-3	7789-12-0/ 10588-01-9	28/10/2008	Carcinogenic, mutagenic and toxic for reproduction (articles 57a, 57b and 57c)	ED/67/2008
Strontium chromate	232-142-6	7789-06-2	20/06/2011	Carcinogenic (article 57a)	ED/31/2011
Tetraboron disodium heptaoxide, hydrate	235-541-3	12267-73-1	18/06/2010	Toxic for reproduction (article 57 c)	ED/30/2010
Trichloroethylene	201-167-4	79-01-6	18/06/2010	Carcinogenic (article 57 a)	ED/30/2010
Triethyl arsenate	427-700-2	15606-95-8	28/10/2008	Carcinogenic (article 57a)	ED/67/2008
Trilead diarsenate	222-979-5	3687-31-8	19/12/2011	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)	ED/77/2011
Tris(2-chloroethyl)phosphate	204-118-5	115-96-8	13/01/2010	Toxic for reproduction (article 57c)	ED/68/2009
Zirconia Aluminosilicate Refractory Ceramic Fibres *are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the two following conditions: a) Al2O3, SiO2 and ZrO2 are present within the following concentration ranges:Al2O3: 35 – 36 % w/w, andSiO2: 47.5 – 50 % w/w, andZrO2: 15 - 17 % w/w, b)*	-	Extracted from Index no. 650-017-00-8	13/01/2010	Carcinogenic (article 57a)	ED/68/2009

Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm).					
Zirconia Aluminosilicate Refractory Ceramic Fibres *are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions: a) oxides of aluminium, silicon and zirconium are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm). c) alkaline oxide and alkali earth oxide (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight*	-	-	19/12/2011	Carcinogenic (article 57 a)	ED/77/2011

EC number, CAS number: the EC number includes both anhydrous and hydrated forms of a substance and consequently the entries cover both these forms. The CAS number included may be for the anhydrous form only, and therefore the CAS number shown does not always describe the entry accurately.

[1] The substance does not meet the criteria for identification as a carcinogen in situations where it contains less than 0.005 % (w/w) benzo[a]pyrene (EINECS No 200-028-5)

[2] The substance does not meet the criteria for identification as a carcinogen in situations where it contains less than 0.005 % (w/w) benzo[a]pyrene (EINECS No 200-028-5) and less than 0,1 % w/w benzene (EINECS No 200-753-7).]

[3] The substance does not meet the criteria for identification as a mutagen in situations where it contains less than 0,1 % w/w benzene (EINECS No 200-753-7).]