

15 June 2011

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

The prioritisation results presented in this report have been obtained by applying ECHA's updated prioritisation approach as described in the document "*General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation*", version 28 May 2010¹.

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 15 December 2010. All substances on the Candidate List except those already included in one of ECHA's previous Recommendations have been considered. The candidate list of 15 December 2010, including indication as to which of the listed substances have been considered in this prioritisation exercise, is provided in Annex 1.

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

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

have been used.

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

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 process in accordance with Article 59 of the REACH Regulation has also been taken into account, where relevant. The same applies for data collected either by consultants to ECHA or by ECHA itself on volumes of the substances on the European market, on their uses and on releases resulting from these uses.

¹ http://echa.europa.eu/doc/consultations/recommendations/axiv_priority_setting_gen_approach_20100701.pdf

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

Group	Substance name	EC
<i>Chromium(VI) compounds</i>	Chromium trioxide	215-607-8
	Chromic acid, oligomers of chromic acid and dichromic acid, dichromic acid	231-801-5 236-881-5
	Sodium dichromate	234-190-3
	Potassium dichromate	231-906-6
	Ammonium dichromate	232-143-1
	Potassium chromate	232-140-5
	Sodium chromate	231-889-5
	Trichloroethylene	201-167-4
<i>Cobalt(II) compounds</i>	Cobalt(II) sulphate	233-334-2
	Cobalt dichloride	231-589-4
	Cobalt(II) dinitrate	233-402-1
	Cobalt(II) carbonate	208-169-4
	Cobalt(II) diacetate	200-755-8

Table 1: Prioritisation of the substances on the Candidate List (as updated on 15 December 2010; 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.

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
Trichloroethylene (VAA)	Carcinogen 1B	<p>According to registration information about 50,000 – 100,000 t/y of trichloroethylene are manufactured or imported. No information on exports is available.</p> <p>The larger part of the manufactured/imported volume is used as intermediate in the manufacturing of other substances. The volume allocated to uses within the scope of authorisation is above 10,000 t/y.</p>	<p>Industry has undertaken considerable efforts to reduce the uses of trichloroethylene or to reduce exposure to the substance. However, in some specific uses the substance could not be replaced so far, e.g. in adhesives for road marking or repair of conveyor belts used in mining tunnels, and for surface cleaning (e.g. degreasing of metal). (RCOM 2010)</p> <p>According to registration information, the substance is still used in industrial settings for surface cleaning (closed and semi-closed systems), as heat transfer fluid, for textile scouring and in adhesives. There are further uses by professionals as process chemical and in adhesives.</p> <p>At least some activities carried out within these uses could result in exposure of the substance to workers and professionals. For instance, operations such as material transfers, maintenance, cleaning and sampling could lead to significant exposure. In particular, uses of the substance in adhesives by professionals could result in widespread use and uncontrolled exposure (≈ wide-</p>	<p>The volumes of trichloroethylene allocated to uses in the scope of authorisation are very high and at least some of the described uses appear to result in significant exposure of industrial workers and professionals and can be considered wide dispersive.</p> <p>Therefore, based on the criteria, trichloroethylene has very high priority.</p>	<p>On the basis of the prioritisation criteria, trichloroethylene gets very high priority for inclusion in Annex XIV.</p> <p>Therefore, it is proposed to prioritise trichloroethylene for inclusion in Annex XIV.</p>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			dispersive use).		
Trichloroethylene (SCA)	Score: 1	Very high volume used for applications in the scope of authorisation. Score: 9	Used at a high number of sites. Score: 3 At least in some applications significant exposure of workers/professionals and wide dispersive use. Score: 3 Overall score: 9	Total score: 19	The same considerations apply as brought forward under the verbal-argumentative approach.
Chromium trioxide (VAA)	Art. 57 (a) & (b); Carcinogen 1A, Mutagen 1B	According to registration information the amount of chromium trioxide used in the EU is in the range 1,000 – 10,000 t/y. The largest part of the registered amount is allocated to uses in the scope of authorisation (this is a volume above 1000 t/y).	<p>The uses identified in the registration dossier in the scope of authorisation are: formulation of mixtures containing chromium trioxide, which are mainly used for metal finishing or, in much smaller amounts, as catalysts containing chromium trioxide. In addition, the substance is used outside the scope of authorisation, e.g. as intermediate in the synthesis of other chromium compounds and in low volumes by professionals as a laboratory agent.</p> <p>As regards the main uses, exposure of workers cannot be excluded and its extent depends on the operational conditions and risk management measures in place. Recent exposure information reported in the Annex XV dossier prepared by Germany shows that workers are exposed to significant concentrations of chromium VI compounds, particularly in the following sectors (of relevance for chromium trioxide): formulation of metal treatment products, use in electrolytic metal treatment, decorative plating and hard chrome plating.</p> <p>According to the registration information the formulation of the metal treatment mixtures is performed at a small number of sites. It can</p>	Chromium trioxide is used in high volumes. The uses falling under authorisation are expected to take place at a high number of sites and significant exposure of workers may occur in a number of uses with releases to the workplace. Some of the uses could therefore be wide-dispersive. Based on the criteria, chromium trioxide has high priority.	<p>On the basis of the prioritisation criteria chromium trioxide gets high priority for inclusion in Annex XIV.</p> <p>Therefore, it is proposed to recommend chromium trioxide for inclusion in Annex XIV.</p> <p>There are other chromium VI compounds on the Candidate List with (partially) the same uses, or which could be used to replace chromium trioxide in (some of) its uses (and vice versa). Therefore, these substances should as well be considered for inclusion in Annex XIV in order to avoid evasion of the authorisation requirement and substitution of SVHCs with other SVHCs.</p>

Substance	Inherent properties	Volumes	Conclusion on		Final conclusion, taking regulatory effectiveness considerations into account
			Wide dispersiveness of uses	Priority	
			be expected however that the surface treatment itself is performed at a high but unknown number of sites in the EU.		
Chromium trioxide (SCA)	Score : 1	High volume allocated to uses in the scope of authorisation. Score: 7	Substance used at a high number of sites. Score: 3. Releases and exposure to workers might be controlled in most instances, however some of the uses appear to have a potential for significant worker exposure. Score 3 Overall score: 9	Total score: 17	The same considerations apply as brought forward under the verbal-argumentative approach.
Chromic acid, oligomers of chromic acid and dichromic acid, dichromic acid	Art. 57 (a); Carcinogen 1B	See chromium trioxide	See chromium trioxide	See chromium trioxide	Product of the dissolution of chromium trioxide in water. The same conclusions apply as for chromium trioxide.
Sodium dichromate (VAA)	Art. 57 (a), (b) & (c); Carcinogen 1B; Mutagen 1B; Toxic for reproduction 1B	According to registration information the total volume used in the EU is in the range of 50,000 – 100,000 t/y. To uses in the scope of authorisation a tonnage in the range of 1,000 – 10,000 t/y is being allocated.	According to information from registration dossiers most of the sodium dichromate supplied to the EU market is used as an intermediate for synthesis of chromium (III) compounds. The main non-intermediate uses of Na ₂ Cr ₂ O ₇ are in metal surface treatment, e.g. for passivation of tin-plated steel (Entec 2008). Exposure of workers depends on the operational conditions and risk management measures in place. Recent exposure information reported in the Annex XV dossier for chromium trioxide prepared by Germany shows that workers are exposed to significant	The volume of sodium dichromate supplied to uses in the scope of authorisation is high. Some of the uses in metal finishing are considered to be widespread with a potential for significant worker exposure. On the basis of the criteria, sodium dichromate has high priority.	On the basis of the prioritisation criteria sodium dichromate gets high priority for inclusion in Annex XIV. Therefore, it is proposed to recommend sodium dichromate for inclusion in Annex XIV. There are other chromium VI compounds on the Candidate List with (partially) the same uses, or which could be used to replace sodium dichromate in (some of) its uses (and vice versa). Therefore, these substances should as well be considered for inclusion in Annex XIV.

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			<p>concentrations of chromium VI compounds, particularly in the following sectors (of relevance for sodium dichromate): formulation of metal treatment products, use in electrolytic metal treatment, surface treatment and electroplating. Generally, process steps during surface treatment such as dipping, pouring and spray applications of treatment agents have a high potential for exposure to fumes and aerosols containing the substance.</p> <p>Metal finishing takes presumably place in a high number of industrial settings. The use of Na₂Cr₂O₇ in metal finishing might therefore be widespread with a potential for significant worker exposure in a number of applications and process steps.</p>		
Sodium dichromate (SCA)	Score: 1	High annual volume in the scope of authorisation. Score: 7.	<p>Uses of sodium dichromate in the scope of authorisation may occur at a high number of industrial sites. Score: 3.</p> <p>Releases and exposure to workers might be controlled in most instances, however some of the uses appear to have a potential for significant worker exposure. Score: 3</p> <p>Overall score: 9</p>	Total score: 17	The same considerations apply as brought forward under the verbal-argumentative approach.
Potassium dichromate (VAA)	Art. 57 (a), (b) & (c); Carcinogen 1B; Mutagen 1B; Toxic for reproduction 1B	Registration data indicate a volume in the range of 1,000 – 10,000 t/y on the EU market. This volume is almost completely used as intermediate for the manufacture of other substances. An amount in the range of 1 - 10 t/y is used as processing aid, for metal surface treatment and as	<p>According to registration information, almost the complete volume of the substance is used as intermediate (manufacture of basic metals and chemicals). A further minor use is as laboratory agent, which presumably is not in the scope of authorisation (Art. 56 (3)).</p> <p>Potassium dichromate is used in the scope of authorisation for formulation of mixtures, metal surface treatment, and as processing</p>	<p>Low volume allocated to uses in the scope of authorisation. Some process steps in metal finishing are considered to bear potential for significant worker exposure.</p> <p>On the basis of the criteria the substance has low priority.</p>	<p>On the basis of the prioritisation criteria, potassium dichromate gets low priority for inclusion in Annex XIV.</p> <p>However, this substance could be used to replace other hexavalent chromium compounds with similar</p>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
		laboratory chemical.	<p>aid.</p> <p>Exposure of workers depends on the operational conditions and risk management measures in place. Recent exposure information reported in the Annex XV dossier for chromium trioxide prepared by Germany shows that workers are exposed to significant concentrations of chromium VI compounds, particularly in the following sectors (of relevance for potassium dichromate): formulation of metal treatment products, use in electrolytic metal treatment, surface treatment and electroplating. Generally, process steps during surface treatment such as dipping, pouring and spray applications of treatment agents have a high potential for exposure to fumes and aerosols containing the substance.</p> <p>However, as the volumes allocated to formulation of mixtures, metal finishing and as processing aid are low, they presumably don't take place in a high number of sites. These uses of $K_2Cr_2O_7$ might therefore not be considered as widespread. Metal finishing might however bear a potential for significant worker exposure in a number of applications and process steps.</p>		<p>hazard profile and similar uses.</p> <p>Therefore, it is proposed to recommend potassium dichromate for inclusion in Annex XIV.</p>
Potassium dichromate (SCA)	Score : 1	Low volume in the scope of authorisation. Score: 1	<p>Uses in the scope of authorisation may occur at a medium number of sites. Score: 2.</p> <p>Releases and exposure to workers might be controlled in most instances, however some of the uses might have a potential for significant worker exposure. Score: 3</p> <p>Overall score: 6</p>	Total score: 8	The same considerations apply as brought forward under the verbal-argumentative approach.

Substance	Inherent properties	Conclusion on			Final conclusion, taking regulatory effectiveness considerations into account
		Volumes	Wide dispersiveness of uses	Priority	
Ammonium dichromate (VAA)	Art. 57 (a), (b) & (c); Carcinogen 1B; Mutagen 1B; Toxic for reproduction 1B	Only registration as transported isolated intermediate in the tonnage band 1 - 1000 t/y.	According to registration information only used as intermediate and as laboratory agent. No uses in the scope of authorisation identified.	No uses identified in the scope of authorisation. Therefore very low priority.	On the basis of the prioritisation criteria, ammonium dichromate gets very low priority for inclusion in Annex XIV. However, this substance could be used to replace other hexavalent chromium compounds with similar hazard profile and similar uses. Therefore, it is proposed to recommend ammonium dichromate for inclusion in Annex XIV.
Ammonium dichromate	Score : 1	No registered volume in the scope of authorisation: Score 0	No uses identified in the scope of authorisation. Score: 0	Total score: 1	The same considerations apply as brought forward under the verbal-argumentative approach.
Potassium chromate (SCA)	Art. 57 (a) & (b); Carcinogen 1B, Mutagen 1B	Registrations in the tonnage band 1 – 10 t/y have been submitted. No information is provided on the amounts being allocated to uses in the scope of authorisation.	According to registration information the only use in the scope of authorisation is for metal surface treatment. Potassium chromate is also used as intermediate in the synthesis of other substances and as a laboratory agent. Further potential uses (not identified in the registrations) have been reported during public consultation on the SVHC identification of the substance (RCOM, 2010): use of potassium chromate as a pyrotechnic delay in ammunition and as a corrosion inhibitor in cooling systems of some nuclear power plants (closed systems, strictly controlled).	Potassium chromate is used in low volumes. In addition, the information on volumes available covers as well uses not in the scope of authorisation (as intermediate or as laboratory agent). There is no detailed information on the uses but it seems that they mostly are carried in closed processes but with potential for significant worker exposure at least in some processes.	Based on the prioritisation criteria, potassium chromate gets low priority for inclusion in Annex XIV. However this SVHC substance could be used to replace other hexavalent chromium compounds with similar uses. Therefore, it is proposed to recommend potassium chromate for inclusion in Annex XIV.

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			<p>From the information available it is difficult to conclude on the supply chain structure. However as the tonnage used is low, it can be expected that the number of sites where the uses relevant for authorisation are performed may not be high.</p> <p>As regards potential worker exposure, monitoring information that workers could be exposed to significant concentrations of chromium VI compounds in metal treatment applications needs to be considered (Chromium trioxide Annex XV SVHC dossier, 2010).</p>	<p>Due to the low volume and its apparently limited uses in the EU, the priority for recommending this substance for inclusion in Annex XIV is low.</p>	
Potassium chromate (SCA)	Score : 1	Low volumes allocated to uses in the scope of authorisation. Score: 1	<p>Substance used at a medium number of sites. Score: 2.</p> <p>Releases and exposure to workers might be controlled in most instances, however some of the uses appear to have a potential for significant worker exposure. Score: 3</p> <p>Overall score: 6</p>	Total score: 8	The same considerations apply as brought forward under the verbal-argumentative approach
Sodium chromate (VAA)	Art. 57 (a), (b) & (c); Carcinogen 1B, Mutagen 1B, Toxic for reproduction 1B	Uses of, sodium chromate in the EU are registered within the 1 - 10 t/y tonnage band.	<p>The registration information indicates that the only use in the scope of authorisation is for metal surface treatment. Sodium chromate is also used as intermediate in the synthesis of other substances and as a laboratory agent. This information is confirmed by comments provided during the public consultation on the SVHC identification of the substance. In these comments it is specified that the substance is used as a corrosion inhibitor in cooling systems and particularly in carbon steel cooling system in absorption refrigerators. From the information available it is difficult to conclude on the supply chain structure.</p>	<p>Sodium chromate is used in low volumes at a presumably low number of sites. In addition, the information on volumes available covers as well uses not in the scope of authorisation (as intermediate or as laboratory agent). There is no detailed information on the uses but it seems that they mostly are carried in closed processes. Potential for significant worker exposure at least in some</p>	<p>Based on the prioritisation criteria, sodium chromate gets very low priority for inclusion in Annex XIV.</p> <p>However this SVHC substance could be used to replace other hexavalent chromium compounds with similar uses.</p> <p>Therefore, it is proposed to recommend sodium chromate for inclusion in Annex XIV.</p>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			<p>However it seems that most of the tonnage of sodium chromate is used for carbon steel cooling systems in absorption refrigerators. No information is available on non-intermediate uses other than as metal surface treatment agent.</p> <p>As the downstream user who uses the substance as corrosion inhibitor in absorption refrigerators appears to use an amount that is close to the entire registered volume (RCOM 2010), it can be assumed that the number of sites where the substance is used is low.</p> <p>As regards potential worker exposure, monitoring information that workers could be exposed to significant concentrations of chromium VI compounds in metal treatment applications needs to be considered (Chromium trioxide Annex XV SVHC dossier, 2010). However, as nearly the entire volume of the substance in the scope of authorisation is used as corrosion inhibitor in (closed) cooling systems the potential for uncontrolled worker exposure appears to be low.</p>	<p>processes cannot be excluded.</p> <p>Due to the low volume and its apparently limited uses in the EU, the priority for recommending this substance for inclusion in Annex XIV is very low.</p>	
Sodium chromate (SCA)	Score : 1	Low volumes allocated to uses in the scope of authorisation: Score: 1	Substance used at a small number of sites. Score: 1. Non diffuse releases and worker exposure controlled. Score: 1 Overall score: 1	Total score: 3	The same considerations apply as brought forward under the verbal-argumentative approach
Cobalt(II) sulphate (VAA)	Art. 57 (a) & (c); Carcinogen 1B; Toxic for reproduction 1B	According to registration information the volume manufactured/imported in the EU is in the range of 1,000 – 10,000 t/y. There is no detailed	Manufacture of other chemicals, including also catalysts, organic textile dyes, pigments, and active substances for the production of batteries (it seems that production of batteries requires prior manufacture of another cobalt	Relatively high volume used in the scope of authorisation. Widespread uses, which in some cases can be considered as wide	Based on the criteria, the substance gets high priority for inclusion in Annex XIV.

Substance	Inherent properties	Conclusion on			Final conclusion, taking regulatory effectiveness considerations into account
		Volumes	Wide dispersiveness of uses	Priority	
		<p>information on volumes in the scope of authorisation available from the registrations, but the major part appears to be used as intermediate.</p> <p>Nevertheless, a volume which according to industry (Cobalt Development Institute, Annex XV Dossier; personal communication with Cobalt REACH Consortium) may represent up to 5% of total use in the EU seems to be allocated to non-intermediate uses in the scope of authorisation.</p> <p>On the basis of the available information on total volume and the percentage allocated to non-intermediate uses it is estimated that an annual tonnage of 100 – 1,000 t is in the scope of authorisation.</p>	<p>compound from cobalt(II) sulphate), appear to be uses of the substance as intermediate.</p> <p>Cobalt(II) sulphate is further used in surface treatment processes (e.g. electrodeposition, colour anodizing, non-electrodeposition, welding and soldering processes - applications in the aerospace-, automotive-, telecommunication-, electronics-, storage media-, military-, etc.- industries), as drier and pigment in coatings and inks (function related to coating formation due to catalysed oxidation of hydrocarbons), and as water treatment chemical / oxygen scavenger / corrosion inhibitor (mixtures added to e.g. process water for protection of the pipes from corrosion by oxygen, or as micro nutrient solution). Several applications in the context of the manufacture / production of inorganic pigments & frits, glass, ceramic ware (use as colorant or for discolouring), varistors and magnets seem to be in the scope of authorisation too.</p> <p>Main route of occupational exposure is via the respiratory tract by inhalation of dusts, fumes and mists containing the substance. Worker exposure in industrial applications may be controlled in most instances, but there are processes with high potential for emissions such as the preparation of pre-sintered materials, calcination and sintering during the manufacture of frits, glass, ceramic ware, and magnets. Also welding/soldering and process steps during surface treatment such as dipping, pouring and spray applications of treatment agents have a high potential for</p>	<p>dispersive.</p> <p>Based on the criteria, the substance gets high priority.</p>	<p>Therefore, it is proposed to recommend cobalt(II)sulphate for inclusion in Annex XIV.</p> <p>As there are other cobalt(II) compounds on the Candidate List that could replace the substance in at least some of its uses, these other cobalt(II) compounds should be grouped with the substance and included in Annex XIV as well.</p>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			<p>exposure to fumes and aerosols containing the substance. Professional applications can be of concern especially when they relate to the use of powders of raw materials, paints / coatings / inks containing the substance as drier or pigment, or water treatment agents. These applications potentially result in wide dispersive use (widespread use and potentially uncontrolled exposure). Potential exposure of workers may further arise from recycling of imprinted paper.</p> <p>Articles containing cobalt sulphate may reach consumers, e.g. in coated articles. Although the cobalt sulphate in those articles can be considered bound in a matrix, exposure could occur if the coating would be ground in order to prepare it for refurbishing (i.e. re-painting, exposure to grinding dust).</p> <p>It appears that the substance is used at a high number of industrial settings and that the number of workers/ professional users involved might also be high.</p>		
Cobalt(II) sulphate (SCA)	Score: 0 -1 ²	Relatively high volume in the scope of authorisation. Score: 5	Used at an unknown but presumably high number of sites. Score: 3. Releases at workplaces in industrial settings seem to be controlled in most cases but some processes, involving handling of powder forms of the substance have a potentially significant exposure potential for industrial	Total score: 14 – 15	The same considerations apply as brought forward under the verbal-argumentative approach.

² Some information has been provided by the Cobalt REACH Consortium regarding a potential concentration threshold of cobalt (II) salts for eliciting cancer effects. For the sole purpose of this prioritisation step a score in the range 0 (cancerogenic with threshold) - 1 (canc. without threshold) is assigned. This scoring does not pre-empt any conclusion by the Risk Assessment Committee when preparing its opinions on the future applications.

Substance	Inherent properties	Conclusion on			Final conclusion, taking regulatory effectiveness considerations into account
		Volumes	Wide dispersiveness of uses	Priority	
			and - where relevant - professional workers. Recycling of imprinted paper and coated articles is a further source of potentially uncontrolled exposure. In conclusion, for some uses there exists a risk of significant and potentially uncontrolled exposure. Score: 3 Overall score: 9		
Cobalt dichloride (VAA)	Art. 57 (a) & (c); Carcinogen 1B Toxic for reproduction 1B	According to registration information the volume manufactured / imported in the EU is in the range of 1,000 – 10,000 t/y. There is no detailed information on volumes in the scope of authorisation available from registration. However, previously received information from stakeholder consultation (background document 2009, RCOM 2008, 2011) and recent information provided by CoRC (personal communication), suggests that only a relatively low volume below 100 t/y is used in applications in the scope of authorisation. These would include uses in surface treatment, as water treatment agent, in humidity indicator cards, and potentially some uses related with ceramics etc.. It appears therefore justifiable to assume that an amount in the	Manufacture of other substances, including also organic textile dyes and pigments, appear to be uses of the substance as intermediate. Registered industrial uses considered to be in the scope of authorisation include the use in surface treatment processes, as water treatment chemical / oxygen scavenger / corrosion inhibitor , and potentially also some uses related to the manufacture / production of inorganic pigments & frits, glass, ceramic ware, varistors and magnets . Information on a further use of the substance in humidity indicator cards for military, export packaging and semiconductor manufacturing (use of cobalt dichloride impregnated in paper cards, and potentially also its regeneration after use) is available (Background document, 2009; Info from public consultations), to which a very small amount <<1 t seems to be allocated. Main route of occupational exposure is via the	Cobalt dichloride is used in relatively low volumes, for uses in the scope of authorisation. Some of the uses have in general a high emission potential and may in some cases lead to significant occupational exposure. Based on the criteria, it appears that the substance has a moderate priority.	Based on the criteria, the substance has a moderate priority for inclusion in Annex XIV. As there are other cobalt(II) compounds with high priority for inclusion in Annex XIV on the Candidate List, cobalt dichloride should be grouped with these other cobalt compounds and included in Annex XIV in order to prevent replacement of these other cobalt compounds with cobalt dichloride . Therefore, it is proposed to recommend cobalt dichloride for inclusion in Annex XIV.

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
		range of 10 – 100 t/y is used in the EU for applications in the scope of authorisation.	<p>respiratory tract by inhalation of dusts, fumes and mists containing the substance. Worker exposure in industrial applications may be controlled in most instances, but there are processes with high potential for emissions, especially when powder materials are handled, such as the preparation of pre-sintered materials, calcination, and sintering during the manufacture of frits, glass, ceramic ware, and magnets. Also process steps during surface treatment such as dipping, pouring and spray applications of treatment agents have a high potential for exposure to fumes and aerosols containing the substance. Professional applications can be of concern especially when they relate to the use of powders of raw materials or water treatment agents. These applications potentially result in wide dispersive use (widespread use and potentially uncontrolled exposure).</p> <p>The relatively low tonnage in the scope of authorisation suggests that that the substance is not used at a high number of industrial settings.</p>		
Cobalt dichloride (SCA)	Score: 0 - 1 ³	Relatively low volume in the scope of authorisation. Score: 3	<p>Used at an unknown but presumably medium number of sites. Score: 2.</p> <p>Releases at workplaces in industrial settings seem to be controlled in most cases but some processes, involving handling of powder forms of the substance have a potentially significant exposure potential for industrial and - where relevant - professional workers. Score: 3</p>	Total score: 9 - 10	The same considerations apply as brought forward under the verbal-argumentative approach.

Substance	Inherent properties	Conclusion on			Final conclusion, taking regulatory effectiveness considerations into account
		Volumes	Wide dispersiveness of uses	Priority	
			Overall score: 6		
Cobalt (II) dinitrate (VAA)	Art. 57 (a) & (c); Carcinogen 1B; Toxic for reproduction 1B	<p>No detailed info on volumes in the scope of authorisation is available from the registration dossiers.</p> <p>According to registration information the volume manufactured/imported in the EU is in the range of 1,000 – 10,000 t/y. Most of this volume is used as intermediate. According to information provided by industry (Cobalt REACH consortium 2011) a volume in the range of 10 – 100 t/y is allocated to uses in the scope of authorisation.</p>	<p>Manufacture of other chemicals, including also catalysts and active substances for the production of batteries (it seems that production of batteries requires prior manufacture of another cobalt compound from cobalt(II) dinitrate), appear to be uses of the substance as intermediate.</p> <p>Registered industrial uses appearing to be in the scope of authorisation include the use in surface treatment processes, and uses as water treatment chemical / oxygen scavenger / corrosion inhibitor. (See further details on these uses in the use description for cobalt(II) sulphate.) A use of the substance itself as a catalyst has also been registered, although information provided by the industry suggests that only other catalysts are manufactured, and that this is in fact a use as intermediate (RCOM, 2010; personal communication with CoRC, 2011)</p> <p>Main route of occupational exposure is via the respiratory tract by inhalation of dusts, fumes and mists containing the substance. Worker exposure in industrial applications may be controlled in most instances, but there are processes with high potential for exposure such as the handling of raw materials in powder form. Also welding/soldering and process steps during surface treatment such as dipping, pouring and spray applications of treatment agents have a high potential for</p>	<p>Relatively low volume used in the scope of authorisation. Widespread uses of which at least some appear to have a potential for significant exposure of workers.</p> <p>Based on the criteria, the substance has moderate priority.</p>	<p>Based on the criteria, the substance gets moderate priority for inclusion in Annex XIV.</p> <p>Therefore, it is proposed to recommend cobalt(II) dinitrate for inclusion in Annex XIV.</p> <p>As there are other cobalt(II) compounds on the Candidate List that could replace the substance in at least some of its uses, these other cobalt(II) compounds should be grouped with the substance and included in Annex XIV as well.</p>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			<p>exposure to fumes and aerosols containing the substance. Professional applications can be of concern especially when they relate to the use of powders of raw materials or water treatment agents. These applications potentially result in wide dispersive use (widespread use and potentially uncontrolled exposure).</p> <p>It is estimated that the substance is used at a medium number of industrial settings and that use by professionals cannot be excluded for some applications (e.g. water treatment, welding/soldering materials).</p>		
Cobalt (II) dinitrate (SCA)	Score: 0 – 1 ³	Relatively low volume in the scope of authorisation. Score: 3	<p>Use at an unknown, but presumably medium number of sites, score: 2. Releases at workplaces in industrial settings seem to be controlled in most cases but some processes, involving handling of powder forms of the substance have a potentially significant exposure potential for industrial and - where relevant - professional workers. Score: 3 Overall score: 6</p>	Total score: 9-10	The same considerations apply as brought forward under the verbal-argumentative approach.
Cobalt (II) carbonate (VAA)	Art. 57 (a) & (c); Carcinogen 1B; Toxic for reproduction 1B	<p>No detailed information on volumes in the scope of authorisation is available from the registration dossiers.</p> <p>According to registration information the volume manufactured / imported in the EU is in the range of 1,000 – 10,000 t/y. According to industry (Cobalt Development Institute,</p>	<p>Manufacture of other substances, including also catalysts and pigments, appear to be uses of the substance as intermediate. Furthermore, use in feed grade materials (animal food supplement) is considered to be outside the scope of authorisation.</p> <p>Registered industrial uses considered to be in the scope of authorisation include the use in surface treatment processes, in the calcination /sintering process in the context of</p>	<p>Cobalt (II) carbonate is used in relatively low volumes, for uses in the scope of authorisation. Some of the uses have in general a high emission potential and may in some cases lead to significant occupational exposure. Environmental releases from</p>	<p>Based on the criteria, the substance has moderate priority for inclusion in Annex XIV.</p> <p>As there are other cobalt(II) compounds with high priority for inclusion in Annex XIV on the Candidate List, cobalt (II) carbonate should be grouped with these other cobalt compounds and included in</p>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
		<p>Annex XV Dossier), almost the complete amount of the substance is used as intermediate. There are however several uses in the scope of authorisation registered.</p> <p>It is therefore assumed that in the EU a volume in the range of 10 – 100 t/y is allocated to uses in the scope of authorisation.</p>	<p>the manufacture / production of inorganic pigments & frits, glass, ceramic ware, varistors and magnets (at least some applications seem to be non-intermediate), as well as in (granular) fertilisers. Fertiliser mixtures containing Cobalt(II) carbonate are used by professionals.</p> <p>Main route of occupational exposure is via the respiratory tract by inhalation of dusts, fumes and mists containing the substance. Worker exposure in industrial applications may be controlled in most instances, but there are processes with high potential for emissions such as the handling of raw materials in powder form, the preparation of pre-sintered materials, calcination and sintering during the manufacture/production of frits, glass, ceramic ware, and magnets. Also welding/soldering and process steps during surface treatment such as dipping, pouring and spray applications of treatment agents have a high potential for exposure to fumes and aerosols containing the substance. Professional applications can be of concern especially when they relate to the use of powders of raw materials.</p> <p>Environmental releases from mixtures (e.g. fertilisers) may in most instances be low but possibly widespread.</p> <p>It is estimated that the substance is used at a medium number of industrial settings.</p>	<p>fertilisers may be low but possibly widespread.</p> <p>Based on the criteria the substance has moderate priority.</p>	<p>Annex XIV in order to prevent replacement of these other cobalt compounds with cobalt carbonate.</p> <p>Therefore, it is proposed to recommend cobalt(II) carbonate for inclusion in Annex XIV.</p>
Cobalt (II) carbonate (SCA)	Score: 0 – 1 ³	Relatively low volumes in the scope of authorisation. Score: 3	Used at an unknown but presumably medium number of sites. Score: 2.	Total score: 9 - 10	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	
			<p>Releases at workplaces in industrial settings seem to be controlled in most cases but some processes, involving handling of powder forms of the substance have a potentially significant exposure potential for industrial and - where relevant - professional workers. Score: 3</p> <p>Overall score: 6</p>		
Cobalt (II) diacetate (VAA)	Art. 57 (a) & (c); Carcinogen 1B; Toxic for reproduction 1B	<p>No detailed information on volumes in the scope of authorisation is available from the registration dossiers.</p> <p>According to registration information the volume manufactured / imported in the EU is in the range of 1000 – 10,000 t/y. Most of this amount (at least 70%, Annex XV report 2010) is used as catalyst and in the manufacture of catalysts, with the first being considered as non-intermediate use. The use as catalyst is by far the main use of this substance (Annex XV report, 2010). Comments received during the consultation on the identification as SVHC (RCOM, 2010) support that this use is actual. Recent personal information by the CoRC suggests that a considerable part of this use may relate to the manufacture of catalysts.</p>	<p>Manufacture of other substances, including also catalysts and pigments, appear to be uses of the substance as intermediate. Furthermore, use in feed grade materials (animal food supplement) is considered to be outside the scope of authorisation.</p> <p>Further registered uses of Cobalt(II) diacetate are those as a catalyst (substance itself), in surface treatment processes and production and use of plastics and/or PET (function: as catalyst for resin polymerisation or as colorant for PET bottles, RCOM 2010) in the manufacture and use of rubber adhesion agents (facilitating adhesion between steel and rubber in tyres) as well as in the calcination/sintering process in the context of the manufacture / production of inorganic pigments & frits, glass, ceramic ware, varistors and magnets.</p> <p>Main route of occupational exposure is via the respiratory tract by inhalation of dusts, fumes and mists containing the substance. Worker exposure in industrial applications may be controlled in most instances, but there are</p>	<p>High volume used in the scope of authorisation. Widespread uses of which at least some appear to have a potential for significant exposure of workers.</p> <p>Based on the criteria, the substance has high priority.</p>	<p>Based on the criteria, the substance gets high priority for inclusion in Annex XIV.</p> <p>Therefore, it is proposed to recommend cobalt(II) diacetate for inclusion in Annex XIV.</p> <p>As there are other cobalt(II) compounds on the Candidate List that could replace the substance in at least some of its uses, these other cobalt(II) compounds should be grouped with the substance and included in Annex XIV as well.</p>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
		<p>In any case, there are also further non-intermediate uses in the scope of authorisation registered, which account for a significant part of the use in the EU (Annex XV dossier, 2010).</p> <p>It is therefore assumed that in the EU a volume in the range of 1,000 – 10,000 t/y is allocated to uses in the scope of authorisation.</p>	<p>processes with high potential for exposure such as the handling of raw materials in powder form, steps during surface treatment such as dipping, pouring and spray applications of treatment agents, which have a high potential for exposure to fumes and aerosols containing the substance, or the preparation of pre-sintered materials, calcination and sintering during the manufacture of frits, glass, ceramic ware and magnets.</p> <p>It appears that the substance is used at a high number of industrial settings and that the number of workers/ professional users involved might also be high.</p>		
Cobalt (II) diacetate (SCA)	Score: 0 – 1 ³	High volume in the scope of authorisation. Score: 7	<p>Used at an unknown but presumably high number of sites. Score: 3.</p> <p>Releases at workplaces in industrial settings seem to be controlled in most cases but some processes, involving handling of powder forms of the substance have a potentially significant exposure potential for industrial and - where relevant - professional workers. Score: 3</p> <p>Overall score: 9</p>	Total score: 16 - 17	The same considerations apply as brought forward under the verbal-argumentative approach.
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.	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	Disodium tetraborate is used in very high volumes for several uses in the scope of authorisation and at very many sites.	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

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
		<p>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.</p> <p>Uses in the scope of authorisation mainly include formulation of mixtures (in most mixtures in concentrations below the specific concentration limit for classification; SCL), repackaging, incorporation into some articles (mainly as flame retardants), uses in metallurgy and other applications.</p>	<p>Europe (EBA, in the Annex XV dossier, 2010).</p> <p>As regards the sectors of 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 used as intermediate or not, i.e. whether the nature of these uses meets the definition in Article 3(15).</p> <p>Uses of disodium tetraborate include (according to information from the Registrations, the European Borates Association (EBA) and the RCOM 2010):</p> <p><i>(Tonnage information provided by EBA, relating to 2008 and expressed here as anhydrous tonnage equivalent. References: Annex XV dossier, 2010; personal communication with EBA)</i></p> <ul style="list-style-type: none"> - 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 	<p>In conclusion, the uses of the substance can be considered wide dispersive.</p> <p>Based on the criteria, the substance has high priority.</p>	<p>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.</p> <p>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. 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.</p> <p>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,</p>

Substance	Inherent properties	Volumes	Conclusion on		Final conclusion, taking regulatory effectiveness considerations into account
			Wide dispersiveness of uses	Priority	
			<p>steel slag stabilisation,)</p> <ul style="list-style-type: none"> - 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, leather tanning, photographic chemicals, photolithography, fireworks, igniters, plasticisers, manufacture of B₂O₃ containing catalysts, in medical devices, in biocides, analytical reagents, pharmaceuticals, etc; Annex XV dossier, 2010, RCOM 2010). <p>The substance seems to be used in mixtures (mainly below the specific 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).</p> <p>At least at a medium number of sites the substance is used 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.</p> <p>As regards workers, there is evidence from the Transitional Dossier (Austria 2008) that a presumably very high number of industrial</p>		<p>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.</p> <p>This new classification in Annex VI took effect on 1 December 2010. Currently the Commission is proposing a restriction for 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.</p> <p>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</p>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			<p>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.</p> <p>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.</p>		<p>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 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.</p> <p>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.</p>
Disodium tetraborate (SCA)	Score: 0	Very high volume used in the scope of authorisation. Score: 9	<p>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.</p> <p>Overall score: 9</p>	Total score: 18	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	
Tetraboron disodium heptaoxide, hydrate (VAA)	Art. 57 (c) Toxic for reproduction 1B	No registrations submitted for this substance.	No registration, it can be concluded that the substance is not used in significant amounts in the EU. In principle the substance could be used for the same applications than disodium tetraborate (overlapping in substance identity).	No registration for the substance submitted. Therefore very low priority.	No registration for the substance has been submitted. Therefore, based on the prioritisation 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. <i>For the overall conclusions on the priority of the boron compounds for inclusion in Annex XIV please refer to Disodium tetraborate.</i>
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, such as in biocides,	As regards the sectors of 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	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.

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
		<p>cosmetics, and pharmaceuticals.</p> <p>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.</p> <p>Uses in the scope of authorisation mainly include formulation of mixtures (in most mixtures in concentrations below the specific concentration limit for classification; SCL), repackaging, incorporation into some articles (mainly as flame retardants), uses in metallurgy and other applications.</p>	<p>(Tonnage information provided by EBA is relating to 2008. References: Annex XV dossier, 2010; personal communication with EBA)</p> <ul style="list-style-type: none"> - 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) - biocides (~5,000 t) - ceramic pigments (~1,500 t) - production of plasterboards and wallboards (~2,500 t) 	<p>substance has high priority.</p>	<p>For the overall conclusions on the priority of the boron compounds for inclusion in Annex XIV please refer to Disodium tetraborate.</p>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			<p>- and other applications (~4,000 t, including cosmetics ~700t - , pharmaceuticals – ~500t - as well as production of paints and inks, cement, photolithography, manufacture of B₂O₃ containing catalysts, in medical devices, analytical reagents, etc.).</p> <p>Very similar to disodium tetraborate, boric acid seems to be used at a high number of sites in many different industrial sectors.</p> <p>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.</p> <p>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.</p>		
Boric acid	Score: 0	Supplied in very high amounts to uses in the scope of authorisation: Score: 9	<p>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.</p>	Total score: 18	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	
2-Methoxyethanol (VAA)I	Art. 57 (c) Toxic for Reproduction 1B	<p>According to registration information 2-methoxyethanol is used in Europe in the range of 1000 – 10000 t/y.</p> <p>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.</p>	<p>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)).</p> <p>Main uses in the scope of authorisation 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.</p> <p>Other uses described earlier, such as solvent in paints, varnishes, colours, glues and adhesives, by which the substance may lead to uncontrolled exposure of workers or consumers, are not among the identified uses in the registrations.</p> <p>Based on the available information on the uses of the substance the potential for any significant exposure of workers in industrial settings appears to be low and potential for exposure of professionals and consumers seems to be non existent.</p>	<p>2-methoxyethanol is supplied in a high volume to uses in the scope of authorisation.</p> <p>However, on the basis of the information available, it appears that these uses take place in few industry sectors and a limited number of industrial settings in closed systems.</p> <p>It further appears that the substance does not end up in products available to consumers or professionals.</p> <p>In conclusion: the substance is used in high volumes, but it appears that releases and exposures are controlled.</p> <p>On the basis of the criteria, the substance has moderate priority.</p>	<p>Based on the criteria, 2-methoxyethanol has moderate priority for inclusion in Annex XIV.</p> <p>Therefore, it is proposed to not recommend 2-methoxyethanol for inclusion in Annex XIV.</p>
2-Methoxyethanol	Score: 0	Based on the information available a high volume is	The substance may be used at a medium number of sites: Score: 2		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	
(SCA)I		allocated to uses in the scope of authorisation. High volume. Score: 7	The substance is used in few industrial sectors and a limited number of industrial settings. Exposure of workers appears to be controlled and exposure of professionals and consumers not probable. Score: 1 Overall score: 2	Total score: 9	argumentative approach.
2-Ethoxyethanol	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.	<p>According to registration information, nearly the complete volume supplied in the EU is used for the manufacture of other substances.</p> <p>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).</p> <p>Uses as laboratory agent do presumably fall under the exemption of uses of substances for scientific research and development from authorisation (Art. 56.3).</p> <p>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 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.</p>	<p>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.</p> <p>Based on the criteria, the substance has very low priority.</p>	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.
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	Total score: 2	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		
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 >500000 t/y. Most of this tonnage is allocated to uses in the scope of authorisation.	<p>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.</p> <p>Technical functions of the substance are according to information included in the Annex XV dossier as binding agent in 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.</p> <p>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.</p> <p>The use-information provided in the</p>	<p>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.</p> <p>On the basis of the prioritisation criteria, the substance has very high priority.</p>	<p>On the basis of the prioritisation criteria, pitch, coal tar, high temperature (CTPHT) gets very high priority for inclusion in Annex XIV.</p> <p>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 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.</p> <p>Furthermore, it is noted that it would</p>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			<p>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).</p> <p>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.</p>		<p>be useful to consider these PAH emissions from the metal industry and their reduction objectives in conjunction with more general objectives for reduction of PAH emissions from industry, incineration processes and other emission sources.</p> <p>Therefore, it is proposed to not prioritise pitch, coal tar, high temperature (CTPHT) now for inclusion in Annex XIV.</p>
Pitch, coal tar, high temperature (CTPHT) (SCA)	Score: 4	Very high volume in the scope of authorisation. Score: 9	<p>Many uses with emissions occurring at a high number of sites. Score: 3.</p> <p>Releases are diffuse and might result in significant exposure of workers and the environment. Score: 3.</p> <p>Overall score: 9</p>	Total score: 22	The same considerations apply as brought forward under the verbal-argumentative approach.
Anthracene oil (VAA)	Carcinogen 1B; PBT and vPvB	<p>Full registrations and registrations as transported isolated intermediate are available, tonnage band > 1000 t/a.</p> <p>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).</p> <p>A complete overview on volumes</p>	<p>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</p>	<p>Anthracene oil is supplied in very high volumes to uses in the scope of authorisation.</p> <p>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</p>	<p>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</p>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
		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 (> 10000t/y).	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 exposure at the workplace.	excluded. On the basis of the criteria, the substance has very high priority.	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 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.	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

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			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).		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 oil, anthracene paste (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-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).

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
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 paste, anthracene fraction (VAA)	Carcinogen 1B; Mutagen 1B; 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 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,	Score: 4	No substance supplied to uses in	No uses in the scope of authorisation. Score:	Total score: 4	The same considerations apply as

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
anthracene paste, distn. lights (SCA)		the scope of authorisation. Score: 0	0		brought forward under the verbal-argumentative approach.
Anthracene (VAA)	PBT	<p>Only registrations as isolated transported intermediate. Tonnage band >1000t/y, no further information on volumes provided in the registrations.</p> <p>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.</p>	<p>The only use identified in the registrations is as intermediate for synthesis of other substances.</p> <p>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.</p> <p>In the registrations no indication could be found that the substance is still used, as reported 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).</p> <p>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</p>	<p>Anthracene is a PBT substance, however without identified uses in the scope of authorisation in the registrations.</p> <p>Based on the criteria, the substance has a very low priority.</p>	<p>Based on the prioritisation criteria, anthracene gets very low priority for inclusion in Annex XIV.</p> <p>Therefore, it is proposed to not prioritise anthracene for inclusion in Annex XIV.</p>

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			considered insignificant.		
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 production of semi-conductors, solar cells and other electronic devices, the triethyl arsenate can be	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.

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
			<p>considered as an intermediate, because the outcome of this doping process, doped silicon ingots, is a new substance of its own, which is not regarded the same as the silicon substance fed into that process.</p> <p>All doping processes are performed in closed chambers where the electronic components or the silicon material is put in contact with the substance in vapour form inside the process chamber. By-products of the reaction and non reacted chemicals are discharged from the chamber via vacuum pumps connected to abatement devices (thermal or wet scrubber). Therefore, exposure of workers to the substance or releases to the environment can be considered insignificant. The uses of triethyl arsenate are not considered as wide-dispersive.</p>		
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 arsenate (VAA)	Carcinogen 1A; Toxic for reproduction 1A	No registration for this substance submitted. 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).	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 criteria.	On the basis of the prioritisation criteria lead hydrogen arsenate gets very low priority for inclusion in Annex XIV. Therefore, it is suggested to not prioritise lead hydrogen arsenate for inclusion in Annex XIV.

Substance	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
	Inherent properties	Volumes	Wide dispersiveness of uses	Priority	
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 15 December 2010)

Light grey background highlights substances already prioritised and included in previous Recommendations, which therefore were not considered anymore in the current prioritisation exercise.

Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
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-Methoxyethanol	203-713-7	109-86-4	15.12.2010	Toxic for reproduction (article 57c)	ED/95/2010
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
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 <i>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, or Al₂O₃: 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).</i>	-	Extracted from Index no. 650-017-00-8	13.01.2010	Carcinogenic (article 57a)	ED/68/2009
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

Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
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, 57d and 57e)	ED/68/2009
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
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(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
Chromic acid, Oligomers of chromic acid and dichromic acid, Dichromic acid	231-801-5 - 236-881-5	7738-94-5 - 13530-68-2	15.12.2010	Carcinogenic (article 57a)	ED/95/2010
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 reproduction (articles 57 a and 57 c)	ED/95/2010
Cobalt(II) dinitrate	233-402-1	10141-05-6	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) 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
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
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
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
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 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 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
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	ED/30/2010

Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
				(articles 57 a and 57 b).	
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
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
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
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 <i>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, and SiO₂: 47.5 – 50 % w/w, and ZrO₂: 15 - 17 % w/w, b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm).</i>	-	Extracted from Index no. 650-017-00-8	13.01.2010	Carcinogenic (article 57a)	ED/68/2009

- [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).]