24 June 2013
Revised 5 July 2013 with regard to decaBDE

Draft results of the 5th prioritisation of the SVHCs on the Candidate List with the objective to recommend priority substances for inclusion in Annex XIV

The prioritisation results presented in this report have been obtained by applying ECHA's updated prioritisation approach as described in the document *"General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation"*, version 28 May 2010[1].

In Table 1 below ECHA's conclusions are provided with regard to the priority of the substances for inclusion in Annex XIV. Basis for the prioritisation presented in this report was the Candidate List as updated on 19 December 2012. The substances to be assessed were chosen based on registration status and available information in Part II of the Annex XV reports (see below).

Choice of substances to be assessed regarding their priority

67 substances were added to the Candidate List in 2012. For 37 of these[2] the European Commission had requested ECHA to submit Annex XV SVHC dossiers at very short notice. Therefore, no Part II of the Annex XV reports (containing information on use, exposure, alternatives and risks) were developed and therefore it was decided to not assess their priority now.

Of the 30 substances left, there are 12 substances for which no full registrations are available[3]. Therefore, they were regarded as low priority and they were not further assessed now. One additional substance (4-tert octylphenol ethoxylates) has no registrations itself. However, as the registrations of the reactant (4-tert octylphenol) in the manufacture of 4-tert octylphenol ethoxylates provide information on the ethoxylates, the priority of the latter could be assessed.

In addition, the consolidated Candidate List entries for aluminosilicate refractory ceramic fibres (Al-RCF) and zirconia aluminosilicate refractory ceramic fibres (Zr-RCF) were also considered in the current prioritisation exercise.

Substances already assessed for priority in the context of the 4th recommendation but not prioritised for inclusion in Annex XIV in 2012 or before were not re-assessed during the current prioritisation exercise[4]. However, these substances, as well as the newly identified substances in Annexes I and II, will be considered in the following recommendations.

In total, 20 substances were assessed regarding their priority for inclusion in Annex XIV.

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

2 See Annex I to this report for a list of these 37 substances.

3 See Annex II to this report for a list of these 12 substances.

4 See Annex III to this report for a table of previously assessed substances which had not been recommended for inclusion in Annex XIV and which have not been re-assessed for this report.

Number of substances to be recommended

Article 58(3) requires that priority shall normally be given to substances with PBT or vPvB properties, or wide dispersive use, or high volumes. It further states that "the number of substances included in Annex XIV ... shall also take account of the Agency's capacity to handle applications in the time provided for."

In this context, latest application dates (LADs) from previous recommendations need to be considered. In particular, applications for the chromium (VI) compounds are anticipated to be submitted in significant numbers. The LADs for these compounds are in March 2016.

It is suggested to follow the agreed approach for setting LADs for the substances in this 5th recommendation. Assuming that it will take a similar period of time from ECHA sending the recommendation to the European Commission to the Commission's final decision about inclusion of recommended substances into Annex XIV, the LADs of the 5th recommendation are envisaged between August 2016 and February 2017.

To be able to handle the expected applications for the chromium (VI) compounds as well as potential applications resulting from the 5th recommendation, it was decided to recommend only a limited number of substances.

In line with the decision to recommend only a limited number of substances in this recommendation, regulatory effectiveness considerations were not taken into account this time. In other words, substances having not the highest priority were not prioritised based on their potential to be used as replacement for already recommended substances.

Prioritisation results

The prioritisation results presented in this report have been obtained by applying ECHA's updated prioritisation approach as described in the document *"General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation"*, version 28 May 2010[1].

As in previous recommendations[5]

- the verbal-argumentative approach *(VAA)* and
- the scoring approach *(SCA)*

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 Table 1 along with the conclusions as to whether the substances should be prioritised for inclusion in Annex XIV. The terms used to describe number of sites, potential for releases, and volumes are described in the General Approach document[1] and should be interpreted only in this context.

The information used for priority setting amongst the Candidate List substances is 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 information received during public consultation on the SVHC identification in accordance with Article 59 of the REACH Regulation has also been taken into account, where relevant.

5 Except for the first Annex XIV recommendation from 1 June 2009.

Based on the information available and the justifications provided in Table 1, ECHA proposes to prioritise the following substances for its 5th recommendation of priority substances for inclusion in Annex XIV (list of substances subject to authorisation):

Substance name	EC
N,N-dimethylformamide (DMF)	200-679-5
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues] (4-tert-Octylphenol ethoxylates) (4-tert-OPnEO)	-
~~Bis(pentabromophenyl) ether (decaBDE)~~	~~214-604-9~~
Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA)	204-650-8
Aluminosilicate Refractory Ceramic Fibres (Al-RCF)	-
Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF)	-

The Candidate List of 19 December 2012, including an indication which of the listed substances have been assessed/not assessed in the current prioritisation exercise, is provided in Annex IV. Also highlighted are substances previously assessed and recommended/not recommended.

Table 1: Prioritisation of the substances assessed as described above

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. The description of the prioritisation approach, including how the wide-dispersiveness of uses has been assessed and how scores on inherent properties (0-4), volumes (0-9) and wide-dispersiveness of uses (0-9) has been derived, is presented in the general approach document available at: http://echa.europa.eu/documents/10162/17232/axiv_prioritysetting_general_approach_20100701_en.pdf*.*

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
N,N-dimethylformamide **(DMF)** *(VAA)*	Art. 57 (c); Toxic to reproduction category 1B	The amount of DMF manufactured and/or imported into the EU is according to registration data in the range of 10,000 – 100,000 t/y. No information on exports is provided. Most of the amount in the EU seems to be used in applications in the scope of authorisation, except limited uses such as intermediate in synthesis and uses in scientific research and development.	According to registration information complemented by information from industry consultations performed in 2011 (Annex XV dossier) and 2012 (public consultation on identification as SVHC), the substance is used mainly as solvent in synthesis of chemicals (e.g. pharmaceuticals, crop protection ingredients) (~ 50%), as solvent in the production of polyurethane coated textiles such as artificial leather (~25%) and synthetic fibres (~10%), as well as other applications such as in the electronic industry, in formulation of mixtures, as gas stabiliser in acetylene cylinders, as cleaning solvent, as intermediate, in laboratories etc. Types of mixtures mentioned in the Annex XV report (here only considered information from 2010 onwards) and in the RCOM (2012) include paints, coatings, adhesives, mastics, sealants, binding agents and finishes and compounds. Use of DMF at industrial sites in solvent-based corrosion inhibitor product(s) has been confirmed in recent registration dossier(s) (ECHA, 2013). Furthermore, the substance may be used by aerospace industry (at least in	The substance is used in very high volume in the scope of authorisation and at very many industrial sites. Significant releases at workplaces may occur, in particular during transfer, mixing, charging and industrial cleaning operations. On the basis of the criteria, the substance has high priority.	On the basis of the prioritisation criteria, N,N-dimethylformamide (DMF) gets high priority. **Therefore, it is proposed to recommend N,N-dimethylformamide (DMF) for inclusion in Annex XIV**.

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
			the USA; in EU not confirmed) in strippers and in epoxy inks (RCOM, 2012). Use of such mixtures is of potential relevance for industrial workers and possibly for professional workers. However, no use of DMF by professionals has been registered except as laboratory chemical. The substance is used at very many industrial sites. A very high number of users in various market sectors are involved in the supply chain. DMF is a water soluble organic solvent that is readily absorbed via all exposure routes. DMF has a relatively low vapour pressure (0.377kPa at 20°C). In industrial settings, the primary routes of exposure to DMF are skin contact and inhalation. According to the use descriptors provided in the registration dossiers the substance is used in closed systems with no or only occasional opportunity for exposure (PROC 1, PROC 2, PROC 3) but also in systems where potential for significant exposure arises (e.g. PROC 4, PROC 5, PROC 8a). The most significant potential for exposure seems to be associated with transfer, mixing, charging and industrial cleaning operations (ECHA, 2013; RCOM, 2012). DMF is not supposed to be a component of the final articles resulting from processes where it is used as solvent		

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
			(e.g. artificial leather articles), although some residues may remain. According to the available information from public consultation there is some evidence that in the majority of cases the concentration of DMF in articles produced within EU is below 0.2%.		
N,N-dimethylformamide **(DMF)** *(SCA)*	Score: 0	Score: 9 Very high tonnage in the scope of authorisation.	Use of substance in the scope of authorisation takes place at a high number of industrial sites. Score: 3 Exposure of industrial workers might be controlled in most instances however, for some of the operations potentially significant exposure cannot be excluded. Score: 3 Overall score: 9	Total score: 18	
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated *[covering well-defined substances and UVCB substances, polymers and homologues]* **(4-tert-octylphenol**	Art 57(f) Equivalent level of concern having probable serious effects to the environment	There appears currently to be no registrations for substances in the group 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO). Information on the uses of 4-tert-OPnEO has been obtained from registrations of 4-(1,1,3,3-tetramethylbutyl)phenol (4-tert-octylphenol; EC 205-426-2) which is used in the	Registration dossiers for 4-tert-octylphenol indicate that its ethoxylates are used in formulation of paints, industrial end-use of paints, consumer and professional end-use of paints and other products, in emulsion polymerisation, and as an intermediate in the production of ether sulphates. It seems that almost 50% of the 4-tert-OPnEO is used as emulsifiers in emulsion polymerisation (Annex XV report). There are industrial, consumer and	These substances are used in high tonnage in products that can be assumed to lead to wide- dispersive emissions to the environment. Therefore, this group of substances has a relatively high to high priority for inclusion in Annex XIV.	On the basis of the prioritisation criteria 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) get a relatively high to high priority for inclusion in Annex XIV. **Therefore, it is proposed to recommend 1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-**

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
ethoxylates; 4-tert-OPnEO) *(VAA)*		manufacture of its ethoxylates. Further information was obtained in the Annex XV report for 4-tert-OPnEO. There are 10,000 - 100,000 t/y of 4-tert-octylphenol registered. Based on the estimated fraction of 4-tert-octylphenol used to manufacture its ethoxylates (registrations, Annex XV report) and the estimated average contribution to the molecular weight of its ethoxylates, the volume of ethoxylates manufactured is assumed to be in the range of 1,000 – 10,000 t/y. Information in the registrations and Annex XV report indicate that some of the 4-tert-OPnEO tonnage is used as intermediate (in the manufacture of ether sulphates) and the substance may have other uses (identified in RCOM (2012)) such as in SRD which are outside the scope of authorisation. Additional volumes of 4-tert-OPnEO might be manufactured by companies	professional end uses of products containing 4-tert-OPnEO. Environmental release categories (ERCs) indicating potential for environmental release are listed in the registrations for these uses. The Annex XV report states that "products for professional and consumer uses (e.g., paints, household care products) are supposed to contain octylphenol ethoxylates in concentrations commonly between 0-10% but also up to 30% in specific products. [....] In conclusion, it can be assumed that products for consumer and professional uses may significantly contribute to the wide dispersive emissions into the environment." As there are no registrations for 4-tert-OPnEO, the information on current uses as outlined above is probably incomplete. In the RCOM (2012) uses of 4-tert-OPnEO identified include use in purification of human blood plasma products, in in-vitro diagnostic devices and in laboratory reagents. There may be further uses of 4-tert-OPnEO as discussed in the Annex XV report, including use as textile and leather auxiliaries, auxiliaries in waste water treatment processes, pore builder/foaming agents for concrete, mould release agent on construction sites and precast concrete production and auxiliaries for cleaning of machinery, constituent (emulsifier) of bitumen/wax emulsions for		**OPnEO) for inclusion in Annex XIV.**

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
		which have registered 4-tert-octylphenol as isolated intermediate under strictly controlled conditions according to REACH Articles 17 and 18. It should also be noted that there is no information available in the Annex XV report on the import/export of 4-tert-OPnEO. Therefore, in conclusion, the volume in the scope of authorisation is estimated to be in the range of 1,000 – 10,000 t/y.	painting/sealing in construction industry, use in metal working fluids, in oil for lubrication or hydraulic devices, in cleaning of metal surfaces and as a component in lubricants, auxiliary in blowing agents for plastics and for retention processes in paper production, use in pesticide formulations and veterinary medicine products.		
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated ***[covering well-defined substances and UVCB substances, polymers and homologues]*** **(4-tert-octylphenol ethoxylates; 4-tert-OPnEO)** *(SCA)*	Score: 0-1	High volume in scope of authorisation. Score: 7	Given that there is industrial, professional and consumer use of products containing 4-tert-OPnEO, the number of sites is assumed to be high. Score: 3 Releases are assumed to be diffuse. Score: 3 Overall score: 9	Total score: 16-17	

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
Bis(pentabromophenyl) ether **(decabromodiphenyl ether; decaBDE)** *(VAA)*	Article 57 (d) PBT; Article 57 (e) vPvB	DecaBDE has not been manufactured in the EU since 1999 (EC (2002) in Annex XV report (2012) and confirmed by registration information). The amount imported into the EU is according to registrations in the lower end of the tonnage range of 10,000-100,000 t/y. The entire amount is allocated to uses in the scope of authorisation. No information on exports is available.	Decabromodiphenyl ether (decaBDE) is used as an additive flame retardant. It is used in applications in the plastics/polymers/composite materials and textile industries (registrations and Annex XV report (2012)). According to registration information, it is also used in adhesives and sealants, and in coating and inks (formulation and application). As an additive flame retardant, it is physically combined with the material being treated rather than chemically bound (as in reactive flame retardants). DecaBDE is a widely used as general purpose flame retardant. Therefore its applications concern many sectors: • in plastics (typically at levels 10-15% and up to 20%): electric/electronic equipment, transportation (e.g. automotive and aviation), construction/ building (e.g. for wires, cables and pipes) etc. (Voluntary Emissions Control Action Programme - VECAP, 2012; confirmed by registration information) • in textiles (at levels 7.5 – 20%): upholstery, window blinds, curtains, mattress textiles (in public buildings in some Member States e.g. prisons), tentage (i.e. military tents, marquees, canvasses) and transport (e.g. interior	The volume of the substance supplied to uses in the scope of authorisation is very high. The uses of the substance are considered to be widespread with a potential for significant releases to the environment. On the basis of the criteria, the substance has very high priority.	On the basis of the prioritisation criteria decaBDE gets very high priority for inclusion in Annex XIV. However, following the proposal by Norway (2 May 2013) to add decaBDE to the Stockholm Convention on Persistent Organic Pollutants (POP), the Commission has requested ECHA to start the preparation of an Annex XV restriction dossier for decaBDE. Therefore, ECHA has decided to refrain from recommending the inclusion of decaBDE in Annex XIV. **Therefore, it is proposed not to recommend Bis(pentabromophenyl) ether (decaBDE) for inclusion in Annex XIV.**

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
			fabrics in cars, rail passenger rolling stock and aircraft); however decaBDE is not used in applications with the potential for prolonged contact with skin (Annex XV report) • in adhesives: aeronautic (civil, defence), and also in the adhesive layer of reflective tapes on various work wear (levels 1-5%; RCOM, 2012) • in coatings / inks: relate to end-uses in electrical/electronic equipment[6], and building/construction (registrations) Emissions of decaBDE to the environment may occur at all its life cycle stages, e.g. uses at industrial/professional sites including probably many SMEs (dust generation from handling bags of decaBDE, particles emission from polymer processing, volatile emissions during compounding and conversion at elevated temperatures, emissions to water as a result of wet processing of textiles), service life of articles (plastics, textiles, work wear etc.), and their disposal. Emissions due to service life and		

[6] Since 1 July 2008, the RoHS Directive restricts the concentration of PBDEs (Polybrominated diphenyl ethers) in polymers used in electrical and electronic equipment (EEE) to a maximum of 0.1%. Electrical and electronic applications that are currently exempt from RoHS include: equipment with military, aerospace and transport applications, large stationary industrial tools, large scale fixed installations and photovoltaic panels for installation by professionals. The RoHS Directive does not apply to textiles.

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
			disposal of articles appear to have the highest contribution to overall emissions (Annex XV report, 2012). Quantitative information on environmental releases during polymer processing and use in textile finishing is available in the annual progress VECAP reports. DecaBDE is identified as an SVHC on the basis of its transformation in the environment to substances which themselves have PBT/vPvB properties. Due to its intrinsic properties, decaBDE is expected to adsorb strongly to organic matter in suspended particles, sewage sludge, sediment and soil. Given its low water solubility (<0.1 µg/l), mobility in soils is also likely to be low. As a consequence, sediments and soils are the primary compartments in which the substance will reside at steady state following release, and these are the most important in terms of the relevance of transformation to PBT/vPvB substances. Monitoring data show that decaBDE is widely dispersed in the environment, and that levels in some European estuarine sediments and soils are in the order of a few milligrams per kilogram (parts per million) on a dry weight basis. It is also found at low concentrations in air and is susceptible to long-range atmospheric transport during dry periods, bound to particulates. Indeed, decaBDE is found		

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
			in remote regions in air, sediment and wildlife. There is no evidence for a decline in emissions from environmental monitoring data despite the industry led VECAP initiative (in place since 2004). As a general purpose flame retardant decaBDE is assumed to be used (and released) at many industrial and professional sites. Annex XV report (and references cited therein) indicate more than 100 sites of compounders/formulators, master batchers, injection moulders and finishers, while coatings and inks as well as articles containing decaBDE are widely used by consumers.		
Bis(pentabromophenyl) ether **(decabromodiphenyl ether; decaBDE)** *(SCA)*	Score: 4	Very high volume allocated to uses in the scope of authorisation. Score: 9	DecaBDE is used at many industrial and professional sites. Furthermore it is used in various consumer uses, therefore high number of sites. Score: 3 DecaBDE is released from occupational sites. Releases are expected from its consumer uses, including service life, and from disposal of articles containing it. Therefore, significant releases of decaBDE to the environment are expected. Score: 3 Overall score: 9	Total score: 22	
Diazene-1,2-dicarboxamid	Article 57(f) ELoC	Diazene-1,2-dicarboxamide (ADCA) has been registered	ADCA is used in industrial settings for the formulation of mixtures and the	The volume of ADCA supplied to uses in the	On the basis of the prioritisation criteria,

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
e **(C,C'-azodi(formamide))** **(ADCA)** *(VAA)*		in volumes in the range of 10,000 - 100,000 t/y. The entire volume of the substance appears to be used in applications in the scope of authorisation.	manufacture of plastic products.. ADCA is used in downstream user sectors such as automotive (sealing, moss and sponge rubber, corrosion protection, artificial leather), construction (cold/hot water pipes, heating pipes, sewage pipes, decking, siding, signal sheets, thermal insulation, vinyl covering), electrical application (cables), shoe soles, sport and leisure products (gymnastic mats, canoes, physiotherapeutic products). The technical function of the substance during formulation is as a foaming (blowing) agent. This blowing action is caused by gases (N_2, CO, CO_2, NH_3) being released during heat induced decomposition of ADCA (process temp. between 190 and 230°C) (HSE, 1998). The pure substance is mixed with additives which adapt the decomposition characteristics of ADCA to the needs of the commercial processors, or which alter the supply form. Although the Annex XV indicated use by professional workers during foaming processes and use by consumers in construction chemicals and air fresheners, many of the registration dossiers have now been updated (April-May 2013), particularly with information on uses. No registration currently identifies the use of the substance by professionals and consumers, while the majority of registration dossiers submitted for ADCA now advise against	scope of authorisation is relatively high. The use of ADCA in the formulation of mixtures and the manufacture of plastic products is considered widespread with a high potential for exposure of workers. Therefore the uses can be considered wide dispersive. On the basis of the prioritisation criteria, ADCA gets high priority for inclusion in Annex XIV.	diazene-1,2-dicarboxamide (ADCA) gets high priority for inclusion in Annex XIV. **Therefore it is proposed to prioritise diazene-1,2-dicarboxamide (ADCA) for inclusion in Annex XIV.**

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
			these uses. Processes categories relevant for the use of ADCA such as calendering operations (PROC 6), industrial spraying (PROC 7) and roller application or brushing (PROC 10) are likely to be associated with the highest potential for inhalation exposure levels in comparison to other processes, due to the nature of these activities (e.g. industrial spraying with potential high fraction of inhalable droplets, etc.). Typical specific industrial processes are powder mixing, co-micronisation, dispersing in liquid carriers, two roll processing, and extrusion. The substance is supplied as powder, low dust powder, liquid (paste) and dust-free solids (granules). In many cases, ADCA is supplied to secondary users, e.g. compounders or formulators. During processing ADCA is decomposed exothermically to a degree of >99.9%. Possible remaining ADCA (as well as its non-gaseous decomposition products) are embedded in the polymer matrix and are typically not available. Risk management measures identified and recommended in the registration dossiers include dust extraction and ventilation and in many cases the use of separate rooms or buildings in order to minimise exposure to the general workforce.		

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
Diazene-1,2-dicarboxamide **(C,C'-azodi(formamide))** **(ADCA)** *(SCA)*	Score: 1	Very high volume in scope of authorisation. Score: 9	Uses of the substance in the scope of authorisation take place at high number of sites. Score: 3 Exposure might be controlled in many instances, however for some of the uses potentially significant exposure of industrial workers cannot be excluded. Score: 3 Overall score: 9	Total score: 19	
Aluminosilicate Refractory Ceramic Fibres ***are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures,***	Art. 57 (a); Carcinogen 1B	According to the current analysis of the registration dossiers received, the annual volume of Aluminosilicate Refractory Ceramic Fibres (Al-RCF) manufactured/ imported in the EU is >10,000 t. This tonnage has to be seen as minimum as there might be more registrations falling under the Candidate List entry. The entire volume is within the scope of authorisation.	The refractory ceramic fibres are used in high temperature industries as insulation which is the only information available from the registration dossiers. According to the Annex XV report, the largest single use of Al-RCF is furnace linings (67 %) and related applications (high temperature insulation: 5 %). Other applications for Al-RCF have been described the Annex XV report, such as in automotive industry, metal treatment and fire protection. Based on information on refractory ceramic fibres (types not further specified) provided in the Annex XV report, occupational exposure may occur during formulation processes, processing, or end-uses, which include: - cutting or machining refractory ceramic fibres (RCF) material after fibre manufacture, - combining or assembling RCF	The volume of Al-RCF supplied to uses in the scope of authorisation is high. The use of Al-RCF for insulation is considered to be widespread. Workers may be exposed during formulation processes, processing, or end-uses. On the basis of the prioritisation criteria, Al-RCF get high priority for inclusion in Annex XIV.	On the basis of the prioritisation criteria, Al-RCF get high priority for inclusion in Annex XIV. **Therefore it is proposed to prioritise Aluminosilicate Refractory Ceramic Fibres (Al-RCF) for inclusion in Annex XIV.**

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
and fulfil the three following conditions: a) oxides of aluminium and silicon are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm) c) alkaline oxide and alkali earth oxide (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight			material with other material, - building or manufacturing at end-user locations industrial furnaces or boilers, refinery or petrochemical plant equipment, kiln, foundry equipment, electric power generators, includes furnace maintenance - removal or after-service of RCF from an industrial furnace. According to the Annex XV report, regular exposure occurs for workers[7] in convertors (850 workers). Sporadically exposure occurs to workers working as installation contractors (1,500 workers) and as end users (21,000 workers). Some registrants provide site numbers in the registration dossiers, others do not. However, based on registration information on the types of uses a high number of sites is anticipated.		

[7] Numbers of workers might have changed as these numbers refer to the year 1999.

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
(Al-RCF) *(VAA)*					
Aluminosilicate Refractory Ceramic Fibres ***are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions: a) oxides of aluminium and silicon are the main components present (in***	Score: 1	Very high volume in the scope of authorisation. Score: 9	Expected to be used at high number of sites in the EU. Score: 3 Potential for significant exposure to workers. Score: 3 Overall score: 9	Total score: 19	

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm) c) alkaline oxide and alkali earth oxide (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight **(Al-RCF)** *(SCA)*					
Zirconia Aluminosilicate Refractory Ceramic Fibres ***are fibres***	Art. 57 (a); Carcinogen 1B	According to the current analysis of the registration dossiers received, the annual volume of Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF)	The refractory ceramic fibres are used in high temperature industries as insulation which is the only information available from the registration dossiers. According to the Annex XV report, the	The volume of Zr-RCF supplied to uses in the scope of authorisation is high. The use of Zr-RCF for insulation is considered	On the basis of the prioritisation criteria, Zr-RCF get high priority for inclusion in Annex XIV. **Therefore it is proposed**

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions: a) oxides of aluminium, silicon and zirconium are the main components present (in the fibres) within variable concentration ranges b) fibres have a		manufactured/ imported in the EU is high (1,000 – 10,000 t/y). This tonnage has to be seen as minimum as there might be more registrations falling under the Candidate List entry. The entire volume is within the scope of authorisation.	largest single use of Zr-RCF is furnace linings (67 %) and related applications (high temperature insulation: 5 %). Other applications for Zr-RCF have been described the Annex XV report, such as in automotive industry, metal treatment and fire protection. Based on information on refractory ceramic fibres (types not further specified) provided in the Annex XV report, occupational exposure may occur during formulation processes, processing, or end-uses, which includes: - cutting or machining refractory ceramic fibres (RCF) material after fibre manufacture, - combining or assembling RCF material with other material, - building or manufacturing at end-user locations industrial furnaces or boilers, refinery or petrochemical plant equipment, kiln, foundry equipment, electric power generators, includes furnace maintenance - removal or after-service of RCF from an industrial furnace. According to the Annex XV report, regular exposure occurs for workers[8] in convertors (850 workers). Sporadically exposure occurs to workers working as installation contractors (1,500 workers) and as end users (21,000 workers).	to be widespread. Workers may be exposed during formulation processes, processing, or end-uses. On the basis of the prioritisation criteria, Zr-RCF get high priority for inclusion in Annex XIV.	**to prioritise Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF) for inclusion in Annex XIV.**

[8] Numbers of workers might have changed as these numbers refer to the year 1999.

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm). c) alkaline oxide and alkali earth oxide (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight **(Zr-RCF)** *(VAA)*			Some registrants provided site numbers in the registration dossiers, others did not. However, based on registration information on the types of uses a high number of sites is anticipated.		
Zirconia Aluminosilicate Refractory Ceramic Fibres ***are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No***	Score: 1	High volume in the scope of authorisation. Score: 7	Expected to be used at high number of sites in the EU. Score: 3 Potential for significant exposure to workers. Score: 3 Overall score: 9	Total score: 17	

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions: a) oxides of aluminium, silicon and zirconium are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres					

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
(µm). c) alkaline oxide and alkali earth oxide (Na2O+K2O+ CaO+MgO+BaO) content less or equal to 18% by weight **(Zr-RCF)** *(SCA)*					
Dibutyltin dichloride **(DBTC)** *(VAA)*	Art. 57 (c); Toxic for reproduction category 1B	DTBC is registered between 1,000-10,000 t/y in the EU, however, most of the volume is used as onsite isolated intermediate. Between 10-100 t/y is supplied to uses within the scope of authorisation.	DBTC is used as additive in the production of rubber tyres. The substance is formulated into a mixture at a small number of sites, with a typical concentration of 45 %. This mixture is used in the production of synthetic rubber tyres to improve the mechanical property of the rubber. According to information in the Annex XV report, the final tyres contain between 0.1 and 1.5 % DBTC. The presence of DBTC at > 0.1% by weight of tin in tyres for supply to and use by the general public is restricted from 1 January 2012 according to entry 20 of Annex XVII to REACH. Based on the Annex XV report, DTBC is only used as additive in the production of off-the-road tyres and tyres produced for export. While the number of sites of formulation	DBTC is used in relatively low volumes for uses in the scope of authorisation. Uses, where significant releases cannot be excluded, take place at a medium number of sites. On the basis of the prioritisation criteria dibutyltin dichloride gets moderate priority for inclusion in Annex XIV.	On the basis of the prioritisation criteria dibutyltin dichloride (DBTC) gets moderate priority for inclusion in Annex XIV. **Therefore, it is proposed <u>not</u> to prioritise dibutyltin dichloride (DBTC) for inclusion in Annex XIV.**

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
			and tyres production is likely to be in the tens, the professional and/or industrial use of the tyres is assumed to take place at a rather high number of sites where vehicles like dump trucks, coal haulers, shovels, bulldozers, cranes etc. (Annex XV report) are used. According to registration information, the use of DBTC as additive in rubber tyres includes processes with likelihood of exposure, such as PROC 4 (use in batch and other process (synthesis) where opportunity for exposure arises), PROC 5 (mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)) or PROC 14 (production of preparations or articles by tableting, compression, extrusion, palletisation). Significant releases cannot be excluded for workers in the production of rubber tyres. According to the exposure scenario provided, inhalation as well as dermal exposure is relevant. On the other hand, for the use of the tyres, given that these are not made available to the public and the expected low frequency of contact with the tyres, the potential for exposure seem to be low.		
Dibutyltin dichloride **(DBTC)** *(SCA)*	Score: 0	A relatively low volume of DBTC is supplied to uses within the scope of authorisation. Score: 3	<u>For production of rubber tyres:</u> The use as additive in rubber tyres is estimated to take place at a medium number of sites: Score: 2 Significant releases cannot be excluded	Total score: 9	

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
			during the use as additive: Score: 3 Overall score: 6 <u>For use of rubber tyres containing DBTC</u>: The professional and/or industrial use of rubber tyres containing DBTC is assumed to take place at a high number of sites. Score: 3 From this use of the substance the potential for exposure seem to be low. Score: 1 Overall score: 3 <u>Conclusion:</u> The relevant score for wide-dispersiveness is the one from the scenario with highest overall score, therefore: Overall score for priority assessment: 6		
Hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthali	Article 57 (f) EloC	The registered volume is in the range 1,000 -10,000 t/y. Part of the volume (exact quantity unknown) is used as monomer / intermediate, with the rest seeming to be in the scope of authorisation.	The substance is used as a curing agent/hardener in epoxy resins, including also potting compounds, and in the manufacture of polyester and plasticizers for thermoplastic polymers. (Registration dossiers and RCOM). Anhydride hardeners are used in impregnation processes for high voltage	The exact volume of the substance supplied to uses in the scope of authorisation is not known. However, based on current information in the registration dossiers, it is expected to be high. The use as a	On the basis of the prioritisation criteria MHHPA gets a relatively high priority for inclusion in Annex XIV. However, given the fact that other substances assessed for this

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
c anhydride [3], Hexahydro-3-methylphthalic anhydride [4] ***[The individual isomers [2], [3] and [4] (including their cis- and trans- stereo isomeric forms) and all possible combinations of the isomers [1] are covered by this entry]*** **(MHHPA)** *(VAA)*			electric machines. Industrial sectors that using the substance in this manner include: electrical (semi-conductors), electronic component and electromechanical industry, aerospace, and defence industries. According to comments provided by the Aerospace and Defence industries during the public consultation on the SVHC dossier, MHHPA is being used as a replacement for CMR 1B and 2 substances (not identified) (RCOM, 2012). After its incorporation in articles, any unreacted substance is embedded in the polymer (<0.4 % (RCOM)). During industrial uses of the substance, worker exposure may occur. According to Annex XV report (2012) the likelihood for exposure to MHPPA is highest during processes (listed in registrations) such as mixing or blending in batch processes for formulation of mixtures and articles where multistage and/or significant contact occurs (PROC 5), transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated or non-dedicated facilities (PROC 8a, 8b), and industrial spraying (PROC 7). Spot exposures occur when mixing or blending in batch processes and the transfer of substances from vessels/containers. Exposure times ranging from 15 minutes daily (or twice a week) to a few hours a day are	curing agent/hardener appears to have a high potential for exposure of workers and may take place at a medium number of sites. On the basis of the prioritisation criteria, MHHPA gets a relatively high priority for inclusion in Annex XIV.	recommendation round have higher priority and taking into account ECHA's capacity to handle the applications for authorisation, in particular for the chromium (VI) compounds related to the previous recommendations, the recommendation of MHHPA is postponed. **Consequently, it is proposed <u>not</u> to recommend Hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4] (MHHPA) for inclusion in Annex XIV.**

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
			related to handling of cyclic anhydrides. No conclusive information on number of sites/ release points is provided in the registration dossiers or other documentation. Only industrial uses have been registered. Industry has stated that for MHHPA 20 companies (mainly in the EU) responded in a survey of representative DUs (RCOM). However, based on one reference in the RCOM, it cannot be totally excluded that some professional use may occur.		
Hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4] ***[The individual isomers [2], [3] and [4] (including their cis- and trans- stereo isomeric forms) and all***	Score: 1	The exact volume of the substance supplied to uses in the scope of authorisation is not known. However, based on current information in the registration dossiers, it is expected to be high. Score: 7	Uses of the substance in the scope of authorisation assumed to take place at a medium number of industrial sites. Score: 2 Exposure of industrial workers might be controlled in most instances however, for some of the processes potentially significant exposure of workers cannot be excluded. Score: 3 Overall score: 6	Total score: 14	

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
possible combinations of the isomers [1] are covered by this entry] **(MHHPA)** *(SCA)*					
Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] ***[The individual cis-[2] and trans-[3] isomer substances and all possible combinations of the cis- and trans-isomers [1] are***	Article 57 (f) EloC	The annual manufacturing and import volume of HHPA is in the lower end of the range of 10,000 - 100,000 t/y. The exact volume of the substance supplied to uses in the scope of authorisation is not known. However, based on current information in the registration dossiers, a tonnage of 1,000 – 10,000 t/y is allocated to uses in the scope of authorisation.	According to information in registration and RCOM (2012), 3-8 % of the total production is used as intermediate in chemicals synthesis processes. 74 % of the total production is used for the manufacturing of resins, and 23 % are used as hardener of epoxy resins. A minor use is as hardener in a Low Density Void Filler in Aerospace and Defence Industries. The uses as hardener are considered to be in the scope of authorisation; there is some unclarity on the function of HHPA in the manufacture of resins (i.e. intermediate/non-intermediate status). According to comments provided by the Aerospace and Defence industries during the public consultation on the SVHC dossier, HHPA is being used as a replacement for CMR 1B and 2 substances (RCOM 2012). Industry also stated that HHPA is used in ink applications and in adhesives (Registration dossiers).	The exact volume of the substance supplied to uses in the scope of authorisation is not known. However, based on current information in the registration dossiers, it is expected to be high. The use as a curing agent/hardener appears to have a high potential for exposure of workers and may take place at a medium number of sites. On the basis of the prioritisation criteria, HHPA gets a relatively high priority for inclusion in Annex XIV.	On the basis of the prioritisation criteria HHPA gets a relatively high priority for inclusion in Annex XIV. However, given the fact that other substances assessed for this recommendation round have higher priority and taking into account ECHA's capacity to handle the applications for authorisation, in particular for the chromium (VI) compounds related to the previous recommendations, the recommendation of HHPA is postponed. **Consequently, it is proposed <u>not</u> to recommend**

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
covered by this entry] **(HHPA)** *(VAA)*			According to Annex XV report (2012) the likelihood for exposure to HPPA is highest during processes such as mixing or blending in batch processes for formulation of mixtures and articles where multistage and/or significant contact occurs (PROC 5) and transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated or non-dedicated facilities (PROC 8a, 8b). Spot exposures occur when mixing or blending in batch processes and the transfer of substances from vessels/containers. Exposure times ranging from 15 minutes daily to a few hours a day is related to handling of cyclic anhydrides. No number of sites / release points is provided in the registration dossiers. Based on the nature of the uses listed, it is estimated that the substance is used at a medium number of sites.		**Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] (HHPA) for inclusion in Annex XIV.**
Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-	Score: 1	High volume in scope of authorisation. Score: 7	Uses of the substance in the scope of authorisation take place at a medium of industrial sites. Score: 2 Exposure of industrial workers might be controlled in most instances however, for some of the processes potentially significant exposure of workers cannot be excluded. Score: 3	Total score: 14	

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
dicarboxylic anhydride [3] ***[The individual cis- [2] and trans- [3] isomer substances and all possible combinations of the cis- and trans-isomers [1] are covered by this entry]*** **(HHPA)** *(SCA)*			Overall score: 6		
4-Nonylphenol, branched and linear ***[substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and***	Art 57(f) Equivalent level of concern having probable serious effects to the environment	The Annex XV report gives a non-exhaustive list of substances which fall under this group entry. Only one of these substances has been registered, 4-nonylphenol branched (EC 284-325-5), for which the tonnage registered is in the range 10,000-100,000 t/y. This tonnage has to be seen as minimum as there might be more registrations falling under the Candidate List entry. Based on available information it appears that 4-	4-nonylphenol branched has mostly intermediate uses, for example in the production of 4-nonylphenol ethoxylates, tris (4-nonylphenyl) phosphite, phenolic oximes, phenol formaldehyde resins, and in the production and end use of polymer preparations and derivatives. In relation to the use in epoxy resins, some of the 4-nonylphenol branched may be used as intermediate in the manufacture of epoxy resins (i.e. further reaction of phenol formaldehyde resins). However, some of it seems to be used as a hardening accelerator of amine based epoxy resins which is	Based on a worst-case scenario substance could be used at high volumes at many sites. However, releases are expected to be low. On the basis of the criteria, the substance has moderate priority.	On the basis of the prioritisation criteria 4-nonylphenol, branched and linear, gets moderate priority for inclusion in Annex XIV. **Therefore it is proposed <u>not</u> to recommend 4-nonylphenol, branched and linear, for inclusion in Annex XIV.**

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
well-defined substances which include any of the individual isomers or a combination thereof] *(VAA)*		nonylphenol branched is mostly used as an intermediate. The amount used in applications in the scope of authorisation (part of the use in adhesives plus a minor use in speciality paints) is assumed to be up to the range of 1,000 – 10,000.	considered to be a non-intermediate use. The use of 4-nonylphenol as an accelerator may occur when amine based epoxy resins are used in adhesives. Adhesives (as a whole) have industrial, professional and consumer uses and therefore are likely to be used at a high number of sites. The 4-nonylphenol branched is effectively bound up in the epoxy resins once formed and, according to the CSR, residual concentrations of non-reacted 4-nonylphenol branched are considered to be very low in cured resin products. Therefore, releases to the environment from these uses are likely to be very low. There are some indications that 4-nonylphenol branched may be used directly in some speciality paints but that, if this is the case (not clear from registration information, as that use may rather refer to the ethoxylates), any quantities used are probably negligible.		
4-Nonylphenol, branched and linear *[substances with a linear and/or branched*	Score: 0-1	Using a worst case assumption that all of the tonnage used in adhesives is non-intermediate, the volume used in the scope of authorisation would be high. It should be noted that this is likely to be an over-estimate.	Using as worst case assumption that all of the tonnage of adhesives are produced through non-intermediate uses of 4-nonylphenol branched, and based on the fact that adhesives (as a whole) have industrial, professional and consumer uses, it is estimated that uses of the substance in the scope of	Total score: 10-11	

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof] *(SCA)*		Score: 7	authorisation are likely to occur at a high number of sites. Score: 3 Given that 4-nonylphenol branched is effectively bound up in the epoxy resins once formed and residual concentrations of non-reacted 4-nonylphenol are considered to be very low in cured resin products, releases of the substances to the environment from these uses are likely to be a very low. Score: 1 Overall score: 3		
Diisopentylphthalate **(DIPP)** *(VAA)*	Art. 57 (c); Toxic to reproduction category 1B	DIPP has been registered for a total tonnage at the lower end of the band of 10-100 t/y. All of the tonnage is allocated to uses in the scope of authorisation.	DIPP has been registered for the following uses: (i) use at industrial sites in the production of propellants and to coat them to regulate the rate of burn (ii) use by consumers to coat the propellant and regulate rate of burn. Both uses are reported with a subsequent service-life which is not further detailed. According to Annex XV dossier, DIPP - in addition to being used at industrial sites and by consumers (e.g. sport shooters and hunters) - is further used by professional users (e.g. policemen, military).	The volume of DIPP supplied to uses in the scope of authorisation is relatively low. The use of DIPP in propellants or to coat them is considered to be widespread. Exposure of industrial workers may occur, however the conditions of use seem to indicate such exposure potential as being low. If direct professional use of propellants takes place,	On the basis of the prioritisation criteria, diisopentylphthalate (DIPP) has a low to moderate priority for inclusion in Annex XIV. **Therefore it is proposed to <u>not</u> prioritise diisopentylphthalate (DIPP) for inclusion in Annex XIV.**

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
			It can be assumed that the supply chain of DIPP within EU consists of a low number of industrial users (the producers of propellants and the producers of ammunition containing propellants) and potentially a high number of professional users. It is noted that DIPP might potentially be used as plasticiser for PVC products and other polymers due to similar structure and physical-chemical properties as other low molecular weight phthalates of carbon backbone lengths of C4-C6, e.g., DBP and DIBP (Annex XV dossier). However there is currently no registration for that use. According to the Annex XV dossier, exposure to DIPP may mainly occur through dermal contact. A good skin penetration potential can be expected similar to the structurally-related DIBP. Due to its low volatility (0.025 Pa at 25°C) inhalation exposure will only be relevant when heating the substance to high temperature or when aerosols are formed. Industrial uses include transfer operations and processing of the substance in closed systems with occasional controlled exposure. With regard to professional users, exposure may occur during handling of propellant and upon use of ammunition (dust from unburned propellant residues). The quantity of residues is	potentially significant exposure cannot be excluded. On the basis of the criteria, diisopentylphthalate has low to moderate priority.	

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
			expected to be very low (Annex XV dossier).		
Diisopentylphthalate **(DIPP)** *(SCA)*	Score: 0	Relatively low volume in the scope of authorisation Score: 3	The substance is used in the production of propellants and their coating, and in the production of ammunition at a small number of industrial sites. Propellants containing DIPP may be used by professional users at a potentially high number of sites. Score: 3 The potential for exposure of industrial workers seems to be low. To the extent professional use occurs, potentially significant exposure of professionals cannot be excluded. Score: 1-3 Overall score: 3-9	Total score: 6-12	
1,3,5-Tris(oxiran-2-ylmethyl)-1,3,5-triazinane-2,4,6-trione **(TGIC)** *(VAA)*	Art. 57 (b); Mutagenic 1B	According to the information provided, the manufactured and imported tonnage is in the range of 100 – 1,000 t/y. Part of the tonnage is used as an intermediate in the production of pharmaceuticals. A volume of 100 – 1,000 t/y is allocated to uses in the scope of authorisation.	According to the registration dossier TGIC is mainly used as a curing agent in polyester powder coatings for metal finishing (industrial use), such as steel garden furniture, car parts, metal fencing, window and door frames. A minor use of TGIC is as curing agent in solder mask inks and in applications such as semiconductor moulding resins, production of computers, electronic and optical products, electronical equipment (e.g. semi-conductors) (industrial and professional use). TGIC is manufactured outside EU (mainly Switzerland). Exposure can occur during formulation and application	The volume of TGIC supplied to uses in the scope of authorisation is relatively high. The use of TGIC as a curing agent is considered to take place at a medium to high number of sites. Potential significant exposure of workers cannot be excluded. On the basis of the prioritisation criteria, TGIC gets moderate to relatively high priority	On the basis of the prioritisation criteria, TGIC gets moderate to relatively high priority for inclusion in Annex XIV. However, given the fact that other substances assessed for this recommendation round have higher priority and taking into account ECHA's capacity to handle the applications for authorisation, in particular for the chromium (VI) compounds related to the

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
			processes. In the final product, TGIC is tightly bound within the polymer. Thus, consumer exposure seems to be negligible. There is a potential for occupational exposure during various batch processes (PROC 4), mixing or blending (PROC 5), transfer of substance or preparation from/to non-dedicated facilities (PROC 8a), roller application or brushing (PROC 10), treatment of articles by dipping and pouring (PROC 13) high (mechanical) energy work-up of substance bound in materials and/or articles (PROC 24). The number of sites is not known. Based on the substance's application range in metal finishing and electronic and electronical industry, a medium to high number of sites is anticipated.	for inclusion in Annex XIV.	previous recommendations, the recommendation of TGIC is postponed. **Consequently, it is proposed <u>not</u> to recommend 1,3,5-Tris(oxiran-2-ylmethyl)-1,3,5-triazinane-2,4,6-trione (TGIC) for inclusion in Annex XIV.**
1,3,5-Tris(oxiran-2-ylmethyl)-1,3,5-triazinane-2,4,6-trione **(TGIC)** *(SCA)*	Score 1	Relatively high volume in scope of authorisation. Score: 5	Use is assumed to take place at a medium to high number of sites. Score: 2-3 Occupational exposure might be controlled in most instances however, for some of the operations potentially significant worker exposure cannot be excluded. Score: 3	Total score: 12-15	

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
			Overall score: 6-9		
1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione **(beta-TGIC; β-TGIC)** *(VAA)*	Art. 57 (b); Mutagenic 1B	The substance had been notified under Directive 67/548/EEC (NONS). There is only one registration (update of notification). The overall volume reported in the notifications is at a low to relatively low volume range. The use of the complete volume seems to be in the scope of authorisation.	According to registration information, beta-TGIC has only one single industrial use: as curing agent in industrial applications of solder resist inks. According to the registrant, the inks are imported, i.e. the substance is not used in the EU in the production of solder resist inks. The number of sites (in the scope of authorisation) using these inks is not known. Based on the substance's application range a small number of sites are anticipated. There is a potential for occupational exposure during process steps such as roller application or brushing (PROC 10) and treatment of articles by dipping and pouring (PROC 13). According to the registration dossier the substance is used in most cases under clean room conditions (presumably as electronic product requirement). Under these conditions the exposure to workers is expected to be low. After the curing stage beta-TGIC is fully bound and not active anymore.	The volume of beta-TGIC supplied to uses in the scope of authorisation is low to relatively low. Its use is considered to take place at small number of sites. Exposure to workers is expected to be low. On the basis of the prioritisation criteria, beta-TGIC gets very low to low priority for inclusion in Annex XIV.	On the basis of the prioritisation criteria, beta-TGIC gets very low to low priority for inclusion in Annex XIV. **Therefore, it is proposed to <u>not</u> recommend 1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione (beta-TGIC) for inclusion in Annex XIV.**
1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-	Score: 1	Low to relatively low volume in scope of authorisation. Score: 1-3	Uses of the substance in the scope of authorisation are assumed to take place at a small number of industrial sites. Score: 1	Total Score: 3-5	

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
2,4,6-(1H,3H,5H)-trione **(beta-TGIC; β-TGIC)** *(SCA)*			Releases and exposure to industrial workers are expected to be low. Score: 1 Overall score: 1		
Diboron trioxide *(VAA)*	Art. 57(c) Toxic for reproduction	The registered volume is in the range of 100 to 1,000 t/y. The amount of the substance allocated to uses in the scope of authorisation is in the same range. Uses outside the scope of authorisation include uses in manufacture of other substances and uses of mixtures below the specific concentration limit for classification (SCL, 3.1%), as well as uses in SRD. As regards the sectors of glass and frits, 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).	According to registrations, uses of diboron trioxide concern the following sectors / applications (some overlapping is possible): - Frits and (borosilicate and crystal) glass (industrial use) - Refractories (formulation and industrial use) - Non oxide ceramic powders - Metallurgy (formulation and industrial/professional use) - Coatings / Inks / Paints (fire resistant additive for paints and electronics, Annex XV report) (formulation and industrial / professional / consumer use) - Abrasives (formulation and industrial / professional / consumer use) - Fluxes for metal smelting - Flux mixtures and pastes for welding, brazing or soldering rods (suitable for alloys and/or ceramic glazings, RCOM) (formulation and industrial / professional use) - Industrial fluids (formulation and industrial / professional / consumer use) - Adhesives (formulation and industrial / professional / consumer use)	Diboron trioxide is used in relatively high volumes in the scope of authorisation. Furthermore, its uses can be considered wide dispersive. Based on the criteria, the substance has relatively high priority.	Diboron trioxide has relatively high priority. However, given the fact that other substances assessed for this recommendation round have higher priority and taking into account ECHA's capacity to handle the applications for authorisation, in particular for the chromium (VI) compounds related to the previous recommendations, the recommendation of diboron trioxide is postponed. **Consequently, it is proposed <u>not</u> to recommend diboron trioxide for inclusion in Annex XIV.**

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
			- Construction materials (formulation and industrial / professional / consumer use) - General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment (potentially includes "boron-diffused emitter for crystalline silicon solar cells", RCOM) - Detergent cleaners (formulation and industrial / professional / consumer use) - Agriculture (formulation and professional use) - Nuclear systems - Production of monocrystalline gallium arsenide wafers (crystal growth) - Manufacture of catalysts, alloys, metal powders, borate polymers - Reagent chemicals / Analytical reagents Further applications (as far as not covered by the above) such as in semiconductors and photochemicals were reported during public consultation (RCOM). Uses in the scope of authorisation appear to comprise in general formulations, uses of some mixtures, incorporation into articles, repackaging, and other applications. Regarding the various mixtures, there is no conclusive information on the concentration of the substance. However, industrial / professional uses of mixtures with concentration ≥ 3.1% (and therefore in the scope of authorisation) appear to occur, for instance of soldering mixtures, flux agents for alloys and/or		

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
			ceramic glazings, or adhesive powders (RCOM). Furthermore, for some mixtures further dilution may be needed prior to end-use. The substance seems to be used at a high number of industrial and professional sites, while some articles containing diboron trioxide are also used by consumers (for instance, article service life is mentioned in registrations among others for uses such as in coatings / inks / paints, adhesives, as flame retardant, in construction materials, in abrasives, etc). Occupational uses involve processes with high potential for exposure, such as hand-mixing with intimate contact and only PPE available during (PROC 19) during use in refractories; mixing or blending in batch processes for formulation of preparations and articles (PROC 5), industrial spraying (PROC 7), treatment of articles by dipping and pouring (PROC 13), processes with minerals/metals at elevated temperature (PROCs 22, 23, 25), high (mechanical) energy work-up of substances bound in materials and/or articles (PROC 24), handling of solid inorganic substances at ambient temperature (PROC 25), as well as activities such as sweeping, discharging, loading/unloading and packing.		
Diboron trioxide	Score: 0	Relatively high volume in scope of authorisation.	Uses in industrial settings and by professionals at a high number of sites. Score: 3.	Total Score: 14	

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
(SCA)		Score: 5	Exposure might be controlled for most uses however, there are processes where potentially significant exposure of workers in industrial settings and of professionals cannot be excluded. Score: 3. Overall score: 9		
1,2-dimethoxyethane; ethylene glycol dimethyl ether **(EGDME)** *(VAA)*	Art. 57 (c); Toxic for reproduction category 1B	The total volume of the substance manufactured/ imported is 100-1,000 t/y and used in processes that are likely to be within the scope of authorisation.	EGDME is used as a polar aprotic solvent in synthesis of fine and bulk chemicals (registration information). A high variety of uses of the substance is described in the Annex XV report, including Grignard-, reduction- and alkylation reactions, reactions involving alkali metals, organo-metallic reactions in general, as well as a specific use as solvent of electrolytes in the production and recycling of Li-batteries. As electrolyte solvent in sealed lithium ion batteries, it is present in a consumer article (Annex XV report, RCOM 2012). The substance is also used in the surface treatment of aluminium and as cleaning solvent within the microelectronics industry. According to information provided in the Annex XV report, it is known that one German producer distributes EGDME as processing aid to more than 100 sites. This can be seen as an illustration of the number of sites using the substance. From the information provided, it seems that EGDME is used at a high number of sites by industrial and professional	EGDME is used in relatively high volume and at a high number of sites where significant releases cannot always be excluded. On the basis of the prioritisation criteria, the substance has relatively high priority.	On the basis of the prioritisation criteria, 1,2-dimethoxyethane (EGDME) gets relatively high priority. However, given the fact that other substances assessed for this recommendation round have higher priority and taking into account ECHA's capacity to handle the applications for authorisation, in particular for the chromium (VI) compounds related to the previous recommendations, the recommendation of EGDME is postponed. **Consequently, it is proposed <u>not</u> to recommend 1,2-dimethoxyethane (EGDME) for inclusion in Annex XIV.**

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
			workers. EGDME is the most volatile (vapour pressure of 6600 Pa at 20 ° C) of the glycol ethers on the Candidate List (also on the list are 1,2-bis(2-methoxy)ethane (TEGDME, triglyme) and Bis(2-methoxyethyl) ether (Diglyme)) and is considered to be very persistent but not bioaccumulative (registration information). Measurements in workplaces, wastewater treatment plants and households (Annex XV report) indicate that releases are likely. An additional potential source of exposure of the general population is believed to be the disposal of lithium batteries containing EGDME (Annex XV report), however battery recycling is mandatory (all industrial batteries and 45 % of portable batteries by September 2016) and closely controlled (RCOM). While for some specific uses (e.g. production of Li-batteries) closed systems are likely to be in place, this cannot always be assumed for SMEs that use EGDME as processing aid in a high variety of processes. Therefore, significant occupational releases cannot be excluded. Taking into account that the substance is very persistent, is used in high amounts, and that releases to the environment are likely, exposure of man via the environment cannot be excluded either.		

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
1,2-dimethoxyethane; ethylene glycol dimethyl ether **(EGDME)** *(SCA)*	Score: 0	Relatively high volume used in scope of authorisation is 100 - 1,000 t/y. Score: 5	It seems that EGDME is used at a high number of sites by industrial and professional workers. Score: 3 Significant occupational exposure to and environmental releases of EGDME cannot be excluded. Score: 3 Overall wide dispersiveness score: 9	Total score: 14	
1,2-bis(2-methoxyethoxy)ethane **(TEGDME; triglyme)** *(VAA)*	Art. 57 (c); Toxic for reproduction category 1B	The substance is registered within the tonnage band 10-100 t/y, which is considered to be low. All uses described in the registration (and more in detail in the Annex XV report) are within the scope of authorisation.	A high variety of uses of the substance is described in the Annex XV report, including Grignard-, reduction- and alkylation reactions, reactions involving alkali metals (e.g. alkali metal dispersion for etching of teflon and fluoropolymers), and the use as part of absorbing liquids in the industrial cleaning of gases. This indicates that the substance is likely to be used at a high number of sites. The substance is mainly used in the fine chemicals sector. PROCs for registered uses indicate closed processes, but also use in batch and other processes (synthesis) where opportunity for exposure arises (PROC 4), as well as transfer at non-dedicated facilities (PROC 8a). It is noted that the substance has a very low vapour pressure (2.7 Pa at 20° C), while the dermal absorption, although not insignificant, is expected to be at least lower compared with other glycol ethers	TEGDME is used in relatively low volume at a high number of sites, while releases are likely to be controlled. On the basis of the prioritisation criteria, 1,2-bis(2-methoxy)ethane (TEGDME) gets low priority.	On the basis of the prioritisation criteria, 1,2-bis(2-methoxy)ethane (TEGDME) gets low priority. **Therefore it is proposed <u>not</u> to recommend 1,2-bis(2-methoxy)ethane (TEGDME) for inclusion in Annex XIV.**

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
			(due to the higher molecular weight). Based on the above, it could be assumed that the releases of the substance are likely to be controlled.		
1,2-bis(2-methoxyethoxy)ethane **(TEGDME; triglyme)** *(SCA)*	Score: 0	Relatively low volume in the scope of authorisation. Score: 3	The substance is likely to be used at a high number of sites. Score: 3 It is assumed that the releases of the substance are likely to be controlled. Score: 1 Overall score: 3	Total score: 6	
Formamide *(VAA)*	Art. 57 (c); Toxic for reproduction category 1B	Most of the volume (> 1000 t/y) is registered as transported isolated intermediate mainly for the manufacture of agrochemicals, pharmaceuticals, crop protection products and industrial chemicals. The remaining volume is in the range of 10-100 t/y. The exact part of this volume allocated to uses in the scope of authorisation is unclear. No information on exports is available. Based on current information in the registration dossiers, a volume of 10-100 t/y is	Formamide has been registered mainly as an intermediate (transported isolated) in the manufacture of agrochemicals, pharmaceuticals, crop protection products and industrial chemicals (Registrations & RCOM (2012)). A relatively low amount is used in industrial and professional environments as solvent and reagent for laboratory and analytical applications (Registrations & RCOM (2012)). Of these only uses such as industrial and professional uses as solvent (unless if for analytical/quality purposes, which could fall under the exemption for SRD), and ancillary to laboratory uses (formulation and packaging) seem to fall under the scope of authorisation. Other uses such as	The exact volume of the substance supplied to uses in the scope of authorisation is not known. However, based on current information in the registration dossiers, it is expected to be relatively low. Releases and exposure to industrial workers and professionals might be controlled in most instances, however some of the uses have a potential for significant worker exposure. On the basis of the criteria, the substance	On the basis of the prioritisation criteria formamide gets low to moderate priority for inclusion in Annex XIV. **Therefore, it is proposed to <u>not</u> recommend formamide for inclusion in Annex XIV.**

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
		considered to be used in applications in the scope of authorisation.	laboratory uses and intermediate uses are assumed to fall under generic exemptions from the authorisation requirement. Due to the low vapour pressure of formamide (0.06 hPa at 20°C), the potential for inhalation exposure may be low, with dermal exposure to be the most likely route. There is a potential for occupational exposure in uses in the scope of authorisation during process steps such as mixing / blending (PROC 5), transfer at non-dedicated facilities (PROC 8a), and batch / other (synthesis) where opportunity for exposure arises (PROC 4). The number of sites (in the scope of authorisation) of use is not known. Based on the use pattern of the substance, a small to medium number of sites is assumed.	has low to moderate priority.	
Formamide *(SCA)*	Score: 0	Relatively low volume allocated to uses in the scope of authorisation. Score: 3	Uses of the substance in the scope of authorisation take place presumably at a small to medium number of industrial / professional sites. Score: 1-2 Exposure of industrial workers and professionals might be controlled in most instances however, for some of the operations potentially significant worker exposure cannot be excluded. Score: 3 Overall score: 3-6	Total score: 6-9	

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
Lead(II) bis(methanesulfonate) *(VAA)*	Art. 57(c) Toxic to Reproduction 1A	The substance had been notified under Directive 67/548/EEC (NONS). The overall volume reported in the notifications is at a relatively low to relatively high volume range. According to a registrant (who has updated his NONS notification), the demand has fallen due to the Restriction of Hazardous Substances Directive (RoHS[9]) (RCOM). The complete volume in the EU is in the scope of authorisation.	The substance is used as additive for electroplating solutions mainly in tin-lead plating by electronic industry, apparently in specialty applications related to circuit boards, as well as related to batteries and electronic assemblies (e.g. in automotive and aerospace sectors) (information from registration, Annex XV report, RCOM). There is no concrete information on the number of sites in the EU using the substance. According to a manufacturer (RCOM), due to RoHS Directive, the application range has significantly decreased, in particular regarding consumer electronic components. The substance is reportedly amongst the two main substances used for Lead, Tin/Lead, and Lead / Tin / Copper plating, being particularly preferred at modern electronic devices (the other soluble lead substance is Lead bis(tetrafluoroborate) – also in the Candidate List; it is the main soluble lead substance used for bearing surfaces and used far more than Lead(II) bis(methanesulfonate) (RCOM)). The same manufacturer (representing a supply of 2 t/y) reported that downstream users comprise submarine battery repair shops and the European Space Agency (RCOM).	The substance is used in relatively low to relatively high volume, presumably at a medium number of sites. Potential significant exposure of workers cannot be excluded, however, exposure at highly specialized workplaces may be controlled. On the basis of the prioritisation criteria Lead(II) bis(methanesulfonate) gets low to moderate priority for inclusion in Annex XIV.	On the basis of the prioritisation criteria Lead(II) bis(methanesulfonate) gets low to moderate priority for inclusion in Annex XIV. **Therefore, it is proposed to <u>not</u> recommend Lead(II) bis(methanesulfonate) for inclusion in Annex XIV.**

[9] Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment)

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
			Based on the substance's application range in electronic industry, a medium number of use sites are anticipated. Workers could potentially be exposed to the substance during formulation and plating operations. It however appears that the use takes place at highly specialized workplaces. Consumers' exposure to the substance itself is not expected, as it is transformed to lead / its alloys during plating.		
Lead(II) bis(methanesulfonate) *(SCA)*	Score: 0	Relatively low to relatively high volume allocated to uses in the scope of authorisation. Score: 3-5	No concrete info on number of sites. Based on its apparently limited application range in electronic industry, a medium number of sites are anticipated. Score: 2 Processes indicate a potential for significant exposure to workers. However, exposure in highly specialized workplaces may be controlled. Score: 1-3 Overall score: 2-6	Total score: 5-11	
[4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimet	Art. 57(a) Carcinogen 1B	According to registration information, the total annual volume of C.I. Basic Violet 3 (BV3) with Michler's Ketone (MK) or Michler's Base (MB) ≥0.1% imported/ manufactured in the EU is in	According to registration information, the substance (with MK/MB≥0.1%) is formulated and used in inks (for printing cartridges and for ball pens). According to the Annex XV dossier, it is also used as a laboratory stain, and has	The substance (with MK/MB ≥0.1%) is used in low amounts in the scope of authorisation. These uses occur at a small number of sites. The potential	On the basis of the prioritisation criteria, [4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
hylammonium chloride **(C.I. Basic Violet 3)** ***[with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]*** *(VAA)*		the range of 1-10 t/y. Further industry consultation in the context of the development of the Annex XV Dossier concluded that, taking into account also cases where the concentration of MK was stated as unknown, up to 18 t/y of BV3 used in the EU may contain MK in concentrations of ≥0.1%. The amount of substance supplied in uses in the scope of authorisation is in the same range (uses outside the scope of authorisation comprise use in SRD, and in inks with MK/MB below 0.1%)	potentially some further uses (during the consultation in the context of the development of Annex XV dossier, for about 2 t/y of imported BV3 – and with unknown MK content - the uses were not identified by industry; an indication on what those uses could be might be given by the information on uses of BV3 with MK/MB < 0.1%, e.g. paper colouring, carbon paper, staining of dried plants, marker). Based on information from industry (Annex XV dossier), formulation of ink and ancillary to laboratory uses (e.g. formulation / packaging of stains) occur in a small number of sites in the EU (<10). For about 2 t/y of the imported BV3 (and with unknown MK content), the use/sites have not been specified. Further uses are expected not to be in the scope of authorisation, such as uses of inks containing <0.1% MK/MB (information on the level of MK/MB in BV3, on BV3 concentrations in inks, as well as statements by industry during consultations suggest that the final concentration of MK/MB in inks for cartridges and ball pens is rather <0.1%), and use as biological stain, (e.g. as Gram stain in microbiological laboratories). Occupational exposure can occur via inhalation of powder dust or aerosols / dermal contact during formulation or packaging, e.g. in processes such as weighing / charging, filling, and cleaning. However, as the concentration	occupational exposure seems to be low. On the basis of the criteria the substance has very low priority.	Violet 3) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] gets very low priority for inclusion in Annex XIV. **Therefore, it is proposed to <u>not</u> recommend [4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) *[with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]* for inclusion in Annex XIV.**

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
			of MK/MB in the raw substance is low, it is assumed that the potential for occupational exposure may be low.		
[4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride **(C.I. Basic Violet 3)** ***[with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]*** *(SCA)*	Score: 1	Low volume in the scope of authorisation. Score: 1	Uses in the scope of authorisation occur at a small number of sites in the EU Score: 1 The potential for occupational exposure seems to be low. Score: 1 Overall score: 1	Total score: 3	
4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol ***[with ≥ 0.1% of Michler's ketone (EC No. 202-027-***	Art. 57(a) Carcinogen 1B	One registration has been received for 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol with Michler's Ketone (MK) or Michler's Base (MB) ≥0.1%, in a tonnage band of 10-100t/y. This amount is considered to	The substance (with MK/MB≥0.1%) is formulated to printing inks (no information about the concentration of MK/MB or the dye in those inks), which are used in industrial and professional sites. The use information in the registration dossier comprises solely lists of use descriptors. According to those, industrial use (as "printing ink") is use of processing aids in processes	The substance (with MK/MB ≥0.1%) has been registered at relatively low amounts. Due to the low concentration of MK/MB in the substance, the potential for exposure seems to be low.	The substance gets low priority. **Therefore, it is proposed to <u>not</u> recommend 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol *[with ≥ 0.1% of Michler's ketone (EC***

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
5) or Michler's base (EC No. 202-959-2)] *(VAA)*		be in the scope of authorisation, based on the registered uses (formulation, industrial use, and professional uses of printing inks; uses of inks may be outside the scope of authorisation if the concentration of MK or MB in inks is ≥0.1% in them; however no conclusive information is available).	and products, not becoming part of articles (ERC 4) (although this seems to be contradictory with the function as printing ink). The three identified professional uses (also as "printing ink") comprise use as processing aid in open systems (ERC 8a), indoor (ERC 8c), and outdoor (ERC 8f) use, resulting in inclusion to a matrix, respectively. Some of the listed process categories could indicate a high potential for occupational exposure, such as mixing/blending (PROC 5), "high (mechanical) energy work-up of substances bound in materials and/or articles" (PROC 24), and "other hot work operations with metals" (PROC 25). However, as the concentration of MK/MB in the raw substance (according to registration) and in the inks is low (in the latter if at all above the generic concentration limit of 0.1%), it is assumed that the potential for occupational exposure may be low. There is no conclusive information about the type of printed articles produced, but it could also be assumed that exposure of consumers or workers from use of such articles will be low (very low concentration, inclusion in matrix).	The substance gets low priority.	***No. 202-027-5) or Michler's base (EC No. 202-959-2)]*** **for inclusion in Annex XIV.**
4,4'-bis(dimethylamino)-4''-	Score: 1	Relatively low volume in the scope of authorisation	No information on number of sites is available. The substance is used at industrial sites and also by	Total score: 5-6	

	Conclusion on				Final conclusion
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
(methylamino)trityl alcohol ***[with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]*** *(SCA)*		Score: 3	professionals, but it is not clear whether apart from formulation also uses of inks are in the scope of authorisation (no information on concentration of dye or MK/MB). Score: 1-2 The potential for occupational exposure or exposure from use of articles seems to be low. Score: 1 Overall score: 1-2		

Annex I

Substances included in the Candidate List ***in 2012***, for which the Commission had requested ECHA to submit Annex XV SVHC dossiers on very short notice (***Part II had not been developed in Annex XV reports***).

No	**Name**	CAS	EC
1	6-methoxy-m-toluidine (p-cresidine)	120-71-8	204-419-1
2	Pyrochlore, antimony lead yellow	8012-00-8	232-382-1
3	4-Aminoazobenzene	60-09-3	200-453-6
4	Silicic acid, lead salt	11120-22-2	234-363-3
5	Lead titanium zirconium oxide	12626-81-2	235-727-4
6	Lead monoxide (lead oxide)	1317-36-8	215-267-0
7	o-Toluidine	95-53-4	202-429-0
8	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2	421-150-7
9	Lead bis(tetrafluoroborate)	13814-96-5	237-486-0
10	Lead dinitrate	10099-74-8	233-245-9
11	Silicic acid (H2Si2O5), barium salt (1:1), lead-doped *[with lead (Pb) content above the applicable generic concentration limit for 'toxicity for reproduction' Repr. 1A (CLP) or category 1 (DSD); the substance is a member of the group entry of lead compounds, with index number 082-001-00-6 in Regulation (EC) No 1272/2008]*	68784-75-8	272-271-5
12	Trilead bis(carbonate)dihydroxide	1319-46-6	215-290-6
13	4,4'-methylenedi-o-toluidine	838-88-0	212-658-8
14	Diethyl sulphate	64-67-5	200-589-6
15	Dimethyl sulphate	77-78-1	201-058-1
16	Furan	110-00-9	203-727-3
17	Lead oxide sulfate	12036-76-9	234-853-7
18	Lead titanium trioxide	12060-00-3	235-038-9
19	Dinoseb (6-sec-butyl-2,4-dinitrophenol)	88-85-7	201-861-7
20	N-methylacetamide	79-16-3	201-182-6
21	Tetralead trioxide sulphate	12202-17-4	235-380-9
22	Acetic acid, lead salt, basic	51404-69-4	257-175-3
23	[Phthalato(2-)]dioxotrilead	69011-06-9	273-688-5
24	Tetraethyllead	78-00-2	201-075-4
25	Pentalead tetraoxide sulphate	12065-90-6	235-067-7
26	1-bromopropane (n-propyl bromide)	106-94-5	203-445-0
27	Dioxobis(stearato)trilead	12578-12-0	235-702-8
28	Methyloxirane (Propylene oxide)	200-879-2	75-56-9
29	Trilead dioxide phosphonate	12141-20-7	235-252-2
30	o-aminoazotoluene	97-56-3	202-591-2

31	4-methyl-m-phenylenediamine (toluene-2,4-diamine)	95-80-7	202-453-1
32	Biphenyl-4-ylamine	92-67-1	202-177-1
33	Fatty acids, C16-18, lead salts	91031-62-8	292-966-7
34	Orange lead (lead tetroxide)	1314-41-6	215-235-6
35	4,4'-oxydianiline and its salts	101-80-4	202-977-0
36	Sulfurous acid, lead salt, dibasic	62229-08-7	263-467-1
37	Lead cyanamidate	20837-86-9	244-073-9

Annex II

Substances included in the Candidate List ***in 2012***, but for which ***no full registrations*** have been received and which were not assessed now.

No	Substance Name	CAS	EC
1	Henicosafluoroundecanoic acid	2058-94-8	218-165-4
2	1,2-Diethoxyethane	629-14-1	211-076-1
3	N-pentyl-isopentylphthalate	776297-69-9	-
4	Heptacosafluorotetradecanoic acid	376-06-7	206-803-4
5	Tricosafluorododecanoic acid	307-55-1	206-203-2
6	Pentacosafluorotridecanoic acid	72629-94-8	276-745-2
7	Methoxyacetic acid	625-45-6	210-894-6
8	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0	284-032-2
9	α,α-Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4*) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]*	6786-83-0	229-851-8
10	[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26) *[with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]*	2580-56-5	219-943-6
11	4,4'-bis(dimethylamino)benzophenone (Michler’s ketone)	90-94-8	202-027-5
12	N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler’s base)	101-61-1	202-959-2

Annex III

Substances included in the Candidate List ***before 2012***, which had already been assessed during previous prioritisation exercises, but ***had not been recommended*** for inclusion into Annex XIV.

Conclusion on					Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide-dispersiveness of uses**	**Priority**	
1-Methyl-2-pyrrolidone (NMP) *(VAA)*	Art. 57(c); Toxic for Repr.1B	According to information provided in the registrations NMP is used in the EU in very high volumes, between 10,000 – 50,000 t/y. All uses seem to fall in the scope of authorisation with the exception of the use in plant protection products and some uses in the pharmaceutical industry. Use in plant protection products and in the pharmaceutical industry may account for 30% of the volume used in the EU. Therefore, it can be concluded, that a very high volume (> 10,000 t/y), at least 70 % of the total imported/manufactured volume, is used in the scope of authorisation.	According to information provided in the Annex XV dossier (no use-specific information in the registrations) NMP is used in the following applications: - Coatings (20 %, e.g. in industrial and professional paints and lacquers), - Cleaners (20 %, e.g. industrial and professional cleaners, graffiti removers), - Electronics (20 %, e.g. in production of semiconductor devices, insulation of magnet wires and as photo-resistant stripper to remove resist from wafers and photo masks during semiconductor manufacturing) - Petrochemical processing (10 %, mainly as solvent in extractive distillation of hydrocarbons). - Agrochemicals (15 %, mainly as part of pesticide formulations - in the scope of the PPP Regulation) - Pharmaceutical industry (15 %, e.g. as aprotic solvent in extraction processes, or as penetration enhancer in pharmaceutical products)	The substance is used in very high quantities in the scope of authorisation. The uses can be considered widespread and some uses have a high potential for releases and worker exposure. On the basis of the criteria the substance has high priority.	On the basis of the prioritisation criteria, 1-methyl-2-pyrrolidone gets high priority for inclusion in Annex XIV. However, a dossier in accordance with Annex XV REACH, proposing to impose restrictions on certain uses of 1-methyl-2-pyrrolidone is currently under preparation[10] (expected date of submission: 19/04/2013). Therefore, ECHA suggests to refrain from recommending the inclusion of NMP in Annex XIV now. This is because after the inclusion of the substance in Annex XIV it would not anymore be possible to impose new restrictions on NMP because of risks arising from the SVHC properties for which it had been included in the authorisation list. **Therefore, it is proposed <u>not</u> to prioritise 1-Methyl-2-pyrrolidone for inclusion in Annex XIV now.**

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

			Further minor uses described in the registration dossiers are in functional fluids or in polymer processing. Additional uses have been described in the RCOM (2011), such as processing aid in the production of poly-aromatic polymers or meta-aramid fibres. Several uses of NMP, such as coating (e.g. construction and road paints, parquet lacquers), cleaners (e.g. paint or graffiti remover, cleaning solvent), functional fluids, polymer processing or petrochemical processing are registered for both, industrial and professional users. Information in the Annex XV dossier suggests that concentrations of NMP in paints are typically in the range of 1-10 %, while cleaning products can contain up to 25 % and therefore are above the specific concentration limit of 5 %. Some uses seem to take place mainly under controlled conditions in closed processes or systems, e.g. in the semiconductor industry. However, exposure from those uses still could occur during transfer, cleaning and maintenance activities (Annex XV dossier, registration information). Moreover, as can be inferred from the respective information provided in the registrations, some of the industrial/professional processes in which NMP is used have a high potential for exposure, e.g. roller application or brushing, non-industrial spraying, dipping and pouring or hand-mixing with direct contact and only PPE		

			available. Also other applications of NMP such as in coatings and paint strippers bear high potential for significant exposure of workers. The substance is easily absorbed by the skin (used as penetration enhancer in pharmaceuticals), therefore also this exposure route is likely. NMP is used at a very high number of industrial sites and by many industrial and professional workers. Even though some uses (e.g. in semiconductor industry) seem to take place under controlled conditions with no potential for significant exposure, this cannot be assumed for most other uses, which on the contrary appear to have a potential for significant exposure of workers (e.g. application of coatings and use of paint strippers). According to industry information provided in the Annex XV dossier, several hundreds of industrial companies and thousands of professional users are involved in the supply chains of coatings and cleaners.		
1-Methyl-2-pyrrolidone (NMP) *(SCA)*	Score: 0	Very high volume used in the scope of authorisation. Score: 9	Uses in industrial settings and by professionals at a high number of sites. Score: 3. No significant release potential expected to arise from some uses. However, other applications such as e.g. coatings and paint stripping bear high potential for significant exposure of workers. Score: 3. Overall score: 9	Total score: 18	**The same considerations apply as brought forward under the verbal-argumentative approach.**

4-(1,1,3,3-tetramethyl-butyl)phenol, (4-tert-octyl-phenol) *(VAA)*	Art. 57 (f); Equivalent level of concern having probable serious effects to the environment	Based on information from registration dossiers uses of 4-tert-octylphenol are: • As a monomer for polymer preparations • As an intermediate for manufacture of ethoxylates, which to some extent will be a component of products (e.g. paints) used by industry, professional users and consumers. • As an intermediate for production of ether sulphates. • As a monomer that is chemically reacted with formaldehyde and possibly other reactants to form 4-tert-OP based phenolic resins. These resins are used in the formulation of adhesives, coatings, printing inks etc. which are used by industry, professional users and consumers. The phenolic resins are also used as a tackifier for the manufacture of tyres and rubber products. Therefore all uses appear to be intermediate and therefore outside the scope of authorisation.	There is no information on uses of the substance in the scope of authorisation.	There is no information on uses of this substance in the scope of authorisation. On the basis of the criteria, the substance has very low priority.	On the basis of the prioritisation criteria 4-tert-octylphenol gets very low priority for inclusion in Annex XIV. **Therefore, it is proposed <u>not</u> to prioritise 4-(1,1,3,3-tetramethylbutyl)phenol (4-tert-octylphenol) for inclusion in Annex XIV.**
4-(1,1,3,3-tetramethyl-butyl)phenol,	Score: 0	All uses are intermediate and therefore outside the scope of authorisation.	There is no information on uses of the substance in the scope of authorisation.	Total score: 0	**The same considerations apply as brought forward under the verbal-**

(4-tert-octyl-phenol) *(SCA)*		Score: 0	Overall score wide-dispersiveness of uses: 0		**argumentative approach.**
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich *(VAA)*	Art. 57(c); Toxic for Repr.1B	No registrations submitted for this substance.	There is no information on uses which would be in the scope of authorisation.	There is no information on uses which would be in the scope of authorisation. On the basis of the criteria, the substance has very low priority.	On the basis of the prioritisation criteria 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich gets very low priority for inclusion in Annex XIV. **Therefore, it is proposed <u>not</u> to prioritise 1,2-Benzene-dicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich for inclusion in Annex XIV.**
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich *(SCA)*	Score: 0	No volume registered. Score: 0	Overall score wide-dispersiveness of uses: 0	Total score: 0	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Bis(2-methoxyethyl) phthalate *(VAA)*	Art. 57(c); Toxic for Repr.1B	No registrations submitted for this substance.	There is no information on uses which would be in the scope of authorisation.	There is no information on uses which would be in the scope of authorisation. On the basis of the criteria, the substance has very low priority.	On the basis of the prioritisation criteria Bis(2-methoxyethyl) phthalate gets very low priority for inclusion in Annex XIV. **Therefore, it is proposed <u>not</u> to prioritise Bis(2-methoxyethyl) phthalate for inclusion in Annex XIV.**
Bis(2-methoxyethyl) phthalate *(SCA)*	Score: 0	No volume registered. Score: 0	Overall score wide-dispersiveness of uses: 0	Total score: 0	**The same considerations apply as brought forward under the verbal-argumentative approach.**

1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP) *(VAA)*	Art. 57(c); Toxic for Repr.1B	No registrations submitted for this substance. No known manufacture or import. According to the Annex XV dossier there is one cable producer who reported the use of **100 - 700 t/y** (year not given but likely ~2010). This tonnage seems to come from stock bought in previous years by the cable producer (quantity of that stock not known) as all its suppliers (indicated as three EU based plasticiser producers) responded to consultation that they currently do not manufacture DHNUP. When enquired by ECHA from the dossier submitter, it was not possible to identify the source of the information regarding the existence of such cable producer nor the size of its stock of DHNUP. The assessment is therefore based on registration information.	There is no confirmed information on uses which would be in the scope of authorisation.	No registration for the substance has been submitted and there is no confirmed information on uses which would be in the scope of authorisation. On the basis of the criteria DHNUP has very low priority.	On the basis of the prioritisation criteria, 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP) gets very low priority for inclusion in Annex XIV. **Therefore, it is proposed <u>not</u> to prioritise 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP) for inclusion in Annex XIV.**
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP) *(SCA)*	Score: 0	No volume registered. Score: 0	No confirmed information on uses which would be in the scope of authorisation. Overall score: 0	Total score: 0	**The same considerations apply as brought forward under the verbal-argumentative approach.**
1,2,3-	Art. 57(a) and	According to registration	According to registration information	Although total tonnage	On the basis of the prioritisation

Trichloropro-pane *(VAA)*	(c); Carcinogen 1B Toxic for Repr.1B	information the total EU tonnage (manufactured and used) is estimated to be 10,000 – 50,000 t/y. 90 % use as intermediate in production of chlorinated solvents and agricultural products. 5 % used as monomer in polymer production (polysulfides, hexafluoro-propylene for manufacture of sealing compounds. No TCP present.) 5% incinerated on site No use in articles or preparations. There is no evidence for direct use of 1,2,3-Trichloropropane as solvent as it was done in the past.	the substance is used as intermediate for synthesis of other substances and as monomer. There is no information on uses in the scope of authorisation	used in the EU is very high, there is no information on uses in the scope of authorisation. On the basis of the criteria 1,2,3-TCP has very low priority.	criteria, 1,2,3-Trichloropropane gets very low priority for inclusion in Annex XIV. **Therefore, it is proposed <u>not</u> to prioritise 1,2,3-Trichloropropane for inclusion in Annex XIV.**
1,2,3-Trichloropro-pane *(SCA)*	Score: 1	No volume in the scope of authorisation. Score: 0	There is no information on uses in the scope of authorisation. Overall score: 0	Total score: 1	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Phenolphthalein *(VAA)*	Art. 57(a); Carcinogen 1B	According to registration information a volume of 10 – 100 t/y is imported, however consultation with industry resulted in an imported tonnage of 1-10 t/y. As the consultation (2011) was carried out after the registrations were submitted (2010) and includes all	Consultation suggests that formulations are prepared by < 10 companies. The substance in powdered form is mixed with alcohol and water. Laboratory scale batches (1-10 l) are made by professionals handling small amounts of phenolphthalein at a time (<250 g). The mixtures are made in batch operation (less than once a month) and distributed to a large number of	Low volume in the scope of authorisation and insignificant releases. On the basis of the criteria phenolphthalein has very low priority.	On the basis of the prioritisation criteria, phenolphthalein gets very low priority for inclusion in Annex XIV. **Therefore, it is proposed <u>not</u> to prioritise phenolphthalein for inclusion in Annex XIV.**

		registrants as well as further companies importing/ exporting phenolphthalein, the latter tonnage is considered relevant for prioritisation. There is currently no manufacture in the EU. Minor amounts are exported. Almost the complete tonnage is used in the formulation of mixtures which are used in the laboratory. Further uses are in formulation of pharmaceuticals and in specialist applications, e.g. disappearing inks and laboratory indicator paper, both of these in the kg/y range. The volume used in applications in the scope of authorisation (formulation of mixtures) is 1-10 t/y.	customers (> 1000). The handling of powders (and solutions) presents potential for occupational exposure. Given the small amounts of substance used and the low frequency of use the workplace exposure levels during formulation are likely to be low. The quantity of mixture (typical concentration between 0.5 and 2 %) used on each occasion is extremely small (<0.5 ml). In conclusion, it is assumed that occupational exposure during use of phenolphthalein is controlled and there is no significant risk of exposure of man via the environment.		
Phenolphthalein *(SCA)*	Score: 1	Low volume in scope of authorisation Score: 1	Small number of formulation sites. (Laboratory use sites are assumed to fall under scientific research and development and thus not in the scope of authorisation) Score: 1 Release of substance likely to be controlled. Score: 1 Overall score: 1	Total score: 3	**The same considerations apply as brought forward under the verbal-argumentative approach.**

2-Methoxy-aniline; o-Anisidine *(VAA)*	Art. 57(a); Carcinogen 1B	According to the Annex XV dossier, the total volume manufactured/imported is between 1,000 and 10,000 t/y. However, on the basis of the registrations it is not possible to confirm the quantity because not in all registrations indicate the tonnage covered. Only uses as intermediate are registered, mainly for the manufacture of fine chemicals, such as azo dyes and pigments (registration information and Annex XV dossier). Therefore, no volume in the scope of authorisation.	There is no information on uses of this substance in the scope of authorisation.	There is no information on uses of this substance in the scope of authorisation. On the basis of the criteria, the substance has very low priority.	On the basis of the prioritisation criteria 2-Methoxyaniline gets very low priority for inclusion in Annex XIV. **Therefore, it is proposed <u>not</u> to prioritise 2-Methoxyaniline for inclusion in Annex XIV.**
2-Methoxyani-line; o-Anisidine *(SCA)*	Score: 1	No volume in the scope of authorisation. Score: 0	Overall score wide dispersiveness of uses: 0	Total score: 1	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Hydrazine *(VAA)*	Art. 57(a); Carcinogen 1B	According to the registration information the total volume used in the EU is in the range of 10,000 – 50,000 t/y. A tonnage in the range of 1,000-10,000 t/y is allocated to uses in the scope of authorisation.	Hydrazine is used as hydrazine hydrate (HH) and anhydrous hydrazine (AH). According to the information from registration dossiers, most of the hydrazine supplied to the EU market is used as intermediate for synthesis and as a monomer (e.g. pharmaceuticals, agrochemicals, chemical blowing agents, coatings). These uses are outside the scope of authorisation. The main non-intermediate use of hydrazine hydrate (HH) is as a corrosion inhibitor. Hydrazine hydrate is used in the treatment of water in nuclear and	The volume of hydrazine supplied to uses in the scope of authorisation is high. The use of hydrazine in corrosion inhibition is considered to be widespread. However, potential for worker exposure and release to the environment appear to be low and controlled across all uses. On the basis of the criteria, hydrazine has moderate priority.	On the basis of the prioritisation criteria hydrazine gets moderate priority for inclusion in Annex XIV. **Therefore, it is proposed <u>not</u> to prioritise hydrazine for inclusion in Annex XIV.**

			fossil fired power plants. It is used to scavenge oxygen from water used in boiler feeds, which keeps corrosion low. This use is expected to take place at a high number of sites. Hydrazine hydrate is also used as a reducing agent in the recovery of precious metals and in the production of basic metals (industrial closed system). A further use is as a reducing agent in the refining of chemicals. However these uses account for lower tonnages in comparison to the main use therefore the number of sites where these uses take place is expected to be much lower than for the main non-intermediate use as a corrosion inhibitor. The Annex XV dossier also mentions the possible use of hydrazine hydrate in electroplating and electroless plating, however it seems that such techniques are only driven by research rather than by application, and commercial uses of such techniques are likely to be limited (Annex XV dossier). There are no registrations covering this use. Therefore, this use is not further considered for prioritisation. The main non-intermediate use of anhydrous hydrazine (AH) is as propellant in aerospace industry and areas of defence. In the context of the aerospace industry, the Annex XV dossier indicates that hydrazine is the fuel used as a monopropellant when decomposed by a suitable solid catalyst. It can also be used as a bipropellant when injected simultaneously with an oxidiser. In the context of defence, hydrazine fuel is used to allow aircraft		

			to maintain electrical and hydraulic power during periods of engine shutdown. The tonnage dedicated to this specialised use is relatively low (1-10 t/y AH) and release and exposure to workers is expected to be low. Regarding workers and the use of hydrazine hydrate in water treatment, exposure may occur during pumping and tank transfer associated with the preparation and dosing of the hydrazine hydrate. However, dilute solutions of hydrazine hydrate are used in closed systems and therefore exposure potential and possible exposure levels seem to be low. During the use of hydrazine hydrate solutions in the production of basic metals e.g. in the removal of selenium from process effluents, the hydrazine hydrate solutions are stored in small plastic vessels in a dedicated room. The solution is fed into the process by pump directly from the storage vessel to the reactor tank. The vessel and pump are located in a separate ventilated room. From this, it is expected that the worker exposure to hydrazine in the production of precious metals and basic metals is low.		
Hydrazine *(SCA)*	Score = 1	High volume in the scope of authorisation. Score = 7	Substance used at a high number of sites. Score = 3 Releases appear to be controlled and potential for exposure of workers low. Score = 1 Overall score = 3	Total score = 11	**The same considerations apply as brought forward under the verbal-argumentative approach.**

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

			substance is enclosed in the detonator and lead diazide decomposes when it explodes. The end use of detonators can therefore lead to release of combustion products (lead oxides, nitrogen oxides and nitrogen), however per unit (e.g. detonator) emission of lead will be very small, at the milligram level. Workers working in firing ranges, quarries, construction and demolition and military personnel may be exposed to these combustion products during the use of detonators containing lead diazide. During the public consultation it was communicated that lead and nitrogen oxides are produced in infinitesimal amount due to the fact that the quantity of lead is lower than a gram by blast hole. These few grams of oxides are emitted to air and disseminated within the tons of blasted rocks.	uses of lead compounds in the EU. On the basis of the criteria, lead diazide has low priority.	
Lead diazide, Lead azide *(SCA)*	Score = 0	Relatively low volume in the scope of authorisation. Score = 3	Substance used in the manufacture of detonators at a small number of sites. Detonators containing lead diazide are used at a high number of sites. Score = 3 Exposure of lead diazide to workers appears to be controlled and release to the environment of lead containing decomposition products insignificant. Score = 1 Overall score = 3	Score = 6	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Lead styphnate *(VAA)*	Art. 57(c); Toxic for Repr.1A	According to the registration information the total volume used in the EU is in the range of 10-100 t/y. All of this tonnage is allocated to uses with in the scope of	According to the information from registration dossiers, most of the lead styphnate supplied to the EU market is used as a primary explosive in firearm ammunition (with sport/hunting ammunition representing the significant	The volume of lead styphnate supplied to uses in the scope of authorisation is relatively low. The use of lead styphnate in ammunition	On the basis of the prioritisation criteria lead styphnate gets low priority for inclusion in Annex XIV. It is noted that lead styphnate

		authorisation.	majority. Other uses (military/security ammunition, detonators for civilian use, powder actuated cartridges, automotive pyrotechnics, detonators for munitions) account for smaller tonnages. The Annex XV dossier reports that the majority of companies known to manufacture lead styphnate use the substance in-house in the preparation of primers for ammunition (small number of sites). There are also EU-based companies which purchase primer caps that already contain lead styphnate and use these in manufacturing of the final ammunition cartridges, from EU manufactures of primer caps. The use of ammunition containing lead styphnate happens at a high number of different sites. Regarding the use of lead styphnate in the manufacture of primers for ammunition, the required workplace hygiene for safe handling of this explosive is very high and therefore worker exposure is likely to be limited. Risk management measures are in place to minimise exposure. The substance is primarily used in 'wet' form. Automated procedures are used where possible (for activities such as filtering, washing, drying, weighing, mixing, sieving and pressing) and workers are omitted from several of the fabrication steps as these are undertaken in closed reinforced spaces. Therefore the potential for worker exposure is likely to be low. Exposure to and release of lead styphnate itself, during the use of ammunition is considered insignificant, as the substance is enclosed in the	is considered to be widespread. Worker exposure to lead styphnate during manufacture of primers appears to be controlled due to the necessary safety measures for handling this explosive substance. Furthermore, exposure of humans and the environment (per site) to lead compounds during use of the ammunition seems also to be low. Lead styphnate decomposes when it explodes, leading to release of lead and other lead compounds (e.g. lead oxide) into the environment. This contributes to the overall environmental release and human exposure to lead (compounds) which needs to be considered in the light of the EU objective to reduce all releases of lead. However, the contribution from using lead primary explosives (lead diazide, lead styphnate and potentially lead picrate) appears to be low compared to the total lead releases resulting from the uses of lead compounds in the EU. On the basis of the	is included in the Candidate List due to its toxicity to reproduction (and not due to the concern related to its decomposition products lead and lead compounds to the environment). The environmental release caused by the use of lead styphnate should be considered in the context of an overall reduction strategy covering releases resulting from intentional use of lead and its compounds. **Therefore, it is proposed <u>not</u> to prioritise lead styphnate for inclusion in Annex XIV now.** Due to its properties as primary explosive it might be possible to use lead styphnate as a replacement for other primary explosives such as lead diazide and lead dipicrate. Therefore grouping of these substances should be considered when a decision is taken to recommend any of them for inclusion in Annex XIV.

			ammunition. However lead styphnate decomposes when it explodes. The end use of ammunition can therefore lead to release of lead containing combustion products (e.g. lead monoxide, lead carbonate) of lead styphnate to the environment. However, per unit emission of lead will be very small, at the milligram level. Workers working in firing ranges and civilians or military personnel practising there may be exposed to these lead containing combustion products.	criteria, lead styphnate has low priority.	
Lead styphnate *(SCA)*	Score = 0	Relatively low volume in the scope of authorisation. Score = 3	Substance used in manufacture of ammunition at a small number of sites. Ammunition containing lead styphnate is used at a high number of sites. Score = 3 Exposure of lead styphnate to workers appears to be controlled and release to the environment of lead containing decomposition products insignificant. Score = 1 Overall score = 3	Total Score = 6	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Lead dipicrate *(VAA)*	Art. 57(c); Toxic for Repr.1A	No registrations submitted for this substance. According to the Annex XV dossier small amounts of the substance (below registration threshold of 1 t/y) are manufactured in the EU and allocated to uses in the scope of authorisation.	It appears that the substance is used in small amounts in uses the scope of authorisation. Lead dipicrate has explosive properties, similar to that of lead diazide and lead styphnate. During the public consultation various parties indicated that the substance is used as a primary explosive in the EU in small quantities. As the explosive properties of lead	The volume of lead dipicrate supplied to uses in the scope of authorisation is very low. Worker exposure to lead dipicrate during production of primers and pyrotechnic devices can be considered controlled due to the necessary safety measures for handling this explosive substance. Furthermore,	On the basis of the prioritisation criteria lead dipicrate gets very low priority for inclusion in Annex XIV. It is noted that lead dipicrate is included in the Candidate List due to its toxicity to reproduction (and not due to the concern related to its decomposition products lead and lead compounds to the environment). The environmental release caused

			dipicrate are similar to that of lead diazide and lead styphnate and because the uses as primary explosive appear to be similar as well, it can be concluded with reasonable certainty that the potential for exposure of workers and for releases of the substance/its combustion products to the environment are in principle the same (albeit the amounts released are smaller due to the lower volume used).	exposure of humans and the environment (per site) to lead compounds during use of the products seems also to be low. Lead dipicrate decomposes when it explodes, leading to release of lead and other lead compounds (e.g. lead oxide) into the environment. This contributes to the overall environmental release and human exposure to lead (compounds) which needs to be considered in the light of the EU objective to reduce all releases of lead. However, the contribution from using lead primary explosives (lead diazide, lead styphnate and potentially lead picrate) appears to be low compared to the total lead releases resulting from the uses of lead compounds in the EU. On the basis of the criteria, lead dipicrate has very low priority.	by the use of lead dipicrate should be considered in the context of an overall reduction strategy covering releases resulting from intentional use of lead and its compounds. **Therefore, it is proposed <u>not</u> to prioritise lead dipicrate for inclusion in Annex XIV now.** Due to its properties as primary explosive it might be possible to use lead dipicrate as a replacement for other primary explosives such as lead diazide and lead styphnate. Therefore grouping of these substances should be considered when a decision is taken to recommend any of them for inclusion in Annex XIV.
Lead dipicrate *(SCA)*	Score = 0	Substance not registered. However, low volume appears to be allocated to uses in the scope of authorisation. Score = 1	Substance used in the production of specialty pyrotechnic devices and primers at a low number of sites. Number of sites at which the devices and primers are used not known but potentially high number. Score = 1 - 3 Exposure of lead dipicrate to workers	Total score = 2 - 4	**The same considerations apply as brought forward under the verbal-argumentative approach**

			presumably controlled and release to the environment of lead containing decomposition products insignificant. Score = 1 Overall score = 1 - 3		
Calcium arsenate *(VAA)*	Art. 57(a); Carcinogen 1A	According to registration information, the tonnage of calcium arsenate manufactured and imported is in range of 100 – 1,000 t/y, registered as transported isolated intermediate. The two uses mentioned in the Annex XV dossier, i.e. • Use as precipitating agent in copper smelting (Use #1) and • Use for manufacturing of diarsenic trioxide (As_2O_3) (Use #2), are parts of the same integrated metallurgical cycle. Currently the information on the processes and the function of the substance is too limited to be able to draw firm conclusions on the intermediate or non-intermediate nature of the uses of the substance. The relevant volume possibly in the scope of authorisation is assumed to be in the range	There is no information available on how many of the copper smelters in the EU use calcium arsenate as precipitating agent (Use #1). There are a number of registrations for copper. As_2O_3 (Use #2) is manufactured in metallurgical processes.The number of smelters in the EU at which the respective processes take place is unknown. The VRAR on lead and lead compounds from 2008 lists 32 production plants in the EU with a lead production of >1000 t/y (in 2002). Even when considering the high uncertainties, the substance is probably used at a medium number (>10 - <100) of sites. No data on environmental emissions or occupational exposure are available. Measured arsenic at smelters cannot be attributed to calcium arsenate alone. Calcium arsenate is not used by professionals or in any consumer products. Registration information regarding the use of calcium arsenate gives conflicting process descriptors for the same use (PROC 3 "closed batch process", PROC 4 "opportunity of exposure arises" and PROC 22 "potentially closed processing operations with mineral/metals at elevated temperature") thereby not allowing a conclusion regarding	Relatively high volume in the scope of authorisation. No consumer exposure expected. There is no indication of significant exposure that could be related to calcium arsenate. On the basis of the criteria calcium arsenate has low priority.	On the basis of the prioritisation criteria and the limited information currently available, calcium arsenate gets a low priority for inclusion in Annex XIV. More information on the processes in which the substance is used and its specific function in these is needed to allow assessment on whether the uses fall in the scope of authorisation. More information is also required to assess whether further regulatory effectiveness considerations, such as suitability of calcium arsenate to replace other arsenic compounds, need to be taken into account before reaching a final conclusion on the priority of calcium arsenate. **Therefore, it is proposed <u>not</u> to prioritise calcium arsenate for inclusion in Annex XIV now.**

		of 100 – 1000 t/y.	potential for releases during use. It is not possible to draw conclusions on the potential exposure of workers due to the presence of the calcium arsenate in the raw materials and its circulation in the metallurgical process. However, taking all available information into account, there is no indication of significant exposure that could be related to calcium arsenate.		
Calcium arsenate *(SCA)*	Score: 1	Based on the current information the volume in the scope of authorisation is between none and relatively high Score: 0-5	Use at a medium number of sites. Score: 2 No indication of significant exposure in the metallurgical sector that could be specifically related to calcium arsenate. Score: 1 Overall score: 2	Total score: 3-8	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Trilead diarsenate (TLDA) *(VAA)*	Art. 57(a) and (c); Carcinogen 1A Toxic for Repr. 1A	The manufactured and imported tonnage in the EU (registered as transported isolated intermediate) is in the range of 10 -100 t/y. According to the Annex XV, TLDA is present in complex raw materials, i.e. by-products from smelting and refining of non-ferrous metals. These raw materials are partly imported and are used in refining of copper, lead and a range of precious metals. There is not enough information on the process	Currently it is assumed that there are no uses in the scope of authorisation.	There is no information on uses in the scope of authorisation. On the basis of the criteria trilead diarsenate has a very low priority.	On the basis of the prioritisation criteria, trilead diarsenate gets very low priority for inclusion in Annex XIV. Further information on the process is needed to assess the function of trilead diarsenate in the metallurgical process which might lead to a re-assessment of the current conclusion. **Therefore, it is proposed <u>not</u> to prioritise trilead diarsenate for inclusion in Annex XIV.**

		available to conclude on the use of TLDA. For the time being it is considered that there is no volume in the scope of authorisation. However, more information is sought after to clarify the exact function of TLDA in the process which might lead to a re-assessment of the volume considered in the scope of authorisation.			
Trilead diarsenate *(SCA)*	Score: 1	No volume in the scope of authorisation. Scope: 0	Overall score: 0	Total score: 1	**The same considerations apply as brought forward under the verbal-argumentative approach.**
2-Ethoxyethyl acetate *(VAA)*	Art. 57(c); Toxic for Repr.1B	No registrations submitted.	There is no information on uses which would be in the scope of authorisation.	There is no information on uses which would be in the scope of authorisation. On the basis of the criteria, the substance has very low priority.	On the basis of the prioritisation criteria 2-Ethoxyethyl acetate gets very low priority for inclusion in Annex XIV. **Therefore, it is proposed <u>not</u> to prioritise 2-Ethoxyethyl acetate for inclusion in Annex XIV.**
2-Ethoxyethyl acetate *(SCA)*	Score: 0	No volume registered. Score: 0	Overall score wide-dispersiveness of uses: 0	Total score: 0	**The same considerations apply as brought forward under the verbal-argumentative approach.**
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 Europe (EBA, in the Annex XV dossier,	Disodium tetraborate is used in very high volumes for several uses in the scope of authorisation and at very many sites. In conclusion, the uses of the substance can be considered wide	When assessed against the general prioritisation criteria it is noted that a very high tonnage is dedicated to uses in the scope of authorisation and that many of these (end) uses must be considered as wide dispersive. This is the case even if the uncertainties on whether

		Although a firm estimate on the amount of the substance allocated to uses in the scope of authorisation cannot be given on the basis of the information available, it still can be concluded that this volume is >10000 t/y. Uses in the scope of authorisation mainly include formulation of mixtures (in most mixtures in concentrations below the specific concentration limit for classification; SCL), repackaging, incorporation into some articles (mainly as flame retardants), uses in metallurgy and other applications.	2010). As regards the sectors off glass / glass fibres (~55% of tonnage) and ceramic (frits, , glazes, enamels; ~15%), there is for some of the uses uncertainty as to whether they are uses as intermediate or not, i.e. whether the nature of these uses meets the definition in Article 3(15). Uses of disodium tetraborate include (according to information from the Registrations, the European Borates Association (EBA) and the RCOM 2010): *(Tonnage information provided by EBA, relating to 2008 and expressed here as anhydrous tonnage equivalent. References: Annex XV dossier, 2010; personal communication with EBA)* - production of insulation and textile **glass fibres** (~100,000 t) - production of **glass** (~45,000 t) - manufacture of **perborate** (~47,000 t) - manufacture of **ceramics** (glazes, enamels, frits) (~40,000 t) - use in **adhesives** (~5,000 t) - as **flame retardant** (for cellulose insulation material, mattresses (phasing out), wood or paper products, ~5,000 t) - in **fertilisers** (~11,000 t), - in **industrial fluids** (lubricants, antifreeze agents, metal working fluid, etc., ~ 2,500 t), - in **buffering / chemical reagents** (~5,000 t), - in **metallurgy** (steel & non-ferrous metal production, metal surface refining, ~2,000 t;.an additional volume of 2,000 t is used in steel slag	dispersive. Based on the criteria, the substance has high priority.	certain uses would actually benefit of the generic exemptions from the authorisation requirement are taken into account. Hence, disodium tetraborate and boric acid fulfil these general criteria for prioritisation. If further grouping considerations are taken into account - to avoid potential replacement of the mentioned boron compounds with another one having a similar hazard potential - this conclusion can as well be drawn for tetraboron disodium heptaoxide, hydrate. From the grouping perspective, it should further be noted that there are some additional boron compounds which are classified as toxic for reproduction (cat 1B) which are not on the Candidate List. The boron compounds currently on the Candidate List are listed in Annex VI to Regulation EC No. 1272/2008 (CLP Regulation) as Repr. 1B with specific concentration limits (SCLs) of more than one order of magnitude above the generic limit of 0.3% (i.e. SCLs are in the range of 4.5% - 8.5% weight by weight). Also SCLs of those boron compounds that as yet have not been identified as SVHCs and placed on the Candidate List but for which uses have been registered are at the same range (i.e. Diboron trioxide, EC 215-540-4; Perboric acid, sodium salt,

			stabilisation,) - in liquid / laundry **detergents** (as stabiliser, ~850t) - in **refractories** (~100 t) and **other applications (**up to 1,400 t, including production of paints and inks, production of construction materials such as plasterboards and wood-based boards, as well in abrasives, cement, leather tanning, photographic chemicals, photolithography, fireworks, igniters, plasticisers, manufacture of B_2O_3 containing catalysts, in medical devices, in biocides, analytical reagents, pharmaceuticals, etc; Annex XV dossier, 2010, RCOM 2010**)**. The substance seems to be used in mixtures (mainly below the specifc concentration limit for classification) at a high number of sites in each of the following industrial sectors: Metallurgy (also by professionals), production of industrial liquids, adhesives (also DU and professionals), agriculture (also by professionals), reagent chemicals (also by professionals), other uses as mentioned above (also by professionals). At least at a medium number of sites the substance is use as flame retardant in the formulation of cellulose insulation material and the production of mattresses and similar furniture articles and probably in the formulation of detergents. As regards workers, there is evidence from the Transitional Dossier (Austria 2008) that a presumably very high number of industrial workers and professionals may be exposed while		tetrahydrate, EC 234-390-0). Pursuant to Article 56(6)(b) the authorisation requirement does not apply to the use of substances in mixtures below the concentration limits specified in Annex VI. This new classification in Annex VI took effect on 1 December 2010. Currently the Commission is proposing a restriction for consumer use as such and in mixtures above the specific concentration limit. The authorisation requirement would not result in further reduction of the availability of boron compounds on their own or in mixtures to the consumers as the same specific concentration limit on substances in mixtures is used for restriction and authorisation. Furthermore, the registrants have to ensure that their registration dossiers, including the CSA with the appropriate ES/RMMs, follow the classification and labelling of the substance. From the available information it can be concluded that boron compounds are, apart from uses in the synthesis of other substances or in manufacture of glass and ceramics, mainly used for the formulation of mixtures. High share of the mixtures for industrial and professional uses currently formulated appear to contain boron compounds below the SCLs. There appear to be some cases where mixtures for

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

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

		of authorisation cannot however not be given on the basis of the information available, Nevertheless, it still can be concluded that this volume is >10000 t/y. Uses in the scope of authorisation mainly include formulation of mixtures (in most mixtures in cocentrations below the specific concentration limit for classification; SCL), repackaging, incorporation into some articles (mainly as flame retardants), uses in metallurgy and other applications.	**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) - and **other applications** (~4,000 t, including cosmetics ~700t - , pharmaceuticals – ~500t - as well as production of paints and inks, cement, photolithography, manufacture of B_2O_3 containing catalysts, in medical devices, analytical reagents, etc.). Very similar to disodium tetraborate,		

			boric acid seems to be used at a high number of sites in many different industrial sectors. As regards workers, there is evidence from the Transitional Dossier (Austria 2008) that a presumably very high number of industrial workers and professionals may be exposed while using the substance. The most relevant exposure routes identified are inhalation and dermal uptake due to activities such as sweeping, discharging, loading/unloading and packing. These activities are relevant across most of the sectors mentioned above. The borate concentration in mixtures for supply to consumers will be limited to the specific concentration limits for classification applicable for boron compounds by a restriction, which presumably will enter into force in autumn 2011.		
Boric acid	Score: 0	Supplied in very high amounts to uses in the scope of authorisation: Score: 9	Uses in industrial settings and by professionals at a high number of sites (widespread use). Score: 3. Releases may be controlled for most uses, but potentially significant exposure of workers in industrial settings and of professionals cannot be excluded (dispersive use). Score 3. Overall Score: 9.	Total score: 18	**The same considerations apply as brought forward under the verbal-argumentative approach.**
2-Methoxyethanol *(VAA)*	Art. 57 (c) Toxic for Reproduction 1B	According to registration information 2-methoxyethanol is used in Europe in the range of 1000 – 10000 t/y. The tonnage allocated to uses in the scope of authorisation	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	2-methoxyethanol is supplied in a high volume to uses in the scope of authorisation. However, on the basis of the information available, it appears that the main volume of these uses take	Based on the criteria, 2-methoxyethanol has moderate priority for inclusion in Annex XIV. **Therefore, it is proposed to not recommend 2-methoxyethanol for inclusion in Annex XIV.**

		is lower than the total volumes but is still within the above given tonnage range. Additionally there are less than 10 t/y imported by several other companies. These importers describe uses as solvents, formulation preparation and professional uses.	further identified use as laboratory agent is most likely as well exempted from authorisation (Art. 56(3)). Main uses in the scope of authorisation from manufacturer's regostrations are as processing aid and as extraction agent. These uses appear to take place in few industrial sectors and a limited number of industrial settings in closed systems. In cases in which the substance is used as processing aid and extraction agent it seems not to remain in the end-products. The potential for any significant exposure of workers from these uses appears to be low. This is backed by the OSPA Charter on Glycolethers which does not support inappropriate end-use applications by the OSPA member companies (downstream users confirm controlled conditions and no product containing methoxyethanol is placed on the market). The importers (all 1-10 t/y, not providing a CSR), give uses as solvent, formulation of preparations and professional uses. These uses might correspond to the uses described earlier, such as solvent in paints, varnishes, colours, glues and adhesives. These uses of the substance may lead to uncontrolled exposure of industrial or professional workers. These uses may lead to uncontrolled exposure of industrial or professional workers.	place in few industry sectors and a limited number of industrial settings in closed systems. Only a very low volume of the substance appears to end up in products available to consumers or professionals. In conclusion: the substance is used in high volumes, but it appears that releases and exposures are either controlled or only a few sites are affected. On the basis of the criteria, the substance has moderate priority.	

2-Methoxyethanol *(SCA)*	Score: 0	Based on the information available a high volume is allocated to uses in the scope of authorisation. High volume. Score: 7	Manufcturers: The substance seem to be used at a medium number of sites. Score: 2 Exposure of workers appears to be controlled. Score: 1 Overall score: 2 Importers: From the available information it is difficult to assess the wide-dispersiveness of the uses. However, given the low tonnage we can either expect uncontrolled releases (score:3) from a medium number of sites (score: 2); or we can expect controlled releases (score: 1) on a high number of sites (score: 3). Total score for wide-dispersiveness would then be: 3 * 2 = 6 1 * 3 = 3	Total score: 9-13	**The same considerations apply as brought forward under the verbal-argumentative approach.**
2-Ethoxyethanol *(VAA***)**	Toxic for Reproduction 1B	According to registration information an amount ranging between 1000 and 10000 t/y of 2-ethoxyethanol is used in the EU. Only a low volume (< 10 t) is allocated to uses in the scope of authorisation.	According to registration information, nearly the complete volume supplied in the EU is used for the manufacture of other substances. A low volume of <10 t/y is allocated to the remaining (industrial) uses, which are formulation of mixtures, as a solvent and as a laboratory chemical (the latter use also by professionals). Uses as laboratory agent do presumably fall under the exemption of uses of substances for scientific research and development from authorisation (Art. 56.3). The remaining uses for mixtures and as solvent bear a potential risk for	The volume of the substance allocated to uses in the scope of authorisation is low. Because of the low volume, and because the uses appear exclusively to be carried out in industrial settings, it is concluded that the uses are not widespread. They should normally be controlled, however, potential exposure of workers cannot be ruled out. Based on the criteria, the substance has very low	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.**

			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.	priority.	
2-Ethoxyethanol *(SCA)*	Score: 0	Low volume. Score: 1	Small number of sites. Score: 1 Uses take place in industrial settings and releases and exposure appear to be controlled. Score: 1 Overall score: 1	Total score: 2	**The same considerations apply as brought forward under the verbal-argumentative approach**
Pitch, coal tar, high temperature (CTPHT) *(VAA)*	Art. 57 (a), (d) & (e); Carcinogen 1B; PBT and vPvB	According to registration information the total tonnage used in the EU is i >500000 t/y. Most of this tonnage is allocated to uses in the scope of authorisation.	Main uses according to registration information are in the metal industry (aluminium, metallurgic smelting, electro steel), the carbon and graphite industry, for refractories, and for activated carbon, CTPHT containing coatings, waterproofing materials, sealings and adhesives, and for clay pigeons. Further uses as fuel in industrial heavy diesel engines, as fuel for industrial energy generation, and as intermediate for the synthesis of other substances. Technical functions of the substance are according to information included in the Annex XV dossier as binding agent in the manufacture of anodes/electrodes in the metal industry and in refractories and as anti-corrosion agent in (specialty) coatings and paints, starting material for active carbon and carbon fibres. From the registrations it cannot be determined whether uses indicated in the consultation (Background document	The substance is used in very high volumes and nearly all uses can be considered wide dispersive, although the main use takes place in (very) large industrial installations. On the basis of the prioritisation criteria, the substance has very high priority.	On the basis of the prioritisation criteria, pitch, coal tar, high temperature (CTPHT) gets very high priority for inclusion in Annex XIV. However, while the Risk Reduction Strategy (RRS) prepared as a part of the transitional dossier under Article 136(3) of REACH and the assessment carried out using the information gathered when preparing and agreeing on the Annex XV SVHC dossier came to some extent to different conclusions on the most 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

			2009, Annex XV dossier 2009) such as binder for briquettes, material for roofing and for (specialty) paving are still continued. The use-information provided in the registrations is to a large extent consistent with the information previously obtained from the Annex XV dossier (2009) and (public) consultation (RCOM 2009, Background document, 2009). Given the very high volume used for anode/electrode manufacture, the number of sites where electrodes are manufactured and taking account of the PAH emissions resulting from the baking of anodes/electrodes, this use is considered wide dispersive. The same applies, for the potential number of sites of use/ worker exposure or (un)controlled releases from uses in refractories, paints and coatings, clay-targets and potentially briquettes, paving and roofing.		way together with other metal industry sources of PAH emissions to ensure that an overall reduction of PAH emissions is achieved. Furthermore, it is noted that it would be useful to consider these PAH emissions from the metal industry and their reduction objectives in conjunction with more general objectives for reduction of PAH emissions from industry, incineration processes and other emission sources. **Therefore, it is proposed to not prioritise pitch, coal tar, high temperature (CTPHT) now for inclusion in Annex XIV.**
Pitch, coal tar, high temperature (CTPHT) *(SCA)*	Score: 4	Very high volume in the scope of authorisation. Score: 9	Many uses with emissions occurring at a high number of sites. Score: 3. Releases are diffuse and might result in significant exposure of workers and the environment. Score: 3. Overall score: 9	Total score: 22	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Anthracene oil *(VAA)*	Carcinogen 1B; PBT and vPvB	Full registrations and registrations as transported isolated intermediate are available, tonnage band > 1000 t/a. The registrations seem to confirm the information received during public commenting on the Annex XV report that the volume on the	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	Anthracene oil is supplied in very high volumes to uses in the scope of authorisation. On the uses in the scope of authorisation no specific information is available but considering their nature and similarity to the fields of application of	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

		European market is very high (well above 100,000 t/y). A complete overview on volumes used in the scope of authorisation cannot be established from the information provided in the registrations. However, the largest amounts seem to be assigned to uses of the substance as an intermediate but the amounts dedicated to non-intermediate uses still seem to be very high (> 10000vt/y).	solvent. The substance is used in the carbon and graphite industry, in the metallurgic smelting, aluminium and electro steel industry, for refractories, coatings, paints, waterproofing materials and sealants. From the information available it appears that most of the anthracene oil is used as intermediate for the manufacture of other substances. However, most of the other reported uses appear to be in the scope of authorisation. On these latter uses no specific information is available but considering their nature and their similarity to the applications of coal tar high temperature, a wide-dispersive use pattern cannot be excluded as they imply use at a high number of sites, diffuse environmental releases and, at least for some of the uses, significant exposure at the workplace.	coal tar high temperature a wide-dispersive use pattern cannot be excluded. On the basis of the criteria, the substance has very high priority.	authorisation requirement given that there are many similar substances coming from coal tar distillation processes, which could (and in fact appear to be) blended in various processing steps). Moreover, as already mentioned with regard to a potential prioritisation of pitch, coal tar, high temperature, it is noted that it would be useful to consider these PAH emissions in conjunction with more general objectives for reduction of PAH emissions from industry, incineration processes and other emission sources. **Therefore, it is proposed to not prioritise anthracene oil now** (and the other anthracene oil substances on the Candidate List by applying the grouping approach).
Anthracene oil *(SCA)*	Score: 4	Very high volumes (> 10000 t/y) seem to be allocated to uses in the scope of authorisation: 9 scores	Many uses that can be considered wide dispersive (with emissions occurring at a high number of sites with diffuse releases that might be significant and not always controlled). Scoring: number of sites: 3; releases: 3, overall: 9	Total score: 22	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Anthracene oil, anthracene paste *(VAA)*	Carcinogen 1B; Mutagen 1B; PBT and vPvB	Registration as transported isolated intermediate, tonnage band > 1000 t/a. No complete information on the tonnages used in the EU provided but presumably > 10000 t/y.	According to information provided in the registrations the substance is used as intermediate in the synthesis of other substances, for manufacture of pure substances and for the production of technical oils. There is not enough information	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

			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).
Anthracene	Score: 4	No clarity on the volumes	No clarity on the nature of the uses	Total score:	**The same considerations**

oil, anthracene low *(SCA)*		supplied to uses in the scope of authorisation			**apply as brought forward under the verbal-argumentative approach.**
Anthracene oil, anthracene paste, anthracene fraction *(VAA)*	Carcinogen 1B; Mutagen1B; PBT and vPvB	No registration has been submitted for this substance.	No registration submitted.	No registration for the substance submitted. Therefore low priority.	On the basis of the criteria, anthracene oil, anthracene paste, anthracene fraction gets low priority for inclusion in Annex XIV. However, the substance should be grouped with the other anthracene oil substances on the Candidate List in case these are recommended for inclusion in Annex XIV.
Anthracene oil, anthracene paste, anthracene fraction *(SCA)*	Score: 4	No registration: Score: 0	No registration: Score: 0	Total score: 4	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Anthracene oil, anthracene paste, distn. lights *(VAA***)**	Carcinogen 1B; Mutagen 1B; PBT and vPvB	Registration as transported isolated intermediate, tonnage band >1000 t/y (no further information on quantities given).	Use as intermediate in the synthesis of other substances, for manufacture of pure substances and in the laboratory.	According to registration information the substance has not uses in the scope of authorisation. Therefore low priority.	On the basis of the criteria, anthracene oil, anthracene paste, distn. lights gets low priority for inclusion in Annex XIV. However, the substance should be grouped with the other anthracene oil substances on the Candidate List in case these are recommended for inclusion in Annex XIV.
Anthracene oil, anthracene	Score: 4	No substance supplied to uses in the scope of authorisation. Score: 0	No uses in the scope of authorisation. Score: 0	Total score: 4	**The same considerations apply as brought forward under the verbal-**

paste, distn. lights *(SCA)*					**argumentative approach.**
Anthracene *(VAA)*	PBT	Only registrations as isolated transported intermediate. Tonnage band >1000t/y, no further information on volumes provided in the registrations. According to information received during public consultation on the proposal to identify anthracene as SVHC (RCOM 2008) the annual manufacture in the EU is less than 5,000 t/y. Most anthracene manufactured (>99.5%) is used as intermediate for the synthesis of other substances. Anthracene supply for other uses was reported to be less than 2 t/y. Use for pyrotechnic mixtures, the only known use in the scope of authorisation, was assumed to be far less than 0.5 t/y.	The only use identified in the registrations is as intermediate for synthesis of other substances. According to information received during public consultation on the proposal to identify the substance as SVHC (RCOM 2008) anthracene is used for the synthesis of anthraquinone. In the registrations no indication could be found that the substance is still used, as ireported during public consultation (RCOM, 2008), in pyrotechnic articles (for special effects, i.e. black smoke for theatre and film productions), as laboratory agent in scientific research, and for manufacture of pharmaceuticals (the latter two uses would be exempted from authorisation). If formulation of specialty "black smoke" pyrotechnic mixtures still takes place in the EU, this may happen at a low number of sites and releases and worker exposure from formulation might occur only from cleaning (only to wastewater) and in the worst case amount to 0.25% (RCOM, 2008). Although the use of anthracene containing pyrotechnics may occur at a high number of sites, this use is not considered wide-dispersive because anthracene is transformed during the end-use and therefore, and in consideration of the low volume supplied to this use, releases are considered insignificant.	Anthracene is a PBT substance, however without identified uses in the scope of authorisation in the registrations. Based on the criteria, the substance has a very low priority.	Based on the prioritisation criteria, anthracene gets very low priority for inclusion in Annex XIV. **Therefore, it is proposed to not prioritise anthracene for inclusion in Annex XIV.**
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 considered as an intermediate, because the outcome of this doping process, doped silicon ingots, is a new substance of its own, which is not regarded the same as the silicon substance fed into that process. All doping processes are performed in	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.**

			closed chambers where the electronic components or the silicon material is put in contact with the substance in vapour form inside the process chamber. By-products of the reaction and non reacted chemicals are discharged from the chamber via vacuum pumps connected to abatement devices (thermal or wet scrubber). Therefore, exposure of workers to the substance or releases to the environment can be considered insignificant. The uses of triethyl arsenate are not considered as wide-dispersive.		
Triethyl arsenate *(SCA)*	Score: 1	Low annual volume. Score: 1.	The substance is only used for doping applications in the semiconductor industry under strictly controlled conditions. This may occur at a medium number of sites. Scoring: number of sites: 2; insignificant worker exposure and environmental releases: 0. Overall score: 0.	Total score: 2	**The same considerations apply as brought forward under the verbal-argumentative approach.**
Lead hydrogen 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.**
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	No uses in the scope of authorisation identified.	No use in the scope of authorisation in the EU	On the basis of the prioritisation criteria acylamide gets very low

		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,		identified, therefore very low priority on the basis of the criteria.	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 IV

Candidate List of Substances of Very High Concern for Authorisation (as updated on 19 December 2012)

Light grey *background highlights substances already prioritised and included in previous Recommendations, which therefore were not considered anymore in the current prioritisation exercise.* ***White*** *(i.e. no) background highlights the substances that were included in the Candidate List until 19 December 2012 and assessed for priority in the context of the 5th and previous recommendations but were not recommended for inclusion in Annex XIV yet.* ***Light blue*** *background highlights new substances included in the Candidate List during 2012, which are assessed for the first time in the present prioritisation exercise. Not yet assessed substances are highlighted in* ***orange****.*

No.	Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
1	1,2,3-Trichloropropane	202-486-1	96-18-4	2011/06/20	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)	ED/31/2011 ☐
2	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	276-158-1	71888-89-6	2011/06/20	Toxic for reproduction (article 57c)	ED/31/2011☐
3	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	271-084-6	68515-42-4	2011/06/20	Toxic for reproduction (article 57c)	ED/31/2011☐
4	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	284-032-2	84777-06-0	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
5	1,2-bis(2-methoxyethoxy)ethane (TEGDME; triglyme)	203-977-3	112-49-2	2012/06/18	Toxic for reproduction (Article 57 c)	ED/87/2012☐
6	1,2-dichloroethane	203-458-1	107-06-2	2011/12/19	Carcinogenic (article 57 a)	ED/77/2011☐
7	1,2-Diethoxyethane	211-076-1	629-14-1	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
8	1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME)	203-794-9	110-71-4	2012/06/18	Toxic for reproduction (Article 57 c)	ED/87/2012☐
9	1,3,5-Tris(oxiran-2-ylmethyl)-1,3,5-triazinane-2,4,6-trione (TGIC)	219-514-3	2451-62-9	2012/06/18	Mutagenic (Article 57b)	ED/87/2012☐
10	1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-	423-400-0	59653-74-6	2012/06/18	Mutagenic (Article 57b)	ED/87/2012☐

No.	Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
	1,3,5-triazine-2,4,6-(1H,3H,5H)-trione (β-TGIC)					
11	1-bromopropane (n-propyl bromide)	203-445-0	106-94-5	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
12	1-Methyl-2-pyrrolidone	212-828-1	872-50-4	2011/06/20	Toxic for reproduction (article 57c)	ED/31/2011☐
13	2,2'-dichloro-4,4'-methylenedianiline	202-918-9	101-14-4	2011/12/19	Carcinogenic (article 57 a)	ED/77/2011☐
14	2,4-Dinitrotoluene	204-450-0	121-14-2	2010/01/13	Carcinogenic (article 57a)	ED/68/2009☐
15	2-Ethoxyethanol	203-804-1	110-80-5	2010/12/15	Toxic for reproduction (article 57c)	ED/95/2010☐
16	2-Ethoxyethyl acetate	203-839-2	111-15-9	2011/06/20	Toxic for reproduction (article 57c)	ED/31/2011☐
17	2-Methoxyaniline; o-Anisidine	201-963-1	90-04-0	2011/12/19	Carcinogenic (article 57 a)	ED/77/2011☐
18	2-Methoxyethanol	203-713-7	109-86-4	2010/12/15	Toxic for reproduction (article 57c)	ED/95/2010☐
19	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	421-150-7	143860-04-2	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
20	4,4'- Diaminodiphenylmethane (MDA)	202-974-4	101-77-9	2008/10/28	Carcinogenic (article 57a)	ED/67/2008☐
21	4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	209-218-2	561-41-1	2012/06/18	Carcinogenic (Article 57a)	ED/87/2012☐
22	4,4'-bis(dimethylamino)benzophenone (Michler’s ketone)	202-027-5	90-94-8	2012/06/18	Carcinogenic (Article 57a)	ED/87/2012☐
23	4,4'-methylenedi-o-toluidine	212-658-8	838-88-0	2012/12/19	Carcinogenic (Article 57a)	ED/169/2012 ☐
24	4,4'-oxydianiline and its salts	202-977-0	101-80-4	2012/12/19	Carcinogenic (Article 57a); Mutagenic (Article 57b)	ED/169/2012 ☐
25	4-(1,1,3,3-tetramethylbutyl)phenol	205-426-2	140-66-9	2011/12/19	Equivalent level of	ED/77/2011☐

No.	Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
					concern having probable serious effects to the environment (article 57 f)	
26	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]	-	-	2012/12/19	Equivalent level of concern having probable serious effects to the environment (Article 57 f)	ED/169/2012 ☐
27	4-Aminoazobenzene	200-453-6	60-09-3	2012/12/19	Carcinogenic (Article 57a)	ED/169/2012 ☐
28	4-methyl-m-phenylenediamine (toluene-2,4-diamine)	202-453-1	95-80-7	2012/12/19	Carcinogenic (Article 57a)	ED/169/2012 ☐
29	4-Nonylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]	-	-	2012/12/19	Equivalent level of concern having probable serious effects to the environment (Article 57 f)	ED/169/2012 ☐
30	5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	201-329-4	81-15-2	2008/10/28	vPvB (article 57e)	ED/67/2008☐
31	6-methoxy-m-toluidine (p-cresidine)	204-419-1	120-71-8	2012/12/19	Carcinogenic (Article 57a)	ED/169/2012 ☐
32	[4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	208-953-6	548-62-9	2012/06/18	Carcinogenic (Article 57a)	ED/87/2012☐
33	[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	219-943-6	2580-56-5	2012/06/18	Carcinogenic (Article 57a)	ED/87/2012☐

No.	Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
34	[Phthalato(2-)]dioxotrilead	273-688-5	69011-06-9	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
35	Acetic acid, lead salt, basic	257-175-3	51404-69-4	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
36	Acids generated from chromium trioxide and their oligomers. Names of the acids and their oligomers: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid.	231-801-5, 236-881-5	7738-94-5, 13530-68-2	2010/12/15	Carcinogenic (article 57a)	ED/95/2010☐
37	Acrylamide	201-173-7	79-06-1	2010/03/30	Carcinogenic and mutagenic (articles 57 a and 57 b)	ED/68/2009☐
38	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	287-476-5	85535-84-8	2008/10/28	PBT and vPvB (articles 57 d and 57 e)	ED/67/2008☐
39	Aluminosilicate Refractory Ceramic Fibres are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions: a) oxides of aluminium and silicon are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (μm) c) alkaline oxide and alkali earth oxide (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight			2011/12/19	Carcinogenic (article 57 a)	ED/77/2011
40	Ammonium dichromate	232-143-1	7789-09-5	2010/06/18	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)	/

No.	Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
41	Anthracene	204-371-1	120-12-7	2008/10/28	PBT (article 57d)	ED/95/2012 ☐
42	Anthracene oil	292-602-7	90640-80-5	2010/01/13	Carcinogenic1, PBT and vPvB (articles 57a, 57d and 57e)	ED/30/2010☐
43	Anthracene oil, anthracene paste	292-603-2	90640-81-6	2010/01/13	Carcinogenic2, mutagenic3, PBT and vPvB (articles 57a, 57b, 57d and 57e)	ED/67/2008☐
44	Anthracene oil, anthracene paste, anthracene fraction	295-275-9	91995-15-2	2010/01/13	Carcinogenic2, mutagenic3, PBT and vPvB (articles 57a, 57b, 57d and 57e)	ED/68/2009☐
45	Anthracene oil, anthracene paste,distn. lights	295-278-5	91995-17-4	2010/01/13	Carcinogenic2, mutagenic3, PBT and vPvB (articles 57a, 57b, 57d and 57e)	ED/68/2009☐
46	Anthracene oil, anthracene-low	292-604-8	90640-82-7	2010/01/13	Carcinogenic2, mutagenic3, PBT and vPvB (articles 57a, 57b, 57d and 57e)	ED/68/2009☐
47	Arsenic acid	231-901-9	7778-39-4	2011/12/19	Carcinogenic (article 57 a)	ED/68/2009☐
48	Benzyl butyl phthalate (BBP)	201-622-7	85-68-7	2008/10/28	Toxic for reproduction (article 57c)	ED/68/2009☐
49	Biphenyl-4-ylamine	202-177-1	92-67-1	2012/12/19	Carcinogenic (Article 57a)	ED/77/2011☐
50	Bis (2-ethylhexyl)phthalate (DEHP)	204-211-0	117-81-7	2008/10/28	Toxic for reproduction (article 57c)	ED/67/2008☐
51	Bis(2-methoxyethyl) ether	203-924-4	111-96-6	2011/12/19	Toxic for reproduction (article 57 c)	ED/169/2012 ☐
52	Bis(2-methoxyethyl) phthalate	204-212-6	117-82-8	2011/12/19	Toxic for reproduction (article 57 c)	ED/67/2008☐

No.	Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
53	Bis(pentabromophenyl) ether (decabromodiphenyl ether; DecaBDE)	214-604-9	1163-19-5	2012/12/19	PBT (Article 57 d); vPvB (Article 57 e)	ED/77/2011☐
54	Bis(tributyltin)oxide (TBTO)	200-268-0	56-35-9	2008/10/28	PBT (article 57d)	ED/77/2011☐
55	Boric acid	233-139-2, 234-343-4	10043-35-3, 11113-50-1	2010/06/18	Toxic for reproduction (article 57 c)	ED/169/2012 ☐
56	Calcium arsenate	231-904-5	7778-44-1	2011/12/19	Carcinogenic (article 57 a)	ED/67/2008☐
57	Chromium trioxide	215-607-8	1333-82-0	2010/12/15	Carcinogenic and mutagenic (articles 57 a and 57 b)	ED/30/2010☐
58	Cobalt dichloride	231-589-4	7646-79-9	2011/06/20 - 2008/10/28	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)	ED/77/2011☐
59	Cobalt(II) carbonate	208-169-4	513-79-1	2010/12/15	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)	ED/95/2010☐
60	Cobalt(II) diacetate	200-755-8	71-48-7	2010/12/15	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)	ED/31/2011 / ED/67/2008☐
61	Cobalt(II) dinitrate	233-402-1	10141-05-6	2010/12/15	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)	ED/95/2010☐
62	Cobalt(II) sulphate	233-334-2	10124-43-3	2010/12/15	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)	ED/95/2010☐
63	Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] [The individual cis- [2] and trans- [3] isomer substances and all possible combinations of the cis- and trans-isomers [1] are covered by this entry]	201-604-9, 236-086-3, 238-009-9	85-42-7, 13149-00-3, 14166-21-3	2012/12/19	Equivalent level of concern having probable serious effects to human health (Article 57 f)	ED/95/2010☐
64	Diarsenic pentaoxide	215-116-9	1303-28-2	2008/10/28	Carcinogenic (article 57a)	ED/95/2010☐

No.	Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
65	Diarsenic trioxide	215-481-4	1327-53-3	2008/10/28	Carcinogenic (article 57a)	ED/169/2012 ☐
66	Diazene-1,2-dicarboxamide (C,C'-azodi(formamide))	204-650-8	123-77-3	2012/12/19	Equivalent level of concern having probable serious effects to human health (Article 57 f)	ED/67/2008☐
67	Diboron trioxide	215-125-8	1303-86-2	2012/06/18	Toxic for reproduction (Article 57 c)	ED/67/2008☐
68	Dibutyl phthalate (DBP)	201-557-4	84-74-2	2008/10/28	Toxic for reproduction (article 57c)	ED/169/2012 ☐
69	Dibutyltin dichloride (DBTC)	211-670-0	683-18-1	2012/12/19	Toxic for reproduction (Article 57 c)	ED/87/2012☐
70	Dichromium tris(chromate)	246-356-2	24613-89-6	2011/12/19	Carcinogenic (article 57 a)	ED/67/2008☐
71	Diethyl sulphate	200-589-6	64-67-5	2012/12/19	Carcinogenic (Article 57a); Mutagenic (Article 57b)	ED/169/2012 ☐
72	Diisobutyl phthalate	201-553-2	84-69-5	2010/01/13	Toxic for reproduction (article 57c)	ED/77/2011☐
73	Diisopentylphthalate	210-088-4	605-50-5	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
74	Dimethyl sulphate	201-058-1	77-78-1	2012/12/19	Carcinogenic (Article 57a)	ED/68/2009☐
75	Dinoseb (6-sec-butyl-2,4-dinitrophenol)	201-861-7	88-85-7	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
76	Dioxobis(stearato)trilead	235-702-8	12578-12-0	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
77	Disodium tetraborate, anhydrous	215-540-4	1303-96-4, 1330-43-4, 12179-04-3	2010/06/18	Toxic for reproduction (article 57 c)	ED/169/2012 ☐
78	Fatty acids, C16-18, lead salts	292-966-7	91031-62-8	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
79	Formaldehyde, oligomeric reaction products	500-036-1	25214-70-4	2011/12/19	Carcinogenic (article 57	ED/30/2010☐

No.	Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
	with aniline				a)	
80	Formamide	200-842-0	75-12-7	2012/06/18	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
81	Furan	203-727-3	110-00-9	2012/12/19	Carcinogenic (Article 57a)	ED/77/2011☐
82	Henicosafluoroundecanoic acid	218-165-4	2058-94-8	2012/12/19	vPvB (Article 57 e)	ED/87/2012☐
83	Heptacosafluorotetradecanoic acid	206-803-4	376-06-7	2012/12/19	vPvB (Article 57 e)	ED/169/2012 ☐
84	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified: Alpha-hexabromocyclododecane Beta-hexabromocyclododecane Gamma-hexabromocyclododecane	247-148-4 and 221-695-9	25637-99-4, 3194-55-6 (134237-50-6) (134237-51-7) (134237-52-8)	2008/10/28	PBT (article 57d)	ED/169/2012 ☐
85	Hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4] [The individual isomers [2], [3] and [4] (including their cis- and trans- stereo isomeric forms) and all possible combinations of the isomers [1] are covered by this entry]	247-094-1, 243-072-0, 256-356-4, 260-566-1	25550-51-0, 19438-60-9, 48122-14-1, 57110-29-9	2012/12/19	Equivalent level of concern having probable serious effects to human health (Article 57 f)	ED/169/2012 ☐
86	Hydrazine	206-114-9	302-01-2, 7803-57-8	2011/06/20	Carcinogenic (article 57a)	ED/67/2008☐
87	Lead bis(tetrafluoroborate)	237-486-0	13814-96-5	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
88	Lead chromate	231-846-0	7758-97-6	2010/01/13	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)	ED/31/2011☐
89	Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9	12656-85-8	2010/01/13	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)	ED/169/2012 ☐
90	Lead cyanamidate	244-073-9	20837-86-9	2012/12/19	Toxic for reproduction	ED/68/2009☐

No.	Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
					(Article 57 c)	
91	Lead diazide, Lead azide	236-542-1	13424-46-9	2011/12/19	Toxic for reproduction (article 57 c),	ED/68/2009☐
92	Lead dinitrate	233-245-9	10099-74-8	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
93	Lead dipicrate	229-335-2	6477-64-1	2011/12/19	Toxic for reproduction (article 57 c)	ED/77/2011☐
94	Lead hydrogen arsenate	232-064-2	7784-40-9	2008/10/28	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)	ED/169/2012 ☐
95	Lead monoxide (lead oxide)	215-267-0	1317-36-8	2012/12/19	Toxic for reproduction (Article 57 c)	ED/77/2011☐
96	Lead oxide sulfate	234-853-7	12036-76-9	2012/12/19	Toxic for reproduction (Article 57 c)	ED/67/2008☐
97	Lead styphnate	239-290-0	15245-44-0	2011/12/19	Toxic for reproduction (article 57 c)	ED/169/2012 ☐
98	Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	1344-37-2	2010/01/13	Carcinogenic and toxic for reproduction (articles 57 a and 57 c))	ED/169/2012 ☐
99	Lead titanium trioxide	235-038-9	12060-00-3	2012/12/19	Toxic for reproduction (Article 57 c)	ED/77/2011☐
100	Lead titanium zirconium oxide	235-727-4	12626-81-2	2012/12/19	Toxic for reproduction (Article 57 c)	ED/68/2009☐
101	Lead(II) bis(methanesulfonate)	401-750-5	17570-76-2	2012/06/18	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
102	Methoxyacetic acid	210-894-6	625-45-6	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
103	Methyloxirane (Propylene oxide)	200-879-2	75-56-9	2012/12/19	Carcinogenic (Article 57a); Mutagenic (Article 57b)	ED/87/2012☐
104	N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base)	202-959-2	101-61-1	2012/06/18	Carcinogenic (Article 57a)	ED/169/2012 ☐

No.	Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
105	N,N-dimethylacetamide	204-826-4	127-19-5	2011/12/19	Toxic for reproduction (article 57 c)	ED/169/2012 ☐
106	N,N-dimethylformamide	200-679-5	68-12-2	2012/12/19	Toxic for reproduction (Article 57 c)	ED/87/2012☐
107	N-methylacetamide	201-182-6	79-16-3	2012/12/19	Toxic for reproduction (Article 57 c)	ED/77/2011☐
108	N-pentyl-isopentylphthalate	-	776297-69-9	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
109	o-aminoazotoluene	202-591-2	97-56-3	2012/12/19	Carcinogenic (Article 57a)	ED/169/2012 ☐
110	o-Toluidine	202-429-0	95-53-4	2012/12/19	Carcinogenic (Article 57a)	ED/169/2012 ☐
111	Orange lead (lead tetroxide)	215-235-6	1314-41-6	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
112	Pentacosafluorotridecanoic acid	276-745-2	72629-94-8	2012/12/19	vPvB (Article 57 e)	ED/169/2012 ☐
113	Pentalead tetraoxide sulphate	235-067-7	12065-90-6	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
114	Pentazinc chromate octahydroxide	256-418-0	49663-84-5	2011/12/19	Carcinogenic (article 57 a)	ED/169/2012 ☐
115	Phenolphthalein	201-004-7	77-09-8	2011/12/19	Carcinogenic (article 57 a)	ED/169/2012 ☐
116	Pitch, coal tar, high temp.	266-028-2	65996-93-2	2010/01/13	Carcinogenic, PBT and vPvB (articles 57a, 57d and 57e)	ED/77/2011☐
117	Potassium chromate	232-140-5	7789-00-6	2010/06/18	Carcinogenic and mutagenic (articles 57 a and 57 b).	ED/77/2011☐
118	Potassium dichromate	231-906-6	7778-50-9	2010/06/18	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)	ED/68/2009☐

No.	Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
119	Potassium hydroxyoctaoxodizincatedichromate	234-329-8	11103-86-9	2011/12/19	Carcinogenic (article 57 a)	ED/30/2010☐
120	Pyrochlore, antimony lead yellow	232-382-1	8012-00-8	2012/12/19	Toxic for reproduction (Article 57 c)	ED/30/2010☐
121	Silicic acid (H2Si2O5), barium salt (1:1), lead-doped [with lead (Pb) content above the applicable generic concentration limit for 'toxicity for reproduction' Repr. 1A (CLP) or category 1 (DSD); the substance is a member of the group entry of lead compounds, with index number 082-001-00-6 in Regulation (EC) No 1272/2008]	272-271-5	68784-75-8	2012/12/19	Toxic for reproduction (Article 57 c)	ED/77/2011☐
122	Silicic acid, lead salt	234-363-3	11120-22-2	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
123	Sodium chromate	231-889-5	7775-11-3	2010/06/18	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)	ED/169/2012 ☐
124	Sodium dichromate	234-190-3	7789-12-0, 10588-01-9	2008/10/28	Carcinogenic, mutagenic and toxic for reproduction (articles 57a, 57b and 57c)	ED/169/2012 ☐
125	Strontium chromate	232-142-6	7789-06-2	2011/06/20	Carcinogenic (article 57a)	ED/30/2010☐
126	Sulfurous acid, lead salt, dibasic	263-467-1	62229-08-7	2012/12/19	Toxic for reproduction (Article 57 c)	ED/67/2008☐
127	Tetraboron disodium heptaoxide, hydrate	235-541-3	12267-73-1	2010/06/18	Toxic for reproduction (article 57 c)	ED/31/2011☐
128	Tetraethyllead	201-075-4	78-00-2	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
129	Tetralead trioxide sulphate	235-380-9	12202-17-4	2012/12/19	Toxic for reproduction (Article 57 c)	ED/30/2010☐
130	Trichloroethylene	201-167-4	79-01-6	2010/06/18	Carcinogenic (article 57	ED/169/2012

No.	Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
					a)	☐
131	Tricosafluorododecanoic acid	206-203-2	307-55-1	2012/12/19	vPvB (Article 57 e)	ED/169/2012 ☐
132	Triethyl arsenate	427-700-2	15606-95-8	2008/10/28	Carcinogenic (article 57a)	ED/30/2010☐
133	Trilead bis(carbonate)dihydroxide	215-290-6	1319-46-6	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
134	Trilead diarsenate	222-979-5	3687-31-8	2011/12/19	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)	ED/67/2008☐
135	Trilead dioxide phosphonate	235-252-2	12141-20-7	2012/12/19	Toxic for reproduction (Article 57 c)	ED/169/2012 ☐
136	Tris(2-chloroethyl)phosphate	204-118-5	115-96-8	2010/01/13	Toxic for reproduction (article 57c)	ED/77/2011☐
137	Zirconia Aluminosilicate Refractory Ceramic Fibres are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions: a) oxides of aluminium, silicon and zirconium are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (μm). c) alkaline oxide and alkali earth oxide (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight			2011/12/19	Carcinogenic (article 57 a)	ED/169/2012 ☐
138	α,α-Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I.	229-851-8	6786-83-0	2012/06/18	Carcinogenic (Article 57a)	ED/68/2009☐

No.	Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number
	Solvent Blue 4) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]					

Notes:

Authentic version: Only the Candidate List published on ECHA's website is deemed authentic. Companies may have immediate legal obligations following the inclusion of a substance in the Candidate List on this website.

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

Reason for Inclusion: Superscript figures denote information on conditions applicable to the classification of the substance. This information can be accessed through the "Details" button at the Candidate List on ECHA's website and is available in the sub-menu "Substance Details" in field "Other remarks".