Updated priority assessment results of the substances included in the draft 7th recommendation for inclusion in Annex XIV **10 November 2016**

This table includes the updated prioritisation results of the substances included in the draft 7th A.XIV recommendation. The prioritisation results have been updated based on the comments received in the public consultation and registration updates submitted by 18 February 2016. The prioritisation results of all substances assessed in the 7th recommendation round can be found in the prioritisation results document which was published at the start of the public consultation on 18 November 2015 (available at: https://echa.europa.eu/documents/10162/13640/prioritisation_results_CL_substances_nov_2015_en.pdf).

ECHA has applied the generic 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 10 February 2014.

The colours used in the table indicate the different substance groups.

Substance	EC no.	CAS no.	Registration status YES/INT/NO (INT=only intermediate registrations)	Scores			Verbal description	Verbal description		Total score	Further considerations (grouping, other)	Final conclusion
				Inherent properties	Volumes	Wide-dispersive use	Inherent properties	Volumes	Wide-dispersive use			
Orange lead (lead tetroxide)	215-235-6	1314-41-6	YES	1	15	12	Toxic for reproduction (Article 57 c)	The amount of orange lead (lead tetroxide) manufactured and/or imported into the EU is according to registration data in the range of 10,000 - <100,000 t/y (min. 45,000 t/y according to information submitted in the public consultation on the 6th draft recommendation (6th REC PC)). Part of the volume is for uses that appear not to be in the scope of authorisation, such as use as intermediate in manufacture of certain pigments, technical ceramic materials (PZT, PTC, PLZT), frits and glass (including crystal and special glass). It is recognized that the intermediate/non-intermediate status of some of these uses (e.g. in glass and frits) is a complex issue, and it is stressed that this prioritisation exercise is not taking a formal position whether certain uses of the substance are regarded as uses as intermediates in accordance with the definition in article 3(15). The volume in the scope of authorisation is estimated to be in the range of 10,000 - <100,000 t/y based on registrations and further information (6th REC PC).	Registered uses of orange lead (lead tetroxide) in the scope of authorisation include uses at industrial sites (e.g. use in the production of batteries, rubber and explosives, use in adsorbents) and uses by professional workers (use in paints). In addition, according to information submitted in the public consultation on 6th draft recommendation, the substance can be used in lubrication and corrosion protection products in the aerospace industry. [initial score 10] The lead registrant and most of the member registrants have updated their registrations during the spring of 2014 and they have removed the consumer use of artists' paints containing orange lead from their dossiers and CSR. Furthermore, the International Lead Association has informed that the use in artists' paints is an obsolete use and the lead registrant has asked the member registrants to update their dossiers. There are some members who have not yet updated their registrations, and the use remains in their dossiers. However, these members refer to the lead registrant's CSR which no longer supports the use. Finally, based on registration information the substance is used in articles (e.g. rubber articles and painted articles). [refined score 12]	28	Grouping: Lead monoxide and lead tetroxide appear to be used in similar applications as other lead substances on the Candidate list, among which pentalead tetraoxide sulphate and tetralead trioxide sulphate (applications in batteries). However, it has not been assessed whether the precise function of these substances in these applications is the same and whether or under which conditions substitution could happen in practice.	On the basis of Art. 58(3) prioritisation criteria further strenghtenend by grouping considerations, orange lead gets priority for inclusion in Annex XIV among the Candidate List substances. **Therefore, orange lead <u>is recommended</u> for inclusion in Annex XIV.**
Sodium perborate; perboric acid, sodium salt	239-172-9; 234-390-0	-	YES	1	15	10	Toxic for reproduction (Article 57 c)	The amount of sodium perborate; perboric acid, sodium salt manufactured and/or imported into the EU is according to registration data in the range of 10,000 - 100,000 t/y. Based on information from the industry received during the preparation of the A.XV SVHC report (and as documented in the A.XV SVHC report), the volume has decreased over the past years and was estimated to be < 40,000 t/y in year 2013. Some uses appear to be outside the scope of authorisation, such as use as laboratory chemical in SRD, use in detergents and bleaching products below the specific concentration limit (SCL), use in cosmetic products. Based on information from registration and from industry submitted during the SVHC public consultation, almost the complete volume used in the EU corresponds to uses appearing to fall in the scope of authorisation. Therefore, it is estimated that the volume in the scope of authorisation is above 10,000 t/y.	Registered uses of sodium perborate; perboric acid, sodium salt in the scope of authorisation include uses at industrial sites (formulation of mixtures) and uses by professional workers (use in detergents and bleaching products above SCL). The consumer use of bleaching products and detergents is also registered but the derogation for detergents from the restriction on the supply of CMRs to the general public expired in June 2013. Therefore, consumer uses of the substance in these products above the specific concentration limit are not allowed anymore. [score 10]	26	Grouping: with sodium peroxometaborate (CL) [it could potentially replace them in some of their uses]	On the basis of Art. 58(3) prioritisation criteria further strenghtenend by grouping considerations, sodium perborate; perboric acid, sodium salt gets priority for inclusion in Annex XIV among the Candidate List substances. **Therefore, sodium perborate; perboric acid, sodium salt <u>is recommended</u> for inclusion in Annex XIV.**

Lead monoxide (lead oxide)	215-267-0	1317-36-8	YES	1	15	7	Toxic for reproduction (Article 57 c)	The amount of lead monoxide manufactured and/or imported into the EU is according to registration data above 100,000 t/y (approx. 540,000 t/y according to information submitted in the public consultation on the 6th draft A.XIV recommendation (6th REC PC)). Part of the volume is for uses that appear not to be in the scope of authorisation, such as uses as intermediate in the manufacture of PVC stabilisers, certain pigments, explosives, technical ceramics, frits and glass (including Lead special glass and Lead crystal glass) as well as some uses as laboratory reagent and in chemical analysis. Based on information provided during the 6th REC PC, the share of the total tonnage for these uses is estimated at ~6.5%. It is recognised that the intermediate/non-intermediate status of some of these uses is a complex issue (e.g. in the manufacture of glass and frits), and it is stressed that this prioritisation exercise is not taking a formal position whether certain uses of the substance are regarded as uses as intermediates in accordance with the definition in Art. 3(15). Therefore, in conclusion, the volume in the scope of authorisation is estimated to be in the range of 100,000 - 1,000,000 t/y based on registrations and further information (6th REC PC).	Registered uses of lead monoxide which appear to be in the scope of authorisation include uses at industrial sites (e.g. production of batteries and rubber, use in adsorbents and catalysts and as laboratory reagent). [initial score 5] In addition, according to the information submitted in the draft 6th A.XIV recommendation public consultation (6th REC PC), the substance is also used for surface treatment (plating) and in lubricant/corrosion inhibitor products in the aerospace industry. Professional uses as laboratory reagent and in chemical analysis are registered and the information provided indicates that the conditions for the generic exemption for SRD are not always met (based on the tonnage for that use). However, based on the information provided in registrations and in the 6th REC PC it appears that the use may rather fulfil the description of an industrial use (limited to industrial facilities and does not seem to be widespread). The lead registrant and most of the member registrants have updated their registrations during the spring of 2014. They have, inter alia, removed the professional and consumer use in paints and pigments (e.g. artists' paints) from their registrations. Furthermore, the International Lead Association has informed that the use in artists' paints is an obsolete use and the lead registrant has asked the member registrants to update their dossiers. There are some members who have not yet updated their registrations, and the professional and consumer uses in paints (and professional use of adsorbents) remain in their dossiers. Other members have updated their dossiers and kept these uses. However, these members refer to the lead registrant's CSR which no longer supports these uses. Finally, according to registrations the substance is used in articles (e.g. rubber articles).[refined score 7]	23	Grouping: Lead monoxide and lead tetroxide appear to be used in similar applications as other lead substances on the Candidate list, among which pentalead tetraoxide sulphate, tetralead trioxide sulphate (applications in batteries). However, it has not been assessed whether the precise function of these substances in these applications is the same and whether or under which conditions substitution could happen in practice.	On the basis of Art. 58(3) prioritisation criteria further strenghtenend by grouping considerations, lead monoxide gets priority for inclusion in Annex XIV among the Candidate List substances. **Therefore, lead monoxide <u>is recommended</u> for inclusion in Annex XIV.**
Pentalead tetraoxide sulphate	235-067-7	12065-90-6	YES	1	15	7	Toxic for reproduction (Article 57 c)	The amount of pentalead tetraoxide sulphate manufactured and/or imported into the EU is according to registration data and other information sources (public consultation on the draft 6th recommendation) above 100,000. Part of the registered tonnage is claimed as being used as an intermediate (tonnage for use in lead-based battery production). However, based on available information it appears that the use described is likely not to be an intermediate use. Therefore, in conclusion, the volume in the scope of authorisation is estimated to be > 10,000 t/y.	Registered uses of pentalead tetraoxide sulphate in the scope of authorisation include uses at industrial sites (use as stabiliser, PVC processing, use in lead battery production). [initial score 5] Furthermore, according to registration data the substance is used in articles in volumes > 10 t/y (e.g. plastic articles). [refined score 7]	23	Grouping: Pentalead tetraoxide sulphate and tetralead trioxide sulphate appear to be used in similar applications as other lead substances on the Candidate list, among which lead monoxide and lead tetroxide (applications in batteries). However, it has not been assessed whether the precise function of these substances in these applications is the same and whether or under which conditions substitution could happen in practice. Other further consideration: The stabiliser sector has a voluntary commitment to replace lead stabilisers completely by end of 2015 across the EU-28. Would this be the case, the substance would remain of high priority (Volume score would remain 15). In 2012 based on aggregated survey data of its member companies, EUROBAT estimated at 39,000 t/y the tonnage of pentalead tetraoxide sulphate produced during the battery manufacturing process by the European battery industry (ECHA RMOA).	On the basis of Art. 58(3) prioritisation criteria further strenghtenend by grouping considerations, pentalead tetraoxide sulphate gets priority for inclusion in Annex XIV among the Candidate List substances. **Therefore, pentalead tetraoxide sulphate <u>is recommended</u> for inclusion in Annex XIV.**
Tetralead trioxide sulphate	235-380-9	12202-17-4	YES	1	15	7	Toxic for reproduction (Article 57 c)	The amount of tetralead trioxide sulphate manufactured and/or imported in the EU is according to registration data > 1,000,000. Part of the registered tonnage is claimed as being used as an intermediate (tonnage for use in lead-based battery production). However, based on available information it appears that the use described is likely not to be an intermediate use. Therefore, in conclusion, the volume in the scope of authorisation is estimated to be > 10,000 t/y.	Registered uses of tetralead trioxide sulphate in the scope of authorisation include uses at industrial sites (use as stabiliser, PVC processing, lead battery production, production and application of coatings and inks for mirror backing, use as an industrial reactant). [initial score 5] Furthermore, according to the registration data the substance is used in articles (such as plastic articles). [refined score 7]	23	Grouping: Tetralead trioxide sulphate and pentalead tetraoxide sulphate appear to be used in similar applications as other lead substances on the Candidate list, among which lead monoxide and lead tetroxide (applications in batteries). However, it has not been assessed whether the precise function of these substances in these applications is the same and whether or under which conditions substitution could happen in practice. Other further consideration: The stabiliser sector has a voluntary commitment to replace lead stabilisers completely by end of 2015 across the EU-28. Would this be the case, the substance would remain of high priority (Volume score would remain 15). In 2012 based on aggregated survey data of its member companies, EUROBAT estimated at 369,000 t/y the tonnage of pentalead tetraoxide sulphate produced during the battery manufacturing process by the European battery industry (ECHA RMOA).	On the basis of Art. 58(3) prioritisation criteria further strenghtenend by grouping considerations, tetralead trioxide sulphate gets priority for inclusion in Annex XIV among the Candidate List substances. **Therefore, tetralead trioxide sulphate <u>is recommended</u> for inclusion in Annex XIV.**

Trixylyl phosphate (TXP)	246-677-8	25155-23-1	YES	1	9	12	Toxic for reproduction (Article 57 c)	The amount of trixylyl phosphate manufactured and/or imported into the EU is according to registration data above 100 t/y. Taking into account the information on volumes and uses reported in the registrations, it is estimated that the volume used in the scope of authorisation is in the range of 100-1,000 t/y.	Registered uses of trixylyl phosphate in the scope of authorisation include uses at industrial sites (formulation and use in lubricants, lubricant additives, greases, hydraulic fluids and metal working fluids, formulation and use in polymer mixtures and compounds in plastics production) and uses by professional workers (use in lubricants, lubricant additives, greases, hydraulic fluids and metal working fluids). [initial score 10] Furthermore, the substance is used in articles (plastic articles). [refined score 12]	22	Grouping: with tris(2-chloroethyl) phosphate (TCEP, EC 204-118-5) (A.XIV)	On the basis of Art. 58(3) prioritisation criteria further strenghtenend by grouping considerations, trixylyl phosphate gets priority for inclusion in Annex XIV among the Candidate List substances. **Therefore, trixylyl phosphate is recommended for inclusion in Annex XIV.**
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] (HHPA)	201-604-9, 236-086-3, 238-009-9	85-42-7, 13149-00-3, 14166-21-3	YES	1	12	5	Equivalent level of concern having probable serious effects to human health (Article 57 f)	The amount of HHPA manufactured and/or imported into the EU according to registration data is >10,000 t/y. Some uses appear not to be in the scope of authorisation, such as use as an intermediate including use as a monomer in the manufacture of thermoplastics. Based on information on the volume corresponding to those uses from registrations, the volume in the scope of authorisation is estimated to be in the range of 1,000 - <10,000 t/y.	Registered uses of HHPA in the scope of authorisation include uses at industrial sites (formulation of mixtures; hardener for epoxy resins; process regulator for polymer processes). [initial score 5]	18	Grouping: with MHHPA [it could potentially replace it in some of its uses]	Given that the substance is concluded as of same or lower priority as other Candidate List substances not considered for being recommended in this round, the recommendation of HHPA is postponed. **Consequently, HHPA is not recommended for inclusion in Annex XIV in this recommendation round.**
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] (MHHPA)	247-094-1, 243-072-0, 256-356-4, 260-566-1	25550-51-0, 19438-60-9, 48122-14-1, 57110-29-9	YES	1	12	5	Equivalent level of concern having probable serious effects to human health (Article 57 f)	The amount of MHHPA manufactured and/or imported into the EU according to registration data is in the range of 1,000 - <10,000 t/y. Some uses appear not to be in the scope of authorisation, such as use as intermediate including use as a monomer in the manufacture of thermoplastics. However, the volume corresponding to those uses is not available from the registration dossiers. Therefore, in conclusion, the volume in the scope of authorisation is estimated to be in the range of 1,000 - <10,000 t/y.	Registered uses of MHHPA in the scope of authorisation include uses at industrial sites (formulation of mixtures; hardener for epoxy resins; process regulator for polymer processes). [score 5]	18	Grouping: with HHPA. [it could potentially replace it in some of its uses]	Given that the substance is concluded as of same or lower priority as other Candidate List substances not considered for being recommended in this round, the recommendation of MHHPA is postponed. **Consequently, MHHPA is not recommended for inclusion in Annex XIV in this recommendation round.**
1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	68515-50-4	NO	1	-	-	Toxic for reproduction (Article 57 c)			-	Grouping: with other phthalates already in A.XIV or included in the 6th A.XIV Recommendation	Although other substances on the Candidate List assessed in this recommendation round get higher priority based on Art. 58(3) prioritisation criteria, **1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear is recommended for inclusion in Annex XIV on the basis of grouping considerations.**
Dihexyl phthalate	201-559-5	84-75-3	NO	1	-	-	Toxic for reproduction (Article 57 c)			-	Grouping: with other phthalates already in A.XIV or included in the 6th A.XIV Recommendation	Although other substances on the Candidate List assessed in this recommendation round get higher priority based on Art. 58(3) prioritisation criteria, **1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear is recommended for inclusion in Annex XIV on the basis of grouping considerations.**
Sodium peroxometaborate	231-556-4	7632-04-4	NO	1	-	-	Toxic for reproduction (Article 57 c)			-	Grouping: with Sodium perborate; perboric acid, sodium salt (CL) [it could potentially replace them in some of their uses]	Although other substances on the Candidate List assessed in this recommendation round get higher priority based on Art. 58(3) prioritisation criteria, **sodium peroxometaborate is recommended for inclusion in Annex XIV on the basis of grouping considerations.**