01/07/2015

Comments and references to responses on ECHA's 6th Draft Recommendation for Tetraboron disodium heptaoxide, hydrate (EC number: 235-541-3)

The present document compiles the comments received during the public consultation on the draft 6th recommendation for inclusion of substances in Annex XIV of REACH for Tetraboron disodium heptaoxide, hydrate (EC number: 235-541-3). The public consultation took place between 1 September and 1 December 2014. Some of the comments submitted contained additional attachment(s), accessible at http://echa.europa.eu/documents/10162/13640/6th_rec_comref_attachments_tetraboron_disodium_heptaoxide_hydrate_en.zip. Those comments are indicated accordingly in the table below.

For each of the comments there is also a reference to specific section(s) of a document containing the responses to comments ("Response document", available at http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_response_doc_boron_substances_en.pdf). The responses in the Response document are arranged by thematic block and level of information (see more detailed explanations at the beginning of that document).

PUBLIC VERSION

CONTENT

I - General comments on the recommendation to include the substance in Annex XIV

Number / Date	Submitted by (name, submitter type, country)	Comment	Reference to responses
2590 2014/11/24	AREVA, Company, France	See comment on boric acid and borates	Please see references to responses in comment # 2587 in the comments and references to responses document for boric acid.

2643 2014/11/25	Frit Consortium, Industry or trade association, Spain	The Frit Consortium would like to inform that substance is not used in the manufacture of frits	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation.
2653 2014/11/25	N.V. EPZ, Company, Netherlands	Tetraboron disodium heptaoxide hydrate is used in boiling water reactors in nuclear power plants together with boric acid. This substance is part of the nuclear safety system. It acts as a kind of pollutant of the primary system to stop the chain reaction immediately. Tetraboron disodium heptaoxide hydrate is used as a preservative agent for closed cooling systems of boiling water reactors in nuclear power plants in a concentration of 2 g/kg. It is used as substance for chemical conditioning of the loop system. Without tetraboron disodium heptaoxide hydrate and boric acid some of the main reactor protecting system are missing and a safe operation of nuclear power plants is impossible. Tetraboron disodium heptaoxide hydrate is stored in a special tank together with boric acid. It will only be used in emergency situations. The risks for workers are only, while measuring the boron concentration and when it is necessary to mix new substances. In one special case this chemical substance has substituted hydrazine. Normally once a year 25 kg of tetraboron disodium heptaoxide hydrate is mixed and filled in the loop system. The mixing process is done by workers. For this procedure there is a special instruction as well as some special personal protection equipment in place.	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks **C.2. Responses to exemption requests referring to other legislation**
2660 2014/11/25	Company, United Kingdom	Tetraboron disodium heptaoxide, hydrate is a key process ingredient in a wide range of industrial processes. Studies have shown that boron exposure in rats etc can have adverse reproductive effects and that these effects could be extrapolated to be similar in humans. However these studies have been carried out at extreme exposure levels, far in	**A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system -

		excess of those that have been observed in studies looking at workers in industries with significant exposure levels such as the study by Duydu et al. in 2011 looking at workers in a Turkish borax processing plant. Since the level of bioaccumulated boron in these workers is more than an order of magnitude lower than the minimum amount required to induce reproductive effects in lab animals it makes no sense to proceed with this material to authorisation on the basis of the existing science. The effect of proceeding to authorisation on industrial users such as ourselves will be two-fold. Firstly this action will put a significant cost and admin burden on the affected industries so that they can carry out more studies to verify just how far below the significant exposure their processes are. Secondly the affected industries will need to re-direct product development efforts away from pulling ahead of their competitors and instead direct their energies into changing process ingredients to alternative materials. Selection of suitable alternative materials will need to be on the basis of there being no reasonable scientific evidence that workers in industrial processes such have suffered, or will in the future suffer exposure that would be detrimental to their health. However if we had taken this development approach several years ago we would have selected Tetraboron disodium heptaoxide, hydrate as no studies have shown detrimental effects to humans at the exposure levels that could be anticipated in industry.	Authorisation is not a ban 5. Availability of suitable alternatives **A.2.20 Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **A.2.22 Disputing the harmonised classification**
2674 2014/11/26	UNIFA, Industry or trade association, France	The BORON, absorbed by plants in the form of borate, is essential to vegetables. It plays meristematic growth, the migration of carbohydrates, synthesis of nucleic acids and proteins. The boron deficiency is linked to the availability of this nutrient in the soil, that can be influenced pH and by various other soil and climate conditions. This results in anomalies of the leaves extremities, fruits and roots. This deficiency is corrected by precise applications of boron to the soil or in foliar spraying, knowing excess of boron can have an adverse effect on vegetables. The boron is a nutrient, which plays a specific role in the metabolism of the cellular multiplication. substitutable by no other chemical element. The industry of the fertilization did not find alternative substances listed in the draft 6th recommendation. An absence of borated fertilization would engender in the short term in France	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:**

		more than 800 per year of yield loss, including the quality of the crops, knowing that certain crops like sugar beet, and rape are more sensitive to boron deficiency than others. Furthermore, if this deficiency corrected because of the absence of borated fertilizer, the issue would remain in the following increased concern. It is important to underline that these crops are grown in all Europe and they are not specific would also have an impact in term of employment in the whole supply chain of fertilizers, which set up the Risk Management Measures (RMM) in the factories and the training courses for the farmers. Consequently, UNIFA recommend that boron substances listed in the draft 6th recommendation included to the annex 14 of REACH regulation and that a Risk Management Option (RMO) is led. (See my attachment)	5. Availability of suitable alternatives **A.2.11 Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV** **A.2.16: Risks should be managed using risk management measures like PPE, LEV, exposure tracking, training** **A.2.20 Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **C.2. Responses to exemption requests referring to other legislation**
2718 2014/11/27	Company, Germany	As indicated in Section 2.2. of ECHA background document, the use of boron compounds as raw material to manufacture the substance glass is a use as "intermediate" which is not in the scope of authorization. Therefore, additional comments are not relevant for our use.	**A.2.4 Claim of use as intermediate:** **- in manufacture of boron glass** **- in manufacture of frits** **- manufacture of starch glues**

			- production of fluoroboric acid (CAS 16872-11-0 - in manufacture of boron carbide, boron nitride, titanium boride, zirconium boride and calcium boride
2769 2014/11/28	European Special Glass Association and European Domestic Glass Association, Industry or trade association, Belgium	2769_FINAL EDG-ESGA - Use of tetraboron disodium heptaoxide as intermediates in the manufacture of borosilicate glass.docx	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.2.4: Claim of use as intermediate: - in manufacture of boron glass - in manufacture of frits - manufacture of starch glues - production of fluoroboric acid (CAS 16872-11-0 - in manufacture of boron carbide, boron nitride, titanium boride, zirconium boride and calcium boride** **A.2.13: Claim that risks for workers are controlled by other legislation** **C.2. Responses to exemption requests**

			referring to other legislation
2791 2014/11/28	PPC ADOB Sp. z o.o. Sp.k., Company, Poland	General comments: Tetraboron disodium heptaoxide, hydrate has been identified as a Substance of Very High Concern (SVHC) for its effect on reproduction and subsequently included in ECHA's 6th draft recommendation of priority substances for inclusion in Annex XIV (list of substances subject to authorisation), for which a public consultation is on-going. PPC ADOB do not support the inclusion of tetraboron disodium heptaoxide, hydrate in the draft ECHA6th prioritisation list for Annex XIV. Despite the identification of certain borates as SVHCs, borates are safe for the general public and for workers. Several epidemiology studies show the absence of health effects for the general public and for highly exposed workers. In our view, using the REACH authorisation process to control borates would not be proportional and would not contribute to regulatory effectiveness. We strongly suggest that the use of boron, one of critical element in fertilizer industry should be excluded from the scope of authorization as it has no alternatives to secure both, high yields and quality of agricultural products. There is known evidence that in case of boron deficiency there is no other element (product) substance that could replace boron, as it plays important role in all metabolic processes during growing period. ARGUMENTS AND RATIONALE 1. A Risk Management Options analysis (RMOa) should be conducted for borates before a decision can be taken on the appropriate regulatory instruments. The implementation of the SVHC Roadmap allows substances with potential concerns to benefit from an RMOa in order to identify the most appropriate risk management options. This is welcomed by industry as it would improve regulatory effectiveness. To our knowledge, for borates an RMOa has not been carried out. Recognizing the experience from the (ex)- 5th list proposal, we would strongly recommend assessing the efficiency of authorisation in order to consider whether	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban 4. Control of risks 5. Availability of suitable alternatives **A.2.3 As a high fraction of the volume of the substance seems to be used in uses that are out of the scope of Authorisation, the substance should not be prioritised.** **A.2.4: Claim of use as intermediate:** **- in manufacture of boron glass** **- in manufacture of frits** **- manufacture of starch**

		this is the right RMM option for borates. 2. Grouping is only effective when all substances of the group are prioritised at the same time. In previous evaluations (2011, 2012) on prioritisation of SVHCs, ECHA suggested "grouping other boron compounds from the candidate list to prevent replacement of the authorised substances by other similar substances". The EBA agrees that the grouping approach should be used to (i) avoid duplicating the administrative burden and (ii) ensure an equal playing field. Should borate substances be recommended for prioritisation in the future (despite our arguments against this step), we consider it appropriate to suggest that all borate substances classified as Repr 1B H360FD be grouped. Today diboron trioxide, boric acid and disodium tetraborates are identified as SVHCs. In March 2014, the RAC recommended the classification & labelling of disodium octaborate and disodium octaborate tetrahydrate as Repr 1B H360FD, yet these are not considered SVHCs at this point. We believe these substances could replace diboron trioxide, boric acid and disodium tetraborates in a number of end uses. This situation should be clarified before considering prioritisation of other borates for inclusion in Annex XIV. 3. The major uses of the borate substances in the EU are outside the scope of authorization, either as intermediates or as mixtures below the specific concentration limit (SCL), or covered by other legislation. Nearly 79% of boron trioxide, the boric acid and disodium tetraborates used in Europe is outside the scope of authorisation, as these substances are mainly used in: - the manufacture of glass and frits or for the synthesis of new substances: in these uses, the substances qualify as an intermediate since they are completely consumed and transformed into another substance. In the new substance formed, boron is part of the chemical structure and thus, these uses fall outside the scope of authorisation. - mixtures below the specific concentration limits - covered by other sector- specific legislation (e.g. biocides, medicinal products for human or veterinary use), again, falling outside the scope of authorization. Boric acid and other borates have used as an antiseptics from over hundred years.	**glues** **- production of fluoroboric acid (CAS 16872-11-0** **- in manufacture of boron carbide, boron nitride, titanium boride, zirconium boride and calcium boride** **A.2.8: Claim that formulation of mixtures where the final concentration of the substance is below the specific concentration limit for classification should fall under the generic exemption of such mixtures.** **A.2.9 ECHA should group the borates on the Candidate List with borates with a harmonised classification that are not yet identified as SVHC. Recommendation should be postponed until all classified boron compounds are included in the Candidate List.** **A.2.11 Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the**

		The most common are aqueous solutions (usually 3%) but they are also available in consistency of gel or ointment (10%). Medicinal products containing borates are popular in treatment for mouth ulcer, inflammation of the skin, eczema, burns, bruises, swelling, superficial damage to the epidermis. Those products are efficient, safe, commonly available (over-the-counter drugs) and not expensive. Please see attached leaflets of some medicines registered in Poland. 2791_annex.zip	**substance for Annex XIV** **A.2.15 Claim that exposure data shows low/no risks** **A.2.20 Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **C.2. Responses to exemption requests referring to other legislation**
2823 2014/11/28	Norway, Member State	The Norwegian CA supports the prioritisation of tetraboron disodium heptaoxide,hydrate for inclusion in Annex XIV.	Thank you for providing your opinion.
2855 2014/11/28	European Diagnostic Manufacturers Association, Industry or trade association, Belgium	In vitro diagnostic (IVD) medical devices are products which are CE-marked under Directive 98/79/EC and provide for the screening, diagnosis, prediction and monitoring of medical conditions in Europe including for infectious, rare or genetic diseases and medical conditions. IVDs are also used to ensure the safety of the European population blood supply. EDMA (the European Diagnostic Manufacturers Association) is the trade association that represents the IVD industry active in Europe. NB: the information submitted by EDMA in this contribution covers Boric Acid, Disodium tetraborate, anhydrous and Tetraboron disodium heptaoxide, hydrate, hereafter "borates". References to borates in this contribution should be understood as references to the three aforementioned substances. This is justified	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.1. General, recommendation process:**

		as one of the most important uses of borates within the IVD industry is the generation of buffer solutions in which both kinds of borates are in fact used (whereas Disodium tetraborate (anhydrous) and Tetraboron disodium heptaoxide are two different salts, when in aqueous solution they dissolve to a single substance – thus in fact there are only two substances concerned when assessing the impact of these three submissions in solution). The IVD industry uses borates for a number of applications both to manufacture IVD and as a component of the final IVD. Use of borates in IVD will be exempted from the requirement to apply for authorisation where borates are found in the final product. Therefore this input by EDMA considers uses of borates as a 'process chemical' only (i.e. where the borates are not found in the final IVD. The main uses by our sectors of borates as 'process chemicals' are as an essential micronutrient and in buffer solutions. EDMA notes that these uses for manufacturing of IVD are likely to be similar for other sectors relying on biotechnology, such as veterinary 'IVD', forensics, biopharmaceuticals and 'in-house' laboratory medicine. The main properties of borates are described here below: • Boron (introduced in the form of boric acid) – is an essential micronutrient in biological fermentation processes for the manufacture of proteins, recombinant proteins, monoclonal antibodies, polyclonal antibodies, viruses, etc. • Biocidal activity – Borates are known to have a mild biocidal activity which is of importance in preparations which contain substances of biological origin or which are used to analyse biological samples. IVD reagent products typically require biocides in their formulations to prevent reagent deterioration during their storage that could result in potential misdiagnosis and harm to patients. Boric acid and sodium borate support the biocide function in certain reagents, while also maintaining compatibility with the chemistry of the product formulations (i.e. proteins and other biological substances remain stable). Depending on the nature of the specific application the biocidal activity of the borates will be sufficient or may need to be supplemented with additional biocidal activity. • Buffer solution – Borates buffers provide excellent buffering properties over a pH range adequate for biochemical investigations. Furthermore borate buffers allow for stable relatively high salinity buffers and are very commonly used as ionic strength adjustment buffers in biological preparations. • Proteins and other biological substances remain stable and thus suitable for	3. Prioritisation approach applied **A.1.5. Aspects not considered in ECHA's prioritisation:** 1. Potential other regulatory actions 2. Aim & proportionality of authorisation system - Authorisation is not a ban 5. Availability of suitable alternatives **A.2.6 Substance is used in very low volumes in specific use (and therefore these uses should be exempted, or other risk management activities should be considered)** **A.2.20 Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **A.2.21 Boron is a critical raw material** **B.2.1: Concerns and uncertainties with respect to the authorisation process, in particular for SMEs**

		analysis within a borate buffer even under strong buffering conditions. It is the combination of the above properties, as well as additional ones (e.g. stability under high voltage conditions) which have allowed a number of key biochemical applications to be developed based on the use of borates, for instance in the fields of immunodiagnosis, blood screening, cytochemistry, protein electrophoresis, etc. The IVD industry is not aware of an alternative to boric acid and disodium tetraborate which would deliver all these properties. The original formulation of borate-containing products and the use of borates as process chemicals have taken the industry many years to develop and no other viable options have been available to date which will achieve the parallel goals of stability and reagent function. There is no alternative to the use of boron as an essential micronutrient. Socioeconomic considerations (these will also be addressed in the socioeconomic consultation): REACH authorisation requirements would be expected to cause considerable disruption to the uses by our industry as 'process chemicals' because of the role which borates play in the functioning and reliability of in vitro diagnostic tests. Authorisation intrinsically pushes industry toward substitution and the application for authorisation itself would represent a significant cost and resource burden for our industry. EDMA believes that it would be disproportionate to subject the use of borates for the manufacture of various assays to REACH authorisation because: • Borates as 'process chemicals' are an industrial use only. Risks associated to the use of borates in IVDs are adequately covered by the IVD industry which regularly uses borates and other biologically active substances under strictly controlled manufacturing conditions and in adherence to their safety data sheets. • Neither fermentation processes nor borate buffers triggered ECHA to prioritise borates for Annex XIV and are not the basis of concern. Rather, other applications have raised concerns which are now being addressed, catching biological fermentation processes and buffers within them. • Substitution for use of borates in biological fermentation will be impossible, given that boron is an essential micronutrient. With regards to borate buffer solutions, though a number of other buffers do exist and are used in biochemical applications, EDMA has not been made aware of any one substance which could substitute for all of the essential properties of borates in the IVD field. • The quantity of borates used as process chemical in the IVD industry is	**C.2. Responses to exemption requests referring to other legislation** **C.3.6: Claim that uses in healthcare sector in small quantities should be exempt from authorisation**

		extremely low and likely amounts to around 5-6 tonnes per year in total (conservative estimate), or 0.003% of the total maximum quantity of Boric Acid and Disodium tetraborate, anhydrous (100,000 tonnes each) estimated by ECHA as being used in the EU. The use of boric acid for biological fermentation is around 10 kg per year (conservative estimate). This amount of material is simply too small to justify the cost of authorisation for upstream suppliers, thus the responsibility for authorisation would fall on the users of borates, which would not benefit from an upstream authorisation process. Moreover, over 90% of our industry is made up of small and medium sized enterprises. • REACH requires an R&D effort to determine if substitution is possible, however the cost and time envisioned to reformulate and re-validate each impacted assay which is manufactured using borates (e.g. to purify proteins, buffer for synthesis of protein conjugates, storage buffer etc.) would not be trivial. An estimate is that costs of substitution (if an alternate would be possible) may reach 750 thousand to 1.5 million euros per assay. Given that IVD manufacturers can place on the market several dozens of assays, these are significant costs when compared to the total European IVD market revenue of €10.5 billion in 2013. • The costs for developing an alternative for borate buffers are not justified by the commercial value of the tests (if it would even be possible to find a substitute). Incurring such prohibitive costs would lead to many tests (particularly those which are older or produced in smaller volume) being taken off the EU market where hospitals, clinical laboratories and Member State payers would not cover these costs due to their own tight budgets. • Authorisation would hurt the competitiveness of the IVD business. Given that in the case of the IVD industry it is the use of borates as process chemical which is being regulated, the authorisation measure would have no impact on the import of devices from outside the EU but would impact manufacturing facilities within the EU. Authorisation is not considered to be an efficient and resource-effective regulatory measure in the case of borates. Indeed it would be expected to have a disruptive and significant impact on thousands of IVDs and present a considerable burden on our industry. Other more efficient and targeted regulatory options should be considered for managing risks arising from the use of borates and which take into account the cost to industry arising from their implementation.	

2953 2014/12/01	ASD, Industry or trade association, Belgium	1.4. Tetraboron disodium heptaoxide, hydrate (CAS 12267-73-1) Cleaning solutions and alkaline degreasing baths require disodium tetraborate and these solutions are used in a large number of applications. Validation and deployment of alternatives will require application specific investigation and this can take considerable time and resource. 2953_ASD answer to ECHA consultation_General Conclusions for all Boron and lead compounds_281114.pdf	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban 5. Availability of suitable alternatives **B.1.1. General principles for setting latest application dates / sunset dates** **B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 1. Extensive time needed in the supply chain to getting organised for preparing application (e.g. due to high number of users) 2. Lack of alternatives, socio-economic aspects **B.2.2 Concerns about**

			workload, timelines and resources needed for those companies already dealing with Cr(VI) applications.
2959 2014/12/01	ADS Group, Industry or trade association, United Kingdom	ADS fully supports the comments made by ASD	Please see references to responses in comment # 2953 (ASD) in section I.
2967 2014/12/01	CEA, Company, France	Comments submitted relate to four boron compounds proposed in the Authorisation List. The same comments were submitted for the 3 other boron substances proposed on the 6th recommendation of new substances to be included in the Authorisation List. 2967_PC-ECHA-boric_acid-comment_CEA_nov2014.pdf	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.2. Prioritisation: Volume** **A.1.3. Prioritisation: Wide-dispersiveness of uses** **A.1.5. Aspects not considered in ECHA's prioritisation:** 1. Potential other regulatory actions 2. Aim & proportionality of authorisation system - Authorisation is not a ban 4. Control of risks 5. Availability of suitable alternatives

			A.2.1: Borates are naturally present in the environment (water, soil, plants). The use of eco-toxicological data obtained in the laboratory claimed to be not relevant given the natural levels of boric acid **A.2.2: Disputing the volume score, claiming that the volume figures used for prioritisation are outdated** **A.2.3: As a high fraction of the volume of the substance seems to be used in uses that are out of the scope of Authorisation, the substance should not be prioritised** **A.2.11: Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV** **A.2.13: Claim that risks for workers are controlled by other legislation** **A.2.16: Risks should be managed using risk management measures like**

			PPE, LEV, exposure tracking, training **A.2.17: Claim that borates should not be prioritised as environmental monitoring shows no impact on the environment** **A.2.18: As it is a threshold substance effects only occur beyond that threshold. Risk associated with liquid discharge from nuclear power plants not considered a concern** **A.2.20 Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **A.2.21: Boron is a critical raw material** **B.2.3: Regulations and regulatory timelines for the nuclear industry should be taken into account** **B.2.4: Investment cycles should be taken into account** **B.2.6: Check effectiveness**

			of harmonised classification before proceeding with further regulatory risk management activities **C.2. Responses to exemption requests referring to other legislation**
2977 2014/12/01	GIFAS, Industry or trade association, France	Please refer to attached letter 2977_20010_ECHA_Annex XIV_Boron_substances.pdf	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives 7. Burden for industry and potential competitive disadvantage **B.1.1. General principles for setting latest application dates / sunset dates:** 3. ECHA's proposal for latest application dates

			B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates: 1. Extensive time needed in the supply chain to getting organised for preparing application (e.g. due to high number of users) 2. Lack of alternatives, socio-economic aspects **B.2.1 Concerns and uncertainties with respect to the authorisation process, in particular for SMEs** **B.2.2: Concerns about workload, timelines and resources needed for those companies already dealing with Cr(VI) applications** **B.2.4: Investment cycles should be taken into account**

II - Transitional arrangements. Comments on the proposed dates

Number / Date	Submitted by (name, submitter type, country)	Comment	References to responses
2660 2014/11/25	Company, United Kingdom	no comment	
2769	European Special		See references to responses in

2014/11/28	Glass Association and European Domestic Glass Association, Industry or trade association, Belgium	2769_FINAL EDG-ESGA - Use of tetraboron disodium heptaoxide as intermediates in the manufacture of borosilicate glass.docx	section I.
2791 2014/11/28	PPC ADOB Sp. z o.o. Sp.k., Company, Poland	Although we do not support the inclusion of tetraboron disodium heptaoxide, hydrate in the draft ECHA 6th prioritisation list for Annex XIV, in case of inclusion we propose (apply) to use the longest possible period of transition. 2791_annex.zip	**B.1.1. General principles for setting latest application dates / sunset dates:** 2. ECHA's proposal for sunset dates 3. ECHA's proposal for latest application dates See also references to responses in section I.
2823 2014/11/28	Norway, Member State	In general, we are in favour that a regulation should enter into force as soon as possible. Hence we are in favour of the shortest LAD slot.	**B.1.1. General principles for setting latest application dates / sunset dates:** 1. Legal background 3. ECHA's proposal for latest application dates
2855 2014/11/28	European Diagnostic Manufacturers Association, Industry or trade association, Belgium	With regards to setting a latest application date – EDMA notes that ECHA has a truly diverse set of registered uses for borates (for example, see Section 2.3 of Draft background document for Boric acid). Given the complex supply chains involved, EDMA strongly suggests that ECHA put in place a later 'latest application date' to help both applicants and ECHA manage the process to apply for authorisation. A later 'latest application date' has been established for other substances with complex supply chains, such as for chromates. With regards to review periods – according to Article 58(1) of REACH it is possible to set review periods for certain uses, if appropriate, in Annex XIV. EDMA notes	**A.1.5. Aspects not considered in ECHA's prioritisation:** 1. Potential other regulatory actions 5. Availability of suitable alternatives **B.1.1. General principles for setting latest**

		that the use of borates in the IVD industry fulfils many of the criteria established by ECHA SEAC and RAC for setting an exceptionally long review period: • The IVD industry has exceptionally long development cycles which can be up to 10 or 12 years, depending on the complexity of the test being developed. This time period includes EU regulatory requirements to perform a conformity assessment process and gain certification by a notified body. Substitution for borates (where at all possible) would trigger re-registration of each devices where there could be an impact on the sensitivity or specificity of a test. • The use of borates for biological fermentation cannot be substituted. • Although the industry has tried different buffers, borate buffers offer a unique combination of properties which are difficult to substitute. Because each test varies according to what is being tested for (i.e. the analyte), the technology being used and the properties of the biological specimen on which the test is being performed, the use of alternate buffers may impact each test differently. Therefore data for the application for authorisation would need to come from substitution trials performed on an individual assay-by-assay basis for thousands of impacted assays on the market. The costs for doing so are prohibitive and disproportionate to the quantity of borates involved and their risk of exposure when used for this purpose. • Any impact of substitution on in vitro diagnostic (IVD) medical device tests would require extensive re-validation of according to EU regulatory requirements under IVD Directive 98/79/EC. • The IVD industry uses low quantities of use of borates: around 0.003% of the total maximum quantity of borates (100,000 tonnes each for boric acid and tetraboron disodium) estimated by ECHA as being used in the EU. Risks associated to the use of borates in IVDs are adequately covered by the IVD industry which regularly uses borates and other biologically active substances under strictly controlled manufacturing conditions and in adherence to their safety data sheets.	**application dates / sunset dates:** 1. Legal background 2. ECHA's proposal for sunset dates 3. ECHA's proposal for latest application dates **B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 1. Extensive time needed in the supply chain to getting organised for preparing application (e.g. due to high number of users) 2. Lack of alternatives, socio-economic aspects **B.2.5 Claim that the use fulfils the RAC/SEAC conditions for longer review period.**
2953 2014/12/01	ASD, Industry or trade association, Belgium	Unworkable for our industry, see section IV 2953_ASD answer to ECHA consultation_General Conclusions for all Boron and lead compounds_281114.pdf	See references to responses in section I.
2959 2014/12/01	ADS Group, Industry or trade association,	ADS fully supports the comments made by ASD	Please see references to responses in comment # 2953 (ASD) in section I.

	United Kingdom		
2967 2014/12/01	CEA, Company, France		See references to responses in section I.
		2967_PC-ECHA-boric_acid-comment_CEA_nov2014.pdf	
2977 2014/12/01	GIFAS, Industry or trade association, France		See references to responses in section I.
		2977_20010_ECHA_Annex XIV_Boron_substances.pdf	

III - Comments on uses that should be exempted from authorisation, including reasons for that

Number / Date	Submitted by (name, submitter type, country)	Comment	References to responses
2660 2014/11/25	Company, United Kingdom	Tetraboron disodium heptaoxide, hydrate is used as a flux in our specialist casting process. It is an essential component in the process although it does not end up in the finished part. Our process is already very well controlled by UK regulations such as CoSHH (Control of substances hazardous to health) IPPC (Integrated pollution prevention and Control) and their EU equivalents. Within our business we carry out rigorous occupational health checks as per the regulations and have never recorded any adverse effects on our workers. If well regulated industrial uses of Tetraboron disodium heptaoxide, hydrate such as our casting process are not exempted then manufacture of our products will be exported outside the EU with the loss of hundreds of jobs.	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.2.20 Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **A.2.21 Boron is a critical raw material** **C.2. Responses to exemption requests referring to other**

			legislation
2674 2014/11/26	UNIFA, Industry or trade association, France	Fertilizers must be exempted because BORON is essential for crops.	**C.2. Responses to exemption requests referring to other legislation**
2769 2014/11/28	European Special Glass Association and European Domestic Glass Association, Industry or trade association, Belgium	Transported isolated intermediates are out of the scope of authorization (Art 2(8)(b) The uses in food contact materials within the scope of Regulation (EC) No 1935/2004 for substances that are found to meet the criteria for classification as carcinogenic, mutagenic or reprotoxic (CMRs) or are identified to be of equivalent concern to substances which are CMRs, persistent, bioaccumulative and toxic (PBTs) or very persistent or very bioaccumulative (vPvBs) due only to their hazards to human health are exempted from the REACH authorisation provisions (Article 56(5)): Are also exempted from authorisation uses or categories of uses for which the risk is properly controlled by the existing specific EU legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance (Article 58(2)). 2769_FINAL EDG-ESGA - Use of tetraboron disodium heptaoxide as intermediates in the manufacture of borosilicate glass.docx	**C.1.1. General principles for exemptions under Art. 58(2)** **C.1.2. Generic exemptions** **C.1.3. Aspects not justifying an exemption from authorisation** **C.2. Responses to exemption requests referring to other legislation**
2791 2014/11/28	PPC ADOB Sp. z o.o. Sp.k., Company, Poland	We strongly suggest that the use of boron, one of critical element in fertilizer industry should be excluded from the scope of authorization as it has no alternatives to secure both, high yields and quality of agricultural products. There is known evidence that in case of boron deficiency there is no other element (product) substance that could replace boron, as it plays important role in all metabolic processes during growing period. 2791_annex.zip	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives **C.2. Responses to exemption requests referring to other legislation**

2823 2014/11/28	Norway, Member State	Norway does not support that any exemptions from the authorisation requirement should be proposed.	Thank you for providing your opinion.
2953 2014/12/01	ASD, Industry or trade association, Belgium	2953_ASD answer to ECHA consultation_General Conclusions for all Boron and lead compounds_281114.pdf	See references to responses in section I.
2959 2014/12/01	ADS Group, Industry or trade association, United Kingdom	ADS fully supports the comments made by ASD	Please see references to responses in comment # 2953 (ASD) in section I.
2967 2014/12/01	CEA, Company, France	2967_PC-ECHA-boric_acid-comment_CEA_nov2014.pdf	**C.2. Responses to exemption requests referring to other legislation**
2977 2014/12/01	GIFAS, Industry or trade association, France	2977_20010_ECHA_Annex XIV_Boron_substances.pdf	See references to responses in section I.
2986 2014/12/01	Company, United Kingdom	Use as fluxing agent in metallurgical processes. Britannia Refined Metals used calcium chloride as a fluxing agent in refining of silver separated from lead metal in primary metal refining. This caused issues with health and safety and posed an environmental risk. Health and safety issues arose due to calcium chloride capturing moisture from the air, giving a risk of explosion due to moisture being charged to molten metal, to the formation of a slippery film on plant, floors, stairs, etc., and to excessive corrosion of steel structures in the vicinity. Environmental risks arose from the solubility of the slag formed which required a leaching step with subsequent water treatment issues. In 1990 a research project revealed that use of borates, in this instance borax, although other borates would also be effective, produced a slag with none of these problems and also produced savings of about £67 000 (equivalent to about £158 000 today). Research was also conducted into other potential fluxing agents, without success. Shortly afterwards, the use of borates as a metallurgical fluxing	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 5. Availability of suitable

		agent was adopted and continues to this day. If we were required to cease this use, we would have to revert to use of calcium chloride, with the risks and costs that that would entail. We would also require a major capital expenditure to reinstate the additional plant for leaching. In addition, the large European metallurgical company who now buys the spent slag for recovery of residual precious metal values would be likely to have a problem with the new slag, as even after leaching, it would be likely to give a leaching problem to their discard slag. In summary, we submit that use of borates as a metallurgical fluxing agent should be exempt so that risks to human health and safety and the environment can be minimised, energy use, cost and resource consumption can be minimised, and precious metal recovery and costs can be maximised. Further, the presence of borates in a final discard slag confers no additional hazardous properties.	alternatives **A.2.19: Alternative substances are usually less well known and might have a higher risk** **A.2.20 Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **C.1.1. General principles for exemptions under Art. 58(2)** **C.1.2. Generic exemptions** **C.1.3. Aspects not justifying an exemption from authorisation**