01/07/2015

Comments and references to responses on ECHA's 6th Draft Recommendation for Boric acid (EC number: 233-139-2, 234-343-4)

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 Boric acid (EC number: 233-139-2, 234-343-4). 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_boric_acid_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
2502 2014/09/05	Ti Automotive Belgium, Company, Belgium	We use boric acid in our plating bath to stabilize the pH. Actually, we have no idea to use a other substance. Boric acid is the classic additive.	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
2506 2014/09/30	Surface Engineering Association, Industry or trade association, United Kingdom	Boric acid is used extensively in the surface engineering sector as a ph regulator in various processing solutions. Surface engineering is a vital part of the manufacturing supply chain and it is important to recognise this link when considering the suitability of legislative control measures. There is no release of boric acid into the environment nor is there and consumer exposure in the surface treatment sector.	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 **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**
2510 2014/10/09	Individual, United Kingdom	I believe that the hazard should be managed as per the proposals for NMP. Usage in electroplating is difficult to replace as organic acids decompose quickly during electroplating. Incidentally I believe it hypocritical of Europe to export the Aircraft manufacture and maintenance using strontium chromate to countries where worker protection would be less (anywhere else on Earth).	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 **A.2.10: Claim that the risk from borates should be managed similarly to NMP**
2511 2014/10/15	European Catalyst Manufacturers Association (ECMA), Industry or trade association, Belgium	a. Use of boric acid in hydrotreating catalysts Boric acid is used as a raw material for manufacture of hydrotreating catalysts containing boron compounds (eg diboron trioxide). The use of boric acid takes place in a continuous process including dissolving, drying, mixing, forming, impregnation, calcination. During the calcination step, the boric acid is fully transformed into diboron trioxide. Hence the use of boric acid for manufacture of catalysts is an intermediate use. b. Description of the supply chain Boric acid is bought or imported into the EU by catalysts manufacturers. The catalysts manufacturers produce Ni or Co catalysts containing diboron trioxide and supply them to the petrochemicals industry. The catalyst producers using boric acid are based in the Netherlands, Germany and Denmark and supply the 28 Member States. Typically, the direct downstream users of the catalyst manufacturers are the petrochemicals companies and refineries. In these cases, the handling of the catalysts for loading and unloading of the reactors is ensured by companies specialized in catalyst handling, which includes SMEs. The catalyst service companies are typically commissioned by the refineries. These companies are not directly involved in the supply chain; however they have a contractual relationship to this supply chain. This organisation is very specific to the catalyst sector. A summary of the supply chain is available in the attached scheme in the section IV Attachments (additional non-confidential information) to comments on ECHA´s draft reccomendation. 2511_20141015- Boric Acid ECHA consultation final (ECMA) Supply Chain .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.2.3: 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.** **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)
2515 2014/10/27	Kavalierglass, a.s., Company, Czech Republic	First of all we would like to ensure you that since year 1972 (start of SIMAX Molten Glass) up to now we did not meet any health problem caused by borates although hundreds of our people had been in touch with Boric Acid.	Thank you for your comment and the additional information provided. This will be taken into account,

		On the other side, for almost a year we have been using silos for storage of all raw material and this fact practically avoided the touch of attendants with pure borates here and the only touch can happen with glass batch Simax which is the mixture of substances where a glass sand prevails to them. The boron itself in glass is firmly bound in glass lattice and poses no threat to contamination of environment. The borrosilicate glass has the highest hydrolithic resistence among all standard glasses and this fact determines its use except others as laboratory glass, dishes and mainly baby bottles. The boron raw materials cannot be substituted in our glass production because they enable to melt a molten glass containig more than 80% of SiO2 and moreover they have the positive influence for chemical and heat resistance of glass. Taking into consideration the facts above we must hereby declare that the treatment with Boric Acid do not represent for us any critical range of activities as far as people health and environment concerns. For reasons above we do not recmmmend to include Boric Acid into substances under Annex XIV.	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 alternatives
2524 2014/10/31	European Borates Association (EBA), Industry or trade association, Belgium	2524_EBA comments - ECHA PC - 6th priority list (final).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:** 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 6. Socio-economic benefits of continued use **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 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 substance for Annex XIV** **A.2.13: Claim that risks for workers are controlled by other legislation** **A.2.14: Claim that authorisation is not necessary as consumers are protected through the restriction in place** **A.2.15: Claim that exposure data shows low/no risks** **A.2.22: Disputing the harmonised classification** **C.2. Responses to exemption requests referring to other legislation**
2529 2014/11/10	Individual, Germany	HACH LANGE is a producer and importer of ready-to-use reagents for fast and simple water quality testing, wastewater and operational analysis. The use of theses reagents underlay article 56 (3) exemption for Scientific Research and Development according ID 0585 (ECHA Q&A, water monitoring). Boric acid is used in several ready to use water quality tests. Total annual	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

		consumption is much less than one tone per year. Nevertheless downstream use is exempted; Hach Lange is forced to apply for Authorization for the production steps. Analog to the ongoing discussion at Commission site about implementation of pre steps into scientific, research and development. This point of view has been directed to Hach Lange in several official documents; e.g. latest ECHA helpdesk answer, official answers of 15th CARACAL meeting held June 9. Final decision expected from 16th CARACAL meeting November 10. As a conclusion of this Hach Lange is requesting to add an exemption note to the boric acid listing on Annex XIV list: Exempted for production of reagents (mixtures) for analytical water quality testing. As an alternative we suggest to add boric acid to the "Restriction List" (Annex XVII). 2529_ECHA attachments.zip *Confidential attachment removed*	substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 1. Potential other regulatory actions **C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation**
2532 2014/11/12	Castolin Iberica, Company, Spain	2532_ECHA-Technical information.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.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

2534 2014/11/13	BJA, National NGO, United Kingdom	The BJA does not support the inclusion of borates in the draft ECHA 6th prioritisation list for Annex XIV. In our opinion borates are safe for workers with no epidemiology studies proving otherwise. Additionally, using the REACH authorisation process to control borates would not be proportional and not contribute to regulatory effectiveness.	**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
2536 2014/11/13	MTU Aero Engines, Company, Germany	Eine Übernahme der Substanz Borsäure in den Anhang 14 ist aus unserer Sicht nicht notwendig. In unserem Unternehmen der Triebwerksindustrie wird dieser Stoff seit Jahrzehnten für die Verfahren Vernickeln, Aufbringung von Verschleißschutzschichten und Kühlschmierstoff eingesetzt. Er wird benötigt um die Sicherheit, dauerhafte Verwendbarkeit und Einsatzfähigkeit von Triebwerken für Luftfahrzeuge zu gewährleisten. Es gibt derzeit keine Alternativen zum Einsatz dieses Stoffes.	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 alternatives
2537 2014/11/14	Company, Belgium	Boric Acid / borax is still widely used as additive to water based adhesives in order to improve "wet tackiness" of the adhesive on all kind of surfaces. Dosage levels are < 1% for boric acid , < 5% for borax These adhesives are also used for food packaging applications. It is rather surprising boric acid /borax would be subject to authorisation while it is mentioned in the Union List of Regulation EC 10/2011 on plastic materials and articles intended to come into contact with food. A specific migration limit of 6 mg/kg food is mentioned as a safe limit (proved through safety assessment studies). It is hard to understand why these chemicals will have to disappear from the EU market , while at the same time these chemicals are proved to be safe for such a sensitive application.	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.2.23: Claim that authorisation requirement for borates would be in conflict with the EU food law (including food contact materials and food or**

			feedingstuffs legislation).
2540 2014/11/14	Company, Germany	Re-Classification of Boric Acid Re-Classification of Diboron trioxide Re-Classification of Sodium Tetraborate As a "Downstream user" involved in development and manufacturing of boron base protective paints for heat treated steel parts for more than 60 years - without having faced any problems regarding boric compounds hazards, neither in respect of our workers nor our customers - we strongly support the considered re-classification of boric compounds to Category 2. In fact we think it was overdue to introduce the investigations carried out on human beings exposed to the chemical in question for longer periods of time. The studies carried out in U.S.A., Turkey and China clearly show that even in the case of mine workers heavily exposed to boric compounds for decades, the hazards were much lower than suspected based on the overdose animal tests which lead to the present classification. That is why we plea for either reclassification to Class 2 or even to non hazardous. No doubt, hazardous chemicals must be classified, labeled and handled with utmost care according to their characteristics. On the other hand it makes no sense to classify substances which even after thorough and repeated investigations did show only low to no hazardous potential for human beings - even if there was an adverse effect in animal tests with severely overdose exposition. An inflationary hazards classification and use of respective symbols must be avoided if the CLP regulation shall be a trustworthy reliable and informative system allowing the people involved to decide from the labeling, if a substance is hazardous and if yes how it can be handled safely in order to protect people and the environment. Moreover, according to our opinion, preparations containing a hazardous	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.1.3. Prioritisation: Wide-dispersiveness of uses:** 1. Scope of the assessment of wide-dispersiveness of uses **A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 5. Availability of suitable alternatives 6. Socio-economic benefits of continued use **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** **A.2.22: Disputing the harmonised classification**

		chemical in a way that no direct exposition is thinkable during use of the final product (in the case of boron compounds such final products might be for instance glasses based on boron silicates or protective paints for steel hardening), there should be no labelling required, whatsoever – particularly if they are distributed only for industrial use. As a matter of fact boric compounds are in some physical and chemical aspects unique. In the case of protective paints for steel hardening they cannot just be substituted by other chemicals. So severely restricting its use by stringent hazards classification / making it a SVHC etc. would enforce big industries (manufacturers of cars, tractors, trucks, gears/transmissions for heavy machinery, wind mills, vessels and aviation industry) to develop completely new and very costly technologies. To avoid this, hazards classification and labeling should be made based not just on assumption or suspicion but strictly based on proven facts. We are deeply concerned that unless reclassification of the a/m boric compounds to Class 2 will not be practiced and, even worse, if they are put on the 5th and 6th list of SVHC / Annex 14, our highly specialized company with 30 employees which is acting for decades as a world leading supplier of stop-off products for heat treatment of steels, will have to be shut down within the next few years. This because of the fact that about 70% of our sales volume are based on products with boric constituents - which the European legislation now intends to bring on the 6th list of SVHC. Our customers in the car and car supplying industries depend on the boron base products because they are the only ones providing the washabiliy of the residues after heat treatment which is mandatory for cost effective and safe treatment of big numbers of parts in serial production. Over decades we have been accompanying the application processes of our boron base protective paints very closely. Also we have been always in close contact to the responsible managers for health and safety protection: In all that time there was not a single report or complaint regarding a negative impact on the workers health.	

		Summary: We are sorry to state that in our case bringing the said boric compounds on the 5th and 6th list of SVHC / Annex 14 will result in 30 employees getting notice of their dismissal within the next 3-4 years – just because of European legislation. 14. Nov. 2014 Bernhard Schinagl On behalf of board of directors	
2541 2014/11/14	Almatis GmbH, Company, Germany	Boric acid is commonly used as a set retarder for calcium-aluminate cement bonded castables. Here, boric acid has a unique behaviour regarding the adjustability of setting time (= castable working time) without excessively retarded strength development of the castable. Other acidic additives (e.g. citric acid) do not deliver such a performance. More than 4 years of intensive R&D efforts to find a replacement for boric acid did not deliver a feasible alternative, and likewise will not in the future. Therefore, there is NO alternative product to replace boric acid as setting time regulating additive in refractory cement bonded castables. Such additives as e.g. boric acid are not used as a consumer product, but in industrial applications only, and therefore under view of the corresponding working conditions and legislations regarding personal protection devices and measurements of dust concentrations. Exposition of the workers involved is minor. The proportion of a refractory castable additive formulation would not exceed 5.5% boric acid by weight. The use of boric acid has unique properties, which also have positive impact on processing(drying) time and service life of castables, and are therefore a positive contribution to energy saving and consequently reduced CO2 emission.	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 alternatives **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.2.20: 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
2546 2014/11/17	Messer Eutectic Castolin Sp. z o.o., Company, Poland	 2546_ECHA-Technical information.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.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
2548 2014/11/18	ANASTA/ANIMA, Industry or trade association, Italy	Soft soldering, brazing and braze welding are industrial processes to join ferrous and non ferrous metals (steels, copper, nickel, titanium alloys, etc.) that are executed without melting the base metal, but only the added metal. They are based on the wetting of the base metal, that is possible only on metals free of oxides because properly de oxidized by using mixtures containing boric acid, disodium tetraborate and boric oxide. 	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.
2550 2014/11/18	Company, Ireland	Boric acid is a widely used and critical substance in the pharmaceutical industry so its inclusion in the Annex XIV could potentially have a signficant impact on our business. Allergan use this material as an excipient in the formulation of	Thank you for your comment and the additional information provided. This will be taken into account,

		medicinal products and medical devices. Due to current exemptions, we understand that we can continue to use boric acid in our manufacturing processes as well as in our laboratories for scientific research & development. However, Allergan is concerned that our supplier may discontinue the manufacture of this substance due to REACH authorisation requirements. Although Allergan do understand the hazards of this substance, we request that ECHA broaden the list of exempt uses to ensure that the supply of this substance will not be restricted across the EU. Under controlled conditions, this substance can be used in a safe and responsible manner. If this substance was to become unavailable it would have a signficant impact on our business due to the costs associated with identifying an effective alternative and validating this alternative.	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 alternatives **C.2. Responses to exemption requests referring to other legislation**
2551 2014/11/18	European Welding Association (EWA), Industry or trade association, France	EWA position in the context of ECHA's 6th recommendation to include borates in Annex XIV of the REACH Regulation The European Welding Association (EWA) is a branch organisation with members (directly or via National Associations) providing a high representation in Europe regarding the manufacture of welding and brazing consumables and equipment. Companies are involved in using borates in soldering and brazing technologies as well as applying borates in the manufacture of brazing and welding products. EWA wishes to contribute to the public consultation regarding the ECHA 6th recommendation for the inclusion of substances in the REACH Regulation Annex XIV, this to express the serious concern and objections of our members. From information published by ECHA it is well understood that a major health concern involves the toxicity for reproduction. Despite no signs of health problems have been reported in our industry, most member companies worked on alternatives for boric acid and other borates in various applications. In (the manufacturing process of) welding and brazing consumables, the form in which boron is used is mainly either as alloy or in a silicate / glass form. The	**C.2. Responses to exemption requests referring to other legislation** See also responses referred to in comment #2524 in this section.

		alloy form is not on the (Candidate) list of Substances of Very High Concern. CPIV (Standing Committee of the European Glass Industries) confirms that boron in boron silicates does not exist as boric acid, disodium tetraborate, nor as diboron trioxide in the silicate or glass. So the silicate form would not be on the (Candidate) list of Substances of Very High Concern neither. However, cases of use of borates in those manufacturing processes are indicated. For technical reasons alternative substances turned out not to be acceptable in all cases of application or formulation as expressed in communications from member companies and industrial associations. Research on suitable alternatives in flux agents, drawing soaps, welding and brazing consumable constituents are ongoing. Despite this, it is clear that forbidding the use of boron as a constituent in fluxes, in particular brazing as a wide spread industrial application will be banned from Europe. Conclusion: EWA supports the arguments of the European Borates Association against the draft ECHA 6th recommendation for the inclusion of borates in the REACH Annex XIV. 2551_Doc EWA-TCC-263-14-final; EWA Position re Borates.docx	
2554 2014/11/19	BROQUETAS,S.L., Company, Spain	2554_ECHA.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:** 4. Control of risks

			5. Availability of suitable alternatives
2556 2014/11/19	UNITI Bundesverband mittelständischer Mineralölunternehmen e.V., Industry or trade association, Germany	Comments of UNITI Bundesverband mittelständischer Mineralölunternehmen e.V. regarding the public consultation on Boric acid to the 6th recommendation of priority substances for inclusion in Annex XIV. The comments are given in the attachement. 2556_UNITI comments_public consultation on Boric acid_19 Nov 2014.zip	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.2.8: 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 substance for Annex XIV** **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** **C.2. Responses to exemption requests referring to other legislation** See also responses referred to in comment #2524 in this section.
2557 2014/11/19	DALIC SAS, Company, France	Dear Sirs, We are a SME of less than 20 people working in the field of surfaces treatment without immersion.	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of

		These localized applications or selective applications are a necessary process in all surface treatment sectors. They can be required at production stage when only a limited area of a new component requires a treatment. So the immersion of the whole component is avoided, the quantity of needed solution and rinsing water are very small and limited to the treated area. They can be required also in production if a defect is detected in a layer deposited for example by immersion or in case of over-machining, and thus the scrapping of the part is avoided. They can be required as well at maintenance stage during the service life of a component for a repair purpose. Our activities involving boric acid concern industry only, e.g. Aerospace, Railways, Defense... Main points of our comments: ☐ Boric acid should not be a priority substance for inclusion in Annex XIV as it is not a PBT substance or a CMR of category 1A. ☐ We are using 50 to 100 kg per year of this substance!! ☐ It is used for nickel sulfamate plating (commercial name of the solution: DALINICKLE PLUS) under controlled conditions (general ventilation, local exhaust, protective mask with A2B2P3 cartridge, gloves, facial screen). ☐ Bore in the coating is measured under the detection limit of 0.0020 % mass/mass, so the corresponding boric acid concentration is 10 times under the regulatory limit of 0.1 % mass/mass. ☐ Finding an alternative for boric acid is complex as the mechanism of its action is not clear. ☐ Some years ago, we try to improve the performances of the DALINICKLE PLUS solution but our conclusion was to double the boric acid content. ☐ The time to qualify such technical coating (no cracks and high corrosion protection of coated aluminium and steel) requires several years of real testing. Please, see attached document. ☐ We are already very affected by REACH regulation with the application for Authorisation of chromium trioxide, by the CLP regulation, with the modification of the labelling of all our electrolytes by 1 June 2015, very involved in the search for less dangerous alternatives for CMR (priority: CrVI) and also in several working groups.	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 alternatives **B.1.1. General principles for setting latest application dates / sunset dates:** 3. ECHA's proposal for latest application dates **B.2.2: Concerns about workload, timelines and resources needed for those companies already dealing with Cr(VI) applications.**

		☐ A new application for Authorisation for a small company like ours, using such small quantity of boric acid would be too much time and money consuming. We hope to have been convincing and thank you for your attention, Yours sincerely, 2557_Flyer Ni D+ GB.pdf	
2558 2014/11/20	Company, Poland	Boric acid and its salts are used to produce various haematology reagents. Borate buffer (composed from boric acid and sodium tetraborate decyhydrate) enables to maintain pH of the solutions within the specific range: 7.8 to 10.6. Borate buffer has bacteriostatic properties and it is also an inhibitor of enzymes. Its use minimizes the need for the use of bacteriostatics and fungistatics. Buffers based on borate compounds have good conductivity properties. Moreover, they are less sensitive to overheating, what facilitates transport and storage of haematology reagents. This issue is especially important during using the reagents in African countries and in Asia, which are the main recipients of the reagents. Haematology reagents containing in its composition borate buffer, dedicated to clinical diagnostics are used only by qualified medical personnel. The reagents are not widely available. Haematology reagents based on borate buffer are stored in properly labelled, tightly closed containers. Disposal of used up reagents is performed in accordance with the requirements applicable in hospitals and diagnostic laboratories. Application in haematology reagents raw materials other than boric acid and its salts may lead to reduction of reagent's stability. It may increase their sensitivity to high temperatures and cause abnormal functioning , which in turn may lead to receiving abnormal blood count for patients.	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 **A.2.21 Boron is a critical raw material**
2560	Company,	The dispersiveness of uses addressed in the Annex XV dossier for boric acid	Thank you for your comment and

2014/11/20	United Kingdom	includes uses as a laboratory chemical. However, the Annex XV dossier only refers to consumer exposure to boric acid and "indirect exposure through the Environment", for which "Exposure through diet" is the only example quoted. Exposure in a professional laboratory workplace in scientific research and development (SRD) and in the SRD supply chain are not mentioned but in all situations are expected to be nominal with the established measures of personal protection for safe use in our laboratories such as the use of ventilated enclosures and the wearing of appropriate personal protective equipment. The purpose in submitting these comments is to ensure that ECHA is familiar with certain critical uses of boric acid in nucleic acid labelling and detection systems, and in reagents allowing for detection of minute protein quantities in SRD. Although our uses of boric acid is in limited volumes and laboratory scales, these uses are critical for the manufacture of Enhanced ChemiLuminescence (ECLTM) detection kits as used in research into the role of proteins in disease processes and the effects of genetic modification on protein expression, and by forensics science laboratories for detection of minute protein quantities. These are niche specialty uses of boric acid, within the general use application as a laboratory chemical described in the dossier. There are currently no known substitutes for our particular uses.	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 **C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation**
2561 2014/11/20	RWE Power AG, Company, Germany	High volumes and wide dispersive use: Since the harmonized classification of boric acid as Toxic for Reproduction, Category 1B, was established, some uses have been substituted. Moreover some mixtures have been modified in order to ensure that boric acid concentration is under the specific classification limit. These evolutions are leading to considerable change within the market and the related exposures. The data concerning the volume and wide dispersive use for prioritization of boric acid are dating back to 2005 - 2008 and should therefore be reassessed. General remarks: The European Commission released its Review of REACH on 5 February 2013	**A.2.2: Disputing the volume score, claiming that the volume figures used for prioritisation are outdated.** **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**

		containing some interesting points on the European Commission's conception of risk management under REACH. Most importantly, the European Commission explicitly mentions that "no automatic link is assumed between the classification of a substance as a CMR (carcinogens, mutagens and reproductive toxins) and its inclusion on the Candidate List". Thus, Authorization is not an inevitable consequence of classification as CMR. Furthermore, the Commission explains that "before considering the inclusion of a substance on the Candidate List, an assessment of the best Risk Management Options under REACH is performed". Similarly to the review of REACH, the Commission, the Member States and ECHA confirm their commitment to the "best RMOs" approach to handle SVHCs. This Roadmap is a significant development, because it provides a more transparent and predictable process to consideration of SVHCs. It will also make conducting an RMO study a routine step before a substance is placed on the Candidate List. A RMO study should therefore be performed (which has not been done for boric acid) before adding and prioritizing a substance on the candidate list following the Review - recommendation: 7.1. "The Member States and ECHA are encouraged to continue discussing and sharing at an early stage RMOs analysis with the view to coordinate activities in relation to identification of SVHCs, including "substances of equivalent concern" for which no guiding criteria are available yet." 2561_ECHA_consultation.pdf	**the generic exemption of such mixtures.** **A.2.11: Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV** **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**
2564 2014/11/20	British Jewellers Association, Industry or trade association, United Kingdom	The BJA does not support the inclusion of borates in the draft ECHA 6th prioritisation list for Annex XIV. In our opinion borates are safe for workers with no epidemiology studies proving otherwise. Additionally, using the REACH authorisation process to control borates would not be proportional and not contribute to regulatory effectiveness. 	**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
2566 2014/11/20	Individual, United Kingdom	Boris acid as used as a flux for soldering process's in the jewellery and silversmithing sector, is used in minute amounts, but is vitally important to create a strong and cohesive joint. Alternative flux's simply do not work as well. The EU has already banned the used of Cadmium in solders which has made the task of soldering more difficult as modern solders do not flow as well as	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

		they did with a minute amount of Cadmiun. AN amount so small as to NOT represent any health risk. Boric acid is also used only in minute amounts due to the fineness of the work, and therefore represents no health risk. Placing more and more pointless restrictions on business is having a devastating effect on our ability to compete in the international market place. I have no doubt that in the Far East, they have precious few restrictions on toxic materials being used as a part process, but giving them a performance and cost advantage. It is right and proper that any toxic materials should be controlled in a manner that will not effect peoples health. However, as often happens targeting the more intense users of toxic materials invariably has huge practical and cost implications for those users where there is no risk. A balance needs to be sought that is practical and viable.	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.2.20: 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**
2567 2014/11/21	AGLUKON Spezialdünger GmbH & Co. KG, Company, Germany	We, AGLUKON Spezialdünger GmbH & Co. KG, are an SME and produce mainly foliar fertilisers, which are distributed in over 70 countries all over the world. Our main business is located outside of Europe. Nearly all of our products (over 90%) contain boric acid in a range of 0,01% to 7% Boron (0,06% to 40% boric acid). Boron is essential for plant growth. Boron deficiency is one of the most widespread deficiencies among plant micronutrients in agriculture and one of the major constraints to crop production. For this reason the use of boric acid in manufacture and application of foliar fertilizers (regardless of the final borates concentration) should be exempted. Taking into account the importance of boric acid for crop nutrition and also that the risk for consumers, industrial as well as for the professional workers is adequately controlled, the conclusion has to be drawn that prioritising boric acid at this time does not achieve the aim of the regulatory process. Because of the above mentioned reasons, AGLUKON Spezialdünger GmbH & Co.	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**

		KG does not support the inclusion of boric acid in the draft ECHA 6th priorisation list of Annex XIV.	
2573 2014/11/21	Company, Finland	CLP -classification of boric acid as having H360FD is highly questional and does not have a solid proof behind it. The data used for priorization of substance is not correct. Proposal is based on relatively old studies. These old reports do not show strong statistical value. The exposure estimates in the studies do not correlate to present industry practices on workers protection. New data would be needed to evaluate if the reprotoxic properties are of equivalent concern compared to known CMR or PBT substances. Use is found purely within industrial application, the risk in industry is well managed and low. The use of boric acid as buffering agent in production of diagnostic kits for example in diagnosis of bacterial infections, should be exempted from the authorization requirement, as there is a community wide limit value for work place exposure. If boric acid would end up to authorization list, it would lead to end of production of these diagnostic kits in Finland and Europe. The production lines would be transferred outside Europe for example India, China, USA etc. Boric acid is used as a starting material for variety of boron derivatives, which are used in Pharmaceutical industry, drug development of novel drugs etc. The whole European community will suffer from authorization of boric acid. The exposure for workers of boric acid is already prevented in the production, as the purity requirements of the product provide for isolation. The substitution to possible alternatives in diagnostic kit products requires firstly an extensive research and development and secondly a long process for products approval. There are no possible alternatives for boric acid. And even if some other acids would be possible to test, they are already in the candidate list, and may well be prioritized for authorization, if their volumes increase. When authorization is required, the drafting of the substitution plan is very challenging due to the fact, that alternatives already are identified as SVHC-substances. Substances that are used in European chemical industry especially in pharmaceutical industry and for example API industry (active pharmaceutical ingredient), are already optimized and the most environmentally safe chemicals	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 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.2.20 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** **C.1.2. Generic exemptions**

		are selected for decates already, and the real SVHC substances are exluded. This means that all the realistic alternatives are already tested and they may have had worse environmental risks than for example boric acid, which has also been used in eye drops in human and animals for decates without even irritating effects. Boric acid is mainly used in chemical industry as a reagent or in pH adjusting in buffer solutions and is handled professionally and without environmental impact or waste. It is not either a part of the product. Chemical processes are optimised due to economical reasons and at the same time waste formation is minimised. Processes are closed batch or flow reactions and employees are well trained to avoid any EHS deviations. Risk assessments are always performed before industrial processes are started. Boric acid is an important starting material for variety of boron compounds, which are further needed in pharmaceutical industry and drug discovery research as intermediates. It is an important acid in buffer solutions, which are needed in production of diagnostic measuring kits to be used in hospitals to analyse the need for antibiotics and minimise unnecessary antibiotics over-presciptioning. Boric acid has been used over several decates as a drug for eye problems, indicating not so severe classification as now has been suggested. If boric acid is set as an authorised compound, it will leed to several big chemical industry companies to move away from EU to more productive countries such as USA or Asian countries. Also thousands and thousands of emplyees will loose their jobs, because boron derivative production and usage will move away from Europe. It is not either a good option to move boric acid use outside of Europe to countries which do not have experience on handling this compound safely and with respective procedures to environment. It will become a global problem, if Europe will outsourse all chemicals to "clean up" it's own environment to just make things worse in Asia, Africa and other continents.	**C.2. Responses to exemption requests referring to other legislation**
2578 2014/11/21	I&P Europe - Imaging and Printing	The substance is classified as reprotoxic on the basis of animal studies. But epidemiological studies of borate mining and processing workers, and of	**A.1.5. Aspects not considered in ECHA's prioritisation:**

	Association e.V., Industry or trade association, Germany	populations living in high-boron areas, have not found adverse reproductive (fertility or development) effects in humans. Thus the data for human exposure do not show such adverse effects even at the greatest possible chronic human exposure levels. The supply of the substance to consumers in mixtures above its specific concentration limit has been prohibited since 1st June 2012 by Regulation (EU) 109/2012; and the derogation (from that same Regulation) covering perborates in detergents expired in 2013. An assessment of the impact of the restriction of Reg. (EU) 109/2012 should be carried out before considering further measures such as Annex XIV inclusion. Our view is that the risks to humans from borates are adequately controlled, and requiring authorisation for use of the substance is not proportionate.	1. Potential other regulatory actions 2. Aim & proportionality of authorisation system - Authorisation is not a ban **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.2.13: Claim that risks for workers are controlled by other legislation** **A.2.14: Claim that authorisation is not necessary as consumers are protected through the restriction in place** **A.2.15: Claim that exposure data shows low/no risks** **A.2.22: Disputing the harmonised classification** **C.2. Responses to exemption requests referring to other legislation**
2579 2014/11/21	Company, Slovakia	Dear Sirs, The use of Boric Acid is fundamental for many industries. For applications in our fields there are currently no alternatives. A total ban on the use of the product	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of

		would from our point of view greatly damage a big segment of European business. The application are in the field of welding, brazing, air-conditioning and automotive etc.. Please contact me for further information if needed under +393401864963. Thanks, Brian 2579_ECHA-Technical information.docx	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
2580 2014/11/21	Company, Italy	 2580_ECHA_Technical_information.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.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
2581 2014/11/21	National NGO, United Kingdom	This substances is a precursor of a range of substances mainly used as fluxes but also reagents that arfe used in the chemical analysis of inorganic no-metallic materials, especially ceramics and minerals. Using the analytical	Thank you for your comment and the additional information provided. This will be taken into account,

		technique X-ray Fluorescence a laboratory could use in excess of 100kg per year of lithium borate fluxes. By restricting the use of such materials, their cost for use in chemical analysis may become prohibitive. This will detrimentally affect control and trade on materials in the ceramic and minerals sector.	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
2582 2014/11/21	Protim Solignum Ltd., Company, United Kingdom	Boric acid is used in construction materials (wood and wood-based board) as a flame retardant (in a mixture with other co-formulants). Where there is sufficient Boric acid in the flame retardant product for it also to be claimed as a wood preservative, the boric acid is being used in a biocidal product within the scope of Directive 98/8/EC ('BPD') and EU 528/2012 ('BPR') so this use is exempt from Authorisation. If the same product is used only as a flame retardant with no biocidal claims, this use is not exempt from the scope of Authorisation. However the evaluation process which has been carried out under the BPD and BPR includes a Human Health Risk Assessment (HHRA) and Environmental Risk Assessment (ERA) for the product. The HHRA scenarios for acute exposure to professional personnel applying the product in an industrial situation show that the workers are adequately protected and that there is no unacceptable risk. Although the end uses of flame retardant treated wood is in situations which are not accessible by adults or children, when the BPR scenarios for secondary human exposure are calculated, and used to carry out risk assessment, it is concluded that flame retardant treated wood has an acceptable risk (See attached document). Therefore, the use of Boric acid as a flame retardant for wood should be exempt from Authorisation. Information on the safe handling of the flame retardant treated wood or wood board is available and passed down the supply chain from treater to merchant or downstream user. Boric acid has been tested to European Standards and proven to be an effective flame retardant which is specified for use (e.g. in public buildings) to comply with European building codes, and cannot currently be substituted by another	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 alternatives **C.2. Responses to exemption requests referring to other legislation**

		substance. This information is provided by Protim Solignum Ltd., manufacturer of flame retardant products for wood, with an annual usage of Boric acid of approximately 40 tonnes per year. The market share is not known but here are other products on the market in Europe containing Boric acid as a flame retardant for wood. The treated wood products are sustainable, fire retardant, and durable, safeguarding humans and animals without adversely affecting the environment. *Confidential attachment removed*	
2583 2014/11/21	Company, Portugal	The uses of Boric Acid are included in other legislation, according to the article 2 (5) of REACH legislation: a) in medicinal products for human or veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC and Directive 2001/83/EC;	**C.1.1. General principles for exemptions under Art. 58(2)** **C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation**
2585 2014/11/22	Castolin Eutectic, Company, United Kingdom	2585_ECHA-Socio-economical arguments.docx *Confidential attachment removed*	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 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 **C.2. Responses to exemption requests referring to other legislation**
2587 2014/11/24	Company, France	For more detailed ifnormation - see attached document. French nuclear industry welcome the opportunity to raise awareness within the Commission of the socio-economic benefits associated with the use of certain borates within the fuel cycle of the civil nuclear industry from a wider EU perspective. French nuclear industry does not support the intention to recommend borates, especially boric acid, for inclusion in Annex XIV. • Borates compounds like boric acid are essential and irreplaceable for nuclear electricity production. Boric acid is a key chemical used to operate nuclear power stations in the control of the nuclear reaction and thereby ensuring safe, reliable operation. • Health and environmental risks are considered to be adequately controlled by our industries. • Since the boric acid or tetraborate disodium harmonized classification (2009) as Toxic for Reproduction, Category 1B, market share has changed and question about relevancy of the data used for prioritization could therefore be raised. Moreover, the major uses of the borate substances in the EU (more than 70 %) are outside the scope of authorisation, either as intermediates or as mixtures below the specific concentration limit (SCL), or covered by other legislation. • Otherwise, some uses of borates are essential and non substitutable, as neutron absorbing capability for nuclear industry. A great number of authorization dossier should then been submitted. As a consequence, there would be a discrepancy with the decision to limit use of these substances, identified as strategic for European economy, and the market reality and needs.	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:** 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**

		According to the important impact on industrial activities, before any inclusion in Annex XIV concerning this group of substances, a « Risk Management Option » study should be implemented in order to ensure that regulation to manage the risks identified is based on a complete and up-to-date analysis. 2587_CP Echa-boric acid- nov2014.pdf	**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.2.8: 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.2.11: 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.2.20 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.2.4: Investment cycles should be taken into account.** **C.2. Responses to exemption requests referring to other legislation**
2591 2014/11/24	Company, United Kingdom	The major use of boric acid by the organisation (>1000 tpa) is as a transported isolated intermediate in chemical processing. Boric acid is reacted with hydrofluoric acid to produce fluoroboric acid solution (CAS No.: 16872-11-0). The boric acid is consumed in the reaction: 4HF + H3BO3 -> HBF4 + 3H2O The fluoroboric acid product has been registered as an on-site isolated intermediate.	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.2.3: 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 glues** **- production of fluoroboric acid (CAS 16872-11-0** **- in manufacture of boron carbide, boron nitride, titanium boride, zirconium boride and calcium boride**
2593 2014/11/24	Company, Germany	see attachment 2593_Comment_K+S_KALI_GmbH_boron2.doc *Confidential attachment removed*	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:** 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 7. Burden for industry and potential competitive disadvantage **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.2.8: 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.2.20: 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** **C2: Responses to exemption request under Art. 58(2) referring to specific Community legislation** **C.3.4: Due to its bio-essentiality (e.g. nutriment for crops) and the consequences of boron deficiencies, the non-availability of borates would have a negative impact on economy and agriculture. Bio-essentiality should be exempted**
2594 2014/11/24	Company, Spain	Boron is one the 7 micro- nutrient for plants. It is therefore essential for plant growth and boron cannot be substituted for this particular use. Overmore, boric acid is the one of the main sources of boron for its use in agriculture and no substitutes are available.	**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
2605 2014/11/24	Westinghouse Electric Company LLC, Company, United States	Please accept these comments on behalf of Westinghouse Electric Company LLC ("Westinghouse") on the European Chemical Agency's ("ECHA") proposal to add boric acid to the authorization list pursuant to the Registration, Evaluation, Authorization and Restriction of Chemicals ("REACH) Directive. In brief, Westinghouse strongly opposes the inclusion of boric acid to the authorization list. By way of background, Westinghouse provides fuel, services, technology, plant design and equipment to utility and industrial customers in the worldwide commercial nuclear electric power industry. Nearly 50 percent of the world's nuclear power plants are based on Westinghouse technology and a significant number of these plants are located in the European Union ("EU"). While Westinghouse does not directly use boric acid in its EU operations, we recognize its criticality to the safe operation of nuclear power plants and therefore believe it's necessary to comment on ECHA's proposal. In regards to operational nuclear safety, boric acid provides the B10 isotope which captures neutrons thus allowing the nuclear plants to control / terminate nuclear reactions. More specifically, a boric acid solution in water is used to administer the B10 isotope throughout the various systems for the uses as noted in the examples below: ☐ All Pressurized Water Reactors ("PWRs") and Voda Voda Energo Reactors ("VVERs") in the EU require boric acid for reactor control during operation. These plants operate for 12-24 months on a given charge of fuel. Control of the core reactivity is accomplished by a decreasing level of dissolved boric acid in the reactor coolant, assuring effective control during the cycle. Removal of that capability would render the plant totally inoperable and require a shutdown. ☐ All PWRs and VVERs in the EU require boric acid to assure safe shutdown in the unlikely event of an accident. The safety injection system injects borated water to assure reactor shutdown and provide the necessary cooling.	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 alternatives

		☐ All PWRs and VVERs in the EU require boric acid to assure spent fuel pool subcriticality. If all plants were shut down today, the fuel would still have a residence time in a boric acid water solution for years until reprocessing can be completed. The above applications clearly demonstrate the role of boric acid in the safe operation of a nuclear power plant. To date, no other chemical has demonstrated the same characteristics as boric acid such that it could safely substitute boric acid for these applications. Aside from the safety issues, placing boric acid on the authorization list will do little to further REACH's main objective of protecting human health and the environment from the risks that can be posed by chemicals since the current risk posed by boric acid in the nuclear industry is negligible. Please consider that the nuclear power industry is one of the most regulated industries in the world – with significant oversight from both environmental and nuclear authorities. For example, in the applications mentioned above, the regulations and licensing requirements for Personal Protective Equipment (PPE), inventory tracking, effluent monitoring, and waste management essentially preclude the boric acid from entering pathways that would lead to human or environmental exposure. Westinghouse is dedicated to conducting its operations in an environmentally sound and socially responsible manner and seriously considers the impact of its actions on the environment and on the health and safety of its employees, subcontractors, customers, and the public. Westinghouse does not believe that the continued use of boric acid by the nuclear industry diminishes these values in any way. Therefore, Westinghouse strongly urges ECHA not to include boric acid on the authorization list.	
2608 2014/11/24	Verband Schmierstoff-Industrie e.V., Industry or trade association, Germany	Boric acid is a key substance in the manufacturing process of metal working fluids. For a number of reasons, we feel that it is an unnecessary burden for SMEs to put boric acid on annex xiv:	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

		1.) The paper of the European Borate Association (attached) explains that the risk of using boric acid to human and environment is negligible und the conditions of normal handling and use. We fully agree with this paper. 2.) Following our investigations some years ago, the reaction products of boric acid used in lubricants contain less than 5.5% boric acid, so labelling due to boric acid content is not required and end users are not affected (the study is attached) since the use is safe. 3.) Boric acid based additives are essential for high quality and long lasting metalworking fluids, which is beneficial for environment and economy. 4.) Authorisation means a very high barrier for SMEs. They do often not have the capacities (in terms of knowledge in language, bureaucracy, requirements for authorisation, specialized staff and funds) for an authorisation process. Especially SMEs hesitate to spend even the reduced amount of money for a temporary authorization for boric acid. Furthermore, there is no guarantee for the approval of the authorisation. 5.) Please keep in mind, that on both sides, ECHA and SMEs, the experience on authorisation processes is limited. Therefore we expect to have complex consultations and believe these are beyond the capabilities of SMEs. We would recommend postponing this process until all participants have a clear picture how to handle the authorisation process. 6.) Suppliers will likely not authorise boric acid for manufacturing lubricant additives (due to cost reasons) since the volumes of boric acid supplied to the lube industry is quite small compared to other industries using boric acid (e.g. glass and ceramic industries). 7.) As a result, SMEs will likely remove lubricants based on boric acid reaction products from their product line. This business will be likely transferred to (much) larger multi-national companies who are in the position - in terms of money and expertise - to go through the authorisation process.	XIV and the corresponding background documentation. Please also see response to comment #2524 (EBA comment) **A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks **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.2.20: 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** **C2: Responses to exemption request under Art. 58(2) referring to specific Community legislation**

		Therefore we advocate for leaving boric acid on the candidate list until we've got more experience on authorisation processes. 2608_EBA comments - 6th priority list _14 Oct 2014.pdf	
2610 2014/11/24	PROBELTE S.A., Company, Spain	boron is considered as essential micro-nutrient for plants, and it can not be substituted for this particular use. Probelte is manufacturing mixture as fertilizer, including boron in the formulation and in different concentration range (from 1 to 50% depend on the mixture, liquid or solid), and according to EU Regulations on fertilizer. It would be a non sense to limit so far the use of this natural element.	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. **C.2. Responses to exemption requests referring to other legislation**
2615 2014/11/24	Company, Belgium	As mentioned in the background document Boric acid can exhibit a multitude of functions, depending on its use, such as micronutrient. The registration dossier specifies o.a. this use without any additional information (publically available) Biotechnology is a 'new' process which is taking more and more importance in the development of new industrial world : not only medical devices, or medicinal products will be covered by this type of process; Boric acid is an essential element such as cobalt and can therefore seen as aid of process . But due to the fact that biotechnology is very new, no real legislation is governing this kind of industry . This means that we cannot rely on : the condition mentioned in document PREPARATION OF DRAFT ANNEX XIV ENTRIES FOR SUBSTANCES RECOMMENDED TO BE INCLUDED IN ANNEX XIV nl. 'there is specificminimum EU legislation in place imposing minimum requirements relating to the protection of human health or the environment for the use of the substance ensuring the risk is properly controlled;'cannot be used	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.2.21 Boron is a critical raw material** **B.2.1: Concerns and uncertainties with respect to the authorisation process, in particular for SMEs**

		This will cause a blocking of new development bearing in mind that a lot of SME or small companies are active in this field , that the quantity used is very small (100g /year) and that the preparation of an authorisation dossier is too time and cost demanding *Confidential attachment removed*	**C.1.1. General principles for exemptions under Art. 58(2)** **C.1.3. Aspects not justifying an exemption from authorisation** **C.2. Responses to exemption requests referring to other legislation**
2616 2014/11/25	Repligen Sweden AB, Company, Sweden	No comment	
2618 2014/11/25	SYMOP, Industry or trade association, France	SYMOP position statement concerning ECHA's 6th recommendation to include borates in Annex XIV of the REACH Regulation SYMOP, the French association for manufacturing technologies, represents French manufacturers of consumables for welding and brazing. SYMOP supports the position of the European Welding Association (EWA), the principal European organisation representing manufacturers of welding and brazing consumables and equipment, regarding the authorisation of borates. Our members use borates in soldering and brazing technologies as well as applying borates to the manufacture of brazing and welding products. SYMOP supports EWA's contribution to the public discussion of ECHA's 6th recommendation for substances to be included in REACH Regulation Annex XIV. EWA has clearly expressed the serious concerns and objections of our members. From information published by ECHA it is well understood that toxicity to reproduction is a major health concern. However, despite no signs of health problems having been reported in our industry, most of our member companies have worked on alternatives to boric acid and other borates in various	Please also see response to comment #2551 (EWA comment) 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

		applications. The conclusion of our member companies is unanimous: for technical reasons, all alternative substances tested have proved unacceptable in all applications and formulations. Research into suitable alternatives for use in fluxing agents, drawing soaps, and as constituents of welding and brazing consumables is ongoing. Despite this, it is clear that forbidding the use of borates at this stage as a constituent of fluxes, in particular brazing fluxes, will result in the virtual elimination of the European brazing industry. Conclusion: SYMOP supports the arguments of the European Borates Association against the draft ECHA 6th recommendation for the inclusion of borates in the REACH Annex XIV. 2618_POsirtion SYMOP borates vd.pdf	
2619 2014/11/25	DSM, Company, Netherlands	DSM as a company involved a.o. in fermentation processes will be severely affected if the Boric acid used as a trace element in several fermentation processes will be included in the authorization list (Annex XIV of REACH regulation) 2619_DSM_Boric_acid_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.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 5. Availability of suitable alternatives **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.2.20 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** **B.2.1: Concerns and uncertainties with respect to the authorisation process, in particular for SMEs** **C.2. Responses to exemption requests referring to other legislation**
2633 2014/11/25	Frit Consortium, Industry or trade association, Spain	The Frit Consortium would like to express its support to the comments provided by the European Borates Association (EBA) to the Public Consultation for substance Boric acid (EC 233-139-2, 234-343-4), which make specific reference to the use of this substance in the manufacture of frits. 2633_Frit Consortium - borates intermediate in frits.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 Please see response to comment #2524 (EBA comment) **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**
2634 2014/11/25	Asociacion Nacional de Fabricantes de Fritas, Esmaltes y Colores Cerámicos (ANFFECC), Industry or trade association, Spain	The "Asociacion Nacional de Fabricantes de Fritas, Esmaltes y Colores Cerámicos (ANFFECC)" would like to express its support to the position stated by the Frit Consortium for substance boric acid	Please see response to comment #2633 (Frits consortium)
2641 2014/11/25	P-D Glasseiden GmbH Oschatz, Company, Germany	As indicated in Section 2.2. of ECHA background document, the use of boron compounds as raw material to manufacture another 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**
2650 2014/11/25	European Owens Corning Fiberglas sprl, Industry or trade association, Belgium	As indicated in Section 2.2. of ECHA background document, the use of boron compounds as raw material to manufacture another 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
2655 2014/11/25	N.V. EPZ, Company, Netherlands	Boric acid is used in pressurized water reactors for reactivity control in nuclear power plants, whereby the boron-10 isotope is a neutron-absorber. Boric acid is used in form of natural boric acid, which contains about 20 At% boron-10 and in combination with enriched boric acid with a boron-10 content of about 98 At%. Boric acid is also used in pressurized water reactors in severe emergency situations as neutron absorbing agent to stop the chain reaction immediately. In boiling water reactors it is also used with Disodiumtetraborate in poisoning basins. These basins contain the poisoning solution to shut down the reactor immediately in case of damage. Without using boric acid it is impossible to produce electricity with light water reactors. There is no substitute available. In the primary loop of a pressurized water reactor the normal boron concentration varies from about 2600 ppm to about 5 ppm. In the fuel cooling installation the normal boron concentration is up to 2600 ppm. A higher concentration is located in the emergency tanks (about 21.000 ppm at about 800C) and in the tank of the boric acid mixing station. By this system boric acid is dissolved in demineralised water. Boric acid is normally delivered in special 25 kilogram paper bags or in 20 or 40 kilogram drums. The mixing process is done by workers. They have to fill the solid boric acid into the mixing tank. This procedure normally does not happen more than 2 times a year. The highest risk is to have direct contact with boric acid during the dissolving process. For this process safety instructions as well as special personal protection equipment have to be followed and used. Authorized personal check annually the boric acid exposition of the workers.	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 alternatives **A.2.21 Boron is a critical raw material**
2656 2014/11/25	Aerospace Industries Association, International	November 25, 2014	Thank you for your comment and the additional information provided. This will be taken into account,

	organisation, United States	European Chemicals Agency Annankatu 18 P.O. Box 400 FI-00121 Helsinki, Finland Re: REACH Authorization List Addition, Boric Acid Submitted online To Whom It May Concern: The Aerospace Industries Association (AIA) appreciates the opportunity to make comment on the European Chemical Agency's Candidate List for inclusion into Annex XIV of REACH (the "Authorization List"). Founded in 1919, AIA is the premier trade association representing over 350 major aerospace and defense manufacturers and suppliers and approximately 844,000 aerospace and defense workers. Our members represent the United States of America's leading manufacturers and suppliers of civil, military, and business aircraft, helicopters, unmanned aerial systems, missiles, space systems, aircraft engines, material, and related components, equipment services, and information technology. The aerospace industry is inherently global, and many of our major suppliers are located within the European Union, hence our significant interest in REACH Authorization. The aerospace industry is firmly committed to the practice of safe and sustainable chemical management and is in alignment with the REACH Program's objective of increasing the protection of human health and the environment. We have specific concerns to the September 1, 2014 proposal for the addition of boric acid (EC Number: 233-139-2, 234-343-4; CAS Number: 10043-35-3, 11113-50-1) onto the Authorization List. Manufacturers utilize boric acid in aerospace for several critical applications including metal finishing, non-metallic finishing, and as replacements for more hazardous materials. Although the material is used minimally, and in a manner	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 **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.2.20: 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** **C.3.4: Claim that uses which can replace Cr(VI) should be exempt from authorisation.**

		which must meet stringent safety requirements, it is integral to the manufacture of safe aerospace products. Many of the aerospace products that use boric acid are subject to a type-approval from the European Aviation Safety Agency (EASA) or the Federal Aviation Administration (FAA) in the U.S. The majority of boric acid applications are within metal finishing processes for which the material is an ingredient of a process bath, and does not become a constituent of the final coating. Many of the final products which depend upon this metal finishing can be found on critical locations of the aircraft, such as leading edge protective devices on propeller, engine fan blades and helicopter rotor blades. Most of the vendors that manufacture leading edge devices on aircraft propeller, turbine fan and helicopter blades are located in the E.U. In many instances, the coatings provide corrosion protection to various substrates. Several of the coatings produced provide an important function in overhaul and build-up repair of worn aircraft components. Often the corrosion protective coating is used as a replacement for another SVHC material, cadmium. Boric acid is used in many metal finishing solutions at low concentrations. It is present in many solutions below the specific concentration limit of 5.5% for the material, however, the pure boric acid powder must be used for solution make-up (onsite formulation) and small amounts are needed for ongoing process control. Affected processes include boric sulfuric acid anodize, sulfamate nickel plate, zinc nickel plate, and nickel acetate sealing after anodize. Major metal finishing processes that depend on the use of boric acid include: • Nickel electroplate – major process baths impacted include: chloride nickel, sulfate nickel, sulfamate nickel, watts nickel (comprised of nickel sulfate and nickel chloride). Sulfamate nickel plate is used to produce a defect-free (e.g. no cracks) coating on high strength steel with good fatigue life properties. It is useful for dimensional restoration of damaged parts and is critical to the maintenance and repair of landing gear. • Cobalt electroplate – chloride cobalt, sulfate cobalt, sulfamate cobalt • Nickel-cobalt electroplate – sulfamate-style baths • Nickel-cadmium electroplate – consists of a cadmium electroplate deposit and a nickel electroplate (usually from a sulfamate nickel bath) deposit where in the two deposits are heat treated to diffuse them together (note that this coating is	

		used to prevent corrosion in environments subject to high temperature). • Zinc electroplate – sulfate and sulfate-chloride style bath • Zinc-nickel and other zinc-alloys – chloride, sulfate, sufamate and combinations thereof style bath formulations; cadmium electroplate – sulfate bath • Cobalt-phosphorus electroplate • Trivalent chrome plating – developed as a replacement for conventional hard chrome plating which uses a chromium trioxide (CrVI) solution, the tri-chrome process formulation contains trivalent chromium (CrIII) compounds that are not carcinogenic. This is a relatively new and important development, and manufacturers are at various stages of evaluation and implementation. Although the concentration of boric acid in this solution is very low, limiting its use will likely result in a decrease in the activity to pursue this alternative (to chrome plating using CRVI), which would be counterproductive. • Boric Sulfuric Acid Anodize (BSAA) – this type of anodizing is an environmentally preferred alternative for chromic acid anodizing. Key suppliers of U.S. manufacturers in the EU require the use of boric sulfuric acid anodize to produce parts. The only approved alternative to boric sulfuric acid anodize is chromic acid anodize, and chromic acid is already on the Authorization List. • Seal after anodizing (nickel acetate seal) – nickel acetate sealing must be conducted at a controlled pH for the process to work correctly. Boric acid is used to adjust and buffer the pH in the proper range. The seal hydrates the pores of the anodize coating and the coating becomes resistant to further staining and corrosion. • Cleaning and descaling copper – electro cleaning of copper and copper alloys is performed after photoresist etching. The concentrated electrocleaner formulation contains up to 25% boric acid in solution prior to mixing. After mixing, the boric acid concentration is relatively low. • Fluoboric acid and boric acid – boric acid is used in the manufacture of fluoboric acid which is used in many surface finishing processes. Residual boric acid (several percent) is sometimes, but not always, present in fluoboric acid. Many plating processes use fluoboric acid in either the formulation of the plating solution or in an acid activation solution. Boric acid is also a critical chemical ingredient to many non-electroplating processes used within aerospace such as: • Photographic processes – boric acid retards or prevents the formation of	

		sludge in the "fixer" (chemical used to process photographic or x-ray film) • Silver brazing flux – brazing is a metal joining process whereby a filler metal is heated and distributed between two or more close-fitting parts, similar to soldering except applying higher temperatures. Silver-brazing fluxes contain boric acid and potassium borates, combined with complex potassium fluoborate and fluoride compounds. Boric acid is a principal constituent used in brazing fluxes because it facilitates the removal of the glasslike flux residue left after brazing. • Liquid penetrant inspection – developer powders are used during the dye penetrant inspection process after liquid dye penetrant is applied to and rinsed from parts. The developer then draws the remaining penetrant to where cracks in the surface can be detected. • Lubricants – several lubricants contain low concentrations of boric acid • Heat treat protective coating – boric acid is mixed with a binder in a solvent matrix and applied to titanium parts to form a lubricating and scale-inhibiting coating for heat treat. The coating is removed after heat treating. As noted above, boric acid is used within a critical process intended to replace more hazardous materials such as chromium (VI) [e.g., BSAA for Chromic Acid Anodize (CAA), tri-chrome electroplating for conventional hard chrome electroplate] and cadmium [e.g., nickel-based plating for Cadmium plating]. There are currently few available replacements for boric acid in the aforementioned critical uses. For electroplating baths, the function of boric acid is to serve as a weak buffer in many of the formulations; its principal effect is controlling the pH in the cathodic film. In the case of nickel electroplating, in the absence of such an effective buffer, the nickel deposits that are produced at ordinary temperatures are hard, cracked and pitted, which would render the coating useless. The use of cracked coatings can serve to generate further cracks in the substrate which can have potential catastrophic safety implications of aerospace products under normal operational loading. Chemically, the use of boric acid in a buffer is imperative and effective. H3BO3, has the capability of ionizing with an H+ and a H2BO3- and the H+ from the boric acid reacts with the OH- to hold the pH stable. This makes it versatile enough to be used in a variety of chemical bath control situations. Therefore, AIA recommends that the inclusion of boric acid onto the ECHA Authorization List be deferred at this time. The use of boric acid has enabled the use of more environmentally preferred, safe, alternatives. Since a	

		replacement material is currently not available, prematurely adding the chemical to the Authorization List would run the risk of unnecessarily damaging aerospace companies financially and has the potential to compromise the safety of our aerospace systems. We thank you for your consideration, and welcome any questions you may have. Best regards, Leslie Riegle Director of Environmental Policy Aerospace Industries Association (AIA) 2656_AIA Comments to Boric Acid.pdf	
2658 2014/11/25	Daido Industrial Bearings, Company, United Kingdom	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 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 sole effect of proceeding to authorisation will to 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 .	**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 **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**
2663 2014/11/26	Company, United Kingdom	Our company agrees with and supports the general comments submitted by The European Borates Association (EBA). Our company requests that Boric Acid is removed from the recommendation of ECHA for inclusion in Annex XIV of REACH.	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

		Costs, expensive product certifications, niche downstream users with specific applications plus technically effective alternative solutions are not yet fully available; time is needed both for developing these solutions and to implement the necessary financial resources without impairing the competitiveness of our industry. Our use of Boric Acid (5,400Kg per annum) is within one component of a 2-component mixture. However, it is fully encapsulated in the liquid product matrix and then reacted in the cured, solid end product. Therefore there is no intended release of the substance during product use and an Annex XIV listing will not be an efficient means to achieve the goal of the legislation. In our industry, technical solutions are available to adequately control the exposure of workers during manufacturing. They are sufficiently protected through the restrictions (REACH Annex XVII) and the risk management measures detailed in the exposure scenarios of the registration dossiers. Additionally other downstream legislation specifically protects certain vulnerable workers from exposure to substances toxic to reproduction, such as pregnant workers (Directive 92/85/EC) and young workers (Directive 94/33/EC). We are of the opinion that existing regulations, controls and restrictions provide the necessary safeguards for workers and consumers. In addition, we note that ECHA's draft 5th priority list was stopped by the European Commission and it does not make sense to skip the substances on that 5th list (which presumably have a higher priority) and instead proceed with those substances on the 6th list. Prioritising borates at this time does not represent regulatory effectiveness and is not proportional.	substances to be included in Annex XIV and the corresponding background documentation. Please see response to comment #2524 (EBA comment) **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.2.9: 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 substance for Annex XIV **A.2.12: ECHA should not proceed with the 6th recommendation, when the 5th is still open** **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** **C.2. Responses to exemption requests referring to other legislation**
2664 2014/11/26	Individual, Poland	Boric acid 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 boric acid 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	**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**

		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 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.	**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.2.8: 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 substance for Annex XIV** **A.2.15 Claim that exposure data**

		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. 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.	**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** **A.2.21 Boron is a critical raw material** **C.2. Responses to exemption requests referring to other legislation**
2667 2014/11/26	Individual, France	Arguments provided by EBA (dated 14-10-2014). Authorisation shall help to improve the risk management of SVHCs. However, risks are adequately controlled under the current regulation, therefore authorisation will not provide a further improvement, but only provide a bureaucratic burden.	Please see response to comment #2524 (EBA comment) **A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks **C.2. Responses to exemption requests referring to other legislation**

2668 2014/11/26	Individual, France	Arguments provided by EBA (14-10-14)and Authorisation shall help to improve the risk management of SVHCs. However, risks are adequately controlled under the current regulation, therefore authorisation will not provide a further improvement, but only provide a bureaucratic burden.	Please see response to comment #2524 (EBA comment) **A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks **C2: Responses to exemption request under Art. 58(2) referring to specific Community legislation**
2673 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 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	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 **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,**

		recommendation included to the annex 14 of REACH regulation and that a Risk Management Option (RMO) is led. (See my attachment) 2673_Commentaires UNIFA_Novembre 2014_EN_VF.pdf	**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**
2676 2014/11/26	Company, Germany	Dear Sir or Madam, We do appreciate and understand ECHA's approach to identify SVHC and ban these from the EU market in order to protect the human life and the environment. Our company is absolutely in line with this approach. Effect on chromium trioxide authorization process However it is to point out that the electroplating industry is currently facing a major challenge with respect to REACH authorization due to the substitution of hexavalent chromium compounds (e.g. chromium trioxide) in a significant number of applications. Such applications comprise, but are not limited to: transportation (cars, trucks, trains, airplanes), sanitary or furniture. The switch to new technologies is complex and costly for plating companies as it requires revamping of existing equipment, investment into new equipment and the product approval at final customer level, e.g. Automotive OEM. The substitution process has already started but will take several years for the complete market to switch. Use in industrial setting/environment regulated Furthermore boric acid is deemed to be toxic to reproduction 1B, i.e. "may damage fertility/the unborn child". Consequently consumers as well as professional users should not be able to get in contact with such substance as	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:** 1. Potential other regulatory actions 2. Aim & proportionality of authorisation system - Authorisation is not a ban 4. Control of risks **A.2.11: Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV**

		they might not be able to handle the substance according to its hazard. In contrast to that industrial users are well trained in the handling of hazardous substances. In addition to that plating facilities are falling under numerous local, federal and EU regulations that strictly restrict the handling and define the waste and waste water quality. Examples of such regulations are (non-exhaustive list): Directive 2010/75/EU, Directive 96/82/EC (resp. 2012/18/EU), ADR, Bundesimmissionsschutzgesetz (German immission control law), Arbeitsschutzgesetz (German occupational safety law). Risk Management Option Assessment missing The high scoring leading to the current prioritization proposal of boric acid is based on the high volumes with a score of 15 and the wide dispersiveness of uses (WDU) in combination with article service-life (ASL) with a score of 12. The high score of the WDU is mainly based on uses by professionals (+5) and the uncertainty on releases from articles (+2). Here it is to point out that professional users as well as consumers are less well trained than industrial workers that are working in a strongly regulated and controlled environment like already mentioned before. If the EU bodies see risks in the handling of boric acid in specific sectors or user groups like professionals or consumers we would ask you to tackle these by specific restrictions in those sectors with risks. Furthermore in our opinion it is questionable why substances falling in the scope of REACH, meaning industrial chemicals, that are strictly regulated, may still be used as food ingredients. Boric acid is considered an approved food ingredient, E284. In our opinion, this is a strong contradiction to the proposal of this substance being SVHC. To date the authorization of boric acid would lead to a heavy burden for the plating industry, its suppliers and its customers as it would clearly interfere with the ongoing hexavalent chromium substitution process. We ask you to postpone the authorization of boric acid in order to allow for a smooth substitution of chromium trioxide. Best regards,	**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.2.23: Claim that authorisation requirement for borates would be in conflict with the EU food law (including food contact materials and food or feedingstuffs legislation).** **B.2.2: Concerns about workload, timelines and resources needed for those companies already dealing with Cr(VI) applications.** **C.2. Responses to exemption requests referring to other legislation**
2678 2014/11/26	UITS, Trade union, France	Industry uses boric acid in small quantity. In surface treatment only 1000 tons are used per year. Boric acid is not present in the final article. It is used as regulator of pH.	Thank you for your comment and the additional information provided. This will be taken into account,

		Borid acid has been proposed without RMO. We think this study must be realized before taking a final decision concerning including boric acid in annexe XIV. More specifically boric acid is used for thermic treatment. For this activity boric acid is used as savings before carburizing. Boric acid stop carbon diffusion during the thermic treatment. There is no alternative for this treatment and 0% of boric acid stay on the piece in the end of the operation. Boric acid has a strong impact in general public but a low stake in industry because of the low tonnage. Acid borique isn't the same matter as cadmium or chromium trioxyde which stay a priority for the surface treatment technologies.	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 **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.2.11: Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV** **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**
2680 2014/11/26	Individual, United Kingdom	Martyn Pugh, Gold & Silversmith does not support the inclusion of borates in the draft ECHA 6th prioritisation list for Annex XIV. In our opinion borates are safe for workers with no epidemiology studies proving otherwise. Additionally, using the REACH authorisation process to control borates would not be proportional and not contribute to regulatory effectiveness.	**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

2683 2014/11/26	Company, Germany	We do not agree with the inclusion of Boric Acid in the draft ECHA6th prioritisation list for Annex XIV as epidemiology studies show the absence of health effects even for highly exposed workers and risks are adequately controlled through risk management measures (RMMs) specified in the exposure scenarios communicated via extended Safety Data Sheets (eSDS) provided by our suppliers. As a downstream user of Boric Acid we have evaluated that these exposure scenarios cover our uses and the conditions of use under which we actually handle Boric Acid. For all identified uses, a Risk Characterization Ratio (RCR) far below 1 was determined. The European Borates Association (EBA) has provided a consolidated response on behalf of the European Borate Manufacturers and Importers. We fully support and endorse the comments submitted to this consultation by the EBA.	Please see response to comment #2524 (EBA comment) **A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks
2685 2014/11/26	EnBW AG, Company, Germany	General remarks The European Commission released its Review of REACH on 5 February 2013 emphasizing the Commission's conception of risk management under REACH. The European Commission explicitly mentions that "no automatic link is assumed between the classification of a substance as a CMR (carcinogens, mutagens and reproductive toxins) and its inclusion on the Candidate List". This appears to acknowledge that Authorization is not an inevitable consequence of classification as CMR1. Furthermore, the Commission explains that "before considering the inclusion of a substance on the Candidate List, an assessment of the best Risk Management Options under REACH is performed". Similarly to the review of REACH, the Commission, the Member States and ECHA confirm their commitment to the "best RMOs" approach to handle SVHCs. This roadmap is a significant development, because it provides a more transparent and predictable process to consideration of SVHCs. It will also make conducting an RMO study a routine step before a substance is placed on the Candidate List. A RMO study should therefore be performed (which has not been done for boric acid) before adding and prioritizing a substance on the candidate list following the Review - recommendation:	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 **A.2.2: Disputing the volume score, claiming that the volume figures used for prioritisation are outdated.**

		7.1. "The Member States and ECHA are encouraged to continue discussing and sharing at an early stage RMOs analysis with the view to coordinate activities in relation to identification of SVHCs, including "substances of equivalent concern" for which no guiding criteria are available yet." Boric acid got the classification "toxic of reproduction" category 1B by the EU Regulation 790/2009 since September 2009 and therefore belongs to the hazardous substances according to the EU Regulation 1272/2008. Prior to this classification, the general rules for handling chemicals were applied when using boric acid. All specific measures which have been introduced and implemented since the classification (such as substitution, prevention and reduction of exposure as well as the protection of the employees) are therefore a maximum of 5 years old. Already now Europe faces a ban of boric acid by inclusion in annex XIV (or use has to be authorised). From the downstream user's perspective this timeline is not plausible, especially as there haven't been studies performed recently by the European public authorities on the effectiveness of the measures taken or on any associated evidence of the remaining health risks of the affected employees as well as the remaining environmental risk, which could justify the inclusion of boric acid in the Annex XIV. The study according to annex XV does not include these aspects. We regard this as an additional reason for the necessity of an RMO study for boric acid. The inclusion of boric acid in the candidate list should therefore be re-evaluated. High volumes and wide dispersive use Since the boric acid harmonized classification as Toxic for Reproduction, Category 1B, was established some uses have been substituted. Moreover some mixtures have been modified in order to ensure that boric acid concentration is under the specific classification limit. These evolutions are leading to considerable change within the market and the related exposures. The data concerning the volume and wide dispersive use for prioritization of boric acid are dating back to 2005 - 2008 and should therefore be revalidated. Any prioritization action should be based on current data – a prioritization based on outdated material can lead to overregulation and might not be in line with the principle of proportionality.	**A.2.11: Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV** **B.2.2: Concerns about workload, timelines and resources needed for those companies already dealing with Cr(VI) applications.** **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**

		The prioritization of boric acid in the candidate list should therefore be re-evaluated. 2685_ECHA Comments Attachement EnBW.docx	
2687 2014/11/26	CooperVision , Company, United States	CooperVision is a manufacturer of globally trusted brands of vision correction devices. It is a world leader in the manufacture of soft contact lenses, related products and services. The sale of these devices is regulated to the utmost standards worldwide to ensure the highest level of protection to end users. The use of boric acid in the manufacture, validation, packaging and use of these devices is critical to the continuing production of these devices within the EU. Should boric acid be included onto Annex XIV of REACH, global supply of these lenses could be impacted. It is estimated that over 30% of all soft contact lenses placed on the market globally contain boric acid buffering solution. CooperVision therefore expresses its concern over the potential inclusion of boric acid onto Annex XIV of REACH. Boric acid is widely used in the manufacture of ophthalmic care products and in the manufacture, validation and packaging of soft contact lenses, regulated under Council Directive 93/42/EEC. The principle function of the substance is to help maintain a hydrating and biocompatible environment for the lenses to ensure its safe operation as a vision correction device. The use of such buffering solutions is important for many contact lens wearers. These solutions must have a stable pH within the physiologic range and at approximately the pH of the tears. The normal range reported in the literature since 1921 on human tear pH has a span of values from 6.6 – 7.8. Boric acid buffers exhibit microbiocidal properties thereby reducing the risk of contamination during the contact lens manufacturing process, additionally boric acid buffers provide a compatible environment with the contact lens polymer, thereby helping to assure the stability of the device over the entire shelf life. The ability of the substance to function in a dual role, renders substitution very challenging. There are currently no clear, single substitutes for this substance in ophthalmic care products. It is likely that a combination of substances would be required in order to achieve an equivalent level function. Should substitutes be identified, the device would be required to go through approximately 45 different validation and notification systems before being placed on the market for global sales. The impact of listing this substance onto Annex XIV will be detrimental to the sector in the EU. Such an action would result in significant	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 **A.2.12: ECHA should not proceed with the 6th recommendation, when the 5th is still open** **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**

		economic losses to the Company and the EU as approximately 50% of its global sales of soft lenses are manufactured within the EU. This industry cannot depend upon a successful authorisation application to continue to meet global demand for these devices, rather it will require to have fully validated substitutes in place prior to the sunset date in order to meet global demand. Given the timeframe and complexity of meeting global validation assessments it is possible that production and packaging of such lenses will move to sites outside of the EU as importation of the finished devices could continue without restriction. Finally, as the EU Commission is currently carrying out a full review of the Authorisation process resulting in a delay of the finalisation of the 5th Recommendation. It would be prudent to delay this 6th Recommendation until this review has been completed and the outcome is known.	
2690 2014/11/26	ASSOGALVANICA, Industry or trade association, Italy	Boric acid is used in the electroplating process as buffer of the pH in the nickel plating bath. As a rule the concentration of boric acid ranges between 35 and 50 g/l. Boric acid is a weak acid and it is very effective as buffer of the pH that otherwise will fluctuate and increase during the electrolytic process. Strong acids, such as sulfuric or hydrochloric, are not an alternative because they give to the nickel coating the "burnt effect". Furthermore, the use of strong acids to control the pH needs frequent and extremely careful additions and even so it is not effective. Sulfuric acid, with concentration between 33 and 66% enhances, as time goes by, the instability of the pH due to the electroplating process. As a matter of fact the process will be no longer under control with dramatic increase of low quality products and waste. In summary, without boric acid it is impossible at present to match the standard of quality required by nickel coating product specifications. Boric acid is an essential component of the bath used in trivalent chromium (CrIII) electroplating process. The concentration of boric acid is about 70 g/l in the bath that is increasingly used for decorative chromium plating. Similar concentrations of boric acid, in the range between 30 and 80 g/l, are used in the still experimental bath of hard chromium plating. The trivalent chromium (CrIII) electroplating process has been developed by industry in order to find a	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 **A.2.11: Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV** **A.2.21 Boron is a critical raw**

		substitute to the chromium trioxide bath. Limitations to the use of boric acid will simply hinder further progress in the R&D of alternatives to hexavalent chromium. Nickel plating and chromium plating processes are both subject to several directives (in particular 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work and 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work) that protect the workers also from the risk of exposure to boric acid. Risk Management Measures implemented in order to comply with these directives protect workers also from boric acid therefore, it can be clearly stated that boric acid is used under strictly controlled and safe conditions. Boric acid is an essential, buffering component also of the bath used in acid (cyanide-free) zinc plating where the concentration of boric acid is about 30 g/l. As a matter of fact, barrel plating of thousand tons of small metal parts would not be possible without the effective pH control of boric acid. A Risk Management Options analysis focused on boric acid should be performed before deciding that listing it in Annex XIV of REACH is the most appropriate regulatory instrument.	**material** **C.2. Responses to exemption requests referring to other legislation** **C.3.4: Claim that uses which can replace Cr(VI) should be exempt from authorisation**
2691 2014/11/26	ECOMETAL, Other contributor, Italy	Boric acid is used in the electroplating process as buffer of the pH in the nickel plating bath. As a rule the concentration of boric acid ranges between 35 and 50 g/l. Boric acid is a weak acid and it is very effective as buffer of the pH that otherwise will fluctuate and increase during the electrolytic process. Strong acids, such as sulfuric or hydrochloric, are not an alternative because they give to the nickel coating the "burnt effect". Furthermore, the use of strong acids to control the pH needs frequent and extremely careful additions and even so it is not effective. Sulfuric acid, with concentration between 33 and 66% enhances, as time goes by, the instability of the pH due to the electroplating process. As a matter of fact the process will be no longer under control with dramatic increase of low quality products and waste. In summary, without boric acid it is impossible at present to match the standard of quality required by nickel coating product specifications.	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

		Boric acid is an essential component of the bath used in trivalent chromium (CrIII) electroplating process. The concentration of boric acid is about 70 g/l in the bath that is increasingly used for decorative chromium plating. Similar concentrations of boric acid, in the range between 30 and 80 g/l, are used in the still experimental bath of hard chromium plating. The trivalent chromium (CrIII) electroplating process has been developed by industry in order to find a substitute to the chromium trioxide bath. Limitations to the use of boric acid will simply hinder further progress in the R&D of alternatives to hexavalent chromium. Nickel plating and chromium plating processes are both subject to several directives (in particular 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work and 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work) that protect the workers also from the risk of exposure to boric acid. Risk Management Measures implemented in order to comply with these directives protect workers also from boric acid therefore, it can be clearly stated that boric acid is used under strictly controlled and safe conditions. Boric acid is an essential, buffering component also of the bath used in acid (cyanide-free) zinc plating where the concentration of boric acid is about 30 g/l. As a matter of fact, barrel plating of thousand tons of small metal parts would not be possible without the effective pH control of boric acid. A Risk Management Options analysis focused on boric acid should be performed before deciding that listing it in Annex XIV of REACH is the most appropriate regulatory instrument.	**A.2.11: Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV** **A.2.21 Boron is a critical raw material** **B.2.2: Concerns about workload, timelines and resources needed for those companies already dealing with Cr(VI) applications.** **C.2. Responses to exemption requests referring to other legislation**
2692 2014/11/27	Orion Diagnostica Oy, Company, Finland	The use of substance will be difficult to replace and in industrial use it is used very controlled way by minimizing any risks it may cause.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 5. Availability of suitable alternatives
2693	Company,	The use of substance (boric acid) will be difficult to replace and in industrial use	**A.1.5. Aspects not considered in**

2014/11/27	Finland	it is used very controlled way by minimizing any risks it may cause. In cases where boric acid is used as process chemical and not ending to end product should be exempted from the list. In our case boric acid is used by professionals in very controlled and limited process step. The process is executed according to very detailed standard operation procedures, safety instructions and using all relevant protective devices. Boric acid is used as one component in sodium borate buffer in one process phase after which it is replaced by another buffer and boric acid or borate is not ending to any end products and end users hands. Over all the operations are arranged according to ISO13485 standard (certified).	**ECHA's prioritisation:** 4. Control of risks 5. Availability of suitable alternatives **C.3.5: Claim that products not containing the substance in the final product should be exempt from authorisation.**
2694 2014/11/27	National Authority, Spain	As stated in the "Assessment of the Risk to Consumers from Borates and the Impact of Potential Restrictions on their Marketing and Use" prepared for the European Commission DG Enterprise and Industry (November 2008): "Boron is one of seven elements which are essential to plant growth and classified as 'micronutrients'. Boron containing fertilisers are applied to a diverse range of crops and plants (both commercially and by consumers) including fruit, vegetables and forestry (an emerging area for boron, with the development of biomass use). It is also considered critical to many crops (in boron-deficient regions), in particular, oilseed rape (used in the food industry and increasingly for biodiesel production) and sugar beet which are particularly prone to boron deficiency with resultant poor yields and/or diseases. By definition, there are no alternatives to boron when a crop is boron-deficient." Being a micronutrient, very low amounts of Boron are added to fertiliser products. Therefore provisions, such as the obligation of paying high taxes, or licenses for the use of boron compounds in the fertiliser industry, could lead to increase the cost of manufacturing fertilisers containing this element. This scenario could result in the fertiliser industries (specially small and medium) avoiding the use of Boron compounds, in order to prevent the rise of costs and prices. As explained before that could be dramatic in the agriculture, specially for many important crops or in Boron-deficient soils. Thus we strongly recommend taking into account the specificities of the agricultural sector when dealing with provisions taken in regard to Boron chemical compounds. Specially when the mentioned Study has concluded that "Overall, there is a real possibility that any potential restrictions on the use of	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 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** **C.2. Responses to exemption requests referring to other legislation**

		borates as a fertilizer mineral would result in costs to the industry and consumers with minimal (or no) benefit in terms of risk avoided. In any event, the risks associated with boron fertilisers are unlikely to be of serious concern”.	
2699 2014/11/27	European Special Glass Association and European Domestic Glass Association, Industry or trade association, Belgium	2699_FINAL EDG-ESGA - Use of borates 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**
2704 2014/11/27	Arbeitsgemeinschaft Oberflächentechnik AOT,	Die Arbeitsgemeinschaft Oberflächentechnik repräsentiert die österreichischen Oberflächentechnikbetriebe. Es werden die Interessen der KMUs als auch der großen Industriebetriebe vertreten.	Thank you for your comment and the additional information provided. This will be taken into account,

	Industry or trade association, Austria	Anwendung von Borsäure In der Oberflächentechnik wird Borsäure bzw. deren Salze als eine der am häufigsten eingesetzten Stoffe verwendet: Nachdem Borsäure zu den schwächsten Säuren zählt, ist der Einsatz als PH-Wert-Puffersubstanz bedeutend. Der Einsatz erfolgt immer in schwach sauren Elektrolyten, beispielsweise in sauren Bädern und Passivierungen mit Nickel-, Chrom(III)-, Zink- oder Zink-Nickel-Verfahren. Die gute Wasserlöslichkeit, die gute Lagerstabilität sowie die Prozesskompatibilität von Borsäure sind die Hauptgründe für die häufige Verwendung. Borsäure wird nicht in galvanisch abgeschiedene Schichten eingebaut und sie reagiert nicht mit anderen Elektrolytbestandteilen. Sie ist nicht in den Endprodukten enthalten, sondern als reine Prozesssubstanz zu verstehen! Borsäure ist nicht flüchtig, somit kann sie nur durch Elektrolytausschleppung aus den Bädern in die Umwelt gelangen. Die Pufferung schwach saurer Elektrolyte ist erforderlich, um ungeordnete, dendritische Abscheidungen („Anbrennungen") im Grenzstrombereich zu vermeiden und somit die anwendbare Stromdichte zu erhöhen. Während der Abscheidung konkurrieren zwei Prozesse zur Entladung positiv geladener Kationen an der Kathode. Einerseits im Rahmen der Stromausbeute die gewünschte Abscheidung der Metallionen, andererseits Entladung von Wasserstoffionen zu Wasserstoffgas. Aufgrund beider Prozesse verbleibt im Elektrolyt nahe der Kathode ein Überschuss negativ geladener Anionen, womit ein erhöhter ph-Wert einhergeht. Aufgrund des Pufferbereiches von Borsäure kann dieser Prozess kontrolliert werden, hohe PH-Werte reduziert und somit Beschichtungsfehler vermieden werden. Somit ist der Einsatz von Borsäure ressourceneffizient. Alternativen In der Oberflächentechnik wird bereits intensiv von Seiten der Chemikalienhersteller an Ersatzstoffen geforscht, Hauptgründe für die Forschung sind technische Vorteile in borsäurefreien Zink-Nickel-Verfahren. Ziel wären erhöhte Grenzstromdichten, verbesserte Haftung der Schichten und gleichmäßigere Passivierbarkeit, jedoch sind zum jetzigen Zeitpunkt noch keine technisch einsetzbaren Alternativen verfügbar.	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 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** **C.3.5: Claim that products not containing the substance in the final product should be exempt from authorisation.**

		Der Einsatz von Borsäure als schwache Säure kann nur durch ähnlich schwach saure Substanzen erfolgen. Viele scheiden als Ersatz in galvanischen Bädern aus: aromatische Alkohole wie Phenol sind giftig und werden im schwach sauren Milieu gasförmig ausgetrieben, Ammonuimsalze fungieren als Komplexbildner und würden die Abwasserbehandlung fast unmöglich machen, außerdem führen sie zu spröden Schichten. Starke Säuren sind als Ersatz ebenfalls ungeeignet, da sie bereits bei niedrigen PH-Werten praktisch vollständig als Anion vorliegen, die Pufferwirkung ist damit erschöpft. Der Arbeitsgemeinschaft Oberflächentechnik AOT spricht sich gegen eine Aufnahme von Borsäure in Anhang XIV REACH aus, da aus unserer Sicht keinerlei Risiken für den Menschen oder die Umwelt mit der Verwendung von Borsäure vorliegen. Die Vorteile bei der Verwendung, die geringen Risiken bei gewissenhaftem Umgang, der Beitrag zur Ressourceneffizienz, sowie der Mangel an Alternativstoffen sind für uns ein klarer Grund Borsäure nicht in Anhang XIV REACH aufzunehmen.	
2707 2014/11/27	Vesuvius Group, Company, United Kingdom	The Vesuvius group of companies endorses the comments submitted by the European Borates Association dated 14 October 2014. *Confidential attachment removed*	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.2.9: 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 substance for Annex XIV** **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**
2711 2014/11/27	Company, Finland	The substance will be difficult to replace. Boric acid is used in the synthesis of raw materials for pharmaceutically active ingredients. In the final product there is no boric acid, so there is no risk of exposure for public. In synthetic industry the substance and its risks can be effectively controlled.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 5. Availability of suitable alternatives

			C.2. Responses to exemption requests referring to other legislation **C.3.5: Claim that products not containing the substance in the final product should be exempt from authorisation.**
2714 2014/11/27	Company, Germany	General remarks The European Commission released its Review of REACH on 5 February 2013 emphasizing the Commission's conception of risk management under REACH. The European Commission explicitly mentions that "no automatic link is assumed between the classification of a substance as a CMR (carcinogens, mutagens and reproductive toxins) and its inclusion on the Candidate List". This appears to acknowledge that Authorization is not an inevitable consequence of classification as CMR1. Furthermore, the Commission explains that "before considering the inclusion of a substance on the Candidate List, an assessment of the best Risk Management Options under REACH is performed". Similarly to the review of REACH, the Commission, the Member States and ECHA confirm their commitment to the "best RMOs" approach to handle SVHCs. This roadmap is a significant development, because it provides a more transparent and predictable process to consideration of SVHCs. It will also make conducting an RMO study a routine step before a substance is placed on the Candidate List. A RMO study should therefore be performed (which has not been done for boric acid) before adding and prioritizing a substance on the candidate list following the Review - recommendation: 7.1. "The Member States and ECHA are encouraged to continue discussing and sharing at an early stage RMOs analysis with the view to coordinate activities in relation to identification of SVHCs, including "substances of equivalent concern" for which no guiding criteria are available yet." Boric acid got the classification "toxic of reproduction" category 1B by the EU Regulation 790/2009 since September 2009 and therefore belongs to the hazardous substances according to the EU Regulation 1272/2008. Prior to this	**A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban **A.1.2. Prioritisation: Volume** **A.1.3. Prioritisation: Wide-dispersiveness of uses:** 1. Scope of the assessment of wide-dispersiveness of uses **A.2.2: Disputing the volume score, claiming that the volume figures used for prioritisation are outdated** **A.2.11: Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV** **A.2.20: Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in**

		classification, the general rules for handling chemicals were applied when using boric acid. All specific measures which have been introduced and implemented since the classification (such as substitution, prevention and reduction of exposure as well as the protection of the employees) are therefore a maximum of 5 years old. Already now Europe faces a ban of boric acid by inclusion in annex XIV (or use has to be authorised). From the downstream user's perspective this timeline is not plausible, especially as there haven't been studies performed recently by the European public authorities on the effectiveness of the measures taken or on any associated evidence of the remaining health risks of the affected employees as well as the remaining environmental risk, which could justify the inclusion of boric acid in the Annex XIV. The study according to annex XV does not include these aspects. We regard this as an additional reason for the necessity of an RMO study for boric acid. The inclusion of boric acid in the candidate list should therefore be re-evaluated. High volumes and wide dispersive use Since the boric acid harmonized classification as Toxic for Reproduction, Category 1B, was established some uses have been substituted. Moreover some mixtures have been modified in order to ensure that boric acid concentration is under the specific classification limit. These evolutions are leading to considerable change within the market and the related exposures. The data concerning the volume and wide dispersive used for prioritization of boric acid are dating back to 2005 - 2008 and should therefore be revalidated. Any prioritization action should be based on current data – a prioritization based on outdated material can lead to overregulation and might not be in line with the principle of proportionality. The prioritization of boric acid in the candidate list should therefore be re-evaluated. *Confidential attachment removed*	**a high burden for industry** **B.2.6: Check effectiveness of harmonised classification before proceeding with further regulatory risk. management activities** **C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation**
2716 2014/11/27	Teollisuuden Voima Oyj, Company,	2716_BORON PRODUCTS_ECHA_TVO.pdf	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable

	Finland		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** **B.2.5: Long review period substitution impossible. Claim that the use fulfils the RAC/SEAC conditions for longer review period.** **C.2. Responses to exemption requests referring to other legislation**
2719 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**
2728 2014/11/27	Company, United Kingdom	1.) My company agrees with the comments submitted by the European Borate Association concerning the negligible risk of boric acid to humans under conditions of normal handling and use. Specifically, the reproductive effects observed in laboratory animals dosed repeatedly with high levels of boric acid have not been detected in populations of workers in several countries. 2.) My company's use of boric acid in EU is confined to the manufacture of other substances under the well-controlled conditions that are in place in	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

		industrial facilities. These substances include borated dispersants and borated friction modifiers used as components in automotive and industrial lubricants, and corrosion inhibitors used in metalworking. The use of boric acid as a transported, isolated intermediate is out of scope for authorisation. Additionally, none of the substances formed by the reaction of boric acid with other intermediates in my company's EU facilities are in scope of the current draft recommendation. 3.) In addition to normal workplace controls when handling chemicals, the occupational handling and use of CMRs such as boric acid in EU facilities is already very well regulated under several EU Directives and associated local regulations. 4.) Any boric acid reaction products placed on the market that contain low levels of residual boric acid, either as substances or in mixtures, below the Specific Concentration Limit of 5.5% w/w are not in scope for authorisation. Additionally, when such substances are used in applications where the potential for human (worker) exposure is typically considered to be relatively high, such as metalworking, a published study by an independent organisation has demonstrated that the measured airborne level of free boric acid is below that considered to result in increased health risk (Boric acid-/Boric MWF: Chemicals legislation, risk assessment, protective measures. February 2014 Fachbereich Holz und Metall der DGUV). 5.) For the above reasons, my company believes that adding boric acid to Annex XIV at this time is disproportionate and will serve no purpose in terms of protecting EU citizens. 6.) Additionally, as a matter of procedure, my company considers that the European Commission should focus their attention and limited resources on ECHA's draft 5th priority list (which presumably have a higher priority) instead of proceeding with the substances on the draft 6th list.	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.2.8: 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 substance for Annex XIV **A.2.12: ECHA should not proceed with the 6th recommendation, when the 5th is still open** **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**
2732 2014/11/27	Company, Germany	The element B is an essential micronutrient to plants which is not substitutable, the use of Boric acid for the formulation of fertilizers should be exempted from the authorization scope. 2732_COMPO.pdf	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 5. Availability of suitable alternatives **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.2.20: 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**
2738 2014/11/27	Saint-Gobain ADFORS, Company, France	As indicated in Section 2.2. of ECHA background document, the use of boron compounds as raw material to manufacture another 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**
2739 2014/11/27	Company, United States	Please see attached document 2739_Boric Acid Letter.pdf	**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.2.9: 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 substance for Annex XIV** **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** **C.2. Responses to exemption requests referring to other legislation**
2740 2014/11/27	EDF SA, Industry or trade association, France	The European Commission released its Review of REACH on 5 February 2013. The European Commission explicitly mentions that "no automatic link is assumed between the classification of a substance as a CMR (carcinogens, mutagens and reproductive toxins) and its inclusion on the Candidate List". This appears to acknowledge that Authorization is not an inevitable consequence of classification as CMR. Furthermore, the Commission explains that "before considering the inclusion of a substance on the Candidate List, an assessment of the best Risk Management Options under REACH is performed". Similarly to the review of REACH, the Commission, the Member States and ECHA confirm their commitment to the "best RMOs" approach to handle SVHCs. This Roadmap is a significant development, because it provides a more transparent and predictable process to consideration of SVHCs. All specific measures which have been introduced and implemented since the	**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 **A.2.2: Disputing the volume score, claiming that the volume figures used for prioritisation are outdated.** **A.2.8: Claim that formulation of**

		classification (such as substitution, prevention and reduction of exposure as well as the protection of the employees) are therefore a maximum of 5 years old. Already now Europe faces a ban of boric acid by inclusion in annex XIV (or use has to be authorised). From the downstream user's perspective this timeline is not plausible, especially as there haven't been studied recently by the European public authorities on the effectiveness of the measures taken as well as any associated evidence of the remaining health risks of the affected employees as well as the environmental risks, which could justify the inclusion of boric acid in the Annex XIV. The study according to annex XV does not include these points from our point of view. Market has changed since 2009. First of all, since the boric acid harmonized classification in 2009 as Toxic for Reproduction, Category 1B, some uses have been substituted. Moreover some mixtures have been modified in order to ensure that boric acid concentration is under the specific concentration limit. These evolutions are leading to some change within the market shares (less amount used by detergent industry getting smaller than the initial assessment of up to 26% of the total amount of borates used in Europe) and then of the related exposure. Relevancy of the 2005-to-2008 data, used for prioritization could therefore be challenged. Uses outside of the authorization scope Some uses are outside of the authorization scope: - depending on regulation on biocidal products (TP 8), cosmetics - considered as intermediate for synthesis of other substances These uses weightsmore than 60% of the amount used in Europe according to the 2009 « Annex XV Transitional report » and more than 70% in the 2014 "Critical Raw Material report ". A critical substance for the European economy Some uses are non substitutable, such as nutriment for certain crops or neutron absorbing capability for nuclear industry. A great number of authorization dossier should then been submitted. Borates are among the 20 critical substances for the European economy (Report on critical raw materials for the EU, Report of the Ad hoc Working Group on defining critical raw materials - May 2014). Substitution of such substances is moreover considered as tough (3rd most difficult substance to substitute among the 20 strategic	**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.2.11: Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV** **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** **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**

		substances and non substitutable for nuclear) according to the same report. As a consequence, a gap would appear between REACH regulation of this substance and the market reality and needs. Authorization seems therefore not to be the best way to manage the risks. According to the impact importance on industrial activities, and taking into account the Review-recommendation, before any recommendation to Annex XIV addition concerning this group of substances, a « Risk Management Option » study should be implemented in order to ensure that regulation to manage the risks identified would be based on a complete and up to date analysis. Nuclear part Using boric acid in nuclear electric power plants is vital to control nuclear fission reactions and to ensure nuclear safety. Boric acid, is used in all nuclear industry around the world and no other chemical compound has the same characteristics required to replace boric acid for this use as expected in the authorization process. Boric acid is also used for its neutron absorbing capacities within the fuel cycle and during dismantling. Moreover boric acid is used in the glass for nuclear waste. In France, the use of boric acid in nuclear power plants is checked by the French Nuclear Safety Authority (ASN). Managing the risk of using boric acid Risks from nuclear boric acid uses are considered to adequately controlled for workers and environment. There are no risks for consumers. Risks for workers are considered to be controlled. To manage the risk of boric acid exposure among employees working in the plants and to protect them, nuclear industries implement the actions required by their national law. Boron has been used for this purpose since the start of nuclear engineering with no known adverse effects to personnel. Impact studies carried out in particular as part of authorization requests for liquid discharge and water intakes on the one hand, and data from the environmental monitoring of sites on the other hand, demonstrate the absence of impact on the environment from boric acid liquid discharges due to the operation of nuclear power plants. The health risk associated with boric acid liquid discharge, based on current	

		knowledge and methods tested by recognised scientific organizations, is not considered to be a concern. Impact studies carried out as part of authorization requests for liquid discharge and water intakes on the one hand, and data from the environmental monitoring of sites on the other hand, demonstrate the absence of impact on the environment from boric acid liquid discharges due to the operation of nuclear power plants. The element boron does not exist by itself in the environment and is combined with other common elements, such as oxygen to make borate and exists then naturally. - Borate under boric acid form occurs naturally in water. The concentration of this substance in sea water varies between 4 and 5mg/L. The maximum concentration in added borate in effluents after mixing, accounts for a few percent of the natural background noise; it is of the same order of magnitude as the natural fluctuations of borate concentration in the environment. - Borate under boric acid form also occurs naturally in soil. The boric acid concentration in soil varies between 0,002 and 0,1 mg/g. - Borate under boric form acid content in plants and particularly in vegetables is very high (from 0,025 to 0,5 mg/g). Managing the source at the origin a treating these effluents allow to limit the flows and concentrations of borate liquid discharges into the surrounding environment. 2740_PC-ECHA-boric_acid-comment-nov 2014-VF-EDF.pdf	
2742 2014/11/27	RWE Power AG, Company, Germany	General remarks The European Commission released its Review of REACH on 5 February 2013 emphasizing the Commission's conception of risk management under REACH. The European Commission explicitly mentions that "no automatic link is assumed between the classification of a substance as a CMR (carcinogens, mutagens and reproductive toxins) and its inclusion on the Candidate List". This appears to acknowledge that Authorization is not an inevitable consequence of classification as CMR1. Furthermore, the Commission explains that "before considering the inclusion of a substance on the Candidate List, an assessment of the best Risk Management Options under REACH is performed". Similarly to the review of REACH, the Commission, the Member States and ECHA confirm their commitment to the "best RMOs" approach to handle SVHCs. This roadmap	**A.1.2. Prioritisation: Volume** **A.1.3. Prioritisation: Wide-dispersiveness of uses:** 1. Scope of the assessment of wide-dispersiveness of uses **A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban

		is a significant development, because it provides a more transparent and predictable process to consideration of SVHCs. It will also make conducting an RMO study a routine step before a substance is placed on the Candidate List. A RMO study should therefore be performed (which has not been done for boric acid) before adding and prioritizing a substance on the candidate list following the Review - recommendation: 7.1. "The Member States and ECHA are encouraged to continue discussing and sharing at an early stage RMOs analysis with the view to coordinate activities in relation to identification of SVHCs, including "substances of equivalent concern" for which no guiding criteria are available yet." Boric acid got the classification "toxic of reproduction" category 1B by the EU Regulation 790/2009 since September 2009 and therefore belongs to the hazardous substances according to the EU Regulation 1272/2008. Prior to this classification, the general rules for handling chemicals were applied when using boric acid. All specific measures which have been introduced and implemented since the classification (such as substitution, prevention and reduction of exposure as well as the protection of the employees) are therefore a maximum of 5 years old. Already now Europe faces a ban of boric acid by inclusion in annex XIV (or use has to be authorised). From the downstream user's perspective this timeline is not plausible, especially as there haven't been studies performed recently by the European public authorities on the effectiveness of the measures taken or on any associated evidence of the remaining health risks of the affected employees as well as the remaining environmental risk, which could justify the inclusion of boric acid in the Annex XIV. The study according to annex XV does not include these aspects. We regard this as an additional reason for the necessity of an RMO study for boric acid. The inclusion of boric acid in the candidate list should therefore be re-evaluated. High volumes and wide dispersive use Since the boric acid harmonized classification as Toxic for Reproduction, Category 1B, was established some uses have been substituted. Moreover	4. Control of risks **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.2.11: 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** **B.2.4: Investment cycles should be taken into account** **B.2.6: Check effectiveness of**

		some mixtures have been modified in order to ensure that boric acid concentration is under the specific classification limit. These evolutions are leading to considerable change within the market and the related exposures. The data concerning the volume and wide dispersive used for prioritization of boric acid are dating back to 2005 - 2008 and should therefore be revalidated. Any prioritization action should be based on current data – a prioritization based on outdated material can lead to overregulation and might not be in line with the principle of proportionality. The prioritization of boric acid in the candidate list should therefore be re-evaluated. 2742_2-2_ECHA_consultation_boric acid paper_final.docx	**harmonised classification before proceeding with further regulatory risk. management activities** **C.2. Responses to exemption requests referring to other legislation**
2744 2014/11/27	Alkanolamine Borates Consortium, Industry or trade association, United Kingdom	See attached 2744_Letter re Borates Authorisation final.docx	**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.2.2: Disputing the volume score, claiming that the volume figures used for prioritisation are outdated**
2747 2014/11/28	Poland, Member State	Boric acid was identified as a Substance of Very High Concern (SVHC) according to article 57 (c) of REACH Regulation as it is classified as Toxic for Reproduction Category 1B and follow entered in Annex VI (list of substances with harmonized classification and labeling) of Regulation (EC) No 1272/2008 (CLP). During prioritization of boric acid the following criteria was taken into account: - intrinsic properties (score: 1), - volume used in the scope of authorization (score: 15), - wide dispersiveness of uses (boric acid is used at industrial sites and by professional workers, score: 12). Boric acid is nonorganic substance one of a lot of boron compounds. Similarly to	**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**

		other boron compounds its chemical properties are unique and in effect very difficult to substitute. In practice it is irreplaceable, what is against key elements of authorization. Bureau for Chemical Substances, PL CA responsible for both areas REACH and CLP would like to draw attention for the following issues, which should be taken during prioritization of boric acid. Firstly we believe that all users of boric acid are adequately protected. - consumers are adequately protected through the restriction (REACH Annex XVII): boric acid is classified as Toxic for Reproduction Category 1B and according to point 30 of Annex XVII of REACH, mixtures and other substances which contains boric acid in concentration equal to or higher than 5.5% are prohibited for supply to the general public. - risk for workers are adequately controlled through chemical management legislation: the Chemical Agent Directive (98/24/EC) lays down minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents, - other downstream legislation protects certain vulnerable workers from exposure to substances/mixtures classified as toxic to reproduction. o Directive 92/85 protects the health and safety of women in the workplace when pregnant or after they have recently given birth and women who are breastfeeding from exposure to boric acid or mixtures contained boric acid in such concentration which lead to classification of mixture as toxic to reproduction o Directive 94/33/EC protects young people at work from exposure to boric acid or mixtures contained boric acid in such concentration which lead to classification of mixture as toxic to reproduction, Secondly, major uses of boric acid in the EU are outside the scope of authorization: ☐ boric acid is mainly used in the manufacturing of glass and frits (in these uses the boric acid is qualifies as intermediate since is completely consumed and transformed into another substance - glass and frits) ☐ boric acid (and other borates) is used in mixtures below specific concentration limits ☐ boric acid is used in other sector-specific legislation (e.g. biocides) which is	**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 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.2.13: Claim that risks for workers are controlled by other legislation** **A.2.14: Claim that authorisation is not necessary as consumers are protected through the restriction in place** **A.2.15: Claim that exposure data shows low/no risks**

		outside the scope of authorization, In certain uses the boron is irreplaceable. ☐ Boron is essential micronutrient for normal, productive plant growth and is one of seven essential micronutrients for plants according to the EU Fertilizers Regulation (2003/2003/EC). Taking into account the essentiality of boron for agriculture, the authorization must be granted for agriculture and would not achieve the aim of authorization. ☐ use of boric acid in nuclear power plants is essential for safety reasons. The natural boron isotope is required and cannot be substituted. Thus, in our opinion, the use of borates in fertilizers and the use of borates in nuclear plants should be exempted from authorization. Total weight of evidence, including worker exposure data, shows that it is improbable that borates will cause reproductive and developmental effects in humans. Developmental and reproductive toxicity effects were observed only in laboratory animals exposed to abnormally high doses of boric acid. In contrast to the laboratory animal data, studies in humans have not demonstrated adverse effects even of high boron exposures. In humans effects on fertility were studied in several highly exposed populations. At a U.S. Borax mine and production facility in Southern California no adverse effects on reproduction were seen in workers exposed up to an average of 28.4 mg B/day (ca. 0.4 mg B/kg bw/day). In a population living in a boron rich region of Turkey (up to 29 mg B/L well water) no effects on fertility were seen over three generations. Chinese boron workers were studied by a research team from the Beijing University of Science and Technology and the China National Environmental Monitoring Centre in collaboration with the University of California at Los Angeles. The boron worker group average exposure was 42 mg B/day (SD 58). The highest exposed workers were exposed to about 5 mg B/kg/day, which is more than 100 times greater than the average daily exposure of the general population. A recent study of workers in Turkey was conducted to investigate the reproductive effects of boron exposure in workers employed in boric acid production plant in Turkey. Boron concentrations were determined in biological samples (blood, urine, semen), in workplace air, in food, and in water sources. The mean calculated daily boron exposure of the highly exposed group was 14.45 ± 6.57 (3.32–35.62) mg B/day. As with the Chinese study, there were no negative effects observed for boron exposure on the reproductive toxicity	**A.2.21 Boron is a critical raw material** **A.2.22: Disputing the harmonised classification** **C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation**

		indicators (concentration, motility, morphology of the sperm cells and blood levels of follicle stimulating hormone (FSH), luteinizing hormone (LH), and total testosterone). The workers working in boron mining and processing industries represent the maximum possible human exposure. Based on the total weight of evidence that includes worker exposure data, epidemiological studies and mechanistic data, the data show that it is impossible that boric acid will cause reproductive or developmental effects in humans. Taking into account all above mentioned information that: - the authorization procedure will not lead to additional protection for workers, - the authorization procedure will not lead to additional protection for consumers, - the fact that no substitutes are available for the most important uses PL CA is of the opinion that prioritizing of boric acid at this time does not represent regulatory effectiveness and is not proportional.	
2752 2014/11/28	BOCI, CFHM, UFBJOP et Comité Francéclat, Industry or trade association, France	Draft recommendation for inclusion of borax and boric acid in the Authorisation List of the European REACH regulation Submission to the European Chemicals Agency (ECHA) produced by The National Jewellery-making, Gold Jewellery-making and Silversmiths, Gift Makers and Decorative Arts Industries Trade Association (BOCI) The French Association of Watchmaking and Microtechnology (CFHM) The French Union of Jewellery, Silverware, Gems and Pearls (UFBJOP) & The Francéclat Committee, the French Watchmaking, Jewellery, Silverware and Tableware Committee	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 **A.2.13: Claim that risks for workers are controlled by other legislation**

		Within the framework of the authorisation procedure established by the European REACH regulation, the above-mentioned organisations would like to present their input about the draft concerning the integration of borax and boric acid to annex XIV because of the consequences said integration would have on the watchmaking, jewellery and high-jewellery sectors. The use of borax and boric acid in the watchmaking, jewellery and high-jewellery sectors Borax is frequently used in jewellery and high-jewellery, either in smelting for example when preparing alloys or in the remelting of precious metal "waste", or combined with boric acid as a brazing flux. Brazing flux Borax and boric acid have been used for a very long time as fluxes for blowtorch brazing of precious metals in the jewellery and high-jewellery sectors. This technique is one of the most commonly used in assemblies and repairs in these sectors. Suppliers of specific brazing processes on the jewellery market offer complex flux formulas. Their main ingredients are borax and boric acid. Their use is explained by their melting characteristics and their stability at high temperature which makes them particularly suitable for precious metal brazing. The main properties of brazing fluxes are: - melting at a temperature at least 100°C lower than the brazing solder solidus; - remaining stable up to the maximum temperature required for brazing; - dissolving metallic oxides that can form before and during brazing; - being sufficiently fluid, even when loaded with dissolved oxides to be easily removed into the capillary gaps of the joint by the brazing solder and to then form a continuous film on the liquid braze;	**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** **A.2.22: Disputing the harmonised classification** **B.2.1: Concerns and uncertainties with respect to the authorisation process, in particular for SMEs** **C.2. Responses to exemption requests referring to other legislation** **C.3.5: Claim that products not containing the substance in the final product should be exempt from authorisation.**

		- being easy to remove after brazing. With this process, the borax and boric acid are removed from the brazed parts at the end of the operation. The finished sold products therefore do not contain these two substances and consumers are not exposed to them in any way. Flux in remelting precious metals (waste smelting and alloy preparation) Borax is also used in smelting for the preparation of precious metal alloys and for remelting precious metal "waste". The primary source of precious metals is of course extraction from minerals, but there is an important secondary circuit that involves recycling metals from waste and scraps which, when processed in the appropriate refining channels, can become new metals. Scrap rates from the manufacture of jewellery or jewellery pieces in precious metals are rather high, at least for the two important manufacturing procedures that are lost-wax casting and machining; these scrap rates vary from 50 to 80% of the material used. All manufacturing waste and scraps are collected and recycled. Some recycling is done internally and some is refined by specialised companies. Considering the monetary value of precious metals, this is an essential condition for the financial health of manufacturing companies. This systematic recycling also helps limit the quantity of precious metals from the primary circuit and therefore reduces environmental damage associated with mineral extraction. Jewellery workshops are generally equipped with a more or less advanced system for collecting and processing precious metal waste and scraps. The first level consists in remelting the waste in a crucible containing fluxes that will facilitate fusion and remove some of the impurities. As well as jewellery workshops, major precious metal refining companies use this technique as the first refining operation for cleaning and standardising the batches of waste they receive.	

		Borax is one of the fluxes used systematically because it dissolves common metal oxides and prevents their creation during smelting. Its properties as a flux combined with its stability at high temperature make it indispensable for remelting precious metals. Similarly to its use in brazing fluxes, borax is used in the manufacture and recycling of jewellery, high-jewellery and watchmaking pieces in precious metals but is not in the finished product and consumers are not exposed to it in any way. Alternatives to borax and boric acid in the watchmaking, jewellery and high-jewellery sectors Since borax and boric acid have been classified in Category 1B for reproductive toxicity, they are subject to the European legislation concerning chemical risks in the workplace, governed by the two directives 2004/37/CE and 98/24/CE which protect workers from risks associated with exposure to chemical substances at their workstations. As a CMR, the rules specific to preventing risks of carcinogenic exposure, mutagenic exposure or exposure that is toxic to reproduction apply and in particular obligate, wherever possible, the replacement of the CMR used in the company by a non-dangerous substance or, at least, by a less dangerous one. Research has been carried out and continues on the replacement of borax and boric acid. In the case of their use in brazing fluxes, a replacement product is being integrated by companies. The first results are not satisfactory from a technical point of view as the product does not cover all the uses (in terms of brazing material, types of brazing solder, types of pieces) of brazing fluxes made with borax and boric acid. Furthermore, from a financial point of view, the proposed product costs 7 times more than the brazing fluxes made with borax and boric acid. In the case of using borax in smelting (preparing alloys, remelting precious metals), there is currently no substitute product. Its ban would therefore be	

		extremely problematic for the jewellery and high-jewellery sectors. The use of borax in smelting is only a tiny part of the product's overall use which makes its replacement particularly difficult for this specific application. Replacement efforts provided by borax suppliers are not necessarily focused on this minor use which is nevertheless essential for our sector. Company testimonials and socio-economic impact Most companies that work with precious metals use borax and boric acid and would therefore be affected by its inclusion in annex XIV of REACH. Companies that do not use it outsource the operations involving these substances. The industrial fabric of jewellery and watchmaking is made up of a few large companies and a multitude of small and very small (craftsmen) businesses. A ban on the use of borax and boric acid pending authorisation would cause great prejudice in these sectors which have already had to deal with the implementation of many restrictions on other substances over the last few years (nickel, lead, cadmium, chromium VI and PAH, for example). Considerable efforts have already been made by professionals and a ban on borax and boric acid, two strategically essential substances in the field of precious metals to which consumers are never exposed, would once again have a significant impact on their business. French companies in the watchmaking and jewellery sectors have been contacted for information about their use of borax and boric acid, and the impact their inclusion in annex XIV would have. You will find a sample of their testimonials in the attached document. For companies that supply and/or recycle precious metals and use borax in large quantities (several tons a year), the inclusion of borax in annex XIV of REACH would result in the loss of an important competitive edge which could, quite simply, lead to an end of their precious metal recycling business, for the benefit of non-European companies. Furthermore, banning borax would lead to a higher risk of non-uniformity in the composition of alloys, alloys whose precious metal content is managed by national French legislation in terms of	

		guaranteeing precious metal products. This non-uniformity could therefore lead to unjustified non-compliances. For all jewellery and high-jewellery manufacturers, whether they are craftsmen, small businesses or mid-sized companies, borax and boric acid are used in small quantities (1 to 5 litres per year for brazing fluxes and 100 g to 10 kg of powdered borax for remelting precious metal waste and scraps). Despite these small quantities, a ban would be extremely prejudicial as these substances are essential when working with precious metals. All highlight the fact that there is currently no alternative to borax for use as a flux in remelting precious metals and preparing alloys that have the required technical characteristics. Many have informed us of the technical problems they have encountered with the product for replacing brazing fluxes made with borax and boric acid, and the disappointing results in terms of quality. For both types of use, it is highlighted that borax and boric acid are not in the finished sold products and therefore come into no contact with the consumer. Many are aware of the dangerous nature of the substances and have therefore, in the absence of a replacement product, implemented protective measures in particular concerning suction systems at workstations and ensuring no pregnant employees work near the workstations, in compliance with recommendations from occupational health. Concerning the prejudice a ban on borax and boric acid would have on them, companies have expressed either an impossibility to continue their activity within the European Union or a drop in quality of pieces made and therefore the impossibility of selling the products considering the quality required by the markets. Conclusion	

		It seems essential that further studies are carried out to determine the best option for risk management of borax and boric acid to establish proportionate measures that can conciliate the necessary health protection with the companies' technical and socio-economic imperatives. The main risk identified associated with the use of borax and boric acid in the watch, jewellery and high-jewellery sectors involves the exposure of workers as these substances are not in the finished product that is sold. Health and safety legislation in the workplace, and particularly the Directive 2004/37/EC concerning the protection of workers against risks associated with carcinogenic exposure, mutagenic exposure or exposure that is toxic to reproduction which already applies and requires a replacement approach, seems to be the option the most suitable for managing the identified risk. It is, in effect, completely adequate and perfectly proportionate to the required objective. Considering the impact that the integration of borax and boric acid into annex XIV would have on our profession and the uncertainty of the capacity an authorisation process would have for better managing the risks presented by these substances as no study assessing the better management of said risks has been carried out, we ask that the integration of borax and boric acid into REACH's annex XIV be suspended until new information can be explored and discussed. 2752_Sample of testimonials.pdf	
2759 2014/11/28	CEZ Group, Company, Czech Republic	Boric Acid is solely used in the nuclear sector of our production. The nuclear energy covers more than 30 % of the electric power production in the Czech Republic with a net capacity of 3, 9 GW (2013). In VVER reactors, Boric Acid is used to control the reactivity of the core. It serves as a fast neutron absorber and is used for long-term control of the reactor. At steady state of the reactor, the critical concentration of Boric Acid is maintained. Its concentration decreases during the campaign. Except water, Boric Acid is the main coolant component of the primary circuit. For the production of electricity in VVER reactors, Boric Acid is irreplaceable. No other chemical substance is known for the controlling of the nuclear reaction.	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

		Therefore, CEZ Group considers that the inclusion of Boric Acid in the candidate list should be re-evaluated and Boric Acid should be deleted from this list. *Confidential attachment removed*	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** **C.2. Responses to exemption requests referring to other legislation**
2766 2014/11/28	Amfep, Industry or trade association, Belgium	We would like to express our grave concerns regarding the ECHA recommendation on Boric acid for inclusion in Annex XIV of REACH (Authorization List) to the European Commission addressed on June 17th, 2010, and the current Recommendation for inclusion in the Authorisation List and public consultation. Industrial biotechnological and laboratory operations commonly use Boric acid in culture media. Catalytic amounts of boric acid are commonly and safely used and essential to activate the fermentation processes related to biotechnological industry for (technical, food and feed) enzymes, food additives, cultures, single-cell proteins, bioethanol and organic substances. The listing in Annex XIV would jeopardize the legitimacy of activities such as cell growth or cell proliferation during fermentation. The current recommendation will have similar consequences as in the case of cobalt salts, a.o. cobalt dichloride and cobalt sulphate. These were included in ECHA's third recommendation for authorisation, but the Commission postponed its decision on the substances in order to clarify if the risks would be better controlled via restriction under REACH, taking into account use of the substances in culture media in biotechnology, pharmaceuticals and in vitro diagnostics. Boric acid is used as an essential trace element in fermentation media . Scientific studies have shown that the substance cannot be substituted with any other substances due to the biological essentiality of boric acid. Boric acid is therefore a critical substance in the supply chain of fermentation based products. The substance is used in fermentation processes dedicated to the preparation of many components such as (technical, food and feed) enzymes, cultures, vitamins, single-cell proteins, bioethanol and organic	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:** 1. Potential other regulatory actions 4. Control of 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** **B.2.1: Concerns and uncertainties with respect to the authorisation process, in particular for SMEs**

		substances. Our industries understand and comply with the June 9th, 2010 classification of Boric acid as a repr. 1B, H360FD, and toxic for reproduction category 2; R60-R61. These human health risks are attributable to inhalation exposures. While recognizing the importance of curtailing the use of Boric acid in applications whereby inhalation is a potential exposure path, there are a number of important uses of Boric acid with minimal to no inhalation exposure, under highly controlled conditions (e.g. Good Manufacturing Practices GMP and FSSC 22000 Food Safety Management System), and for which scientific research and development and future production of products and their availability for the various markets will be seriously impacted by its inclusion in Annex XIV. The industry prepares stock solutions by mixing Boric acid and other trace metals. The concentration of Boric acid in the resulting stock solution for fermentation processes usually ranges between 4 to 25 g/L (0.4%-2.5%). The concentration of Boric acid in fermentation solutions usually ranges between 1 to 10 mg/L (0.0001%-0.001%)1. Following the fermentation process, the remaining Boric acid, if any, is separated from the end products using separation and purification processes. Companies preparing or using Boric acid for culturing media must comply with the industrial hygiene framework of occupational exposure limits values recognized as good occupational hygiene practice (ECHA, 2009). Our understanding is that the REACH Regulation does not apply if a substance is used in Food-, Feed- products and Active Pharma Ingredients (API's) within the scope of a number of regulations In addition, our understanding is that substances used in the manufacture of pharmaceutical products and technical products are not exempted from the Authorization requirement. This is the case for Boric acid because it is used as a process chemical in fermentation processes leading to for instance detergent enzymes or biofuel and important fermentation based pharmaceutical products like penicillin. The inclusion of Boric acid on the Authorization list (Annex XIV of REACH Regulation) would have several impacts: • The burden to seek authorization for any use of Boric acid would be disruptive to the entire EU biotechnological fermentation industries and the availability of pharmaceutical products as well as Technical, Food and Feed products produced in Europe.	**C.2. Responses to exemption requests referring to other legislation**

		• The burden to seek authorization for any use of Boric acid would most likely lead to relocation of production units of fermentation companies outside of the EU, thus impacting on European Member States economies and their competiveness on the global market. • The burden to seek authorization for any use of Boric acid will also create a negative competition effect for small and medium size companies in comparison to large fermentation companies. In light of the aforementioned issues, we would like the European Commission and the EU Member States to re-assess the prioritization of Boric acid for inclusion on the REACH Authorization list. We would suggest that, before inclusion of Boric acid on the Authorization list, its socio-economic aspects should be comprehensively re-evaluated taking into account the impact of a prohibition or restriction on the enzyme and biofuel industry, sustainable economics, and the role of Boric acid as an essential substance in the supply chain of medicines to patients. Any prohibition or need to seek authorization would put at risk the supply chain of this essential substance and affect the availability of Boric acid supply to industries even though they obtained an exemption for use of Boric acid for their specific use. We would also like to emphasize that practical operations of Article 58 (2) – exemption for authorisation for uses such as Boric acid as trace element for fermentation should be in general seriously considered. The REACH regulation aims to ensure a high level of protection of human health and the environment, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. We see this balance is severely endangered, when high costs and efforts are needed to apply for authorization for the use of a substance as boric acid, even though this substance is essential for life without any alternative, and authorization must be granted. This won't stay the only essential element subject to authorization, and it would set the precedence that even the fundamental conditions of life could require a costly authorization. We would welcome the opportunity as stakeholders to discuss the issues highlighted above directly with you and work with you to resolve our very grave concerns. 2766_281114 Letter of concern boric acid-final.docx	
2770 2014/11/28	essenscia/bio.be, Industry or trade	We would like to express our grave concerns regarding the ECHA recommendation on Boric acid for inclusion in Annex XIV of REACH	Thank you for your comment and the additional information provided.

	association, Belgium	(Authorization List) to the European Commission addressed on June 17th, 2010, and the current Recommendation for inclusion in the Authorisation List and public consultation. Industrial biotechnological and laboratory operations commonly use Boric acid in culture media. Catalytic amounts of boric acid are commonly and safely used and essential to activate the fermentation processes related to biotechnological industry for (technical, food and feed) enzymes, food additives, cultures, single-cell proteins, bioethanol and organic substances. The listing in Annex XIV would jeopardize the legitimacy of activities such as cell growth or cell proliferation during fermentation. The current recommendation will have similar consequences as in the case of cobalt salts, a.o. cobalt dichloride and cobalt sulphate. These were included in ECHA's third recommendation for authorisation, but the Commission postponed its decision on the substances in order to clarify if the risks would be better controlled via restriction under REACH, taking into account use of the substances in culture media in biotechnology, pharmaceuticals and in vitro diagnostics. Boric acid is used as an essential trace element in fermentation media . Scientific studies have shown that the substance cannot be substituted with any other substances due to the biological essentiality of boric acid. Boric acid is therefore a critical substance in the supply chain of fermentation based products. The substance is used in fermentation processes dedicated to the preparation of many components such as (technical, food and feed) enzymes, cultures, vitamins, single-cell proteins, bioethanol and organic substances. Our industries understand and comply with the June 9th, 2010 classification of Boric acid as a repr. 1B, H360FD, and toxic for reproduction category 2; R60-R61. These human health risks are attributable to inhalation exposures. While recognizing the importance of curtailing the use of Boric acid in applications whereby inhalation is a potential exposure path, there are a number of important uses of Boric acid with minimal to no inhalation exposure, under highly controlled conditions (e.g. Good Manufacturing Practices GMP and FSSC 22000 Food Safety Management System), and for which scientific research and development and future production of products and their availability for the various markets will be seriously impacted by its inclusion in Annex XIV. The industry prepares stock solutions by mixing Boric acid and other trace metals. The concentration of Boric acid in the resulting stock solution for fermentation processes usually ranges between 4 to 25 g/L (0.4%-2.5%).	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:** 1. Potential other regulatory actions 4. Control of 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** **B.2.1: Concerns and uncertainties with respect to the authorisation process, in particular for SMEs** **C.2. Responses to exemption requests referring to other legislation**

		The concentration of Boric acid in fermentation solutions usually ranges between 1 to 10 mg/L (0.0001%-0.001%)1. Following the fermentation process, the remaining Boric acid, if any, is separated from the end products using separation and purification processes. Companies preparing or using Boric acid for culturing media must comply with the industrial hygiene framework of occupational exposure limits values recognized as good occupational hygiene practice (ECHA, 2009). Our understanding is that the REACH Regulation does not apply if a substance is used in Food-, Feed- products and Active Pharma Ingredients (API's) within the scope of a number of regulations In addition, our understanding is that substances used in the manufacture of pharmaceutical products and technical products are not exempted from the Authorization requirement. This is the case for Boric acid because it is used as a process chemical in fermentation processes leading to for instance detergent enzymes or biofuel and important fermentation based pharmaceutical products like penicillin. The inclusion of Boric acid on the Authorization list (Annex XIV of REACH Regulation) would have several impacts: • The burden to seek authorization for any use of Boric acid would be disruptive to the entire EU biotechnological fermentation industries and the availability of pharmaceutical products as well as Technical, Food and Feed products produced in Europe. • The burden to seek authorization for any use of Boric acid would most likely lead to relocation of production units of fermentation companies outside of the EU, thus impacting on European Member States economies and their competiveness on the global market. • The burden to seek authorization for any use of Boric acid will also create a negative competition effect for small and medium size companies in comparison to large fermentation companies. In light of the aforementioned issues, we would like the European Commission and the EU Member States to re-assess the prioritization of Boric acid for inclusion on the REACH Authorization list. We would suggest that, before inclusion of Boric acid on the Authorization list, its socio-economic aspects should be comprehensively re-evaluated taking into account the impact of a prohibition or restriction on the enzyme and biofuel industry, sustainable economics, and the role of Boric acid as an essential substance in the supply	

		chain of medicines to patients. Any prohibition or need to seek authorization would put at risk the supply chain of this essential substance and affect the availability of Boric acid supply to industries even though they obtained an exemption for use of Boric acid for their specific use. We would also like to emphasize that practical operations of Article 58 (2) – exemption for authorisation for uses such as Boric acid as trace element for fermentation should be in general seriously considered. The REACH regulation aims to ensure a high level of protection of human health and the environment, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. We see this balance is severely endangered, when high costs and efforts are needed to apply for authorization for the use of a substance as boric acid, even though this substance is essential for life without any alternative, and authorization must be granted. This won't stay the only essential element subject to authorization, and it would set the precedence that even the fundamental conditions of life could require a costly authorization. We would welcome the opportunity as stakeholders to discuss the issues highlighted above directly with you and work with you to resolve our very grave concerns. footnotes : Michael C. Flickinger, (2013) Upstream Industrial Biotechnology. New Jersey: John Willey & Sons, ISBN: 978-1-118-13123-7 • Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings; • Regulation (EC) No 1332/2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97; • Regulation (EC) No 1333/2008 on food additives; • Regulation (EDC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC; • Regulation (EC) No 1831/2003 on additives for use in animal nutrition; • Regulation (EC) No 1935/2005 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC; • Regulation (EC) No 10/2011 on plastic materials and articles intended to	

		come into contact with food; • Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency; • Directive 2001/82/EC on the Community code relating to veterinary medicinal products; • Directive 2001/83/EC on the Community code relating to medicinal products for human use. 2770_letterofconcernboricacidbiobe.doc	
2773 2014/11/28	WKÖ, Other contributor, Austria	See PDF attached. 2773_su_85_WKÖ Borate.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:** 1. Potential other regulatory actions 4. Control of risks 5. Availability of suitable alternatives **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.2.11: Requests authorities to**

			conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV **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** **B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 2. Lack of alternatives, socio-economic aspects **C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation** **C.3.5: Claim that products not containing the substance in the final product should be exempt from authorisation**
2778 2014/11/28	Europacable, Industry or trade association, United Kingdom	Boris acid is a contamination in zinc borate, which is a flame retarder in PVC compounds, used in cable manufacturing. No substitute is currently available, except increasing the amount of antimony trioxide (heavy metal) which is not preferred for human health and environmental reasons. Boric acid is also used for nickel electroplating in copper conductors of cables and in lubricants in the drawing process of copper conductors. Substitutes are under study for this last two applications. However, solutions are not yet available.	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
2785 2014/11/28	Aurubis AG, Company, Germany	Aurubis is the leading integrated copper group and the world's largest copper recycler. We produce some 1 million t of copper cathodes each year and from them a variety of copper products. Production expertise is our strength and the driving force of our success. Aurubis has about 6,500 employees, production sites in Europe and the USA and an extensive service and sales system for copper products in Europe, Asia and North America. Thanks to our wide range of services, we rank among the global leaders in our industry. Our core business is the production of marketable copper cathodes from copper concentrates, copper scrap and recycling raw materials. These are processed within the Group into continuous cast wire rod, shapes, rolled products and strip as well as specialty wire made of copper and copper alloys. Precious metals and a number of other products, such as sulfuric acid and iron silicate, round off our product portfolio. Customers of Aurubis include companies in the copper semis industry, the electrical engineering, electronics and chemical industries as well as suppliers of the renewable energies, construction and automotive sectors. Aurubis is oriented to growth and to increasing corporate value: the main focuses of our strategy are on expanding our leading market position as an integrated copper producer, utilizing growth opportunities and practicing a responsible attitude when dealing with people, resources and the environment. Aurubis shares are part of the Prime Standard Segment of the Deutsche Börse and are listed in the MDAX and the Global Challenges Index (GCX). Summary: Aurubis is using boric acid in various applications. It is used as a processing aid in industrial plating bathes for copper products, as part of a ramming mix for induction furnaces infeed and as laboratory chemical. Regarding the uses described above the substance is only handled by industrial users. The substance is not part of a finished article which may be used by consumer and the use in our applications is essential as there is no alternative available.	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 3. Use specific scrutiny foreseen at application stage 4. Control of risks 5. Availability of suitable alternatives 7. Burden for industry and potential competitive disadvantage **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.** **C.1.1: General principles for**

		For the use in the production of industrial plated copper products resulting considerable cost for an authorisation would only apply for EU manufacturers whereas imports of such articles from non EU companies would not be affected. For the sintering additive authorisation would not apply as the content of boric acid in the mixture is below the specific concentration limit set out in Annex XI of the CLP regulation and defined in Article 56(6b) REACH regulation. The use in laboratory would fall under the PPORD exemption for authorisation set out in Article 56(3) REACH regulation. Risk for workers is minimised as the substance is used in a closed system. Risk for the environment is adequately controlled due to waste water collection as well as treatment and off gas cleaning systems. Due to the argumentation described above and in the information attached a listing of the substance would lead to negative effects on cost and price competitiveness as well on the global competitive position of EU companies without a benefit for human health or environment protection. We strongly recommend not to include boric acid on Annex XIV or to exclude the described uses from authorisation. In order to allow a complete view on all aspects and consequences of such a listing for our industry, please find attached our input based on the list of questions proposed by commission to the socio-economic public consultation. *Confidential attachment removed*	**exemptions under Art. 58(2)** **C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation** **C.3.5: Claim that products not containing the substance in the final product should be exempt from authorisation.**
2788 2014/11/28	Federchimica, Industry or trade association, Italy	Federchimica, due to the inclusion, in the "Candidate List" of Boric Acid (EC: 233-139-2; EC: 234-343-4); Sodium tetraborate anhydrous (EC: 215-540-4) and heptaoxide Tetraboron disodium hydrate (EC: 235-541-3) and diboron trioxide (EC 215-125-8) consider useful to point out that, in light of the information currently available, it is unjustified and inappropriate to proceed with their prioritization and with the Authorization process. In fact 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.	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:**

		ARGUMENTS AND RATIONALE 1. Consumers, industrial and professional workers are adequately protected by virtue of existing REACH restrictions or other EU regulations. a. Consumers are adequately protected through the restrictions (REACH Annex XVII) and the risk management measures detailed in the exposure scenarios of the registration dossiers. In February 2012, the Commission adopted restrictions on borates. Consequently, the use of borates in mixtures above the specific concentration limits is prohibited in consumer markets since 1 June 2012. An assessment of the impact of these restrictions should be conducted first before considering other regulatory options such as authorisation. The use of mixtures containing borates below the specific concentration level does not raise concern as consumers are not subject to prolonged exposure to borates and the threshold level for health effects observed in animals cannot be reached. b. Risks for workers are adequately controlled through the risk management measures detailed in the exposure scenarios of the registration dossiers and other chemical management legislation. The REACH registration dossiers for diboron trioxide, boric acid and disodium tetraborates identified Risk Management Measures (RMM) where appropriate to ensure that health risks to workers are adequately controlled. RMM are communicated via the eSDS, which allows the site risk assessment to be carried out as required by the Chemical Agents Directive (98/24/EC); these mechanisms assist in ensuring worker safety. Additionally other downstream legislation specifically protects certain vulnerable workers from exposure to substances toxic to reproduction, such as pregnant workers (Dir. 92/85/EC) and young workers (Dir. 94/33/EC). Further, for all identified uses, a Risk Characterisation Ratio (RCR) < 1 was determined and compliance with the DNELs can be achieved with common hygiene measures, i.e. without a need to use Personal Protective Equipment (PPE). This results from the low potency hazard of borates. c. Total weight of evidence, including worker exposure data, shows that it is	4. Control of risks **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 glues** **- production of fluoroboric acid (CAS 16872-11-0** **- in manufacture of boron carbide, boron nitride, titanium boride, zirconium boride and calcium boride** **A.2.9: 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 substance for Annex XIV**

		improbable that borates will cause reproductive and developmental effects in humans Although reproductive and developmental effects have been demonstrated in laboratory animals exposed to abnormally high doses of boric acid, similar effects have not been observed in highly exposed human populations or workers. The absence of adverse reproductive effects in extensive investigations of borate workers in the United States, Turkey and China chronically exposed to high levels of borates and in populations living in high boron areas demonstrate that the actual health risk from exposure to borates is small. Workers in boron mining and processing industries represent the maximum possible human exposure. Based on the total weight of evidence that includes worker exposure data, epidemiological studies and mechanistic data, the data show that it is improbable that boric acid will cause reproductive or developmental effects in humans. 2. The major uses of the borate substances in the EU are outside the scope of authorisation, either as intermediates or as mixtures below the specific concentration limit (SCL), or covered by other legislation. Nearly 79% of diboron 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), again, falling outside the scope of authorisation. 3. Boron is irreplaceable in certain uses a. Bioessentiality Boron is an essential micronutrient for normal, productive plant growth and is one of seven essential micronutrients for plants according to the EU Fertiliser Regulation. The use of boron in fertilizers accounts for about 13.7% of the diboron trioxide, boric acid and disodium tetraborates entering the EU market.	**A.2.14: Claim that authorisation is not necessary as consumers are protected through the restriction in place** **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** **A.2.22: Disputing the harmonised classification** **C.2. Responses to exemption requests referring to other legislation**

		Acknowledging the essentiality of boron for agriculture, the authorisation would have to be granted for agriculture and would not achieve the aim of authorisation. It would become a "tax system". b. Essential for nuclear safety The use of boric acid in nuclear power plants is essential for safety reasons. The natural boron isotope, 10B, is required and cannot be substituted. Therefore the authorisation would have to be granted and would not achieve the aim of authorisation. 4. 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 this is the right RMM option for borates. 5. 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". Federchimica 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. In conclusion, it is the position of the Federchimica that the authorisation procedure will not lead to additional protection for workers and consumers. Taking into account the socio- economic importance of borates and the fact that no substitutes are available for the most important uses, means that prioritising borates at this time does not represent regulatory effectiveness and is not proportional. 2788_Annex I.pdf *Confidential attachment removed*	
2792 2014/11/28	Industry or trade association, Belgium	Please see attachement 2792_FEFCO comments on uses that should be expemt from the 6th ECHA priority list for authorization_to ECHA.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:** 4. Control of risks 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** **C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation**

2793 2014/11/28	Evonik Industries AG, Company, Germany	(1) Criteria in REACH Article 58 (3) Among the criteria in Article 58 (3) of the REACH regulation only the third one is fulfilled by boric acid: (a) The substance is not bioaccumulating and therefore neither PBT nor vPvB. (b) No use by private end users is identified in the draft background document. Therefore the use is not "wide dispersive" in terms of existing EU guidance. (c) The production volume is high, though not very high. For (b) see: Technical Guidance Document on Risk Assessment (2003) (EUR 20418 EN/2), Part II, p. 208: "The term wide dispersive use should be used for a wide range of activities particularly when end users come into contact with the products. This means a large number of small point sources like households or line sources like traffic." – "Wide dispersive use (many small point sources or diffuse releases; normally no emission reduction measures)". Emission from articles is negligible. (2) Substitution of essential micronutrients is absurd Boric acid is a naturally occurring inorganic substance. This means that there is some natural background exposure that is tolerated by all living organisms and may even be essential, which is confirmed by the use as fertiliser. Listing in REACH Annex XIV would initiate an obligation to present substitution plans periodically until substitution is complete. Substitution of a substance essential for life would be fatal! (3) Safe exposure levels exist and are met In Germany an occupational exposure limit of 0.5 mg/m3 is in place (TRGS 900, 2014 edition). It is associated with group Y, which means that no developmental damage is expected if the exposure limit is kept. I see no need for phasing out a substance that can be handled safely. Epidemiology results from highly exposed workers can confirm the low potential for adverse effects at realistic exposure levels. (4) Unsafe uses should be identified before heavily burdening all uses irrespective of their safety No use by private end users is identified in the draft background document for inclusion of boric acid in Annex XIV. Exposure from articles is negligible in view of the negligible vapour pressure of the substance. If ECHA fears that some	**A.1.3. Prioritisation: Wide-dispersiveness of uses:** 2. Assignment of WDU score based on use types and their associated volumes **A.1.5. Aspects not considered in ECHA's prioritisation:** 1. Potential other regulatory actions 4. Control of risks **C.2. Responses to exemption requests referring to other legislation**

		uses of boric acid by some professional users are associated with unsafe exposure this problem should be addressed in a proportionate and stepwise procedure. I believe that boric acid is rather a case for focussed restrictions than for general substitution.	
2794 2014/11/28	Chemlink Specialities Ltd, Company, United Kingdom	*Confidential attachment removed*	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.2.8: 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 substance for Annex XIV** **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** **C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation**
2795 2014/11/28	Company, Spain	As a fertilizer producer, we think that boric acid is not to be considered under autorisation, because there is no possible substitute for boric acid. We need	**A.1.5. Aspects not considered in ECHA's prioritisation:**

		that raw material to produce some products like orthoboric acid with 2-aminoethanol, that acts like a boron nutrients in agriculture.	5. Availability of suitable alternatives
2796 2014/11/28	Company, Netherlands	We would like to express our grave concerns regarding the ECHA recommendation on Boric acid for inclusion in Annex XIV of REACH (Authorization List) to the European Commission addressed on June 17th, 2010, and the current Recommendation for inclusion in the Authorisation List and public consultation. Industrial biotechnological and laboratory operations commonly use Boric acid in culture media. Catalytic amounts of boric acid are commonly and safely used and essential to activate the fermentation processes related to biotechnological industry for (technical, food and feed) enzymes, food additives, cultures, single-cell proteins, bioethanol and organic substances. The listing in Annex XIV would jeopardize the legitimacy of activities such as cell growth or cell proliferation during fermentation. The current recommendation will have similar consequences as in the case of cobalt salts, a.o. cobalt dichloride and cobalt sulphate. These were included in ECHA's third recommendation for authorisation, but the Commission postponed its decision on the substances in order to clarify if the risks would be better controlled via restriction under REACH, taking into account use of the substances in culture media in biotechnology, pharmaceuticals and in vitro diagnostics. Boric acid is used as an essential trace element in fermentation media (1). Scientific studies have shown that the substance cannot be substituted with any other substances due to the biological essentiality of boric acid. Boric acid is therefore a critical substance in the supply chain of fermentation based products. The substance is used in fermentation processes dedicated to the preparation of many components such as (technical, food and feed) enzymes, cultures, vitamins, single-cell proteins, bioethanol and organic substances. Our industries understand and comply with the June 9th, 2010 classification of Boric acid as a repr. 1B, H360FD, and toxic for reproduction category 2; R60-R61. These human health risks are attributable to inhalation exposures. While recognizing the importance of curtailing the use of Boric acid in applications whereby inhalation is a potential exposure path, there are a number of important uses of Boric acid with minimal to no inhalation exposure, under highly controlled conditions (e.g. Good Manufacturing Practices GMP and FSSC 22000 Food Safety Management System), and for which scientific research and	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:** 1. Potential other regulatory actions 4. Control of 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** **B.2.1: Concerns and uncertainties with respect to the authorisation process, in particular for SMEs** **C.2. Responses to exemption requests referring to other legislation**

		development and future production of products and their availability for the various markets will be seriously impacted by its inclusion in Annex XIV. The industry prepares stock solutions by mixing Boric acid and other trace metals. The concentration of Boric acid in the resulting stock solution for fermentation processes usually ranges between 4 to 25 g/L (0.4%-2.5%). The concentration of Boric acid in fermentation solutions usually ranges between 1 to 10 mg/L (0.0001%-0.001%)(1). Following the fermentation process, the remaining Boric acid, if any, is separated from the end products using separation and purification processes. Companies preparing or using Boric acid for culturing media must comply with the industrial hygiene framework of occupational exposure limits values recognized as good occupational hygiene practice (ECHA, 2009). Our understanding is that the REACH Regulation does not apply if a substance is used in Food-, Feed- products and Active Pharma Ingredients (API's) within the scope of a number of regulations (2). In addition, our understanding is that substances used in the manufacture of pharmaceutical products and technical products are not exempted from the Authorization requirement. This is the case for Boric acid because it is used as a process chemical in fermentation processes leading to for instance detergent enzymes or biofuel and important fermentation based pharmaceutical products like penicillin. The inclusion of Boric acid on the Authorization list (Annex XIV of REACH Regulation) would have several impacts: • The burden to seek authorization for any use of Boric acid would be disruptive to the entire EU biotechnological fermentation industries and the availability of pharmaceutical products as well as Technical, Food and Feed products produced in Europe. • The burden to seek authorization for any use of Boric acid would most likely lead to relocation of production units of fermentation companies outside of the EU, thus impacting on European Member States economies and their competiveness on the global market. • The burden to seek authorization for any use of Boric acid will also create a negative competition effect for small and medium size companies in comparison to large fermentation companies. In light of the aforementioned issues, we would like the European Commission and the EU Member States to re-assess the prioritization of Boric acid for	

		inclusion on the REACH Authorization list. We would suggest that, before inclusion of Boric acid on the Authorization list, its socio-economic aspects should be comprehensively re-evaluated taking into account the impact of a prohibition or restriction on the enzyme and biofuel industry, sustainable economics, and the role of Boric acid as an essential substance in the supply chain of medicines to patients. Any prohibition or need to seek authorization would put at risk the supply chain of this essential substance and affect the availability of Boric acid supply to industries even though they obtained an exemption for use of Boric acid for their specific use. We would also like to emphasize that practical operations of Article 58 (2) – exemption for authorisation for uses such as Boric acid as trace element for fermentation should be in general seriously considered. The REACH regulation aims to ensure a high level of protection of human health and the environment, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. We see this balance is severely endangered, when high costs and efforts are needed to apply for authorization for the use of a substance as boric acid, even though this substance is essential for life without any alternative, and authorization must be granted. This won't stay the only essential element subject to authorization, and it would set the precedence that even the fundamental conditions of life could require a costly authorization. We would welcome the opportunity as stakeholders to discuss the issues highlighted above directly with you and work with you to resolve our very grave concerns. (1) Michael C. Flickinger, (2013) Upstream Industrial Biotechnology. New Jersey: John Willey & Sons, ISBN: 978-1-118-13123-7. (2) • Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings; • Regulation (EC) No 1332/2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97; • Regulation (EC) No 1333/2008 on food additives; • Regulation (EDC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC;	

		• Regulation (EC) No 1831/2003 on additives for use in animal nutrition; • Regulation (EC) No 1935/2005 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC; • Regulation (EC) No 10/2011 on plastic materials and articles intended to come into contact with food; • Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency; • Directive 2001/82/EC on the Community code relating to veterinary medicinal products; • Directive 2001/83/EC on the Community code relating to medicinal products for human use. 2796_AMFEP 14_56 Letter of concern ECHA recommendation on Boric acid.pdf	
2797 2014/11/28	ABB Kabeldon, Company, Sweden	Advantages with boric acid in connection to our products We produce cable distribution cabinets with components* were boric acid is needed for manufacturing of electrical contact equipment. The products are used to distribute electricity in the low voltage grid. We use boric acid in electroplating of copper, brass and aluminum, both for protection against oxidation and for a good and well defined electrical contact. The boric acid is needed to get nickel to bind to these materials. The layer of nickel is a barrier layer between the copper/brass/aluminum and tin to prevent diffusion between the different materials. The tin is added on copper, brass and aluminum for protection against oxidation and to improve the electrical contact. The nickel itself is also a good protection against corrosion. We have asked different producers of chemical for replacements and alternative methods. The only alternative they have proposed is adding a layer of copper and/or a thicker layer of tin. If the nickel were to be removed the materials may diffuse into each other and lower the protection against oxidation (see the attached report "Electrical contacts, Review and recent developments"). A lower protection against oxidation increase the environmental impact and increase safety risks. If the product oxidize the electrical contact will be inferior which lead to more electrical losses. This makes the products less energy efficient and also lower the life time of the whole product. If the products electrical contacts is insufficient there is a risk of overheating and in worst cases risk for fire that then can affect humans and properties.	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 **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**

		Risks with boric acid connected our products The boric acid is delivered as powder in bags. The powder is poured into the containers for electroplating where it dissolves in the mixture. Personal protection equipment is used in accordance with the information from the producer along with other protective measures. The risk for exposure is considered to be low and we are continuously working on evaluating our use in accordance to Swedish law** to ensure proper protection. A measurement of exposure is planned to be performed soon. Conclusion The benefit for the society, the environment and from indirect safety risks is bigger than the health risks from our use of boric acid. *Product information: http://new.abb.com/low-voltage/products/cable-distribution-cabinets ** AFS 2011:19, Kemiska arbetsmiljörisker, Arbetsmiljöverkets föreskrifter om kemiska arbetsmiljörisker samt allmänna råd om tillämpningen av föreskrifterna http://www.av.se/dokument/afs/afs2011_19.pdf 2797_Electrical contacts, Review and recent developments.pdf	
2798 2014/11/28	BP Europa SE, Company, Germany	Introduction and context: BP is a globally operating company with strong position on industrial lubricants. BP produces industrial lubricants in various European countries for the European market. We are a member of different industrial associations that cover this sector (Union of the European Lubricants Industry (UEIL) and Verband Schmierstoff-Industrie e.V (VSI)). As a formulator of metalworking fluids (MWFs), we are an industrial downstream user of boric acid. Our final MWF products are used by industrial and professional users only. Specific comments on the justification:	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. Please see response to comment #2524 (EBA comment)

		BP supports the arguments of the European Borates Association (EBA) and those of VSI in that borates should not be included in the ECHA 6th prioritisation list for Annex XIV. Fundamentally BP believes that the application of REACH Authorisation to the manufacture of MWFs containing boric acid would be highly disproportionate creating a significant burden for industry without delivering any benefit to Human health or the Environment. More specifically from our perspective we would make the following comments concerning the Prioritisation exercise:- Intrinsic properties: Boric acid is classified as Repr. Cat.1B according to the harmonised classification in Annex VI of CLP. A Specific Concentration Limit (SCL) of 5.5% w/w applies for this hazard class and category. Although reproductive effects have been demonstrated in laboratory animals exposed to boric acid it is noted that the potency of the reproductive effect is relatively low and we continue to believe that the observations in rodents have low relevance to man. This can be further strengthened with the fact that similar effects have not been observed in highly exposed human populations of borate workers in the United States, Turkey and China (the EBA provide additional information in their comments). Volume used in the scope of authorisation: It is noted that all of the volume of boric acid used by BP to blend metal working fluids (MWFs) results in free boric acid concentrations in the MWF concentrate below the 5.5% SCL for boric acid. Similarly a market survey data from the German organisation Deutsche Gesetzliche Unfallversicherung (DGUV, German Social Accident Insurance) - Information sheet no FB HM-030 (issue 02/2014) - shows that this is the case across the market surveyed in Germany. It is reasonable to expect this practice to extend across other Member States. On this basis, as the concentration of free boric acid in MWF concentrates is less than the 5.5% SCL for boric acid, it would seem that all (or at least the vast majority) of formulated metal working fluid concentrates in the EU market are out of scope of Authorisation. As the usual dilution rate of the concentrate in	Please also see response to comment #2608 (VSI comment) **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.2.8: 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.2.22: Disputing the harmonised classification** **C.2. Responses to exemption requests referring to other legislation**

		water is 1 in 20, this would further indicate that working concentrations of free boric acid in MWFs are less than 0.275%w/w and all expected downstream use of diluted MWFs in machining operations would also be out of scope for Authorisation. It would seem therefore that the only element of the use of boric acid in the manufacture and use of MWFs that is in scope for REACH Authorisation would be the transfer of boric acid from storage or containers into the blending vessel during formulation of the MWF concentrate. The boric acid as a raw material is usually supplied to BP sites in so-called 'big bags' (500-1000 kg) and is then transferred from these bags directly into mixing vessels. BP has many safety precautions in place to protect workers so that they can handle this material safely with minimum exposure, these include engineered ventilation extract systems, approved systems of work and the use of approved personal protection wear (e.g. dusk masks). BP has quantified boric acid exposure from two typical working operations of a production site in Germany. These measurements show that the German threshold limit for safe use (2.6 mg/m3 boric acid) is not exceeded. If the EU market for metal working fluids were taken to be 200,000 tonnes/year (Klein market research study) and it is assumed that 50% of the products contain free boric acid at no more than 5.5%, then the amount of boric acid in MWF products would be less than 5500 tonnes/year (EBA data indicates that 2012 volumes for boric acid in Industrial fluids which includes MWF's were 5,400 tonnes). However, as indicated above, because the concentration in the MWF concentrates is less than the SCL for boric acid, the handling of MWF concentrates and their in use dilutions is out of scope of Authorisation. It is clear that boric acid would be in scope for Authorisation only in respect of it being loaded into blending vessels under controlled industrial conditions during the manufacture of MWF concentrates. Wide-dispersiveness of uses: The only operation in the MWF formulation and use supply chain that appears to be in scope for REACH Authorisation is the transfer of boric acid as a raw material into lubricant blending tanks and this is limited to only tens of lubricant blending facilities in the whole EU. It is notable that this handling	

		operation would be exempt from Authorisation if the same operation was to charge a reactor with boric acid being used as a chemical intermediate. This questions if Authorisation is a proportionate measure to manage these limited and controlled operations in handling boric acid in lubricant blending. Boric acid handling in lubricant blending is carried out at industrial facilities where controls on worker exposure, environmental emissions and waste disposal apply. The in scope MWF application of boric acid does not involve professional or consumer activities. Boric acid from MWFs is not incorporated into any articles. It would seem that the lubricant blending activities involving boric acid that are in scope of Authorisation do not represent wide dispersive use. Other controls apply to the use and disposal of MWFs which are out of scope of Authorisation so significant dispersion of boric acid does not occur in these uses. Conclusions: As a European metalworking fluid manufacturer BP is committed to the Product Stewardship principle to supply products that can be manufactured, transported and used safely. We work with our suppliers, customers and regulatory authorities to reduce the health and environmental impact of metalworking fluids. We believe the use of boric acid is adequately controlled within our industry. BP supports the arguments of the EBA and those of VSI that boric acid should not be included in the ECHA 6th prioritisation list for Annex XIV. In our opinion the application of REACH Authorisation to the manufacture of MWFs containing boric acid would be highly disproportionate creating a significant burden for industry without delivering any benefit to Human health or the Environment. The disproportionate nature of applying REACH Authorisation to the formulation of MWFs is made clear when it is considered that the only operation in scope for Authorisation in this supply chain is the loading of boric acid into lubricant blending tanks. This operation is carried out under well controlled industrial conditions at a limited number of EU facilities and is identical to the loading of boric acid into chemical reactors where boric acid is used as a chemical intermediate. Such operations when associated with the use of boric acid as a chemical intermediate are exempt from REACH	

		Authorisation. 2798_Boric acid additional information.zip	
2800 2014/11/28	ACEA, Industry or trade association, Belgium	We think that authorization is not the appropriate RMO for these substances and would immediately lead to a loss of competitiveness and competency for the European Automobile Industry because processes involving borates would probably be transferred outside of Europe. 2800_20141128_Proposal for annex XIV recommendation on Borates Final.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.1.3. Prioritisation: Wide-dispersiveness of uses:** 1. Scope of the assessment of 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 6. Socio-economic benefits of continued use 7. Burden for industry and potential competitive disadvantage **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 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** **A.2.14: Claim that authorisation is not necessary as consumers are protected through the restriction in place** **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.2.24: Predictability of including substances in Annex XIV** **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.2.2: Concerns about workload, timelines and resources needed for those companies already dealing with Cr(VI) applications** **C.2. Responses to exemption requests referring to other legislation** **C.3.3: Claim that past model parts should be exempt from authorisation** **C.3.4: Claim that uses which can replace Cr(VI) should be exempt from authorisation.** **C.3.5: Claim that products not containing the substance in the final product should be exempt from authorisation.**
2802	FRANCISCO. R.	Boron is a micronutrient required for all plant nutrition. The form that plants	

2014/11/28	ARTAL, S.L., Company, Spain	absorb it is in Boric acid form [B(OH)3]. Because plant physiology of the plant, boron is necessary for the development of crops. For authorization under REACH, if the costs of evaluation and registration are high, no economic recovery is justified in the market and prices to farmers would increase. Should consider the risk-benefit aspects according to usage. The agricultural uses are safe, has historically shown that they are well by traditional use. in the case of our company, over the last 5 years, we have used more than 95 tons of boric acid, and more than 17 tons of sodium tetraborates. For the acid boric, our formulas have 10% of its total amount, and for the sodium tetraborates, our formulas have less than 1% of its total amount. for more information, we also attach one internal document. 2802_BORON.docx	**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**
2804 2014/11/28	Individual, Spain	In agriculture, Boron is one the seven micronutrient for plants. It is the therefore essential for plant growth and boron cannot be substitued for this particular use. For the REACH authorization, evaluation and registration cost are really high, and the agriculture market will not recover this inclution.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 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** **C.2. Responses to exemption requests referring to other legislation**
2806 2014/11/28	Slovenske elektrarne, a.s., Company, Slovakia	we recommend exemption of particular use	**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
2816 2014/11/28	Company, Netherlands	Vishay BCcomponents B.V.strongly suggests to not include Boric acid (cas nr 10043-35-3) on Annex XIV as it will strongly affect the business of formed anode foil for use in electrolytic capacitors and the business of electrolytic capacitors itself. *Confidential attachment removed*	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**
2829 2014/11/28	Norway, Member State	The Norwegian CA supports the prioritisation of boric acid for inclusion in Annex XIV.	Thank you for your support
2835 2014/11/28	Intermag Sp. z o.o., Company, Poland	2835_boron consulatation.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:** 4. Control of risks 5. Availability of suitable alternatives 7. Burden for industry and potential competitive disadvantage

			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.2.20: 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** **B.2.1: Concerns and uncertainties with respect to the authorisation process, in particular for SMEs** **C.2. Responses to exemption requests referring to other legislation**
2837 2014/11/28	Company, Denmark	Boric acid is used as a source for boron, a biologically essential nutrient (a trace element) in very low concentrations (less than 0.5 mg boric acid/litre) in the fermentation processes leading to the production of a proteinaceous active pharmaceutical ingredient. During the fermentation process Boric Acid is used by the production organisms. While growing and producing the active pharmaceutical ingredient the organisms will integrate Boron into the biomass. The only risk of exposure arises when the substance is weighed of. However due to the very low concentration in the final fermentation broth, the amount weighed of is in a scale comparable to laboratory work level (R&D and QC) which is in general considered out of scope for authorisation due to the small amounts and consequently a very low risk. This is easily controlled today by proper risk management measures	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

2838 2014/11/28	Vattenfall AB; registration no.: 12955024114-93, Company, Sweden	General remarks The European Commission released its Review of REACH on 5 February 2013 containing some interesting points on the European Commission's conception of risk management under REACH. Most importantly, the European Commission explicitly mentions that "no automatic link is assumed between the classification of a substance as a CMR (carcinogens, mutagens and reproductive toxins) and its inclusion on the Candidate List". This appears to acknowledge that Authorization is not an inevitable consequence of classification as CMR1. Furthermore, the Commission explains that "before considering the inclusion of a substance on the Candidate List, an assessment of the best Risk Management Options under REACH is performed". Similarly to the review of REACH, the Commission, the Member States and ECHA confirm their commitment to the "best RMOs" approach to handle SVHCs. This Roadmap is a significant development, because it provides a more transparent and predictable process to consideration of SVHCs. It will also make conducting an RMO study a routine step before a substance is placed on the Candidate List. A RMO study should therefore be performed (which has not been done for boric acid) before adding and prioritizing a substance on the candidate list following the Review - recommendation: 7.1. "The Member States and ECHA are encouraged to continue discussing and sharing at an early stage RMOs analysis with the view to coordinate activities in relation to identification of SVHCs, including "substances of equivalent concern" for which no guiding criteria are available yet." Boric acid got the classification "toxic of reproduction" category 1B by the EU Regulation 790/2009 since September 2009 and therefore belongs to the hazardous substances according to the EU Regulation 1272/2008. Prior to this classification, the general rules for handling chemicals were applied when using boric acid. All specific measures which have been introduced and implemented since the classification (such as substitution, prevention and reduction of exposure as well as the protection of the employees) are therefore a maximum of 5 years old. Already now Europe faces a ban of boric acid by inclusion in annex XIV (or use has to be authorised). From the downstream user's	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks **A.2.2: Disputing the volume score, claiming that the volume figures used for prioritisation are outdated.** **A.2.11: Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV** **B.2.6: Check effectiveness of harmonised classification before proceeding with further regulatory risk. management activities**

		perspective this timeline is not plausible, especially as there haven't been studies recently by the European public authorities on the effectiveness of the measures taken as well as any associated evidence of the remaining health risks of the affected employees as well as the remaining environmental risk, which could justify the inclusion of boric acid in the Annex XIV. The study according to annex XV does not include these points from our point of view. We see this as an additional reason for asking an RMO study for boric acid. The inclusion of boric acid in the candidate list should therefore be re-evaluated. High volumes and wide dispersive use Since the boric acid harmonized classification as Toxic for Reproduction, Category 1B, was established some uses have been substituted. Moreover some mixtures have been modified in order to ensure that boric acid concentration is under the specific classification limit. These evolutions are leading to considerable change within the market and the related exposures. The data concerning the volume and wide dispersive used for prioritization of boric acid are dating back to 2005 - 2008 and should therefore be revalidated. Any prioritization action should be based on current data – a prioritization based on outdated material can lead to overregulation and might not be in line with the principle of proportionality. The prioritization of boric acid in the candidate list should therefore be re-evaluated.	
2843 2014/11/28	Freiberger Compound Materials GmbH, Company, Germany	This comment aims only to raise awareness for this very special but extremely important use of Boric acid for the chemical synthesis of ultra-pure diboron trioxide for the entire semiconductor industry in Europe. 2843_Freiberger - comment for boric acid to the ECHA consultation on the 6th priority list.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.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
2844 2014/11/28	Company, Denmark	We do not support the inclusion of boric acid in the draft ECHA 6th 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. From our point of view, using the REACH authorisation process to control borates would not be proportional and would not contribute to regulatory effectiveness. We are a manufacturer of active ingredients used in plant protection products and are utilizing boric acid as a scavenger (corrosion inhibitor). According to REACH we would be qualifying as a downstream user (DU). During the synthesis of the active ingredient two transported isolated intermediates are reacted in order to give an on-site isolated intermediate. During this reaction fluoride ions are liberated, which on acidification forms HF that is extremely corrosive. In order to avoid the formation of HF boric acid (B(OH)3) is added to the reaction. The boron derivative acts as a scavenger for fluoride ions, and prevents the formation of HF. When the reaction is run in a normal glass reactor no corrosion has been observed when boron acid is used as scavenger. There is no boric acid in the final active ingredient. Alternatives: Other chemicals have been tried instead of boron acid, but are not compatible with the reaction. Consumers are adequately protected through the restrictions (REACH Annex XVII) and the risk management measures detailed in the exposure scenarios of the registration dossiers. In February 2012, the Commission adopted restrictions on borates. Consequently, the use of borates in mixtures above the specific concentration limits is prohibited in consumer markets since 1 June 2012. An assessment of the impact of these restrictions should be conducted first before considering	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.2.9: 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**

		other regulatory options such as authorisation. The use of mixtures containing borates below the specific concentration level does not raise concern as consumers are not subject to prolonged exposure to borates and the threshold level for health effects observed in animals cannot be reached. Furthermore our use of the substance does not result in any exposure to consumers. Risks for workers are adequately controlled through the risk management measures detailed in the exposure scenarios of the registration dossiers and other chemical management legislation The REACH registration dossier for boric acid identifies Risk Management Measures (RMM) where appropriate to ensure that health risks to workers are adequately controlled. RMM are communicated via the eSDS, which allows the site risk assessment to be carried out as required by the Chemical Agents Directive (98/24/EC); these mechanisms assist in ensuring worker safety. Additionally other downstream legislation specifically protects certain vulnerable workers from exposure to substances toxic to reproduction, such as pregnant workers (Dir. 92/85/EC) and young workers (Dir. 94/33/EC). Further, for all identified uses, a Risk Characterisation Ratio (RCR) < 1 was determined and compliance with the DNELs can be achieved with common hygiene measures, i.e. without a need to use Personal Protective Equipment (PPE). This results from the low potency hazard of boric acid. Total weight of evidence, including worker exposure data, shows that it is improbable that borates will cause reproductive and developmental effects in humans Although reproductive and developmental effects have been demonstrated in laboratory animals exposed to abnormally high doses of boric acid, similar effects have not been observed in highly exposed human populations or workers. The absence of adverse reproductive effects in extensive investigations of borate workers in the United States, Turkey and China chronically exposed to high levels of borates and in populations living in high boron areas demonstrate that the actual health risk from exposure to borates is small. Workers in boron mining and processing industries represent the maximum possible human exposure. Based on the total weight of evidence that includes worker exposure data, epidemiological studies and mechanistic data, the data show that it is improbable that boric acid will cause reproductive or	**borates before recommending the substance for Annex XIV** **A.2.14: Claim that authorisation is not necessary as consumers are protected through the restriction in place** **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** **C.2. Responses to exemption requests referring to other legislation**

		developmental effects in humans. 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 this is the right RMM option for borates. 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. In conclusion, our stance is that the authorisation procedure will not lead to additional protection for workers and consumers. The prioritising of boric acid at this time does not represent regulatory effectiveness and is not proportional.	
2846 2014/11/28	National Association of Goldsmiths,	The NAG does not support the inclusion of borates in the draft ECHA 6th prioritisation list for Annex XIV.	**A.1.5. Aspects not considered in ECHA's prioritisation:**

	Industry or trade association, United Kingdom	In our opinion borates are safe for workers with no epidemiology studies proving otherwise. Additionally, using the REACH authorisation process to control borates would not be proportional and not contribute to regulatory effectiveness.	2. Aim & proportionality of authorisation system - Authorisation is not a ban 4. Control of risks
2848 2014/11/28	Company, United Kingdom	We do not support the inclusion of boric acid in the draft ECHA 6th 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 are a manufacturer of crop nutrition and are utilizing boric acid as an intermediate. According to REACH we would qualify as a downstream user (DU). The crop nutrition is produced by mixing three transported isolated intermediates. All the substances are handled under strictly controlled conditions during synthesis; therefore exposure will only occur in case of accidents and other unforeseen situations. The identification of the intermediates and produced substance together with their ratios and volumes are mentioned in the confidential attachment. Please take the volumes used as intermediate under consideration when you (ECHA) do the prioritisation of the substance. Alternatives: Boron is an essential micro-nutrient for plant growth and cannot be substituted for this particular use. In conclusion, our stance is that the authorisation procedure will not lead to additional protection for workers and consumers. The prioritising of boric acid at this time does not represent regulatory effectiveness and is not proportional. *Confidential attachment removed*	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 **C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation**

2850 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 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	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:** 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** **B.2.1: Concerns and uncertainties with respect to**

		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 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 authorisation process, in particular for SMEs** **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**

		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 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.	
2864 2014/11/28	Company, Spain	We disagree about including the boric acid in the list of SVHC, we have been using it for a long time and never any health problem have occured to our employees or suppliers operators.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks
2870 2014/11/28	European Borates Association, Industry or trade association, Belgium	2870_EBA comments - ECHA PC - 6th priority list - glass-frits.pdf	**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**
2872 2014/11/28	Company, Belgium	we use only a few grams of boric acid per year still it is an essential micronutrient for growth of Pichia pastoris. which is a part of our process to produce "nanobodies" .	Thank you for your comment and the additional information provided. This will be taken into account,

		it is essential for our company that we can still use this product	where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation.
2875 2014/11/28	Company, France	We fully share the position of our supplier EBA (European Borates Association). We join the EBA comments on the 6th priority list of substances for inclusion in Annex XIV 2875_EBA comments - 6th priority list (final).pdf	Please see response to comment 2524 (EBA comment) **C.2. Responses to exemption requests referring to other legislation**
2876 2014/11/28	Company, Spain	Our company uses boric acid in an important manufacturing line for us. We are not a member of any specific association for this manufacturing process, that is, we will not be able to exchange any information with any other company to apply for an authorisation.	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.
2878 2014/11/28	Company, France	The chapter 3 of the draft background document for Boric acid do not describe the use as micronutrient for plant cell culture and microorganisms fermentation. As a matter of fact Boron element (delivered by Boric acid) is an essential microelement for the growth and development of plant cells that can not be replaced. In case of depletion in the culture media, the cells propagation ceases immediately and the cells die. This type of use is an industrial use only (R&D and commercial purposes) that presents a very low risk of exposure for employees (low quantity handled, low concentration, low frequency, conditions of use). 2878_Additional non Condidential information.doc	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.2.6: 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) **C.2. Responses to exemption requests referring to other legislation**
2879 2014/11/28	Company, Sweden	Boric Acid serves an important role in radiation protection and promoting global healthcare, by enabling production of Positron Emission Tomography (PET) radio isotopes. Dissolved in a solution of water, boric acid mixed with sodium tetra borate is sealed in stainless steel tanks of the radiation shielding for the lifecycle of a cyclotron [minimum 20 years]. Cyclotrons are used to produce short-lived radioactive nuclides for medical imaging and diagnostic purposes, using Positron Emission Tomography (PET) technology. The radioactive nuclides produced by the cyclotron are used to label biomarkers that can be injected into patients to early diagnose cancer tumors and follow up therapy results via a PET scanner. Using PET technique significantly improves the selection of efficient therapy. Currently, there is no other known substitute substance which is available with the same desired properties as Boron for its efficiency in neutron shielding, capture and attenuation, and providing radiation protection for workers and environment. The current proposal will negatively impact global healthcare diagnostics, reducing or even eliminating the availability of PET isotopes and tracers in the EU, unless there was a positive action on the exemption requested . Some customer with existing facilities are forced to the Cyclotron self-shield with boron loaded water stainless steel container. The alternative would be building a new facility with a concrete bunker to house the cyclotron. This bunker consist of two meter concrete walls which leads to significant infrastructure investments, often forcing the customer to abandon the plans for a cyclotron facility and hence the isotope production.	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 **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** **C.3.6: Claim that uses in healthcare sector in small quantities should be exempt from authorisation.**

		The annual volume used in this application is estimated to be 7500kg.	
2882 2014/11/28	EDF Energy, Company, United Kingdom	Please see the attachmed document for EDF Energy's full set of comments on the recommendation to include the substance in Annex XIV. 2882_28112014 ECHA Boric Acid Position FINAL.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 4. Control of risks 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** **B.2.5: Long review period substitution impossible. Claim that the use fulfils the RAC/SEAC conditions for longer review period.** **C.2. Responses to exemption requests referring to other legislation**
2888	FERTINAGRO	For fertilizer manufacturers, boron plays a very important role for the features	Thank you for your comment and

2014/11/28	NUTRIENTES, S.L., Company, Spain	it offers to plant development. The reasons are: - No boric acid is used as such, is reacted to obtain a salt, in most cases. - The amounts in the fertilizer products are very low, so it is not considered that would create a risk to health or the environment. - It is one of seven micronutrients essential for normal plant growth, not replaceable by other elements. - Allows better metabolize plant activity, pollination and fruit set , the consistency of the tissue, disease resistance and frost, etc. - It is essential for normal plant growth because it promotes proper cell division, cell elongation, the strength of the cell wall, pollination, flowering, seed production and transfer of sugar. - Boron is also essential for the hormonal system. - It is a safe, essential and traditional use in agriculture. - Moreover, due to the high costs of assessment and recording for authorization under REACH, would not justify its recovery in the market and prices to farmers would increase. - There is sufficient evidence to show that agricultural uses are safe, has historically shown that they are well by traditional use.	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 alternatives
2889 2014/11/29	ECIA European Cellulose Insulation Association, Industry or trade association, Belgium	ECIA is represented by 13 cellulose insulation producers in Europe with 23 production sites. It is not recommended to include boric acid in Annex XIV. The use of boric acid as a fire retardant in cellulose insulation is absolutely safe: The exposure amounts for workers are much lower that any amount which could have reprotoxic effect.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks
2890 2014/11/29	German Refractory Association, Industry or trade association, Germany	The production capacity/output of the members of the German Refractory Association (VDFFI) represent about 70% of the total amount of refractory products manufactured in Germany and about 25% of the European refractory production. The refractory industry makes use of boric acid for the production of articles (crucibles) as well as a component in mixtures. The products are mainly used in foundries of the steel, ferrous and non-ferrous metal industry. The content of boric acid in crucibles and in the majority of the mixtures is below the specific concentration limit of boric acid. Refractories are not consumer products; they are only used for industrial	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**

		purposes. The exposure of workers during the manufacturing of crucibles or mixtures is well below the DNEL for boric acid of 8,3mg/m3 respectively below the German AGW (occupational exposure limit) of 0,5 mg/m3 (related to Boron), which is continually being verified by exposure level measurements. An adequate substitute substance, not containing any boron, has not been identified yet, despite of many years of research in this field. Moreover, without the use of boric acid, the refractory materials will undergo a certain type of corrosion, which - in the worst case - will cause a deterioration and perforation of the furnace wall with an uncontrolled released of hot, liquid metal. Furthermore, an authorisation of boric acid will not cause any improvement in safety at work and a substitution of boric acid with boron-free substances is not feasible.	**ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban 4. Control of risks 5. Availability of suitable alternatives
2905 2014/11/30	ZVO/ VECCO, Industry or trade association, Germany	Please read: IV. Attachment (additional non-confidential information) to comments on ECHA's draft recommendation 2905_2014-11-30 Comment on Boric Acid Joint Application Surface technology.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:** 1. Potential other regulatory actions 4. Control of risks 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 **B.2.2: Concerns about workload, timelines and resources needed for those companies already dealing with Cr(VI) applications** **C.2. Responses to exemption requests referring to other legislation** **C.3.4: Claim that uses which can replace Cr(VI) should be exempt from authorisation**
2906 2014/11/30	Individual, Netherlands	Although borate has a reproduction hazard as intrinsic property, high production volume and wide-dispersive use, the background document completely ignores the fact, which was also acknowledged by RAC in its evaluations, the complete lack of risks. Even in highest possible exposed groups it was not possible to identify reproductive effects. RAC commented to this that "Assuming a similar sensitivity of humans as in the four laboratory species studied, it would have been unlikely to observe any adverse effects on human male fertility at those exposure levels." Risk assessment of all individual uses also indicates there is no clear risk. Authorisation of this substance therefore means a legal action involving costs and efforts in order to limit risks to society that do not exist. This would be completely against the aim of authorization as expressed in art. 55 of REACH, which explicitly states that it is meant to assure that "the risks from substances of very high concern are properly controlled".	**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 **A.2.22: Disputing the harmonised classification**
2923 2014/11/30	Company, Belgium	Comments on the inclusion of borates in the draft ECHA 6th prioritisation list for Annex XIV have been provided by the EBA. As a company we support the general comments submitted by the EBA. ECHA's draft 5th priority list was stopped by the European Commission, so it does not make sense to skip the substances on the 5th list and instead proceed	Please see response to comment #2524 (EBA comment) Thank you for your comment and the additional information provided. This will be taken into account,

		with the substances on te 6th list. *Confidential attachment removed*	where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.2.12: ECHA should not proceed with the 6th recommendation, when the 5th is still open** **C.1.2. Generic exemptions**
2930 2014/11/30	Association of European Airlines, Industry or trade association, Belgium	This comment is handed in by the European Association of Airlines (AEA) as a common concern shared by all 30 AEA members: the European Aviation industry, the airlines who are responsible for an airworthy fleet, and maintain the aircraft according to their EASA and FAA licenses. These comments also concern independent MRO (maintenance, repair and overhaul) services in Europe. Both airlines and independent MRO companies guarantee a whole raft of requirements ranging from safeguarding air safety, properly managing aircraft operation, and minimizing costs. The statement is made in close cooperation with several AEA members and with ASD (Aerospace and Defence Industries Association of Europe), the national trade organization in Europe who represent a.o. the Original Equipment Manufacturers (OEMs), and the AIA (Aerospace Industries Association), who represent the OEMs outside Europe (US). Therefore the following statement refers to the official ASD statement and the paper from the AIA () which was handed in to this public consultation as well. Boron compounds are used for an extensive range of applications during maintenance, repair and overhaul. Examples of uses are electroplating processes like nickel plating or anodizing, cleaning materials / processes, corrosion inhibitors or fluxes. Aviation materials must be able to withstand extreme conditions including temperatures, humidity, altitude, pressure, friction, and rapid, repeated cycling during normal use. In addition, they must resist attack by aggressive fluids such as hydraulic fluids and de-icing agents.	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 **B.2.2: Concerns about workload, timelines and resources needed for those companies already dealing with Cr(VI) applications**

		Many components that use boron compounds are inaccessible and difficult to inspect for damage following product delivery without disassembly. These components are expected to last for the anticipated product lifespan which can exceed 25 years. See for a more detailed description of the use the ASD input and AIA input from OEMs. Today there are no qualified commercially available alternatives that meet the aerospace performance criteria of longevity, reliability and compatibility exhibited by some boron compounds for a range of applications. Authorisation of these products is creating a severe disadvantage for the European airline industry. The aviation industry and especially the companies who perform the MRO services are directly dependent on processes, products and maintenance procedures developed by the OEMs and certified by the airworthiness authorities (European Aviation Safety Agency (EASA) and United States Federal Aviation Administration (FAA)). Due to the strict airworthiness requirements OEMs are responsible for the safety of the aircraft system as well as for stringent maintenance procedures. Therefore airlines and MRO providers are in the first place bound to the research and developments done by OEMs. AEA members and MRO companies are not in the position to perform the important REACH process of "Analysis of Alternatives". Nevertheless – looking at on-going REACH authorization processes for e.g. Chromium Trioxide many AEA members are heavily burdened by securing the product availability and handling the unknown and inexperienced REACH authorization process. For further details of the certification and qualification and industrialization process we refer to the joint paper developed between industry EASA and ECHA "An elaboration of key aspects of the authorisation process in the context of aviation industry".	
2939 2014/11/30	Company, United Kingdom	OVERVIEW Our company is a manufacturer of frits, primarily for glass and ceramic application, analytical fluxes for extractive metallurgy and brazing fluxes for metal joining applications. A significant number of these frits and brazing fluxes utilize the listed borates as an intermediate (uses that fall outside the scope of authorization), or contain the listed borates in the finished product.	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

		In line with submissions to the ECHA consultation from the European Borates Association and the Frit Consortium, our company does not support the inclusion of the listed borates in the draft ECHA 6th prioritization 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 authorization process to control the listed borates would not be proportional and would not contribute to regulatory effectiveness. ARGUMENTS AND RATIONALE 1. Industrial and professional workers are adequately protected by virtue of existing REACH restrictions and other EU regulations. a. Risks for workers are adequately controlled through the risk management measures detailed in the exposure scenarios of the registration dossiers and other chemical management legislation The REACH registration dossiers for diboron trioxide, boric acid and disodium tetraborates identified Risk Management Measures (RMMs), where appropriate, to ensure that health risks to workers are adequately controlled. RMMs are communicated via the eSDS, which allows the site risk assessment to be carried out as required by the Chemical Agents Directive (98/24/EC); these mechanisms assist in ensuring worker safety. Additionally, other downstream legislation specifically protects certain vulnerable workers from exposure to substances toxic to reproduction, such as pregnant workers (Dir. 92/85/EC) and young workers (Dir. 9433/EC). Furthermore, for all identified uses, Risk Characterisation Ratios (RCRs) <1 were determined and compliance with the DNELs can be achieved with common hygiene measures, i.e. without a need to use Personal Protective Equipment (PPE). This results from the low potency hazards of the listed borates. b. The major uses of the listed 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 the diboron trioxide, the boric acid and disodium tetraborates used in Europe is outside the scope of authorization, as these substances are mainly used in: • The manufacture of glass and frits or for the synthesis of new substances in	background documentation. Please see also responses given to comments by European Borates Association (EBA) (#2524 and 2870) and #2633 (Frits consortium) **A.1.3. Prioritisation: Wide-dispersiveness of uses:** 2. Assignment of WDU score based on use types and their associated volumes **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 glues** **- production of fluoroboric acid (CAS 16872-11-0**

		these uses, the substances qualify as an intermediate since they are completely consumed and transformed into another substance. In the new substance that is formed, boron is part of the chemical structure and thus, these uses fall outside the scope of authorization. • Mixtures below the specific concentration limits • Covered by other sector-specific legislation (e.g. biocides), again, falling outside the scope of authorization. 2. 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 should improve regulatory effectiveness. To our knowledge, for thelisted borates, an RMOa has not been carried out. Based on experience from the (ex-) 5th list proposal, we would strongly recommend assessing the efficiency of authorization in order to consider whether this is the most appropriate RMM option for borates. 3. Boron is not replaceable in certain uses We are not aware of any SVHC-free alternatives to borate-containing high temperature brazing fluxes that offer the required time and temperature stability over the life of the flux. These properties are critical to their niche applications, in particular in the oil and gas industry, e.g. in the (EU-based) manufacture of oil well drilling pipe centralisers. Notwithstanding the lack of viable alternatives, the complexities of qualifying new substances / products for application in these industry, in addition to recognising the importance of these specialized engineering industries to EU competitiveness, suggests that the authorization would have to be granted for these uses, and would not achieve the aim of authorization. In conclusion, it is the position of our company that the authorization procedure will not lead to additional protection for workers and consumers. Taking into account the socio-economic importance of borates and the fact that, for the most important uses, no substitutes are available, means that prioritizing borates at this time does not represent effectiveness and is not proportional.	**- 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.2.11: 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.2.14: Claim that authorisation is not necessary as consumers are protected through the restriction in place** **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**

			A.2.22: Disputing the harmonised classification **C.2. Responses to exemption requests referring to other legislation**
2944 2014/11/30	Austrian workers' compensation board, National Authority, Austria	The substitution of reprotoxic boron compounds had allready a great impact with entering these substances into the candidate list. This process will further improve if these boron compounds enter Annex XIV.	Thank you for your support
2948 2014/12/01	European Federation of Pharmaceutical Industries and Associations, Industry or trade association, Belgium	2948_EFPIA comments_Boric Acid_Inclusion into ANNEX XIV_REACH.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 **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)** **C.2. Responses to exemption requests referring to other legislation**

2950 2014/12/01	ASD, Industry or trade association, Belgium	1.1. Boric acid (CAS 10043-35-3, 11113-50-1) BoriC acid is used for an extensive range of applications in the aerospace and defence industries, including; Fluxes Metalworking fluids Nickel plating Anodising Corrosion inhibitors Reaction inhibitors A number of commercially available brazing fluxes and flux solutions use boric acid as part of the formulation in order to provide a number of functionalities to the mixture, including wetting and melting pOint. Boric acid has traditionally been used in water soluble metalworking fluids as it acts as a corrosion inhibitor, helps to prevent biological growth and increases the stability of the fluid. Removing boric acid from a fluid is not a viable option in all applications due to usage of tougher metals and more advanced, severe metalworking processes. There are a number of different methods that can be used to electroplate nickel onto a metal object. The methods utilized by the aerospace and defence industries requires boric acid as part of the bath composition where it acts as a buffer solution and protects against biological growth. Nickel plating is used to provide corrosion and wear resistance to components and also utilized in highly specialised applications including printed circuit boards and antennas used in space and defence applications. Other electroplating processes require boric acid, including zinc alloy electroplate technologies. These have been used as an alternative to cadmium plating for some applications as some cadmium plating processes require the use of chromium (VI) compounds that are currently on Annex XIV. Similarly, previous environmental regulations have encouraged development of chrome-free processes. From such development work evolved the Boric Sulphuric Acid Anodise (BSAA) process which can be used as a chrome-free alternative in some but not all corrosion protection applications. The chemical properties of boric acid also make it suitable for corrosion inhibition within nuclear applications. Furthermore, as a neutron absorber, the substance is used to inhibit the rate of nuclear fission inside reactors and this	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.**

		highlyspecialised application has no known alternative. 2950_ASD answer to ECHA consultation_General Conclusions for all Boron and lead compounds_281114.pdf	
2956 2014/12/01	ASD, Industry or trade association, Belgium	Comments have already been made in this section but the attachment contains significant furtehr details 2956_ASD answer to ECHA consultation on BORICACID_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 **A.2.12: ECHA should not proceed with the 6th recommendation, when the 5th is still open** **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** **C.3.4: Claim that uses which can**

			replace Cr(VI) should be exempt from authorisation.
2963 2014/12/01	ADS Group, Industry or trade association, United Kingdom	ADS fully supports the comments made by ASD	Please see responses given to comments by ASD (#2956).
2964 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. 2964_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**
2973 2014/12/01	GIFAS, Industry or trade association, France	Please refer to attached letter 2973_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**
2990 2014/12/01	Company, Netherlands	This comment is handed in by the European Association of Airlines (AEA) as a common concern shared by all AEA members: the European Aviation industry, the airlines who are responsible for an airworthy fleet, and maintain the aircraft according to their EASA and FAA licenses. These comments also concern independent MRO (maintenance, repair and overhaul) services in Europe. Both airlines and independent MRO companies guarantee a whole raft of requirements ranging from safeguarding air safety, properly managing aircraft operation, and minimizing costs. The statement is made in close cooperation with several AEA members and with ASD (Aerospace and Defence Industries Association of Europe), the national trade organization in Europe who represent a.o. the Original Equipment Manufacturers (OEMs), and the AIA (Aerospace Industries Association), who represent the OEMs outside Europe (US). Therefore the following statement refers to the official ASD statement and the paper from the AIA () which was handed in to this public consultation as well. Boron compounds are used for an extensive range of applications during maintenance, repair and overhaul. Examples of uses are electroplating processes like nickel plating or anodizing, cleaning materials / processes, corrosion inhibitors or fluxes. Aviation materials must be able to withstand extreme conditions including temperatures, humidity, altitude, pressure, friction, and rapid, repeated cycling during normal use. In addition, they must resist attack by aggressive fluids such as hydraulic fluids and de-icing agents. Many components that use boron compounds are inaccessible and difficult to inspect for damage following product delivery without disassembly. These components are expected to last for the anticipated product lifespan which can exceed 25 years. See for a more detailed description of the use the ASD input and AIA input from OEMs. Today there are no qualified commercially available alternatives that meet the aerospace performance criteria of longevity, reliability and compatibility exhibited by some boron compounds for a range of applications. Authorisation	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 **B.2.2: Concerns about workload, timelines and resources needed for those companies already dealing with Cr(VI) applications**

		of these products is creating a severe disadvantage for the European airline industry. The aviation industry and especially the companies who perform the MRO services are directly dependent on processes, products and maintenance procedures developed by the OEMs and certified by the airworthiness authorities (European Aviation Safety Agency (EASA) and United States Federal Aviation Administration (FAA)). Due to the strict airworthiness requirements OEMs are responsible for the safety of the aircraft system as well as for stringent maintenance procedures. Therefore airlines and MRO providers are in the first place bound to the research and developments done by OEMs. AEA members and MRO companies are not in the position to perform the important REACH process of "Analysis of Alternatives". Nevertheless – looking at on-going REACH authorization processes for e.g. Chromium Trioxide many AEA members are heavily burdened by securing the product availability and handling the unknown and inexperienced REACH authorization process. For further details of the certification and qualification and industrialization process we refer to the joint paper developed between industry EASA and ECHA "An elaboration of key aspects of the authorisation process in the context of aviation industry". 	
2991 2014/12/01	EURELECTRIC, Industry or trade association, Belgium	EURELECTRIC is concerned that boric acid uses would be either limited or subject to unsuitable requirements. Indeed, even if the European Chemical Agency (ECHA) does authorise the use of boric acid in the nuclear fuel cycle, we still have concerns that authorisation will be required on a regular basis. Given the fact that boric acid has no substitute, the rolling application process is particularly costly and contributes to undermining the regulatory certainty needed for investments in nuclear power plants. Given its importance for nuclear power generation, we don't support the inclusion of boric acid in the Authorisation List. A "Risk Management Option" study should be undertaken for boric acid, and borates in general, before any inclusion in Annex XIV is considered, in order to ensure that the most appropriate regulation to manage risk is chosen, based on a complete and up-to-date analysis. 2991_EURELECTRIC-statement boric acid-final.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:** 4. Control of risks 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.2.20 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** **B.1.3: Review periods** **C.2. Responses to exemption requests referring to other legislation**
3001 2014/12/01	FORATOM, Industry or trade association, Belgium	The European Commission released its Review of REACH on 5 February 2013. The European Commission explicitly mentions that "no automatic link is assumed between the classification of a substance as a CMR (carcinogens, mutagens and reproductive toxins) and its inclusion on the Candidate List". This appears to acknowledge that Authorization is not an inevitable consequence of classification as CMR. Furthermore, the Commission explains that "before considering the inclusion of a substance on the Candidate List, an assessment of the best Risk Management Options under REACH is performed". Similarly to the review of REACH, the Commission, the Member States and ECHA confirm their commitment to the "best RMOs" approach to handle SVHCs. This Roadmap is a significant development, because it provides a more transparent and predictable process to consideration of SVHCs. All specific measures which have been introduced and implemented since the classification (such as substitution, prevention and reduction of exposure as well as the protection of the employees) are therefore a maximum of 5 years old. Already now Europe faces a ban of boric acid by inclusion in annex XIV (or use has to be authorised). From the downstream user's perspective this timeline is not plausible, especially as there haven't been studies recently by the European public authorities on the effectiveness of the measures taken as well as any associated evidence of the remaining health risks of the affected	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.2.2: Disputing the volume score, claiming that the volume**

		employees as well as the environmental risks, which could justify the inclusion of boric acid in the Annex XIV. The study according to annex XV does not include these points from our point of view. Market has changed since 2009. First of all, since the boric acid harmonized classification in 2009 as Toxic for Reproduction, Category 1B, some uses have been substituted. Moreover some mixtures have been modified in order to ensure that boric acid concentration is under the specific concentration limit. These evolutions are leading to some change within the market shares (less amount used by detergent industry getting smaller than the initial assessment of up to 26% of the total amount of borates used in Europe) and then of the related exposure. Relevancy of the 2005-to-2008 data, from 2005 to 2008, used for prioritization could therefore be challenged. Uses outside of the authorization scope Moreover some uses are outside of the authorization scope: - depending on regulation on biocidal products (TP 8), cosmetics - considered as intermediate for synthesis of other substances These uses weigts more than 60% of the amount used in Europe according to the 2009 « Annex XV Transitional report » of and more than 70 % according to the 2014 "critical raw materials report". Authorization seems therefore not to be the best way to manage the risks. A critical substance for the European economy Otherwise, some uses are non substitutable, as for use as nutriment for certain crops or as neutron absorbing capability for nuclear industry. A great number of authorization dossiers should then been submitted. Borates are among the 20 critical substances for the European economy (Report on critical raw materials for the EU, Report of the Ad hoc Working Group on defining critical raw materials - May 2014). Substitution of such substances is moreover considered as though (3rd most difficult substance to substitute among the 20 strategic substances) according to the same report. As a consequence, a shift would appear between the decision to limit use of this substance and the market reality and needs. According to the impact importance on industrial activities, and taking into account the Review-recommendation, before any recommendation to Annex XIV addition concerning this group of substances, a « Risk Management Option	**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.2.20 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** **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**

		» study should be implemented in order to ensure that regulation to manage the risks identified would be based on a complete and up to date analysis. Considerations on Nuclear Using borate in nuclear electric power plants is vital to control nuclear fission reactions and to ensure nuclear safety. Borate and especially boric acid, is used in all nuclear industry around the world and no other chemical compound has the same characteristics required to replace borate for this use as expected in the authorization process. Borate is also used for its neutron absorbing capacities within the nuclear fuel cycle and during dismantling. Moreover borate is used in the glass for nuclear waste. Managing the risk of using borates Risks from nuclear boric acid uses are considered to adequately controlled for workers and environment. There are no risks for consumers. Risks for workers are considered to be controlled by appropriate facility and equipment. To manage the risk of boric acid exposure among employees working in the plants and to protect them, nuclear industries implement the actions required by their national law. Boron has been used for this purpose since the start of nuclear engineering with no known adverse effects to personnel. Boric acid releases are regulated and most regulation requirements address concentration values in the environment. Impact studies carried out in particular as part of authorization requests for liquid discharge and water intakes on the one hand, and data from the environmental monitoring of sites on the other hand, demonstrate the absence of impact on the environment from borate liquid discharges due to the operation of nuclear power plants. In certain countries (Germany for example), all boric acid is stored after bitumization without any discharge. The health risk associated with controlled borate liquid discharge, based on current knowledge and methods tested by recognised scientific organizations, is not considered to be a concern. The element boron does not exist by itself in the environment and is combined with other common elements, such as oxygen to make borate and exists then naturally. - Borate under boric acid form occurs naturally in water. The concentration of	

		this substance in sea water varies between 4 and 5mg/L. The maximum concentration in added borate in effluents after mixing, accounts for a few percent of the natural background noise; it is of the same order of magnitude as the natural fluctuations of borate concentration in the environment. - Borate under boric acid form also occurs naturally in soil. The boric acid concentration in soil varies between 0,002 and 0,1 mg/g. - Borate under boric form acid content in plants and particularly in vegetables is very high (from 0,025 to 0,5 mg/g). Effluent discharges containing borate are strictly regulated and monitored by competent authority in each country. Managing the source at the origin a treating these effluents allow to limit the flows and concentrations of borate liquid discharges into the surrounding environment. Regarding new reactors ("new build" like EPR), efforts has been made for waste discharges containing borate which will be subject to a systematic action to optimize and reduce discharges but borate must still be used. 3001_FORATOM-boric acid-ECHA-VF.docx	
3002 2014/12/01	European Semiconductor Industry Association, Industry or trade association, Belgium	Boric acid is used as a buffer in nickel and other metal plating processes in semiconductor manufacturing. Low volume used The use of boric acid as a buffer in nickel and other metal plating processes in semiconductor manufacturing is very low. Its use however has a very high economic value for the production of semiconductor devices. ESIA estimates that the aggregated volume of boric acid use in metal plating in EU semiconductor manufacturing is in the range of 600-800 kg per year of concentrated (100%) boric acid and in addition less than 2500 kg per year of boric acid contained in mixtures below the Specific Concentration Limit (SCL) (boric acid SCL is ≥ 5.5%). No wide-dispersive use: The use of boric acid as a buffer in plating processes such as nickel and other metal plating in semiconductor manufacturing does not qualify as a wide dispersive use. The semiconductor manufacturing industry sector employs stringent risk management measures and safety practices to prevent boric acid release	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.1.3. Prioritisation: Wide-dispersiveness of uses:** 1. Scope of the assessment of wide-dispersiveness of uses 2. Assignment of WDU score based on use types and their associated volumes **A.1.5. Aspects not considered in ECHA's prioritisation:**

		during all stages of the manufacturing process, including the waste stage thus preventing worker exposure. Furthermore the substance is not incorporated into the final product. Uses of boric acid take place in dedicated equipment in a highly automated clean room 'controlled environment' greatly minimizing risk of exposure to workers. Inside the semiconductor wafer manufacturing clean room, the presence of uncontrolled particles, as well as chemical vapors and gases constitutes an unacceptable risk not only from a safety and health but also from a production perspective. As boron (boric acid) is a typical dopant in device manufacture, even minor releases of boric acid could lead to yield loss and serious device performance issues due to (cross)-contamination. This risk is controlled through the application of closed system manufacturing equipment. In addition, automated chemical delivery systems are installed to create a barrier between workers and the process and protect against chemical and physical hazards in the work environment. During maintenance activities, technical measures are in place to prevent worker exposure: • Equipment is drained and purged prior to invasive maintenance; • Maintenance occurs at room temperature under local exhaust ventilation; • Tasks are risk assessed and workers wear appropriate PPE; • Dermal exposure is controlled. The EU REACH use descriptors generally applied to the semiconductor manufacturing industry also apply to the use of boric acid in metal plating by the industry. These descriptors are outlined in the table in the document attached. Boric acid is used as a buffer in nickel plating as part of the manufacturing process of semiconductor 'wafer bumping'. Semiconductor wafer bumping is the process that forms little solder bumps (i.e. with a diameter of 20 to 100 µm) on a finished die patterned semiconductor wafer. The solder bumps form the electrical and mechanical connection between a semiconductor wafer (respectively the chips on it) and a package substrate. Nickel is plated as a very thin layer (i.e. below 4µm) below the wafer "bump", as part of the underbump metallurgy (UBM) layer. Boric acid concentration in the plating solution used in the nickel plating process	1. Potential other regulatory actions 4. Control of risks 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.2.8: 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.2.20 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** **B.2.4: Investment cycles should be taken into account** **C.2. Responses to exemption requests referring to other legislation**

		is below the SCL for boric acid (SCL is ≥ 5.5%) and it is a key component in the plating reaction sequence as a pH buffer and to improve the overall plating quality. Without boric acid the properties of a metal deposition, such as surface morphology, smoothness and internal stress are compromised and the required product reliability standards is not met. In addition to using boric acid below the SCL, for leading edge wafer bump processes, there is also a use of boric acid at a concentration of 100% where neat boric acid is needed to replenish the plating bath with the buffer component. Replenishment use of boric acid in concentrations above the SCL would require authorization if boric acid above the SCL moved to REACH Annex XIV. Preparation of replenishment mixture for a metal plating bath in semiconductor manufacturing occurs under exhaust/ ventilation in the cleanroom, so that any potential exposure is minimized. Inside the semiconductor wafer manufacturing clean room, the presence of uncontrolled particles, as well as chemical vapors and gases constitutes an unacceptable risk not only from a safety and health but also from a production perspective. This is controlled through the application of enclosed manufacturing equipment or 'closed systems'. Furthermore, automated chemical delivery systems are installed to create a barrier between workers and the process and protect against chemical and physical hazards in the work environment. Boric acid does not remain in the finished product. The plated layer on the semiconductor wafers does not contain boric acid. Boric acid remains as part of the spent plating solution and is treated and disposed of in accordance with applicable legislation. 3002_ESIA Input to the ECHA Public Consultation_BoricAcid_PDF Dec 1 2014.pdf	
3007 2014/12/01	Bundesverband Keramische Industrie e.V., Industry or trade association, Germany	The Frits Consortium and Cerame-Unie had submitted comments in response to this section and Bundesverband Keramische Industrie e.V. fully supports this.	Please see response to comment #2633 (Frits consortium) Please see response to comment #3011 (Cerame-Unie)
3011 2014/12/01	Cerame-Unie - the European Ceramics Industry Association, Industry or trade	The European Ceramic Industry, Cerame-Unie, covers a wide range of products including brick & roof tiles, clay pipes, wall & floor tiles, refractory products, sanitary ware, table & decorative ware, technical ceramics, abrasives and enamels. It accounts for more than 200.000 direct employments and a turnover	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of

	association, Belgium	of € 25 billion within the EU. Borates, including boric acid, diboron trioxide and disodium tetraborates are used as an intermediate in the production of frits. Frits are subsequently used by ceramic manufacturers to produce glazes. Glazes are the thin, glassy coatings fused onto ceramics in tiles, tableware and porcelain. The borates in the frits are used to initiate glass formation and reduce glass viscosity (helping to form a smooth surface) and to reduce thermal expansion (facilitating a good fit between the glaze or enamel and the item it covers). Borates also increase the refractive index, or luster, and enhance the durability of the glaze. Using borates significantly lowers the glaze firing temperature. The use of borates also provides manufacturers alternatives to other substances that pose health risks (such as lead oxides). Further details on the use of borates in frits can be found in the comments provided by the Frits consortium. These comments are fully supported by Cerame-Unie. Borates are also used as a raw material in ceramic articles like tiles where its application reduces both the firing time and temperature needed and at the same time increases the dry mechanical strength of the product, allowing for thinner and more light-weight products. In the refractory industry, borates are used in the production of refractory articles (such as heat resistant crucibles) as well as in mixtures (unshaped refractory products). These refractory products are only used in industrial applications, with no consumer exposure. The content of boric acid in crucibles and in the majority of mixtures is below the specific concentration threshold applicable to boric acid. Boron free substitutes for this application are not yet known in that quality. Moreover, without the addition of boric acid, the refractory materials will undergo a certain type of corrosion, which - in the worst case - will lead to an uncontrolled released of hot, liquid metal due to a perforation/deterioration of the furnace wall. Boric acid is also used as an intermediate in the high volume manufacturing of boron carbide, boron nitride, titanium boride, zirconium boride and calcium boride. These substances are important for the refractory and technical ceramic industry.	ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. Please see response to comment #2632 (Frits consortium) Please also see response to comment #2522 (EBA comment) **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.2.3: 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 glues** **- production of fluoroboric acid (CAS 16872-11-0** **- in manufacture of boron carbide, boron nitride, titanium boride, zirconium boride and**

		In the abrasive industry boric acid is also used as pH buffer for certain electroplating processes. It is essential to regulate the pH value of the nickel baths. The amounts required are typically below 1 ton per year. The application of boric acid in the electroplating processes in the abrasive industry takes place under controlled conditions. According to the information received from our members, there is currently no alternative available for their specific application. In case an authorization for boric acid would be required the production of high quality super abrasives in Europe might no longer be possible for those companies using boric acid. Borates are also used in preparing samples into glass beads for XRF analysis. They are also used as fluxes and reagents for wet chemical analysis, atomic absorption, ICP, ICP-MS and a whole range of other chemical analysis techniques. If borate based products were to cease to be available, it would be impossible to analyse any refractory, ceramic, geological materials and a whole range of ores, minerals and raw materials. Cerame-Unie also wants to highlight that for the borates no risk management options assessment (RMOa) was carried out. We consider such RMOa to be an essential step that should take place before a substance is added to REACH Annex XIV. Such approach is also reflected in the SVHC Roadmap. Disodium octaborate and disodium octaborate tetrahydrate have been recommended by the RAC to be classified and labelled as Repr 1B H360FD. This is the same classification and labelling as the borates currently under consideration. In many ceramic applications described above, the borates which are proposed for authorisation can be replaced by Disodium octaborate and disodium octaborate tetrahydrate, that are not yet on the candidate list, although they have the same classification. Cerame-Unie strongly believes that an authorisation of borates in general is not the best risk management option. Furthermore, a grouping approach is essential and the authorisation requirement at this stage for only boric acid, diboron trioxide and disodium tetraborates is meaningless. Cerame-Unie also fully supports the input given by the European Borates Association (EBA).	**calcium boride** **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 substance for Annex XIV**

3022 2014/12/01	LightingEurope, Industry or trade association, Belgium	3022_LE_consultation_Boric Acid_20141201_final_final.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 **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** **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**

			You might also be interested in response: **C.2: Responses to exemption requests referring to other legislation**

II - Transitional arrangements. Comments on the proposed dates

Number / Date	Submitted by (name, submitter type, country)	Comment	Reference to responses
2502 2014/09/05	Ti Automotive Belgium, Company, Belgium	We need at least 3-4 years to find a other solution.	**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 2. Lack of alternatives, socio-economic aspects
2511 2014/10/15	European Catalyst Manufacturers Association (ECMA), Industry or trade association, Belgium	2511_20141015- Boric Acid ECHA consultation final (ECMA) Supply Chain .docx	Please see references to responses in section I
2524 2014/10/31	European Borates Association (EBA), Industry or trade association, Belgium	2524_EBA comments - ECHA PC - 6th priority list (final).pdf	Please see references to responses in section I
2529 2014/11/10	Individual, Germany	2529_ECHA attachments.zip *Confidential attachment removed*	Please see references to responses in section I
2532 2014/11/12	Castolin Iberica, Company, Spain	2532_ECHA-Technical information.docx	Please see references to responses in section I
2536	MTU Aero Engines,	Das vorgeschlagene Umsetzungsdatum ist nicht realisierbar.	**B.1.2. Aspects not considered**

2014/11/13	Company, Germany	Eine Fristverlängerung um 36 Monate wäre in jedem Fall erforderlich.	**by ECHA when proposing latest application dates/sunset dates:** 2. Lack of alternatives, socio-economic aspects
2540 2014/11/14	Company, Germany	-	
2541 2014/11/14	Almatis GmbH, Company, Germany	Due to lack of alternatives, and the outlook that any feasible alternative could/would be evaluated mid- or longterm, any date for application or sunset date is inappropriate.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives
2546 2014/11/17	Messer Eutectic Castolin Sp. z o.o., Company, Poland	2546_ECHA-Technical information.docx	Please see references to responses in section I
2550 2014/11/18	Company, Ireland	The maximium transitional arrangements should be implemented for this substance to allow industry to seek alternatives.	**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 2. Lack of alternatives, socio-economic aspects
2551 2014/11/18	European Welding Association (EWA), Industry or trade association, France	2551_Doc EWA-TCC-263-14-final; EWA Position re Borates.docx	Please see references to responses in section I
2554 2014/11/19	BROQUETAS,S.L., Company, Spain	2554_ECHA.pdf	Please see references to responses in section I
2556 2014/11/19	UNITI Bundesverband mittelständischer Mineralölunternehmen e.V., Industry or trade association, Germany	2556_UNITI comments_public consultation on Boric acid_19 Nov 2014.zip	Please see references to responses in section I
2557 2014/11/19	DALIC SAS, Company,	unthinkable 2557_Flyer Ni D+ GB.pdf	Please see references to responses in section I

	France		
2560 2014/11/20	Company, United Kingdom	We use boric acid as an essential ingredient in products used in SRD and forensic science. Taking in to account the complexity of the supply chain and that there are currently no known technically equivalent substitutes for our use application of boric acid, we request the period for application for authorization be extended to 48 months (instead of the proposed 24 months) after date of inclusion in Annex XIV, allowing time for investigating the possibility of the scientific development and validation of a viable alternative, in case our use of boric acid would not be exempt from the authorization requirement.	**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 **C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation**
2561 2014/11/20	RWE Power AG, Company, Germany	Dates proposed until now for substances to be added to Annex XIV are leading to very short implementation delay, compared to design, building and operation cycles for certain industrial activities as well as related investments. Concerning boric acid, some uses (as for nuclear power plant) are relying on long term investments (60 years for an EPR, without time frames for dismantling activities and spent fuel treatment taken into account) which is not accordance with the order of magnitude of transitory periods (years). Up to now, article 58.1.c.i, indicating that these dates «should take into account, where appropriate, the production cycle specified for that use» has not been taken into account. 2561_ECHA_consultation.pdf	**B.2.4: Investment cycles should be taken into account**
2562 2014/11/20	Company, Sweden	We use boric acid as an essential micronutrient in the manufacture of fine chemicals, which are used for purification of Active Pharmaceutical Ingredients (API) by Life Sciences, Pharmaceutical and Biopharmaceutical industries. The supply chain has high complexity and is highly regulated. The biopharmaceutical industry is heavily dependent on supply sustainability from us. For patient safety reasons the product quality and performance/function require high levels of consistency to meet our highly regulated biopharmaceutical customer requirements.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives **B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 1. Extensive time needed in the

		Considering the complexity of the supply chain and that there are currently no known technically equivalent substitutes for our use of boric acid, we request the period for application for authorization to be extended to 48 months after date of inclusion in Annex XIV, should our industrial use of boric acid as an essential micronutrient not be exempted from the authorization requirements.	supply chain to getting organised for preparing application (e.g. due to high number of users)
2567 2014/11/21	AGLUKON Spezialdünger GmbH & Co. KG, Company, Germany	If an authorisation would be necessary, we, AGLUKON Spezialdünger GmbH & Co. KG, would try to work together with our raw material suppliers and would ask them to consider our uses in their application. If our uses could not be taken into account by our suppliers, our only opportunity getting an authorisation would be to prepare an application for authorisation by ourselves. Normally small to medium sized companies like us do not have the personal and economic capacity to handle regulatory requirements of this extent, so we would require a greater time to organise ourselves. Furthermore regarding the high number of uses and the complexity of the supply chain, the latest "Latest Application Date" slot should be assigned, if boric acid would be included in Annex XIV, in order to give especially small and medium sized companies the possibility to react ether technically and/or economically.	**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) **C.2. Responses to exemption requests referring to other legislation**
2573 2014/11/21	Company, Finland	If the unfortunate authorization would occur in case of boric acid, the transitional arrangements would need several years or decates to replace the present situation. Or in practice, the production of diagnostic kits would probably cease in Europe.	**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 2. Lack of alternatives, socio-economic aspects
2578 2014/11/21	I&P Europe - Imaging and Printing Association e.V., Industry or trade association, Germany	We have no comment to make on this point.	
2579 2014/11/21	Company, Slovakia	2579_ECHA-Technical information.docx	Please see references to responses in section I
2580	Company,		Please see references to responses

2014/11/21	Italy	2580_ECHA_Technical_information.docx	in section I
2582 2014/11/21	Protim Solignum Ltd., Company, United Kingdom	No dates should be required for the use of Boric as a fire retardant in wood because this use should be exempt from authorisation. *Confidential attachment removed*	**C.1.1. General principles for exemptions under Art. 58(2)**
2585 2014/11/22	Castolin Eutectic, Company, United Kingdom	 2585_ECHA-Socio-economical arguments.docx *Confidential attachment removed*	Please see references to responses in section I
2587 2014/11/24	Company, France	Dates proposed until now when substances are added to Annex XIV are leading to very short implementation delay, compared to design, build and operation cycles for certain industrial activities as well as related investments. Concerning borate, some uses (as for nuclear power plant) are relying on long term investments (60 years for an EPR without taken into account used for dismantling activities and spent fuel treatment) which is not accordance with the order of magnitude of transitory periods in years. Up to no, article 58.1.c.i, indicating that these dates « should take into account, where appropriate, the production cycle specified for that use » has not been taken into account. A RMO study is absolutely necessary before adding these groups of substance which use is concerning so much industrial sectors, taken into account the unsuccessful substitution program. 2587_CP Echa-boric acid- nov2014.pdf	Please see references to responses in section I **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**
2591 2014/11/24	Company, United Kingdom	No comment. 	
2593 2014/11/24	Company, Germany	 2593_Comment_K+S_KALI_GmbH_boron2.doc *Confidential attachment removed*	Please see references to responses in section I
2608 2014/11/24	Verband Schmierstoff-Industrie e.V., Industry or trade association, Germany	 2608_EBA comments - 6th priority list _14 Oct 2014.pdf	**A.2.12: ECHA should not proceed with the 6th recommendation, when the 5th is still open**
2615 2014/11/24	Company, Belgium	no alternatives for bioessential elments are available , this is intrinsic to bio essential element . transitional arrangements cannot be a solution 	**C.2. Responses to exemption requests referring to other legislation**

		Confidential attachment removed	
2616 2014/11/25	Repligen Sweden AB, Company, Sweden	No comment	
2618 2014/11/25	SYMOP, Industry or trade association, France	To be discussed with manufacturers of consumables for welding and brazing. Research into suitable alternatives for use in fluxing agents, drawing soaps, and as constituents of welding and brazing consumables is ongoing. 2618_POsirtion SYMOP borates vd.pdf	**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 2. Lack of alternatives, socio-economic aspects
2619 2014/11/25	DSM, Company, Netherlands	 2619_DSM_Boric_acid_Nov2014.pdf	Please see references to responses in section I
2633 2014/11/25	Frit Consortium, Industry or trade association, Spain	The Frit Consortium would like to express its support to the comments provided by the European Borates Association (EBA) to the Public Consultation for substance Boric acid (EC 233-139-2, 234-343-4) 2633_Frit Consortium - borates intermediate in frits.pdf	Please see response to comment #2524 (EBA comment)
2656 2014/11/25	Aerospace Industries Association, International organisation, United States	AIA recommends that the inclusion of boric acid onto the ECHA Authorization List be deferred at this time. The use of boric acid has enabled the use of more environmentally preferred, safe, alternatives. Since a replacement material is currently not available, prematurely adding the chemical to the Authorization List would run the risk of unnecessarily damaging aerospace companies financially and has the potential to compromise the safety of our aerospace systems. 2656_AIA Comments to Boric Acid.pdf	**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 2. Lack of alternatives, socio-economic aspects
2658 2014/11/25	Daido Industrial Bearings, Company, United Kingdom	no comment	
2664 2014/11/26	Individual, Poland	Although we do not support the inclusion of boric acids 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.	**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

2673 2014/11/26	UNIFA, Industry or trade association, France	2673_Commentaires UNIFA_Novembre 2014_EN_VF.pdf	Please see references to responses in section I
2685 2014/11/26	EnBW AG, Company, Germany	Dates proposed until now when substances are added to Annex XIV are leading to a very short implementation time, compared to design, build and operation cycles for certain industrial activities as well as related investments. Concerning boric acid, some uses (as for nuclear power plants) are relying on long term investments (60 years for an EPR without taking into account time frames for dismantling activities and spent fuel treatment). Therefore, the proposed dates do not conform to article 58.1.c.i, indicating that these dates « should take into account, where appropriate, the production cycle specified for that use ». 2685_ECHA Comments Attachement EnBW.docx	**B.2.4: Investment cycles should be taken into account**
2693 2014/11/27	Company, Finland	Transitional arrangements would require a long time at least 20 years to replace boric acid if at all possible.	**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 2. Lack of alternatives, socio-economic aspects
2699 2014/11/27	European Special Glass Association and European Domestic Glass Association, Industry or trade association, Belgium	2699_FINAL EDG-ESGA - Use of borates as intermediates in the manufacture of borosilicate glass.docx	Please see references to responses in section I
2707 2014/11/27	Vesuvius Group, Company, United Kingdom	*Confidential attachment removed*	Please see references to responses in section I
2714 2014/11/27	Company, Germany	Dates proposed until now when substances are added to Annex XIV are leading to a very short implementation time, compared to design, build and operation cycles for certain industrial activities as well as related investments. Concerning boric acid, some uses (as for nuclear power plants) are relying on long term investments (60 years for an EPR without taking into account time frames for dismantling activities and spent fuel treatment).	**B.2.4: Investment cycles should be taken into account**

		Therefore, the proposed dates do not conform with article 58.1.c.i, indicating that these dates « should take into account, where appropriate, the production cycle specified for that use ». *Confidential attachment removed*	
2716 2014/11/27	Teollisuuden Voima Oyj, Company, Finland	2716_BORON PRODUCTS_ECHA_TVO.pdf	Please see references to responses in section I
2732 2014/11/27	Company, Germany	2732_COMPO.pdf	Please see references to responses in section I
2739 2014/11/27	Company, United States	2739_Boric Acid Letter.pdf	Please see references to responses in section I
2740 2014/11/27	EDF SA, Industry or trade association, France	Nuclear industry requires investments which can be granted only with regulatory guarantees for a period of nominal life of power plants and even farther by considering decommissioning. The principle of a limited duration authorization, even renewable, is not bearable for such investments. A RMO study is absolutely necessary before adding this group of substances whose uses affect so many industrial sectors, taken into account the unsuccessful substitution attempts. 2740_PC-ECHA-boric_acid-comment-nov 2014-VF-EDF.pdf	**A.2.11: Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV** **B.1.3. Review periods**
2742 2014/11/27	RWE Power AG, Company, Germany	Dates proposed until now when substances are added to Annex XIV are leading to a very short implementation time, compared to design, build and operation cycles for certain industrial activities as well as related investments. Concerning boric acid, some uses (as for nuclear power plants) are relying on long term investments (60 years for an EPR without taking into account time frames for dismantling activities and spent fuel treatment). Therefore, the proposed dates do not conform with article 58.1.c.i, indicating that these dates « should take into account, where appropriate, the production cycle specified for that use ». 2742_2-2_ECHA_consultation_boric acid paper_final.docx	**B.2.4: Investment cycles should be taken into account**
2744 2014/11/27	Alkanolamine Borates Consortium,	No comments 2744_Letter re Borates Authorisation final.docx	Please see references to responses in section I

	Industry or trade association, United Kingdom		
2752 2014/11/28	BOCI, CFHM, UFBJOP et Comité Francéclat, Industry or trade association, France	2752_Sample of testimonials.pdf	Please see references to responses in section I
2759 2014/11/28	CEZ Group, Company, Czech Republic	*Confidential attachment removed*	Please see references to responses in section I
2766 2014/11/28	Amfep, Industry or trade association, Belgium	Boric acid is used as an essential trace element in fermentation media . Scientific studies have shown that the substance cannot be substituted with any other substances due to the biological essentiality of boric acid. 2766_281114 Letter of concern boric acid-final.docx	**B.1.3. Review periods**
2770 2014/11/28	essenscia/bio.be, Industry or trade association, Belgium	Boric acid is used as an essential trace element in fermentation media . Scientific studies have shown that the substance cannot be substituted with any other substances due to the biological essentiality of boric acid 2770_letterofconcernboricacidbiobe.doc	**B.1.3. Review periods**
2773 2014/11/28	WKÖ, Other contributor, Austria	See PDF attached. 2773_su_85_WKÖ Borate.pdf	Please see references to responses in section I
2778 2014/11/28	Europacable, Industry or trade association, United Kingdom	Boric acid in flame retarder of PVC can currently only be replaced by antimony trioxide, which will not be an preferable solution for human health and environmental reasons.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives
2785 2014/11/28	Aurubis AG, Company, Germany	*Confidential attachment removed*	Please see references to responses in section I
2788 2014/11/28	Federchimica, Industry or trade association, Italy	Considering the indispensability of the substance, the maximum applicable timeframes for the preparation of an authorization dossier should be given. 2788_Annex I.pdf *Confidential attachment removed*	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives
2792 2014/11/28	Industry or trade association, Belgium	Please see attachement 2792_FEFCO comments on uses that should be expemt from the 6th ECHA priority list for authorization_to ECHA.pdf	Please see references to responses in section I
2793	Evonik Industries AG,	The classification of boric acid has been questioned by Poland. Please make	**B.2.7: Disputing harmonised**

2014/11/28	Company, Germany	sure that the Annex XIV process is not continued before this discussion with Poland has been finalised. 	**classification and asking for a hold to the recommendation process**
2794 2014/11/28	Chemlink Specialities Ltd, Company, United Kingdom	 *Confidential attachment removed*	Please see references to responses in section I
2796 2014/11/28	Company, Netherlands	Boric acid is used as an essential trace element in fermentation media . Scientific studies have shown that the substance cannot be substituted with any other substances due to the biological essentiality of boric acid. 2796_AMFEP 14_56 Letter of concern ECHA recommendation on Boric acid.pdf	**C.2. Responses to exemption requests referring to other legislation**
2797 2014/11/28	ABB Kabeldon, Company, Sweden	 2797_Electrical contacts, Review and recent developments.pdf	Please see references to responses in section I
2798 2014/11/28	BP Europa SE, Company, Germany	No specific comments on this aspect 2798_Boric acid additional information.zip	Please see references to responses in section I
2800 2014/11/28	ACEA, Industry or trade association, Belgium	In Chromium plating, Boric Acid has a role in the process of CrIII technology, instead of CrVI technology, whose sunset date is scheduled for September 2017. We are extremely concerned about a substitution of a current process with Annex XIV substances, to a new process, which has taken several years development for the automotive sector, if substances in this new technique will then be subject to further substitution pressure in the future. 2800_20141128_Proposal for annex XIV recommendation on Borates Final.pdf	**C.3.4: Claim that uses which can replace Cr(VI) should be exempt from authorisation**
2802 2014/11/28	FRANCISCO. R. ARTAL, S.L., Company, Spain	 2802_BORON.docx	Please see references to responses in section I
2806 2014/11/28	Slovenske elektrarne, a.s., Company, Slovakia	- 	
2816 2014/11/28	Company, Netherlands	no comments *Confidential attachment removed*	Please see references to responses in section I
2829	Norway,	In general, we are in favour that a regulation should enter into force as soon as	**B.1.1. General principles for**

2014/11/28	Member State	possible. Hence we are in favour of the shortest LAD slot.	**setting latest application dates / sunset dates:** 3. ECHA's proposal for latest application dates
2835 2014/11/28	Intermag Sp. z o.o., Company, Poland	2835_boron consulatation.pdf	Please see references to responses in section I
2838 2014/11/28	Vattenfall AB; registration no.: 12955024114-93, Company, Sweden	Dates proposed until now when substances are added to Annex XIV are leading to very short implementation time, compared to design, build and operation cycles for certain industrial activities as well as related investments. Concerning boric acid, some uses (as for nuclear power plant) are relying on long term investments (60 years for an EPR without taken into account time frames for dismantling activities and spent fuel treatment). Up to now, article 58.1.c.i, indicating that these dates « should take into account, where appropriate, the production cycle specified for that use » has not been taken into account.	**B.2.4: Investment cycles should be taken into account**
2843 2014/11/28	Freiberger Compound Materials GmbH, Company, Germany	2843_Freiberger - comment for boric acid to the ECHA consultation on the 6th priority list.pdf	Please see references to responses in section I
2848 2014/11/28	Company, United Kingdom	*Confidential attachment removed*	Please see references to responses in section I
2850 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	**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 application dates / sunset dates:**

		possible to set review periods for certain uses, if appropriate, in Annex XIV. EDMA notes 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.	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**
2864 2014/11/28	Company, Spain	We desagree about continuing with the proposed dates.	Thank you for your opinion
2870	European Borates		Please see references to responses

2014/11/28	Association, Industry or trade association, Belgium	2870_EBA comments - ECHA PC - 6th priority list - glass-frits.pdf	in section I
2875 2014/11/28	Company, France	2875_EBA comments - 6th priority list (final).pdf	Please see references to responses in section I
2878 2014/11/28	Company, France	NA 2878_Additional non Condidential information.doc	Please see references to responses in section I
2879 2014/11/28	Company, Sweden	There are currently no viable alternative to the use of boric acid for the neutron capture in the shielding required for radiation protection in the application of a cyclotron. Without exemptions for our use or if an authorisation is not granted in the future, then there would be a serious disruption both to scientific research & development and the manufacture of medical products within the EEA using nuclear technology for medical purposes. In case ECHA does not exempt this use from the authorization requirement, taking into account the scientific and technical requirements to develop, validate and qualify a change in the technology to provide radiation protection for this cyclotron application, we request ECHA set a review period not less than 40 years for this cyclotron application.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives **B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 2. Lack of alternatives, socio-economic aspects
2882 2014/11/28	EDF Energy, Company, United Kingdom	Please see the attachmed document for EDF Energy's full set of comments on the recommendation to include the substance in Annex XIV. 2882_28112014 ECHA Boric Acid Position FINAL.pdf	Please see references to responses in section I
2889 2014/11/29	ECIA European Cellulose Insulation Association, Industry or trade association, Belgium	If boric acid would fall under authorisation, which is absolutely not recommended, the proposed timeframe for an application date and Sunset date is far too short. During the last decade, a lot of research work has been performed in order to find alternatives to boric acid as a fire retardant. The outcome of these studies is that no other materials can provide similar reaction to fire and smoulder resistance to that of boric acid. Furthermore, all other materials tested are significantly more expensive than boric acid. All of these alternatives are high in price and some have unpredictable adverse effects such as off gassing, fast aging, corrosion and abrasion. With all this background	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives

		knowledge gathered in various research done all over the globe, no suitable alternative for boric acid in cellulose insulation have been found. Some substances were found which have a fire protection property, but none of them has a smouldering protection property as boric acid does. All of these alternatives had unpredictable side effects like off gazing, fast aging, corrosion, abrasion. With all this background knowledge gathered in various research done all over the globe, no suitable alternative for boric acid in cellulose insulation could be found, it is not realistic to find an alternative within the next years.	
2905 2014/11/30	ZVO/ VECCO, Industry or trade association, Germany	Please read: IV. Attachment (additional non-confidential information) to comments on ECHA's draft recommendation 2905_2014-11-30 Comment on Boric Acid Joint Application Surface technology.pdf	Please see references to responses in section I
2923 2014/11/30	Company, Belgium	*Confidential attachment removed*	Please see references to responses in section I
2930 2014/11/30	Association of European Airlines, Industry or trade association, Belgium	We clearly ask for the refusal of the inclusion of boric acid and boron compounds to the authorization list, recognizing 5th recommendation is still open and a huge burden on the whole industry which is struggling by the on-going authorization procedures. Due to the industry's characteristics the search for alternatives requires at least more than 10 years for every substance and use combination. Therefore - in line with the ASD and AIA position - including boron compounds in the authorization list seems to be not proportional. Postpone 6th recommendation, because the 5th recommendation is not even final yet.	**A.2.12: ECHA should not proceed with the 6th recommendation, when the 5th is still open** **B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 2. Lack of alternatives, socio-economic aspects **B.2.1: Concerns and uncertainties with respect to the authorisation process, in particular for SMEs**
2948 2014/12/01	European Federation of Pharmaceutical Industries and	2948_EFPIA comments_Boric Acid_Inclusion into ANNEX XIV_REACH.pdf	Please see references to responses in section I

	Associations, Industry or trade association, Belgium		
2950 2014/12/01	ASD, Industry or trade association, Belgium	Unworkable in our industry- see section IV 2950_ASD answer to ECHA consultation_General Conclusions for all Boron and lead compounds_281114.pdf	Please see references to responses in section I
2956 2014/12/01	ASD, Industry or trade association, Belgium	Not workable for our industry- see section IV 2956_ASD answer to ECHA consultation on BORICACID_281114.pdf	Please see references to responses in section I
2963 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 section I
2964 2014/12/01	CEA, Company, France	2964_PC-ECHA-boric_acid-comment_CEA_nov2014.pdf	Please see references to responses in section I
2973 2014/12/01	GIFAS, Industry or trade association, France	2973_20010_ECHA_Annex XIV_Boron_substances.pdf	Please see references to responses in section I
2990 2014/12/01	Company, Netherlands	We clearly ask for the refusal of the inclusion of boric acid and boron compounds to the authorization list, recognizing 5th recommendation is still open and a huge burden on the whole industry which is struggling by the on-going authorization procedures. Due to the industry's characteristics the search for alternatives requires at least more than 10 years for every substance and use combination. Therefore - in line with the ASD and AIA position - including boron compounds in the authorization list seems to be not proportional. Postpone 6th recommendation, because the 5th recommendation is not even final yet.	**A.2.12: ECHA should not proceed with the 6th recommendation, when the 5th is still open** **B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 2. Lack of alternatives, socio-economic aspects **B.2.1: Concerns and uncertainties with respect to**

			the authorisation process, in particular for SMEs
2991 2014/12/01	EURELECTRIC, Industry or trade association, Belgium	2991_EURELECTRIC-statement boric acid-final.pdf	Please see references to responses in section I
3001 2014/12/01	FORATOM, Industry or trade association, Belgium	Dates proposed until now when substances are added to Annex XIV are leading to very short implementation delay, compared to design, build and operation cycles for certain industrial activities as well as related investments. Concerning borate, some uses (as for nuclear power plant) are relying on long term investments (60 years for an EPR without taken into account used for dismantling activities and spent fuel treatment) which is not accordance with the order of magnitude of transitory periods in years. Nuclear industry requires investments which can be granted only with regulatory guarantees for a period of nominal life of power plants and even farther by considering decommissioning. The principle of a limited duration authorization, even renewable, is not bearable for such investments. A RMO study is absolutely necessary before adding this group of substances whose uses affect so many industrial sectors, taken into account the unsuccessful substitution attempts. 3001_FORATOM-boric acid-ECHA-VF.docx	**A.2.11: Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV** **B.2.4: Investment cycles should be taken into account**
3002 2014/12/01	European Semiconductor Industry Association, Industry or trade association, Belgium	ESIA has no comments on transitional arrangements, application dates or sunset dates. ESIA would like to comment on the length of the review period for authorizations granted. Should use of boric acid in metal plating in the semiconductor industry require authorisation, a review cycle of 12 years would be requested in order for the industry to be able to attempt a phase-out of the use of the substance. According to the ECHA paper entitled "Setting the Review Period when RAC and SEAC give Opinions on an Application for Authorisation" Helsinki, 13 September 2013, (SEAC/20/2013/03), the criteria and considerations listed below in italics may lead to a recommendation of a long review period: • The applicant's investment cycle is demonstrably very long (i.e. the production is capital intensive) making it technically and economically meaningful to substitute only when a major investment or refurbishment takes	**B.2.5: Claim that the use fulfils the RAC/SEAC conditions for longer review period**

		place. Semiconductor R&D timelines and investment cycles are extremely long. The semiconductor production process is highly capital intensive with high volumes of semiconductor devices being produced. Critical changes to production are in many instances impossible to perform in a shorter period of time due to both the technical and economic challenges faced. • The costs of using the alternatives are very high and very unlikely to change in the next decade as technical progress (as demonstrated in the application) is unlikely to bring any change. For example, this could be the case where a substance is used in very low tonnages for an essential use and the costs for developing an alternative are not justified by the commercial value. Boric acid is a critical material in metal plating in semiconductor manufacturing. Comparatively with other sectors it is used in a low amount in the semiconductor industry however it is essential to the metal plating manufacturing step and may also be used due to its unique properties in future technologies in the semiconductor industry. The risk of the substance is very well managed in semiconductor manufacturing and the socio economic benefits of having this production in Europe are unquestionable. There are no identified substitutes that could replace boric acid's function in the production process and the costs of developing a potential alternative solely for production in Europe (as boric acid is not banned in other regions of production) are unlikely to be justified by the commercial value for the industry suppliers. More likely, in the case of wafer bump, since it is the last module in semiconductor manufacturing sequence, companies would find it more financially viable to re-locate the operation to the start of the subsequent assembly process, which typically takes place out of Europe. • The applicant can demonstrate that research and development efforts already made, or just started, did not lead to the development of an alternative that could be available within the normal review period. The semiconductor industry has a relatively long and cost intensive planning for a semiconductor technology development cycle. Many of the substance/materials are critical to the technology development process. Replacing a substantive material or compound does NOT entail a drop in	

		replacement. This semiconductor development cycle of 10 years (see graph in the document attached) is typical where an alternative material already exists and does not need to be invented. Where there are no alternatives, no substitution material exists and this timeline cycle below is not the case. The nature of material substitution as it applies within the semiconductor industry is not at all well understood outside of the industry. Material substitution requires first an invention in many cases and much research and development activity from the material and equipment suppliers, a significant lead-time for stringent material qualification, and then subsequent integration and verification of technical performance into individual company technologies. Only after these aspects have been successful, can the act of final replacement be attempted in volume manufacturing. The time horizon for sunset use of a substance on the Authorization list is well below the semiconductor development cycle • The remaining risks are low and the socio-economic benefits are high, and there is clear evidence that this situation is not likely to change in the next decade. As stated in response to "General comments on the recommendation to include the substance in Annex XIV", the volume of boric acid used in semiconductor manufacturing is small. Stringent measures are also in place in order to ensure that worker exposure risk in semiconductor manufacturing cleanrooms is minimized. Overall it can be stated that the remaining risk of boric acid use in metal plating in semiconductor manufacturing is low. At the same time the socio-economic benefits are high. The semiconductor industry is at the heart of technological progress and innovation. The importance of the sector is recognized by the EU Commission. The Electronic Leaders Group (ELG) set up by the EU Commission in 2013, has put forward a target of doubling the economic value of semiconductors production in Europe by 2020-2025. In Europe, the semiconductor ecosystem itself employs approximately 200,000 people directly. More than 1,000,000 induced jobs are found through the integration of components into systems, applications and services across Europe, Overall, micro- and nano-electronic components and systems enable the generation of at least 10% of GDP in Europe and the world. 3002_ESIA Input to the ECHA Public Consultation_BoricAcid_PDF Dec 1	

		2014.pdf	
3007 2014/12/01	Bundesverband Keramische Industrie e.V., Industry or trade association, Germany	The Frits Consortium and Cerame-Unie had submitted comments in response to this section and Bundesverband Keramische Industrie e.V. fully supports this.	Please see response to comment #2633 (Frits consortium) Please see response to comment #3011 (Cerame-Unie)
3022 2014/12/01	LightingEurope, Industry or trade association, Belgium	3022_LE_consultation_Boric Acid_20141201_final_final.pdf	Please see response to comment #3022 in Section I

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

Number / Date	Submitted by (name, submitter type, country)	Comment	Reference to responses
2502 2014/09/05	Ti Automotive Belgium, Company, Belgium	We use boric acid in our plating bath to stabilize the pH. Actually, we have no idea to use a other substance. Boric acid is the classic additive.	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.
2505 2014/09/19	Company, United Kingdom	Based on the information in the document 'Generic Exemptions from the Authorisation Requirement', can it be assumed for boric acid, borates, diboron trioxide, etc. that where significant work in reformulating products so that the boric level is below 5.5%w/w, (i.e. below the LCL) that these products are exempt from authorisation? Additionally, the formulations in which these borates are used are analytical reagents, specifically for use in water testing, are they exempt under Art 56(3) of REACH?	**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**

			C.3.1: Claim that solutions below the specific concentration limit should be exempt from authorisation
2506 2014/09/30	Surface Engineering Association, Industry or trade association, United Kingdom	Use of boric acid as a ph regulator in surface engineering applications should be exempt from authorisation as there are no releases of boric acid to the environment nor any consumer exposure. Authorisation is not the most proportionate or suitable risk management option in this case.Typically, boric acid concentrations in nickel electroplating solutions will be around 50 gramme/litre and there are no known alternatives for this particular use.	**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 **C.1.3. Aspects not justifying an exemption from authorisation** **C.3.5: Claim that products not containing the substance in the final product should be exempt from authorisation**
2508 2014/10/02	European Borates Association (EBA), Industry or trade association, Belgium	OVERVIEW EBA challenges the score assigned by ECHA to boric acid as regards to the volumes under the scope of authorisation. ARGUMENTS Boron is one of seven essential micronutrients required by plants for normal and productive growth and accordingly is incorporated in the EU Fertiliser Regulation. The use of boron in fertilizers accounts for over 8% of the diboron trioxide, boric acid and disodium tetraborates entering the EU market. Acknowledging the essentiality of boron for agriculture, the authorisation would have to be granted for agriculture and would not achieve the aim of authorisation. It would become a "tax system".	**A.1.2. Prioritisation: Volume** **A.1.3. Prioritisation: Wide-dispersiveness of uses** **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.2.5: Disputing the volume score, claiming various uses**

		As reported in the registration dossiers, the total volume placed on the market of boric acid in 2012 by EBA member companies was 91,213 metric tonnes, which represented 95% of the volume placed on the market in Europe. The remaining 5% was placed on the market by companies that are not members of EBA. Nearly 70% (~63,000metric tonnes) of the volume placed on the market are in uses that fall outside the scope of authorisation, as an intermediate, in articles, covered by other legislation or in mixtures below the concentration limit. It is our understanding that the essential use of boric acid as a micronutrient shall not fall under the scope of authorisation. Consequently, another 22,629 metric tonnes (25%) will fall outside the scope of authorisation. Therefore, out of a total volume of 91,213 metric tonnes, the remaining volume assessed to be in scope of authorisation is 5.643 metric tonnes (6%). The volume score for boric acid should thus be reduced from 15 (very high volume 10,000 – 100,000 T) to 12 (high volume 1,000 – 10,000 T). The total sore for boric acid would then be 25 instead of 28. CONCLUSION The score assigned by ECHA to boric acid needs to be revised according to the information provided here-above and the prioritisation needs to be re-evaluated in light of the new score.	**of the substance as being outside the scope of authorisation, e.g. the essential use of boric acid as micronutrient** **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** **C.1.3. Aspects not justifying an exemption from authorisation** **C.2. Responses to exemption requests referring to other legislation**
2511 2014/10/15	European Catalyst Manufacturers Association (ECMA), Industry or trade association, Belgium	2511_20141015- Boric Acid ECHA consultation final (ECMA) Supply Chain .docx	Please see references to responses in section I
2515 2014/10/27	Kavalierglass, a.s., Company, Czech Republic	As mentioned above.	
2518 2014/10/29	Company, France	Boric acid was included in the list of candidate substances for REACH Authorisation on the 18th of June 2010 according to article 57(c) of REACH: boric acid is classified in Annex VI, of Regulation No 1272/2008 as Toxic for Reproduction, Category 1B, H360-FD (May damage fertility. May damage the	**A.2.19: Alternative substances are usually less well known and might have a higher risk**

		unborn child). On the 1st of September 2014, boric acid was included in an ECHA draft recommendation for inclusion in REACH Authorisation List without any excepted use or category of use. 1. In Regulation N°1272/2008, boric acid is classified as toxic for reproduction, Category 1B, H360-FD but only for concentrations above 5.5%. Therefore, concentrations of boric acid under 5.5% should be considered as excepted use for REACH Authorisation since for these concentrations boric acid is not classified anymore as toxic for reproduction and consequently does not meet Article 57(c) of REACH. 2. Boric acid classification as toxic for reproduction, Category 1B, is based on adverse effects observed in testicular toxicity of animals fed with very high doses of boron: a lowest adverse effect level of 58.5 mg B/kg bw/day can be derived from a 2-year studies in rats1. These effects cannot be extrapolated to humans: on the contrary, epidemiological studies, on highly exposed boron workers, show the absence of adverse effects on men fertility or on sperm quality2,3,4. Robbins and all2 compared boron workers group exposed to an average of 42 mg B/day to two other workers groups (192 workers in total) over three months to study the correlation between boron exposure (air, food, fluid) and semen parameters. Sperm characteristics do not differ from the three different groups. Scialli and all3 reviewed data from 75 Chinese boron workers in North China exposed to an average of 31.3 mg B/ day, 16 of them had a mean boron intake of 125 mg B/ day due to water contamination. No male reproductive effects (semen analysis, reproductive outcome) could be significantly linked with boron exposure even for highly exposed workers, compared to controls. Duydu and all4 investigated the reproductive effects of boron exposure (air, food, water) in 102 Turkish workers of a boric acid production plant exposed to an average of 14.45 mg B/ day compared to control groups. No links between boron exposures and reproductive effects (sperm cells analysis) were observed. Robbins, Scialli and Duydu's studies show that reproductive effects observed on animals for high dose of boron exposure can not be extrapolated to humans. Indeed, extensive evaluations of sperm parameters have demonstrated no effects on male fertility for cohorts of highly boron-exposed workers. Even though the average boron exposure of Robbins, Scialli and Duydu's studies is under the no-adverse-effect level for reproductive effects observed in	**A.2.22: Disputing the harmonised classification** **C.1.3. Aspects not justifying an exemption from authorisation** **C.2. Responses to exemption requests referring to other legislation** **C.3.1: Claim that solutions below the specific concentration limit should be exempt from authorisation**

		male rats (17.5 mg B/kg bw/day), they represents extreme boron exposure conditions; it is very unlikely that other workplace exposures will be as high. Consequently, doubts are seriously raised about the relevance of toxic reproductive human effects to boron exposure. According to criteria for classification of reproductive toxicity described in Regulation No 1272/2008, this implies that boric acid classification in Category 2 for reproductive toxicity is more appropriate. Therefore, if boric acid re-classification in Category 2 for reproductive toxicity can not be discuss at this stage of ECHA public consultation, at least, concentrations of boric acid under 5.5% should be considered as excepted use for REACH Authorisation of boric acid since no clear evidence of human reproductive toxicity linked with boron exposure can be made at all. 3. Boric acid is not metabolized and boron is excreted quickly with mean elimination half-lives of 1h in the mouse5, 3h in the rat6 and 13h in humans7,8 (range 4 –28h). Boric acid is neither pBt nor vPvB. Consequently, at low concentrations, there is no risk of boron accumulation due to boric acid low potential for accumulation: concentrations of boric acid under 5.5% should all the more be considered as excepted use or category of use in REACH Authorization List. Including boric acid in REACH Authorization List without any excepted use or category of use would create an irrational fear on a substance for which there are serious doubts on its human reprotoxic effects. Substances alternatives are usually less known in terms of epidemiology especially accumulative properties and theses unknown effects could be worse than the hypothetic human reproductive toxicity of boric acid. References: 1. Weir RJ & Fisher RS, 1972, Toxicologic studies on borax and boric acid, Toxicology and Applied Pharcology 23: 351-364. 2. Robbins and all, 2010 3. Scialli AR, Bonde JP, Brüske-Holfed I, Dwight Culver B, Li Y, Sullivan FM, An overview of male reproductive studies of boron with an emphasis on studies of hightly exposed Chinese workers, Reproductive Toxicology 2010 (29) 10-24 2010 4. Duydu Y, Basaran N, Ustundag A, Aydin S, Undeger U, Ataman OY, Aydos K, Dûker Y, Ickstadt K, Waltrup BS, Golka K, Bolt HM (2011). Reproductive toxicity parameters and biological monitoring in occupationally and	

		environme,ntally boron-exposed persons in Bandirma, Turkey. Arch Toxicol. 2011 Jun; 85(6):589-600. PMID:21424392. 5. Farr LE & Konikowski T (1963). The renal clearance of sodium pentaborate in mice and men. Clin. Chem. 9(6):717-726. 6. Vaziri ND, Oveisi F, Culver DB, Pahl MV, Andersen ME, Strong PL & Murray J (2001) 7. Astier A, Baud F & Fourneir A, 1988, Toxicokinetics of boron after an acute accidental intoxication by boric acid, J. Pharm. Clin. 7: 57 - 62. 8. Litovitz TL, Klein-Schwartz W, Oderda GM & Schmitz BF, 1988, Clinical manifestations of toxicity in a series of 784 boric acid ingestions, Am. J. Emergency Medicine 6: 209 - 213.	
2524 2014/10/31	European Borates Association (EBA), Industry or trade association, Belgium	2524_EBA comments - ECHA PC - 6th priority list (final).pdf	Please see references to responses in section I
2529 2014/11/10	Individual, Germany	2529_ECHA attachments.zip *Confidential attachment removed*	**C.2. Responses to exemption requests referring to other legislation**
2532 2014/11/12	Castolin Iberica, Company, Spain	2532_ECHA-Technical information.docx	**C.2. Responses to exemption requests referring to other legislation**
2536 2014/11/13	MTU Aero Engines, Company, Germany	Die Anwendung im Luftfahrtbereich muß weiterhin möglich sein. Im speziellen für die Verfahren Vernickeln, Aufbringung von speziellen Verschleißschutzschichten und Einsatz von Kühlschmierstoff. Gründe: Im Luftfahrtbereich gilt: Höchstmöglicher Anspruch an das Thema Sicherheit und Langlebigkeit. Dieser Auftrag kann nur weiter erfüllt werden wenn die bestmöglichen Schichtsysteme auch weiterhin zur Verfügung stehen. Ein verantwortungsbewußter und sicherheitstechnisch optimaler Umgang mit Borsäure ist in der Bundesrepublik und unserem Unternehmen jederzeit	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks **C.1.1. General principles for exemptions under Art. 58(2)** **C.1.2. Generic exemptions**

		gewährleistet. Alle Vorgaben der Sicherheits und Überwachungsbehörden werden eingehalten.	**C.1.3. Aspects not justifying an exemption from authorisation**
2537 2014/11/14	Company, Belgium	use in adhesives (see comment above)	**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**
2540 2014/11/14	Company, Germany	-	
2541 2014/11/14	Almatis GmbH, Company, Germany	Uses in refractory castables as additive to control set and working time should be exempted. The use is in industrial scale, and not a "consumer product". Use of the product is controlled by legislation. Concentration of boric acid does not exceed 5.5%.	**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** **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**

2546 2014/11/17	Messer Eutectic Castolin Sp. z o.o., Company, Poland	2546_ECHA-Technical information.docx	**C.2. Responses to exemption requests referring to other legislation**
2548 2014/11/18	ANASTA/ANIMA, Industry or trade association, Italy	According to our knowledge, for soft soldering, brazing and braze welding no substances alternative to 'the listed borates' are available for formulating de oxidizing mixtures. Following is a list* of the most relevant industrial sectors where soft soldering, brazing and braze welding processes, and associated use of deoxidizing mixtures, are not technologically replaceable. *List of the most relevant industrial sectors ☐ Chilling, heating and air conditioning ☐ Gas networks and transportation ☐ Goggles ☐ Hard steel tools ☐ House appliances ☐ Cooking tools ☐ Electro mechanics (transformers, motors, …) ☐ Plumbing ☐ Machinery for cosmetic industry ☐ Drilling and offshore ☐ Solar panels ☐ Automotive ☐ Railway industry ☐ Valves Taps Fittings Industry	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives **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**
2550 2014/11/18	Company, Ireland	Its uses in medical products, medical devices and SRD is already exempt.	**C.1.2. Generic exemptions**
2551 2014/11/18	European Welding Association (EWA), Industry or trade association, France	- fluxes for soft soldering, brazing and braze welding; alternative substances are not acceptable in all uses for technical reasons - manufacture of covered electrodes and tubular cored wires for electric arc welding; alternative substances are not acceptable in all uses for technical reasons	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives

		2551_Doc EWA-TCC-263-14-final; EWA Position re Borates.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**
2554 2014/11/19	BROQUETAS,S.L., Company, Spain	2554_ECHA.pdf	**C.2. Responses to exemption requests referring to other legislation**
2555 2014/11/19	Company, France	Castolin France does not support the inclusion of borates in the draft ECHA 6th priorisation list for Annex XIV. Boric acid and borax are largely used in brazing technology. Brazing technology is a very common technique which allows joining of different alloys with each other that is not possible by means of standard welding processes. These alloys include steel, stainless steel, cast iron, copper, bronze, brass, nickel, tungsten carbides, silver… Brazing products are a combination of brazing alloys and flux, brazing paste, and brass alloy which are rods coated with a fluxing agent. Boric acid is the main component of brazing flux. It is used in hydrated form or sometimes in the calcined state, which then reacts as boric acid, but its melting point is slightly higher. Boric acid has the property to facilitate removal of oxides before brazing and removal of residues after brazing which are in the form of a vitrified layer. The melting point of boric acid is lower than borates but higher than fluorides. Thus, boric acid enters in the composition of most Castolin's brazing fluxes as main component. In combination with other compounds, boron compounds, fluorides and chlorides, we can adjust activity temperature of the flux, specifically for each application. After numerous bibliographic research studies and information taken from different providers, we have been unable to find a suitable substitute that offers similar technical advantages such as these compounds. Castolin has been working on new formulations since 2009, to try find a find alternatives for all our fluxes without boric acid (and borax). The results have been sucessfull however are in a lot of cases not acceptable by end user for	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 alternatives **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**

		several technical reasons. This being said, joints performed with these new formulations have not performed exactly the same with regards to mechanical properties and sealing properties. In some cases we are not able to deliver an acceptable product because of these different elements, but we have provided products with a quantity of boric acid under the limit of 5,5%. Even these new formulations might be sanctioned if boric acid is prohibited or coverered by authorization. Finally, all elements that we use in our formulations to substitute boric acid are borate and fluoride compounds which are for some of them newly classified as CMR, and whose future may be under the guide of going the same way. We haven't analyzed the fumes of these numerous formulations with substitutes during brazing and large ranges of heating temperatures depending of alloys used. Brazing process is used in manual or automatic by flame, induction, resistance, furnace… Brazing doesn't have derogations, It has numerous uses in industries such as: aerospace, military applications, power, electric, medical, measurement, cooling and refrigeration, automotive, lighting industry, art etc. As in brazing or brass welding boric acid or borax are in solid form on coated rods and users are protected from ingesting it. The REACH registration dossiers for diboron trioxide, boric acid and disodium tetra borates identified Risk Management Measures (RMM) where appropriate to ensure that health risks to workers are adequately controlled. RMM are communicated via SDS, which allows the site risk assessment to be carried out as required by Chemical Agents Directive (98/24/EC); these mechanisms assist ensuring worker safety. Additionally other downstream legislation specifically protects certain vulnerable workers from exposure to substances toxic to reproduction, such as pregnant workers (Dir. 92/85/EC) and young workers (Dir. 94/33/EC) We propose that the use of: brazing coated rods, brazing fluxes and paste, brass welding coated rods and fluxes manufaturing and using in brazing and brass welding to be exempted.	**C.2. Responses to exemption requests referring to other legislation**
2556 2014/11/19	UNITI Bundesverband mittelständischer Mineralölunternehmen	2556_UNITI comments_public consultation on Boric acid_19 Nov 2014.zip	**C.2. Responses to exemption requests referring to other legislation**

	e.V., Industry or trade association, Germany		
2557 2014/11/19	DALIC SAS, Company, France	uses with controlled conditions uses involving small quantities SME 2557_Flyer Ni D+ GB.pdf	**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)** **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) **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**
2560 2014/11/20	Company, United Kingdom	ECL detection kits are used for applications ranging from routine protein detection to multiplex analysis using fluorescence based detection systems. ECL-based detection systems allow researchers not only to avoid the necessity of handling hazardous radioisotopes, but to have a tool at their disposal that makes protein analysis faster, more sensitive and more flexible than ever before. ECL Direct Nucleic Acid Labeling and Detection Systems are based on the direct	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

		labeling of DNA or RNA probes with horseradish peroxidase (HRP) in a simple 20-min chemical reaction. The resulting probe can be used without purification. Detection is achieved by generation of light via the HRP-catalyzed breakdown of luminol. This is a two-step process involving boric acid at each stage. 2-D Quant Kit is designed for the accurate determination of protein concentration in samples prepared for electrophoresis techniques such as 2-D electrophoresis, SDS-PAGE, or IEF. The procedure works by quantitatively precipitating proteins while leaving interfering substances behind. The assay is based on the specific binding of copper ions to protein. Precipitated proteins are re-suspended in a copper-containing solution and unbound copper is measured with a colorimetric agent containing boric acid. The risk of intentional or non-intentional release of boric acid in our production facility is close to zero because the manufacturing processes are carried out in professional laboratories where high standards of operational controls and hygiene are maintained. Only licensed waste contractors are used to collect and incinerate the small quantities of waste chemicals resulting from the manufacturing processes. Our manufacturing laboratories fall under the jurisdiction of the Environment Agency – this is the UK Competent Authority for enforcement of Health, Safety and Environment legislation. We believe that the uses of boric acid highlighted above should be specifically exempted from any future provisions of REACH annex XIV. The total amount of boric acid that we use is approximately 40 kg/year. The handling of boric acid is done in laboratories with high hygiene standards and safety control measures to minimize exposure to personnel handling the substance. There are currently no known technically equivalent substitutes for these specific uses of boric acid. We request ECHA's consideration to exempt from the authorization requirement the use of boric acid as an ingredient in the formulation of products used in SRD, forensic science and in similar laboratory conditions. This exemption is necessary to avoid disruption in forensic science work and in SRD activities by	documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 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)** **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) **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**

		the Life Sciences, Biopharmaceutical and Pharmaceutical industries. There are currently no known technically equivalent substitutes for these specific uses of boric acid. Considering the difficulty to develop alternatives for these very specific uses of boric acid and the high complexity of the supply chain we request ECHA to set a review period no less than 12 years for these specific uses of boric acid, in case these uses of boric acid would not be exempted from the authorization requirement.	
2561 2014/11/20	RWE Power AG, Company, Germany	Using boric acid in nuclear electric power plants is vital to control nuclear fission reactions and to ensure nuclear safety. Boric acid is used in all pressurized water nuclear reactors around the world (and to a lesser extent in boiling water reactor nuclear power plants); no other chemical compound has the same characteristics required to replace boric acid for this use as expected in the authorization process. Boric acid is also used for its neutron absorbing capacities within the fuel cycle and during dismantling. Moreover boric acid is used in the glass for nuclear waste. The uses of boric acid that are applied in German nuclear power plants are mostly via closed systems. The only process intrinsic contact is during the fabrication of the solution by the plant´s chemistry department. The environment is not stressed by the processes on the site. The following EU legislation and subsequent German law is applied to secure the uses of boric acid in German nuclear power plants and therefore could be regarded as a candidate to fulfill the criteria for an exemption for nuclear industry mentioned in article 58 (2) of EU Regulation 1907/2006: "Uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled." Boric acid is classified as CMR 1B according to EU Regulation 790/2009 and therefore requires a safety data sheet according to Regulation 1907/2006 also defining it´s content. The safety data sheets are used for establishing operator´s guidelines for handling chemicals following a mandatory risk	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 alternatives **C.2. Responses to exemption requests referring to other legislation**

		assessment in hazardous working environments. This process is required by German labor protection law which is implementing the EU Council Directive 89/391/EEC. Consequently the uses of boric acid on nuclear sites are established following EU regulation. 2561_ECHA_consultation.pdf	
2562 2014/11/20	Company, Sweden	Our and our subcontractors' industrial use of boric acid is in gram quantities as an essential micronutrient required for the formulation of cell culture media used in biological fermentation processes. Cell culture media are used by the Life Sciences, Biopharmaceutical and Pharmaceutical industries to grow cells leading to the expression of biomolecules, such as recombinant proteins, monoclonal antibodies, vaccines and viruses. These biomolecules are essential Active Pharmaceutical Ingredients (API) used in the formulation of medicines. The biomolecules may also be used in research and development, and new drug discovery. Research areas include gene mutations, cell transformation and other advanced techniques. We also use biological fermentation processes to manufacture specific beaded chromatography media, which are used by the Life Sciences, Biopharmaceutical and Pharmaceutical industries in separation processes for purification of API. The purified APIs are then used in the formulation of medicines for human therapies and treatment which are not subject to Title VII of the REACh regulation. Any remaining boric acid from the biological fermentation process is treated in the industrial waste water treatment plant at the facility or handled as hazardous waste and treated by authorized waste vendor. The final chromatography media products we manufacture and place on the global market do not contain boric acid. The total amount of boric acid that we use is <1 kg/year. This estimated amount includes the use by subcontractors. The handling of boric acid in professional laboratories or industrial environments is carried out under strict industrial hygiene controls and safety measures to minimize exposure to personnel. There are currently no scientific and technically viable alternative available for these essential micronutrient uses of boric acid.	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 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** **B.1.1. General principles for setting latest application dates / sunset dates:**

		We request ECHA's consideration to exempt the use of boric acid as an essential micronutrient in the formulation of cell culture media used in biological fermentation processes from the authorization requirements. This exemption is necessary to avoid serious disruption in the manufacture of Active Pharmaceutical Ingredients and medicinal products by the Life Sciences, Biopharmaceutical and Pharmaceutical industries and to ensure that innovation in the field of drug discovery in the European Economic Area and globally is allowed to continue and not curtailed through the authorization process. Currently there are no known scientific and technically viable alternatives available for our industrial use of boric acid as an essential micronutrient, required for the formulation of cell culture media used in biological fermentation processes. Considering the technical difficulty to develop alternatives for these highly specific applications of boric acid and the socio economic impact on the complex supply chain, we request ECHA to set a review period not less than 12 years for these specific uses of boric acid, should these uses of boric acid not be exempted from the authorization requirement. 	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) **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**
2566 2014/11/20	Individual, United Kingdom	As I have commented under general comments, Boric Acid as used as a flux for soldering process's does not represent a health risk, and as such should be exempt. Bear in mind that there is a huge army of individual craftspeople working from home, who simply would not be able to cope or comply with yet more complex forms, licences, and other bureaucratic burdens which are a cost, and hindering yet again our competitiveness. 	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks **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) **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**
2567 2014/11/21	AGLUKON Spezialdünger GmbH & Co. KG, Company, Germany	The use of boric acid in manufacture and application of foliar fertilizers (regardless of the final borates concentration) should be exempted. Boron is an essential nutrient for plants and most organisms, and is acquired from aqueous solution as boric acid. Boron in soil solution is mainly present as boric acid or borate. Boric acid, a charge-neutral molecule, is the major chemical form of B taken up by plants. It is unalienable that an authorisation need to be granted for this essential and absolutely necessary use. As a consequence companies which produce fertilizers containing boric acid would have to pay fees for the use of boric acid. An unessential charging system, which increases prices on all levels, would be established. This can not be within the meaning of that regulatory process. Furthermore the risks for industrial and professional workers using fertilizers containing boric acid are adequately controlled through the risk management measures detailed in the exposure scenarios of the registration dossiers and other chemical management legislation, such as pregnant workers(Dir. 92/85/EC) and young workers (Dir. 94/33/EC). Professional workers which use liquid foliar fertilizers containing boric acid over 5,5% are well versed with substances and mixtures which are classified as toxic for reproduction. Under occupational conditions, the main intake pathway for boric acid proceeds via the respiratory tract. The exposure is mainly due to dusts. Using liquid foliar fertilizers the main route of exposure of boric acid is excluded. Nevertheless professional workers use already protection measurements like engineering controls (automatic clearance of packages) and personal protection equipment. So during this process the contact of the professional worker with the hazardous material is already today minimized. On the user level it is common practice for farmers to mix foliar fertilizers with plant protection products, which have mostly much higher risks concerning	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks **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** **C.2. Responses to exemption requests referring to other legislation**

		toxicity. This means that farmers are not only well equipped with their machinery, but also educated in the use of hazardous products. Consumers using foliar fertilizers containing boric acid are adequately protected through the restrictions (REACh Annex XVII) and the risk management measures detailed in the exposure scenarios of the registration dossiers. Consumers only use foliar fertilizers containing boric acid under the specific concentration limit (<5,5% boric acid). There is a very small risk for consumers, because they are not subject to prolonged exposure to boric acid and no health effects could be observed.	
2573 2014/11/21	Company, Finland	Use as a buffering agent, in diagnostic kit preparation, as a starting material or as a solvent for boron reagents to be used in API industry, as a firefighting agent.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks **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** **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**
2578 2014/11/21	I&P Europe - Imaging and Printing Association e.V., Industry or trade	Member companies use the substance to formulate some photographic processing chemicals, mostly developers and fixers. It is present in the processing chemicals as sold below its specific concentration limit, and at much lower levels in the "working strength" solutions actually used in photographic	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks

	association, Germany	processing. Thus the only aspect of this photographic use that would require authorisation is the industrial formulation of the processing chemicals. Member companies also use the substance as a cross-linking agent for polyvinyl alcohol when manufacturing coated inkjet printing media or digital film for medical diagnostic- and documentation applications. It is first made into a "hardener solution" below its specific concentration limit, and this solution is added to the coating formulations. It hardens the polyvinyl alcohol in the coating layer by chemical reaction between boric acid and the PVA-OH functions, during the controlled drying of the coating. Thus the only aspect of this photographic use that would require authorisation is the industrial formulation of a solution that is subsequently added to the coating formulations. Given the restriction of Reg. (EU) 109/2012, risks relating to the photographic processing chemicals are adequately controlled, so the industrial use in formulating these products should be exempted. . Similarly, the industrial use in formulating solutions for use in hardening polyvinyl alcohol when coating inkjet printing media or digital film for medical diagnostic- and documentation applications should be exempted.	**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** **C.1.3. Aspects not justifying an exemption from authorisation**
2579 2014/11/21	Company, Slovakia	2579_ECHA-Technical information.docx	**C.2. Responses to exemption requests referring to other legislation**
2580 2014/11/21	Company, Italy	2580_ECHA_Technical_information.docx	**C.2. Responses to exemption requests referring to other legislation**
2581 2014/11/21	National NGO, United Kingdom	Chemical analysis; see above.	**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**

2582 2014/11/21	Protim Solignum Ltd., Company, United Kingdom	Boric acid is used in construction materials (wood and wood-based board) as a flame retardant (in a mixture with other co-formulants). Where there is sufficient Boric acid in the flame retardant product for it also to be claimed as a wood preservative, the boric acid is being used in a biocidal product within the scope of Directive 98/8/EC ('BPD') and EU 528/2012 ('BPR') so this use is exempt from Authorisation. If the same product is used only as a flame retardant with no biocidal claims, this use is not exempt from the scope of Authorisation. However the evaluation process which has been carried out under the BPD and BPR includes a Human Health Risk Assessment (HHRA) and Environmental Risk Assessment (ERA) for the product. The HHRA scenarios for acute exposure to professional personnel applying the product in an industrial situation show that the workers are adequately protected and that there is no unacceptable risk. Although the end uses of flame retardant treated wood is in situations which are not accessible by adults or children, when the BPR scenarios for secondary human exposure are calculated, and used to carry out risk assessment, it is concluded that flame retardant treated wood has an acceptable risk (See attached document). Therefore, the use of Boric acid as a flame retardant for wood should be exempt from Authorisation. Information on the safe handling of the flame retardant treated wood or wood board is available and passed down the supply chain from treater to merchant or downstream user. Boric acid has been tested to European Standards and proven to be an effective flame retardant which is specified for use (e.g. in public buildings) to comply with European building codes, and cannot currently be substituted by another substance. This information is provided by Protim Solignum Ltd., manufacturer of flame retardant products for wood, with an annual usage of Boric acid of approximately 40 tonnes per year. The market share is not known but here are other products on the market in Europe containing Boric acid as a flame retardant for wood. The treated wood products are sustainable, fire retardant, and durable, safeguarding humans and animals without adversely affecting the environment. *Confidential attachment removed*	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 5. Availability of suitable alternatives **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**

2583 2014/11/21	Company, Portugal	The uses of Boric Acid are included in other legislation, according to the article 2 (5) of REACH legislation: a) in medicinal products for human or veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC and Directive 2001/83/EC;	**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**
2585 2014/11/22	Castolin Eutectic, Company, United Kingdom	2585_ECHA-Socio-economical arguments.docx *Confidential attachment removed*	Please see references to responses in section I
2587 2014/11/24	Company, France	2587_CP Echa-boric acid- nov2014.pdf	Please see references to responses in section I
2591 2014/11/24	Company, United Kingdom	The organisation's use of boric acid in chemical processing is already adequately controlled through existing chemical management legislation including the Chemical Agents Directive (98/24/EC). Workers are adequately protected from exposure; raw material discharge, storage and reaction are in enclosed systems.	**C.2. Responses to exemption requests referring to other legislation**
2593 2014/11/24	Company, Germany	2593_Comment_K+S_KALI_GmbH_boron2.doc *Confidential attachment removed*	Please see references to responses in section I
2608 2014/11/24	Verband Schmierstoff-Industrie e.V., Industry or trade association, Germany	2608_EBA comments - 6th priority list _14 Oct 2014.pdf	Please see references to responses in section I
2615 2014/11/24	Company, Belgium	Use as bioessential element for growth of microorganism (process in biotechnology) Boric acid is similar to the Cobalt salt , it can be seen as an essential element ;essential trace elements that are required for the growth of most organisms. Although they are present in only small quantities, they have important biological effects because of their participation in an amplification mechanism. It is not possible to remove essential elements in biological processes without	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives **C.1.1. General principles for exemptions under Art. 58(2)**

		killing them microorganism *Confidential attachment removed*	**C.1.2. Generic exemptions** **C.1.3. Aspects not justifying an exemption from authorisation**
2616 2014/11/25	Repligen Sweden AB, Company, Sweden	The industrial use of boric acid as a source of boron in microbial fermentation processes should be exempted from the authorization requirement because boron cannot be replaced or excluded in these processes since it is an essential micro nutrient for living organisms. The volumes of boric acid in this application are small (typically less than 1 kg per production site per year) and the handling is safe since it is done in laboratories or industrial environments with high hygienic standard and safety measures to protect the people working there. The products that are put on the market do not contain boron.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 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)** **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** **C.3.5: Claim that products not**

			containing the substance in the final product should be exempt from authorisation
2618 2014/11/25	SYMOP, Industry or trade association, France	Welding and brazing technologies 2618_POsirtion SYMOP borates vd.pdf	**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**
2619 2014/11/25	DSM, Company, Netherlands	Boric acid is used as an essential trace element in several fermentation media. Scientific studies have shown that boric acid cannot be substituted with any other substance due to the biological necessity of boric acid. Therefore, it is a critical substance in the supply chain of fermentation based products 2619_DSM_Boric_acid_Nov2014.pdf	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives **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**
2633 2014/11/25	Frit Consortium, Industry or trade association, Spain	The Frit Consortium considers that according to the indications of the REACH Regulation, the use of borates in the manufacture of frits should be considered as an intermediate use, and it should therefore be excluded from the authorization process. Further details on this position can be found in the document attached to this Public Consultation. 2633_Frit Consortium - borates intermediate in frits.pdf	Please see references to responses in section I
2656 2014/11/25	Aerospace Industries Association, International	Major metal finishing processes that depend on the use of boric acid include: • Nickel electroplate – major process baths impacted include: chloride nickel,	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable

	organisation, United States	sulfate nickel, sulfamate nickel, watts nickel (comprised of nickel sulfate and nickel chloride). Sulfamate nickel plate is used to produce a defect-free (e.g. no cracks) coating on high strength steel with good fatigue life properties. It is useful for dimensional restoration of damaged parts and is critical to the maintenance and repair of landing gear. • Cobalt electroplate – chloride cobalt, sulfate cobalt, sulfamate cobalt • Nickel-cobalt electroplate – sulfamate-style baths • Nickel-cadmium electroplate – consists of a cadmium electroplate deposit and a nickel electroplate (usually from a sulfamate nickel bath) deposit where in the two deposits are heat treated to diffuse them together (note that this coating is used to prevent corrosion in environments subject to high temperature). • Zinc electroplate – sulfate and sulfate-chloride style bath • Zinc-nickel and other zinc-alloys – chloride, sulfate, sufamate and combinations thereof style bath formulations; cadmium electroplate – sulfate bath • Cobalt-phosphorus electroplate • Trivalent chrome plating – developed as a replacement for conventional hard chrome plating which uses a chromium trioxide (CrVI) solution, the tri-chrome process formulation contains trivalent chromium (CrIII) compounds that are not carcinogenic. This is a relatively new and important development, and manufacturers are at various stages of evaluation and implementation. Although the concentration of boric acid in this solution is very low, limiting its use will likely result in a decrease in the activity to pursue this alternative (to chrome plating using CRVI), which would be counterproductive. • Boric Sulfuric Acid Anodize (BSAA) – this type of anodizing is an environmentally preferred alternative for chromic acid anodizing. Key suppliers of U.S. manufacturers in the EU require the use of boric sulfuric acid anodize to produce parts. The only approved alternative to boric sulfuric acid anodize is chromic acid anodize, and chromic acid is already on the Authorization List. • Seal after anodizing (nickel acetate seal) – nickel acetate sealing must be conducted at a controlled pH for the process to work correctly. Boric acid is used to adjust and buffer the pH in the proper range. The seal hydrates the pores of the anodize coating and the coating becomes resistant to further staining and corrosion. • Cleaning and descaling copper – electro cleaning of copper and copper alloys is performed after photoresist etching. The concentrated electrocleaner formulation contains up to 25% boric acid in solution prior to mixing. After	alternatives **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** **C.3.4: Claim that uses which can replace Cr(VI) should be exempt from authorisation** **C.3.5: Claim that products not containing the substance in the final product should be exempt from authorisation**

		mixing, the boric acid concentration is relatively low. • Fluoboric acid and boric acid – boric acid is used in the manufacture of fluoboric acid which is used in many surface finishing processes. Residual boric acid (several percent) is sometimes, but not always, present in fluoboric acid. Many plating processes use fluoboric acid in either the formulation of the plating solution or in an acid activation solution. Boric acid is also a critical chemical ingredient to many non-electroplating processes used within aerospace such as: • Photographic processes – boric acid retards or prevents the formation of sludge in the "fixer" (chemical used to process photographic or x-ray film) • Silver brazing flux – brazing is a metal joining process whereby a filler metal is heated and distributed between two or more close-fitting parts, similar to soldering except applying higher temperatures. Silver-brazing fluxes contain boric acid and potassium borates, combined with complex potassium fluoborate and fluoride compounds. Boric acid is a principal constituent used in brazing fluxes because it facilitates the removal of the glasslike flux residue left after brazing. • Liquid penetrant inspection – developer powders are used during the dye penetrant inspection process after liquid dye penetrant is applied to and rinsed from parts. The developer then draws the remaining penetrant to where cracks in the surface can be detected. • Lubricants – several lubricants contain low concentrations of boric acid • Heat treat protective coating – boric acid is mixed with a binder in a solvent matrix and applied to titanium parts to form a lubricating and scale-inhibiting coating for heat treat. The coating is removed after heat treating. Manufacturers utilize boric acid in aerospace for several critical applications including metal finishing, non-metallic finishing, and as replacements for more hazardous materials. Although the material is used minimally, and in a manner which must meet stringent safety requirements, it is integral to the manufacture of safe aerospace products. Many of the aerospace products that use boric acid are subject to a type-approval from the European Aviation Safety Agency (EASA) or the Federal Aviation Administration (FAA) in the U.S. The majority of boric acid applications are within metal finishing processes for	

		which the material is an ingredient of a process bath, and does not become a constituent of the final coating. Many of the final products which depend upon this metal finishing can be found on critical locations of the aircraft, such as leading edge protective devices on propeller, engine fan blades and helicopter rotor blades. Most of the vendors that manufacture leading edge devices on aircraft propeller, turbine fan and helicopter blades are located in the E.U. In many instances, the coatings provide corrosion protection to various substrates. Several of the coatings produced provide an important function in overhaul and build-up repair of worn aircraft components. Often the corrosion protective coating is used as a replacement for another SVHC material, cadmium. Boric acid is used in many metal finishing solutions at low concentrations. It is present in many solutions below the specific concentration limit of 5.5% for the material, however, the pure boric acid powder must be used for solution make-up (onsite formulation) and small amounts are needed for ongoing process control. Affected processes include boric sulfuric acid anodize, sulfamate nickel plate, zinc nickel plate, and nickel acetate sealing after anodize. As noted above, boric acid is used within a critical process intended to replace more hazardous materials such as chromium (VI) [e.g., BSAA for Chromic Acid Anodize (CAA), tri-chrome electroplating for conventional hard chrome electroplate] and cadmium [e.g., nickel-based plating for Cadmium plating]. There are currently few available replacements for boric acid in the aforementioned critical uses. For electroplating baths, the function of boric acid is to serve as a weak buffer in many of the formulations; its principal effect is controlling the pH in the cathodic film. In the case of nickel electroplating, in the absence of such an effective buffer, the nickel deposits that are produced at ordinary temperatures are hard, cracked and pitted, which would render the coating useless. The use of cracked coatings can serve to generate further cracks in the substrate which can have potential catastrophic safety implications of aerospace products under normal operational loading. Chemically, the use of boric acid in a buffer is imperative and effective. H3BO3, has the capability of ionizing with an H+ and a H2BO3- and the H+ from the boric acid reacts with the OH- to hold the pH stable. This makes it versatile enough to be used in a variety of chemical bath control situations.	

		2656_AIA Comments to Boric Acid.pdf	
2658 2014/11/25	Daido Industrial Bearings, Company, United Kingdom	Boric acid is a key process ingredient in a wide range of electroplating processes. Boric acid is essential to control the process although it does not end up in the finished part. The electroplating industry has taken great strides in recent years to develop ever safer and more environmentally friendly materials. Boric acid is a key ingredient in such technologies. Electroplating is a key technology used in the manufacture of many different products. Electroplating is a process that 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 the use of boric acid in electroplating is not exempted then manufacture of these products will be exported outside the EU with the loss of hundreds of jobs.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 5. Availability of suitable alternatives **A.2.13: Claim that risks for workers are controlled by other legislation** **C.2. Responses to exemption requests referring to other legislation**
2663 2014/11/26	Company, United Kingdom	Uses when the substance is fully encapsulated into a liquid mixture matrix, and where there is no intended release during final product use, should be exempted.	**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**
2664 2014/11/26	Individual, 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. Boron is irreplaceable as a micronutrient	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. for plants Boron is one of the 7 essential micronutrients for plants (according to the EU Fertiliser Regulation) which are implemented as a set for fertilizers. Each of them has a definite impact on the plant and on the operation of the other components of fertilizer. Excluding one of them causes the fertilizer product to cease to be not full-fledged. The use of boron in fertilizers accounts for about 13.7% of the diboron trioxide, boric acid and disodium tetraborates entering the EU market. Boron is necessary for all plants, aiding in the transfer of sugars and nutrients from leaves to fruit, and increasing pollination and seed development. Boron also improves winter hardiness of plants, enhances root growth and root nodule development for fixing nitrogen, provides better water use efficiency and drought tolerance. The use of boron as a fertilizer has a great impact on harvest of all plants and there is no possibility to replace it by any other micronutrients and opposite. The most sensitive plants for deficiency of boron are corn, sugar beet and rape. Most of soils worldwide show boron deficiency and the influence of boron shortage for plants is very significant. For sugar beets, for example, the deficit of this micronutrient can cause the decrease of yields of roots of even 50% (Artyszak A.,Fragm.Agron.31(3) 2014, 7-18). Also the sugar yield is diminished significantly, because one of the important functions of boron is sugar translocation into the plants. Boron increases the rate of transport of sugars (which are produced by photosynthesis in mature plant leaves) to actively growing regions. Without an adequate amount of boron, the beet roots are not fully of standard value. Taking into consideration the acreage of sugar beets in Poland (about 190 000 ha in 2014) and European Union (1463 000 ha), the yield decrease will have significant influence of economy, especially in agriculture. Other plants heavily impacted by boron deficiency are corn and rapeseed, with the acreage in the world of 170 mln ha (939 mln mt) for corn and 30 mln ha (67 mln mt) for rapeseed, respectively. The shortage of boron causes incomplete pollination, grain formation and precludes proper creation of corn cobs. It is said that corn requires about 20 g of B for 1 mt of corn. Taking into consideration current yield of corn, the total use of boron is:	**A.1.5. Aspects not considered in ECHA's prioritisation:** 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** **C.2. Responses to exemption requests referring to other legislation**

		- 18789 mt worldwide (the yield 939 mln mt) - 1330 mt in EU (the yield 66.5 mln mt) - 79 mt in Poland (the yield 3.9 mln mt) For oilseed rape, boron deficiency shows diminished growth, the formation of empty seats in the roots and basis of blades, small lateral root growth and poor tying of the pods after flowering are the effects of boron deficiency, which in turn has a negative impact on the yield of oilseed rape. In young plants a reddish coloration of leaves and petioles appear. If boron deficiency is not removed, the plant does not grow and is creeping close to the ground. In general, the rapeseed requires about 350-450 g B/ha. That gives the consumption of boron, respectively: - 10500 mt worldwide (the acreage 30 mln ha) - 2275 mt in EU (the acreage 6.5 mln ha) - 294 mt in Poland (the acreage 840 000 ha) b. for humans Boron is much more than just another mineral in human nutrition. It affects a broad range of life processes involving macrominerals, energy substrates such as glucose and triglycerides, amino acids and proteins, free radicals, bone mineralization, prostate health, mental function, estrogen metabolism and numerous body systems. Boron is a mineral that is critical to our health. One of the first recognized roles of boron in human nutrition was its contribution to promoting and maintaining good bone mineralization. In areas around the world where boron intake is 1 mg or less per day, the incidence of arthritis ranges from 20% to 70%. In areas where boron intake is usually 3-10 mg per day, the incidence of arthritis is 0-10%. Boron has also demonstrated an ability to protect against bone loss in the presence of a vitamin D deficiency. It has been demonstrated that the combination of Boron, vitamin D, calcium and magnesium in adequate amounts act synergistically to maintain good bone mineralization. It has been observed that dietary boron has a similar effect as supplementation with estrogen in humans. Boron is also necessary for the formation of specific steroid hormones. It is a trace mineral required to convert estrogen and vitamin D to their most active forms. Studies have shown that boron provides protection against osteoporosis	

		and reproduces many of the positive effects of estrogen therapy in postmenopausal women. Boron and its compounds could protect against prostate cancer by inhibiting the activity of many serine protease enzymes, including prostate-specific antigen (PSA). Another very important boron function in human organisms is its impact on the cognitive function. Studies have shown that low boron diet can cause decrease of manual dexterity, hand-to-eye coordination, attention, perception, and short- and long-term memory. Inadequate boron intake can also contribute to a lack of energy, ability to stay focused on tasks and mental alertness. Although there is no recommended dietary allowance for boron, evidence places the optimal daily boron intake at 2-3 mg or more. Another thing which should be strongly considered is the influence on the availability of food and nutrient content of agricultural crops. More than two billion people in the world are undernourished, 800 million are starving. Every action which results in diminishing food availability should be very carefully considered and broadly consulted, especially with WHO and IFPRI. Shenggen Fan, the general director of IFPRI says that 800 million people in the world go hungry because there is not enough food. It is about the quantity of calories delivered. Two billion people are affected by chronic hunger, because their diet is too low in nutrients. The effects of this hidden malnutrition are equally lethal, as the effects of hunger. The difference is that malnourished man dies slower. Many programs, like for example HarvestPlus, are conducted, just to eliminate the problem of insufficient microelement nutrition. Bill Gates, the main sponsor of HarvestPlus program, says: "Two billion people in the developing world suffer from diets lacking essential vitamins and minerals. Foods rich in vitamins and minerals are essential for a healthy diet. When diets do not contain sufficient amounts of vitamin A, folic acid, iodine, iron, and zinc, the consequences include significantly lower birth weight, a decrease in cognitive development, and increased susceptibility to other diseases."	
2667 2014/11/26	Individual, France	Arguments provided by EBA (date 14-10-14)and: various studies have demonstrated that metal working fluids containing boric acid have significantly longer service lives than metal working fluids with biocides. Waste water treatment of metal working fluids containing boric acid is	Please see response to comment #2524 (EBA comment) **A.1.5. Aspects not considered**

		easier, because boric acid can be neutralized and will then be transferred in Boron and Water, where Boron is an essential nutrient and not environmentally hazardous. Replacement would result in higher use of biocides which are more critical to human health and environment and would need other waste water treatment processes. This would have significant economical impact on small and medium sized enterprises (SME's), as they are the main customers for those kind of products.	**in ECHA's prioritisation:** 5. Availability of suitable alternatives **B.1.1. General principles for setting latest application dates / sunset dates:** 3. ECHA's proposal for latest application dates
2668 2014/11/26	Individual, France	Arguments provided by EBA (date 14-10-14)and Use: formulation of metal working fluids (mixtures) should be exempt, as adequate Risk Management Measures have already been implemented. Measurement of airborne concentration have provided evidence that the risk is adequately controlled. Use in Metal working fluids (concentrates and emulsions) as risk are adequately controlled. As the main exposure route in these uses is dermal and boric acid and sodium borates are not absorbed through the skin, the critical concentration to provoke reprotoxic effects (LOAEL) in the human body will not be achieved by skin contact.	Please see response to comment #2524 (EBA comment) **A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks **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**
2673 2014/11/26	UNIFA, Industry or trade association, France	Fertilizers must be exempted because BORON is essential for crops. 2673_Commentaires UNIFA_Novembre 2014_EN_VF.pdf	**C.2. Responses to exemption requests referring to other legislation**
2685 2014/11/26	EnBW AG, Company, Germany	Using boric acid in nuclear electric power plants is vital to control nuclear fission reactions and to ensure nuclear safety. Boric acid is used in all pressurized water nuclear reactors around the world (and to a lesser extend in boiling water nuclear power plants); no other chemical compound has the same characteristics required to replace boric acid for this use as expected in the authorization process. Boric acid is also used for its neutron absorbing	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

		capacities within the fuel cycle and during dismantling. Moreover boric acid is used in the glass for nuclear waste. The uses of boric acid in German nuclear power plants take mostly place within closed systems inside buildings with monitored building sumps, mostly inside the controlled area as defined by EU Directive 2013/59/EURATOM. The yearly waste is less than 1 ton per plant and is stored in barrels on the site. Consequently the amount of boric acid handled in nuclear power plants is small. Therefore the usage of boric acid in nuclear power plants does not constitute any danger for the environment. The only process with a potential exposition of staff is the production of the solution by the plant´s chemistry department. Boric acid is classified as toxic for reproduction Category 1B according to EU Regulation 790/2009 (belongs since then to the CMR substances) and therefore requires a safety data sheet according to Regulation 1907/2006 also defining it´s content and the personnel safety measures when dealing with this substance. The safety data sheets are used for establishing operator´s guidelines for handling chemicals following a mandatory risk assessment in hazardous working environments. This process is required by German labor protection law implementing the EU Council Directive 89/391/EEC. Consequently the uses of boric acid on nuclear sites are governed by EU regulations adequately controlling the relevant risk. Measurements of the hazardous substances in the workplace atmosphere by the institution for statutory accident insurance and prevention (Berufsgenossenschaft Textil, Energie und Elektro) at a representative German nuclear power plant for the process of mixing boric acid revealed, that the mixing process utilizes only 1% of the workplace exposure of 0.5 mg/m3. Nevertheless dust musk FFP3 and full body protective covers are worn. So the protection of health is ensured for our workers. Consequently, if the above arguments for the re-evaluation of boric acid as member of the candidate list are not followed it is suggested to exempt nuclear uses from authorization, as EU legislation (and subsequent German law) is applied to control the risks of the uses of boric acid in nuclear power plants. The criteria for an exemption for nuclear industry mentioned in article 58 (2) of EU Regulation 1907/2006 are fulfilled:	be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks

		"Uses or categories of uses may be exempted from the authorization requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled." 2685_ECHA Comments Attachement EnBW.docx	
2687 2014/11/26	CooperVision , Company, United States	CooperVision anticipates that the use of boric acid in the final medical device will be exempted from Authorisation in accordance with Article 56, as the concentration of the substance in the final product will be below the levels at which the substance is considered safe for use. CooperVision requests an exemption from Authorisation for use in quality control, validation and biocompatibility testing. Such uses are carried out under controlled conditions within the scope of the medical devices directive and in accordance with adopted, internationally recognised, industry standards such as ISO 10993. Article 3(23) of REACH, defines scientific research and development as any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume of less than 1 tonne per year. The use of the substance in biocompatibility and validation activities of the medical device meets this definition and thereby should fall within the exemption laid down in article 56(3) of REACH. In addition, formulation of mixtures to be used as such should also fall within the scope of this exemption. CooperVision requests an exemption for the use of boric acid in the formulation of buffering solutions for the production of contact lenses. The function of the substance contained in a buffer solution is to provide a medium allowing the lenses to be maintained in a sterile environment during storage prior to use. This packaging environment is critical to the correct and safe functioning of the device. The buffer solution allows for the fulfilment of the requirements under the medical devices directive that the devices are packaged and delivered and fit for purpose. It is acknowledged that medical devices directive provides a framework that aims to ensure that the benefits of using medical devices outweigh any risk, whilst guaranteeing the free movement of such devices within the internal market. Imposing Authorisation on the use of boric acid in the manufacture of	**C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation** **C.3.1: Claim that solutions below the specific concentration limit should be exempt from authorisation**

		medical devices acts to contravene this objective at least in part. CooperVision requests that an exemption from Authorisation is granted for the use of the substance in buffer solution used for packaging and storage of soft contact lenses on the basis that the provisions of the exemptions of Article 60(2) should also include the incorporation of a substance during the manufacturing process where the final product falls within the scope of the medical devices directive.	
2692 2014/11/27	Orion Diagnostica Oy, Company, Finland	In cases where boric acid is used as process chemical and not ending to end product should be exempted from the list. In our case boric acid is used by professionals in very controlled and limited process step. The process is executed according to very detailed standard operation procedures, safety instructions and using all relevant protective devices. Boric acid is used as one component in sodium borate buffer in one process phase after which it is replaced by another buffer and boric acid or borate is not ending to any end products and end users hands. Over all the operations are arranged according to ISO13485 standard (certified) and Directive 98/79/EC.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks **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** **C.3.5: Claim that products not containing the substance in the final product should be exempt from authorisation**
2693 2014/11/27	Company, Finland	All uses in industrial (chemistry, pharmaceuticals) perspective, because chemical and pharma industry have already a really long experience on safe handling, and waste control in production lines.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks **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**
2699 2014/11/27	European Special Glass Association and European Domestic Glass Association, Industry or trade association, Belgium	Borosilicate glass Justification is developed in the attachment 2699_FINAL EDG-ESGA - Use of borates as intermediates in the manufacture of borosilicate glass.docx	Please see references to responses in section I
2707 2014/11/27	Vesuvius Group, Company, United Kingdom	Mixing/blending and transfer operations intended to manufacture mixtures where the boric acid is below the specific concentration limit and/or articles should be exempt from authorisation where the manufacturer can demonstrate adequate risk management measures are in place. *Confidential attachment removed*	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks **C.2. Responses to exemption requests referring to other legislation** **C.3.1: Claim that solutions below the specific concentration limit should be exempt from authorisation**
2711 2014/11/27	Company, Finland	Use of boric acid in industrial synthesis should be exempted.	**C.1.2. Generic exemptions**
2712 2014/11/27	Individual, Germany	application as biocidal product within the scope of Directive 98/8/EC and medicinal product (726/2004, 2001/82/EC, 2001/83/EC) is covered but application as medical device (disinfectant) within the scope of 93/42/EC should be covered as well	**C.2. Responses to exemption requests referring to other legislation**
2714 2014/11/27	Company, Germany	Using boric acid in nuclear electric power plants is vital to control nuclear fission reactions and to ensure nuclear safety. Boric acid is used in all pressurized	Thank you for your comment and the additional information

		water nuclear reactors around the world (and to a lesser extend in boiling water nuclear power plants); no other chemical compound has the same characteristics required to replace boric acid for this use as expected in the authorization process. Boric acid is also used for its neutron absorbing capacities within the fuel cycle and during dismantling. Moreover boric acid is used in the glass for nuclear waste. The use of boric acid in German nuclear power plants takes mostly place within strictly closed systems inside buildings with monitored building sumps, mostly inside the controlled area as defined by EU Directive 2013/59/EURATOM. The yearly waste is less than 1 ton per plant and is stored in barrels on the site. Consequently the amount of boric acid handled in nuclear power plants is small. Therefore the usage of boric acid in nuclear power plants does not constitute any danger for the environment. The only process with a potential exposition of staff is the production of the solution by the plant´s chemistry department. Boric acid is classified as toxic for reproduction Category 1B according to EU Regulation 790/2009 (belongs since then to the CMR substances) and therefore requires a safety data sheet according to Regulation 1907/2006 also defining it´s content and the personnel safety measures when dealing with this substance. The safety data sheets are used for establishing operator´s guidelines for handling chemicals following a mandatory risk assessment in hazardous working environments. This process is required by German labor protection law implementing the EU Council Directive 89/391/EEC. Consequently the uses of boric acid on nuclear sites are governed by EU regulation adequately controlling the relevant risks. Measurements of the hazardous substances in the workplace atmosphere by the institution for statutory accident insurance and prevention (Berufsgenossenschaft Energie Textil Elektro) at a representative German nuclear power plant for the process of mixing boric acid revealed, that the mixing process utilizes only 1% of the workplace exposure of 0.5 mg/m3. Nevertheless dust musk FFP3 and full body protective covers are worn. So the protection of health is ensured for our workers. Consequently, if the above arguments for the re-evaluation of boric acid as member of the candidate list is not followed it is suggested to exempt nuclear	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 **A.2.13: Claim that risks for workers are controlled by other legislation** **C.2. Responses to exemption requests referring to other legislation**

		uses from authorization, as EU legislation (and subsequent German law) is applied to control the risks of the uses of boric acid in nuclear power plants. The criteria for an exemption for nuclear industry mentioned in article 58 (2) of EU Regulation 1907/2006 are fulfilled: "Uses or categories of uses may be exempted from the authorization requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled." *Confidential attachment removed*	
2716 2014/11/27	Teollisuuden Voima Oyj, Company, Finland	2716_BORON PRODUCTS_ECHA_TVO.pdf	Please see references to responses in section I
2732 2014/11/27	Company, Germany	The element B is an essential micronutrient to plants which is not substitutable, the use of Boric acid for the formulation of fertilizers should be exempted from the authorization scope. 2732_COMPO.pdf	**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**
2739 2014/11/27	Company, United States	rust removal, complex silicate descaling (in food and oil field related situations), transportation pre-soaks for touchless vehicle washing and wheel cleaning 2739_Boric Acid Letter.pdf	**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
2740 2014/11/27	EDF SA, Industry or trade association, France	2740_PC-ECHA-boric_acid-comment-nov 2014-VF-EDF.pdf	Please see references to responses in section I
2742 2014/11/27	RWE Power AG, Company, Germany	Using boric acid in nuclear electric power plants is vital to control nuclear fission reactions and to ensure nuclear safety. Boric acid is used in all pressurized water nuclear reactors around the world (and to a lesser extend in boiling water nuclear power plants); no other chemical compound has the same characteristics required to replace boric acid for this use as expected in the authorization process. Boric acid is also used for its neutron absorbing capacities within the fuel cycle and during dismantling. Moreover boric acid is used in the glass for nuclear waste. The use of boric acid in German nuclear power plants takes mostly place within strictly closed systems inside buildings with monitored building sumps, mostly inside the controlled area as defined by EU Directive 2013/59/EURATOM. The yearly waste is less than 1 ton per plant and is stored in barrels on the site. Consequently the amount of boric acid handled in nuclear power plants is small. Therefore the usage of boric acid in nuclear power plants does not constitute any danger for the environment. The only process with a potential exposition of staff is the production of the solution by the plant´s chemistry department. Boric acid is classified as toxic for reproduction Category 1B according to EU Regulation 790/2009 (belongs since then to the CMR substances) and therefore requires a safety data sheet according to Regulation 1907/2006 also defining it´s content and the personnel safety measures when dealing with this substance. The safety data sheets are used for establishing operator´s guidelines for handling chemicals following a mandatory risk assessment in hazardous working environments. This process is required by German labor protection law implementing the EU Council Directive 89/391/EEC. Consequently the uses of boric acid on nuclear sites are governed by EU regulation adequately controlling the relevant risks.	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

		Measurements of the hazardous substances in the workplace atmosphere by the institution for statutory accident insurance and prevention (Berufsgenossenschaft Energie Textil Elektro) at a representative German nuclear power plant for the process of mixing boric acid revealed, that the mixing process utilizes only 1% of the workplace exposure of 0.5 mg/m3. Nevertheless dust musk FFP3 and full body protective covers are worn. So the protection of health is ensured for our workers. Consequently, if the above arguments for the re-evaluation of boric acid as member of the candidate list is not followed it is suggested to exempt nuclear uses from authorization, as EU legislation (and subsequent German law) is applied to control the risks of the uses of boric acid in nuclear power plants. The criteria for an exemption for nuclear industry mentioned in article 58 (2) of EU Regulation 1907/2006 are fulfilled: "Uses or categories of uses may be exempted from the authorization requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled." 2742_2-2_ECHA_consultation_boric acid paper_final.docx	
2744 2014/11/27	Alkanolamine Borates Consortium, Industry or trade association, United Kingdom	See attached 2744_Letter re Borates Authorisation final.docx	**C.2. Responses to exemption requests referring to other legislation**
2747 2014/11/28	Poland, Member State	Major uses of boric acid in the EU are outside the scope of authorization: ☐ boric acid is mainly used in the manufacturing of glass and frits (in these uses the boric acid is qualifies as intermediate since is completely consumed and transformed into another substance - glass and frits) ☐ boric acid (and other borates) is used in mixtures below specific concentration limits ☐ boric acid is used in other sector-specific legislation (e.g. biocides) which is outside the scope of authorization, In certain uses the boron is irreplaceable. ☐ Boron is essential micronutrient for normal, productive plant growth and is	**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** **C.1.1. General principles for exemptions under Art. 58(2)** **C.1.2. Generic exemptions**

		one of seven essential micronutrients for plants according to the EU Fertilizers Regulation (2003/2003/EC). Taking into account the essentiality of boron for agriculture, the authorization must be granted for agriculture and would not achieve the aim of authorization. ☐ use of boric acid in nuclear power plants is essential for safety reasons. The natural boron isotope is required and cannot be substituted. Thus, in our opinion, the use of borates in fertilizers and the use of borates in nuclear plants should be exempted from authorization.	**C.1.3. Aspects not justifying an exemption from authorisation** **C.2. Responses to exemption requests referring to other legislation**
2752 2014/11/28	BOCI, CFHM, UFBJOP et Comité Francéclat, Industry or trade association, France	2752_Sample of testimonials.pdf	Please see references to responses in section I
2759 2014/11/28	CEZ Group, Company, Czech Republic	Phasing out of Boric Acid would mean the end of production of electricity in VVER reactors in the Czech Republic and would cause the loss of energy security, competitiveness of the Czech industry and jobs. Authorisation of Boric Acid by the European Chemicals Agency would mean an ambitious periodical process linked to the necessary evidence of no alternative substance. This would cause economic and social consequences in times of serious crisis on the European energy market. Because of the evidence of no alternative substances, the use of Boric Acid in the nuclear power generation should be exempted from authorization, if the inclusion in annex XIV is enacted. *Confidential attachment removed*	**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** **C.2. Responses to exemption requests referring to other legislation**
2766 2014/11/28	Amfep, Industry or trade association,	Use of the substances in culture media in biotechnology, pharmaceuticals and in vitro diagnostics. 2766_281114 Letter of concern boric acid-final.docx	**C.1.1. General principles for exemptions under Art. 58(2)**

	Belgium		**C.1.2. Generic exemptions** **C.1.3. Aspects not justifying an exemption from authorisation**
2768 2014/11/28	Chemetall GmbH, Company, Germany	Chemetall declines a prohibition of boric acid in cleaners/de-scaling products for removing incrustations in industrial phosphating devices, as it will have immense negative impacts on major industries like the automotive and automotive component industry, however, it cannot be expected that the prohibition will lead to an increased safety for human health or better protection for the environment. In the following the impacts of a prohibition will be shown and it will be demonstrated that the use of boric acid is safe and there are no increased risks for workers. Applied Use Scenario: Boric acid is used in cleaners/de-scaling products for removing incrustations in industrial phosphating devices. Zinc phosphating is a method used for increasing the protection of metal surfaces from corrosion and for improving the paint adhesion properties. Pretreatment of metal surfaces is one of Chemetall's core businesses. It is the technology of choice of the automobile industry and other industries refining metal parts. Currently there is no other economic reasonable alternative. For the phosphating process, the parts are plunged into a bath, where the chemical process takes place. During this process cryolite (Na3[ALF6]) arises as an unwanted byproduct, which incrusts the pretreatment line. This incrustation must be removed regularly, in order to guarantee an ideal pretreatment process. For the removal a special cleaner/de-scaling product is requisite. Typically, it is a mixture out of a strong acid (e.g. sulfuric acid or nitric acid) and boric acid. The boric acid is essential for complexing and thus solving the cryolite. This process is state of the art in pretreatment lines using zinc phosphating processes and there is currently no economic reasonable alternative on the market. No Use Scenario As there is no alternative for removing the cryolite incrustations (and a fast substitution is improbably or even impossible), it can be expected that a	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.2.20 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**

		prohibition of boric acid will influence the market. A prohibition of boric acid is equal to a prohibition of phosphatizing processes of metal surfaces within the EU, due to the fact that the cleaning of the plant will not be feasible anymore. This leads to a competitive disadvantage of the European automobile industry. As there is no other commercial relevant process, it can be assumed that this process might be transferred to non-EU countries and the finished metal parts will be reimported. A change of the location outside the EU will neither increase the safety for human health nor will lead to a better protection of the environment. It is merely a dislocation of the problem. Even if it is difficult to make a reliable forecast, a prohibition could even have worse impacts on the industries using this process and their suppliers. The worst case scenario could be, that not only the pretreatment process will be transferred to non-EU countries, but rather the whole production of the parts (like automobile body parts), due to shorter delivery routes . This could have an immense impact on the European industry and their supply chain. As the automotive and other metal refining industries and their suppliers are crucial industries in the EU, it is important not to prohibit boric acid as plant cleaner. Human health an environmental impacts The cleaner is usually a mixture out of a strong acid (e.g. sulfuric acid, nitric acid) and boric acid. Strong acids require special precautionary measures in order to protect workers against chemical burns. For this reason, the cleaner is always handled with special care and the mixing process is always under controlled conditions (e.g. extraction system) done by professionals. Beside this, workers are wearing personal protective equipment (PPE). Hence the contamination of the workers is very low. Furthermore, the cleaner is intended for professional use only. Boric acid does not end up in articles or private applications at any time. It is merely used for the elimination cryolite crust in bonder plants. All workers who handle the cleaner are specially trained and wear PPE. On top of that, every plant comes with special risk management systems in case of accidents. For the cleaning of the bonderizing device, the pool of the device will be filled with the cleaner until the cryolite crust is solved. Afterwards the cleaner solution will be drained and the pool will be rinsed with water. The cleaner is	**an exemption from authorisation** **C.3.5: Claim that products not containing the substance in the final product should be exempt from authorisation**

		pumped directly from the vessel into the pool. The workers will not come into contact with the cleaner at any time. Boric acid is neither a threat during the production nor during the use. Number of people exposed The number of people exposed to boric acid is approximately very low. Beside this, these people are well trained professionals either in the production of boric acid or workers responsible for the cleaning of the bonderizing devices. Conclusion In summary, boric acid is no threat for the human health. All risks outgoing from boric acid are controllable and the contamination of workers is very low or even not existing. It cannot be assumed that a prohibition will induce a higher safety. However, it can be expected a prohibition will harm the European automobile industry and other metal refining industries and their suppliers. In the worst case these industries will shift their production to non-EU countries.	
2770 2014/11/28	essenscia/bio.be, Industry or trade association, Belgium	Use of the substances in culture media in biotechnology, pharmaceuticals and in vitro diagnostics 2770_letterofconcernboricacidbiobe.doc	**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**
2773 2014/11/28	WKÖ, Other contributor, Austria	See PDF attached. 2773_su_85_WKÖ Borate.pdf	Please see references to responses in section I
2774 2014/11/28	Rockwood Lithium GmbH, Company,	Rockwood Lithium declines a prohibition of boric acid, as it cannot be expected that the prohibition will lead to an increased safety for human health or better protection for the environment but on the other hand will feature a significant	Thank you for your comment and the additional information provided. This will be taken into

	Germany	negative impact on the battery industry. In the following we will highlight the effects of a prohibition and demonstrate the safety level within the production process is very high and there are no increased risks for workers. Applied Use Scenario: Boric acid is used in the production of LiBOB (Lithium bis-(oxalato)borate, CAS-No. 244761-29-3, REACH-Reg.No. 01-0000019322-77-0000), a widely used a conductive agent for the use in high performance lithium ion batteries as employed in many nowadays sold electric vehicles, laptops, computers and other electronic equipment. Within the production process of LiBOB, boric acid, oxalic acid and a lithium containing salt are mixed together and react in a solid state reaction to the final product. No Use Scenario LiBOB is a halide-free conductive salt with advantages compared to the currently used products: unlike other competitive products LiBOB does not form any toxic gases such as HF and significantly contributes to the long term stability of lithium io batteries. A prohibition of boric acid for this use would mean that other conductive like the traditional fluorinated compounds like LiPF6, LiBF4 or lithium triflates will be used. These latter compounds have a considerable higher negative impact on the environment compared to LiBOB; the production process of LiBOB does not include any toxic side products and does not require the use of fluorinated educs such as PF5. In addition, a recycling of substantial amounts of batteries stemming from automotive applications is much more benign when fluorine-free salts are used. Human health an environmental impacts Boric acid is used as a key component in the production process of LiBOB. During the transfer in the chemical plant the release of boric acid dust is minimized by the reactor design. From a process point of view. the boric acid is completely transformed into the intended final product and no part of the boric acid is released to the environment. Any worker handling the process and cleaning equipment is specially trained and obliged to wear the personal protection equipment. Furthermore, each production site of Rockwood Lithium undergoes a special risk management	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 **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**

		routine to assess safety measures on a regular basis. One can conclude that boric acid does not feature any threat a thread during the process nor the use of the final products; a prohibition of boric acid does therefore not result in a higher safety level for human beings and environment. Number of people exposed The number of people exposed to or working with boric acid is very low, representing just one trained employee during the process of material transfer. Beside this, all workers are well trained professionals in the production process of LiBOB. Conclusion Inconclusion, the use of boric acid does not feature any risk for the safety of our workers and users of the related products. Due to an intense training and appropriate safety measures the risk of contamination is minimized. A prohibition of boric acid does not contribute to an increased safety level. From the application point of view, the prohibition of boric acid will favor products which are much more harmful when used in batteries; this in turn will lead to a negative impact of the battery industry and result in products which are much more dangerous when being used and deposited at the end of the product life cycle. A potential recycling will be hampered and the relaase of toxic byproducts will be much more difficult to be controlled.	
2778 2014/11/28	Europacable, Industry or trade association, United Kingdom	Boric acid in flame retarder of PVC can only be replaced by antimony trioxide, a heavy metal, which is not preferred.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives **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
2785 2014/11/28	Aurubis AG, Company, Germany	See detailed information in the attachment (section V). *Confidential attachment removed*	Please see references to responses in section I
2788 2014/11/28	Federchimica, Industry or trade association, Italy	Federchimica by means of this document considers useful to point out that it is unjustified to proceed with the Authorization process for boric acid / borates. Below are the uses for which boric acid / borates are essential and for which there are not, to date, alternatives which are viable both in terms of performance and in economic terms. Sectors impacted by any bans/restrictions in the use of boric acid/borates. CERAMIC PAINT - PRODUCTION OF FRITS The importance of the frits sector related to the uses of borates is well known, as was indicated in the Danish proposal of inclusion of disodium tetraborate anhydrous in Annex XV of REACH. Table 4 of the mentioned document describes that glass and ceramics amount to 65% of the relative uses of borates in industry. Moreover, this document specifies that the demand for borates in the frits and ceramic sector has increased in the past years, and that the expected tendency is a 2-4% increase per year over the next five years. Besides, other reports prepared by the European Commission specifically state that "one of the largest uses of borates in Europe is in frits and glazes for ceramics. Use of borates in frits Boron is introduced in the formulation of frits by means of different raw materials that fall in the generic description of "borates" (e.g. boric acid, boric oxide, disodium tetraborate…). Borates are well-known to contribute decisively in the formation of the vitreous structure of the frit and other similar materials (e.g. glass). Together with other compounds (e.g. silica), borates are typically grouped as "network formers" due to their recognised ability to act as generators of the glassy matrix that constitute the frit. The generation of Si-O-B bonds are particularly known to take part in the generation of the vitreous matrix. Intermediate use of borates in the manufacture of frits During the manufacturing process of frits, borates are chemically transformed	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.2.4: 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**

		into a complex solid solution in the form of a vitreous matrix containing boron. During the different chemical reactions that take place in the process, chemical bonds of the raw materials are broken, and atoms are rearranged within the vitreous structure of the newly formed substance, i.e. the frit. As explained above, the structural properties that borates bring to frits are extensively recognized in scientific literature. For this reason, it is considered that the use of borates in the manufacture of frits match the definition of intermediates as indicated in Article 3(15) of the REACH Regulation. More details in Annex II. FERTILIZERS Boron is one of the 7 essential micronutrients for plants, which is fundamental for their growth and development. 5% of the European production of boric acid and borates is used in this industry. That's why the consumption of these substances as fertilizers is increasing. The new classification of the listed products based on boron is a big problem for the fertilizer industry, in fact, the boron in these forms is present in many formulations. It is known that this element is essential for all cultivated plants and is particularly lacking in many parts of Italy and in the Mediterranean area; Boron is not present in constitutional form in Italian soils, so contributions through foliar products, in particular on fruit crops, are rather important. Boric acid and borates are one of the cheapest forms to distribute or to produce other borates compounds usable for the same purpose. The impact is certainly important also from a technical point of view for the farmers, who will have difficulty in distributing this essential element. For example, in order not to exceed the threshold above which the product is considered repro-toxic, compared to 1 kg of fertilizer based on sodium octoborate or boric acid, you will need to distribute 9 kg of a formulation containing 0.9% of boron. Since, to limit the used quantities and to improve its effectiveness this form of distribution is made through foliar applications, it will be impossible to achieve these applications and their cost would be huge superior. The fertilizer industry will be heavily penalized even in exports to countries where REACH is not applied. The ban in the use of boric acid and sodium tetra borate would result in the elimination of a large number of fertilizers containing boron and will have a considerable economic impact. It is estimated that, due to limitations in the use	**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** **C.3.1: Claim that solutions below the specific concentration limit should be exempt from authorisation**

		of boric acid and borates, the reduction in revenue for many domestic companies producing fertilizers will be about 6-8%. Considering this point it is evident that there are no alternatives to the use of boric acid/borates in fertilizers unless other derivatives of boron as borate of calcium and boron-ethanolamine (obtained, however, by boric acid). The characteristics of boron-containing fertilizers are defined in the EC Regulation 2003/2003 (Annex I, section E). A survey performed by Federchimica among its members shows that: Referring to volumes from 1-100 tons/year used for the production of fertilizers the volume of the final product containing boron may exceed 10000 tonnes. These products contain a concentration of Boron not exceeding the 0,5%. STICKERS (MAINLY FOR PAPER PROCESSING INDUSTRY) Borates are used in the preparation of different types of adhesives, in particular in the field of adhesives for paper. Boric acid and borates are mainly used in the following products / applications: - adhesives based on dextrin for the production of spiral tubes of paper; - casein-based adhesives for the labeling of glass bottles and other containers; - adhesives based on polyvinyl alcohol and polyvinyl acetate for the production of spiral tubes and for the manufacture of paper articles (eg. for bonding of the various layers of corrugated cardboard). Currently ,a viable alternative to borax exists only in the use with dextrin, but at the moment it has not yet become established because it involves the classification of the adhesive as R34 or R41 depending on the concentration and it is also more expensive. The adhesives based on casein could be replaced by synthetic adhesives based on acrylic polymers, while adhesives based on polyvinyl alcohol may be reformulated with cuts of ethylene polymers. These alternatives, however, would be less easily biodegradable and would entail an increase in costs of production and, therefore of the finished product. Moreover as far as the omo-polymeric vinyl adhesives (PVAc) are concerned, there are no current alternatives that allow us to achieve the same application properties obtained with the borates. The possible reason for the particular efficiency of boric acid in this application may be due to specific interactions that boron is able to establish with the hydroxyl groups of polyvinyl alcohol used in these formulations, interactions not replicable using similar compounds of elements with different electronegativity, electronic configuration and atomic	

		size. Generally, without borates, the production of adhesives for the above mentioned applications would become much more expensive without obtaining the same application properties, customers should apply greater amounts of product in thicker films, also machineries should work at a slower rate thereby leading to a slowdown in production. INDUSTRIAL FLUIDS The GAIL brings together all the active companies which are operating in Italy in the Italian field of industrial lubrication. One of the main activities of the members is the production and sale, both in Italy and abroad, of cooling lubricants for metal working. The cooling lubricants are necessary to carry out machining and are widely used in all mechanic's workshops, both in the small one who normally carry out contract work, and in the large ones such as the big carmakers. The cooling lubricants are sold to customers in a concentrated form and they are diluted with water, to form emulsions, usually in percentages varying between 3 and 10%, which are used on machine tools. Some essential features for a good cooling lubricant are: ☐ Long life of the emulsions, which must not degrade for formation of bacteria and / or fungi and must maintain a high pH stability (normally between 8.5 and 9.5) to avoid formation of corrosion on processed parts; ☐ Excellent compatibility with operators: it must not develop bad odors and should not be irritating for skin and eyes; ☐ It should not be classified as hazardous. Most cooling lubricants produced in Italy and in Europe contains boric amides (synthesis products between boric acid and primary or tertiary amines)which have anti-corrosive functions and stabilize the pH, to allow, as mentioned, long durations of the emulsions in exercise, which generally work lots of years. The volume of cooling lubricants sold in Italy is about 15.000 tons / year, which are used to prepare approximately 300.000 tons of emulsion (which therefore contains about 285.000 tons of water): cooling lubricants are essential and there's no alternative to use it in machining. The only theoretical alternative would be the use of whole lubricating oils, mineral-based, to be used pure and no more in emulsion, but in this case the required volume - due to the lack water solubility of these lubricants - would be about 230,000 tons / year (total consumption of lubricants for industry in Italy) versus the above mentioned	

		15,000 tons / year of cooling lubricants sold today throughout the country. This would lead to a dramatic worsening in workers' health, in environmental protection and in cost for end-users. Now cooling lubricants have a boron content of 0,5-1% and therefore the total contribution of boric acid placed annually in the market is equal to approximately 900 tons. A study carried out by the German DGUV (Annex I) shows that even if the content of boric acid in the cooling lubricant is very high, the higher than the 5,5% specified by law as the limit for the labeling of the preparation, the content of free boric acid in the cooling lubricant is much lower than this limit. To date there are no working alternatives to the use of boric acid derivatives in the field of metalworking fluids. The only alternatives are, according to us , more damaging than boric acid, and can be summarized in: - Use of amines (the most used is the dicyclohexylamine) - Increased use of biocides - Use of phenoxyethanol / Phenoxypropanol We suggest therefore, in the interest of the health of the large number of metal workers involved and of the environment in which we live, to enter boric acid in the XIV attachment or at least not to delete the specific limits that, until now, have allowed us to have a product that meets the above conditions: its inclusion in Annex XIV would cause the immediate removal from the market, certainly without waiting for the latency periods specified in the Rules. ABRASIVE OILS In the Abrasives field the use of borax (sodium tetra borate decahydrate) is typical of the producers of vitrified rigid abrasives with inorganic bond. Borax is used as a low-melting (the substance has the function of lowering the melting temperature of the binder), allowing significant energy savings and hence lower CO2 emissions. In addition, borax and boric acid are substances used even in frits for the manufacture of abrasive disks then completely falling back in "Ceramics" themes (also in this application, after the melting, the borates are not made available). OTHER USES Boron in used as crosslinker in the production of galactomannans and galactomannan derivatives used in different applications like textile, paper, oil	

		and gas industries. Boron compounds, reacts in alkaline medium as typical crosslinking agent, giving different physical properties to the natural polymer useful for specific applications. Other use is as purifying auxiliary agent. The use of these products are strictly controlled as intermediate chemical for environmental and workplace activities. These specific applications can be heavily affected by boron authorization with immediate delocalization of production of these chemicals where the residual quantity of boron available is below the classification threshold CONCLUSIONS. Boric acid / borates are therefore irreplaceable, in many applications and could be replaced only in very few cases with no evidence of better performance. The obligation to authorize the placing on the market and use of boric acid / borates can cause the disappearance of production in the European market of many essential and useful products, which carry no risk neither for consumers nor for the environment, without protecting, at the same time, the European market from the entrance, from outside EU countries, of finished articles containing such substances or of mixtures containing such substances below the lowest of the concentration limits that would result in classification as dangerous (art. 56.6.b). Federchimica believes that: 1. It is inadequate, in the light of what said, to promote the inclusion of these substances in Annex XIV. Every possible action should be based, as required by REACH, on a "risk-based" approach; 2. it is desirable to provide exemptions from the authorization for specific uses of the substances for which, for example, technical progress and / or controlled exposure ensure that there is no particular concern for man and environment; 3. it is important to note the significant fallout of a possible elimination of the specific limits, for all the branches mentioned above, as shown in the individual sections; 4. in general it is essential that, to identify any substances for authorization process, you apply objective criteria that consider also the exposure and any risks posed by them. This has to happen both in the phase of identifying for the candidate list (anticipate some RMO elements) and in the phase of prioritization, where criteria should be applied on the basis of "objective risk" posed by substances, taking into account also the measures of risk management already existing.	

		2788_Annex I.pdf *Confidential attachment removed*	
2792 2014/11/28	Industry or trade association, Belgium	Please see attachement	Please see references to responses in section I
		2792_FEFCO comments on uses that should be expemt from the 6th ECHA priority list for authorization_to ECHA.pdf	
2793 2014/11/28	Evonik Industries AG, Company, Germany	(1) All industrial uses should be exempted from the authorisation requirement. The main reasons are: (1.1) Safe use of boric acid is possible because a threshold for adverse effects exists. (1.2) Industrial standards for occupational safety and hygiene are high in the member states. (1.3) In view of the extremely low vapour pressure of boric acid, transport with surface waters is the only relevant route of environmental exposure to boric acid from industrial plants. It is restricted to a well-defined and minor section of the environment where monitoring of concentrations and effects can be easily achieved. [According to handbook information boric acid is converted into diboron trioxide when heated. Diboron trioxide has a melting point of 450 °C, which implies a vapour pressure below 1013 hPa even at this temperature.] (1.4) Application and results of exposure control at industrial plants may be checked with enforcement activities. (2) All professional uses where formation of dust is excluded should be exempted from the authorisation requirement. The main reasons are: (2.1) Indirect exposure via the environment can be neglected because - releases are low and - environmental transport processes are both very slow and associated with very low concentrations - while a safe exposure level exists. (2.2) Assuming usual occupational hygiene practice, dust inhalation and ingestion appears to be the most likely route of exposure. Skin penetration might be more relevant, so its relevance should be determined in appropriate studies before imposing restrictions or even banning boric acid.	**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 **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)** **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**
2794 2014/11/28	Chemlink Specialities Ltd,		Please see references to responses in section I

	Company, United Kingdom	*Confidential attachment removed*	
2796 2014/11/28	Company, Netherlands	Use of the substances in culture media in biotechnology, pharmaceuticals and in vitro diagnostics. 2796_AMFEP 14_56 Letter of concern ECHA recommendation on Boric acid.pdf	**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**
2797 2014/11/28	ABB Kabeldon, Company, Sweden	We propose an exemption for boric acid in electroplating of electrical contact equipment. No substitute is known today and the risk for exposure is considered to be low. We are continuously working on evaluating our use in accordance to Swedish law** to ensure proper protection. The benefit for the society, the environment and from indirect safety risks is bigger than the health risks from our use of boric acid. ** AFS 2011:19, Kemiska arbetsmiljörisker, Arbetsmiljöverkets föreskrifter om kemiska arbetsmiljörisker samt allmänna råd om tillämpningen av föreskrifterna Electrical contacts, Review and recent developments 2797_Electrical contacts, Review and recent developments.pdf	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of 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.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**
2798 2014/11/28	BP Europa SE, Company,	No specific comments on this aspect 2798_Boric acid additional information.zip	Please see references to responses in section I

	Germany		
2800 2014/11/28	ACEA, Industry or trade association, Belgium	By placing the borates on Annex XIV, we anticipate the need to extend further the authorization for chromium VI compounds in the plating process. 2800_20141128_Proposal for annex XIV recommendation on Borates Final.pdf	**B.2.2: Concerns about workload, timelines and resources needed for those companies already dealing with Cr(VI) applications**
2801 2014/11/28	Company, Spain	Use in Agriculture / Fertilizers' manufacturing Boron is an essential nutrient for crops in order to obtain proper growth and yields. Ways available to introduce this essential micronutrient are almost exclusively limited to the use of this chemical compound. The fact of leaving this nutrient out of the fertilizers' formulas can have very negative consequences over different aspects: •Crops' health. It is obvious that if boron is not supplied, crops are going to suffer all the problems that come from its lack. Liebig Law •Economic impact. As a consequence of the fact written above, farmers will have to use higher quantities of agrochemicals in order to overcome those lacks, or at least, decrease its negative impact. •Environmental pollution. If a higher quantity of agrochemicals are used, pollution suffered by ground waters and soils in general will be increased considerably. •Nutritional security. It is demonstrated that borates decompose quickly, having a very low risk of getting into the food chain. It is sure that incrementing the number and quantity of agrochemicals used to obtain the same crop yields, will step up the probability of having nutritional problems.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 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** **C.2. Responses to exemption requests referring to other legislation**
2802 2014/11/28	FRANCISCO. R. ARTAL, S.L., Company, Spain	2802_BORON.docx	Please see references to responses in section I
2804 2014/11/28	Individual, Spain	In agriculture, Boron cannot be substitued.It is an historical use, a lot a crop need Boron and without its application the production is imposible. Boron is now known to be essential for cell wall structure and function, likely through its role as a stabilizer of the cell wall pectic network and subsequent regulation of cell wall pore size. A role for B in plant cell walls, however, is inadequate to explain all of the effects of B deficiency seen in plants. The	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 5. Availability of suitable alternatives

		suggestion that B plays a broader role in biology is supported by the discovery that B is essential for animals where a cellulose-rich cell wall is not present. Careful consideration of the physical and chemical properties of B in biological systems, and of the experimental data from both plants and animals suggests that B plays a critical role in membrane structure and hence function. The use of Boron like fertilser is not dangerous because crops needs a few quantity of boron and in punctual way, the products do not contain high concentration of Boron.	**C.2. Responses to exemption requests referring to other legislation**
2806 2014/11/28	Slovenske elektrarne, a.s., Company, Slovakia	We propose to exclude the specific use of Boric acid in nuclear power plants from uses which are subject to authorisation. Reasoning: Boric acid can not be substituted by another substance in nuclear industry, benefits of using the substance outweigh the risks and there are no suitable alternative substances or technologies. Handling with Boric acid is performed only by high professionally trained nuclear stuff under controlled conditions.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 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** **C.2. Responses to exemption requests referring to other legislation**
2810 2014/11/28	Company, Spain	Endeka Ceramics express its support to the diferent documents and comments issued by Frit Consortium and EBA about the Considerations on the use of borates (boric acid) in the manufacture of frits and the authorisation process under REACH.	Please see response to comment #2633 (Frits consortium) Please see response to comment #2524 (EBA comment)
2816 2014/11/28	Company, Netherlands	Use of boric acid (cas nr 10043-35-3) for production of etched and formed anode foil for use in electrolytic capacitors and for production of electrolytic capacitors	**C.1.1. General principles for exemptions under Art. 58(2)** **C.1.2. Generic exemptions**

		Confidential attachment removed	**C.1.3. Aspects not justifying an exemption from authorisation**
2818 2014/11/28	Company, Slovakia	Boric acid is used as biochemical substrate. Industrial and laboratory operations commonly use fermentation processes to produce substances for the pharmaceutical sector such as proteins, peptides, vitamins, industrial enzymes. Many of these substance are manufactured in large industrial scale fermenters i.e. vessels in which microorganisms grow under controlled contained conditions to produce a valuable compound of interest. In industrial scale fermentation processes, the production organisms are typically controlled in a complex fermentation medium. A complex medium is understood to be a medium comprising a complex nitrogen and carbon source such a soybean meal, cotton seed meal, corn steep liquor, yeast extract, hydrolyzed casein, molasses, and mixture trace vitamins, minerals and elements. One of the primary advantages of utilizing complex media in fermentation is that a wide range of raw materials is available to allow a complete or nearly complete source nutrient source to specific microorganisms. However some substances in the media may not be readily available for organisms. Within many industries, highly refined, high-producing microbial strains have been developed for industrial processes on complex media. To maintain their good performance in media, catalytic elements are commonly needed to utilize specific or enzyme cofactors in the processes. These elements include biogenic substances like iron, cooper, calcium, manganese, zinc, cobalt, molybdenum, selenium, barium, boron. Boron is involved in the processes of calcium and phosphorus uptake of the microorganisms and has influence on the saccharide, protein and nucleoside metabolism; it also plays an important role in stabilizing the cell membrane. The only available source to supplement the boron needs of microorganisms is boric acid or sodium tetra borate. In some specific cases, the use of trace amounts of boric acid is also specifically	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. **C.2. Responses to exemption requests referring to other legislation**

		used to direct the forms of an active molecule and enzymes or to inhibit the production of other substances generated in the fermentative process. Many pharmaceutical products derived from such fermentations therefore depend on the use of boric acid. We hence would ask that the use of boric acid as biochemical substrate in fermentation processes and in the production of dehydrated culture media is exempted from the REACH authorisation requirement.	
2829 2014/11/28	Norway, Member State	The Norwegian CA does not support that any exemptions from the authorisation requirement should be proposed.	Thank you for your support
2835 2014/11/28	Intermag Sp. z o.o., Company, Poland	2835_boron consulatation.pdf	Please see references to responses in section I
2837 2014/11/28	Company, Denmark	It is our opinion that the risk associated with the use of boric acid as a biologically essential nutrient in the manufacturing of pharmaceutical active ingredients on the basis of fermentation is comparable to the risk when used in R&D activities, which is exempt from authorisation. Taking this and the very low quantities into account, we consider the costs and burdens related to authorisation of Boric Acid used as a biologically essential nutrient disproportionate. We suggest that boric acid for this use is exempt from authorisation.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban **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)** **C.2. Responses to exemption requests referring to other legislation**
2838 2014/11/28	Vattenfall AB; registration no.: 12955024114-93, Company,	Using boric acid in nuclear electric power plants is vital to control nuclear fission reactions and to ensure nuclear safety. Boric acid is used in all pressurized water nuclear reactors around the world (and to a lesser extend in boiling water nuclear power plants); no other chemical compound has the same	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives

	Sweden	characteristics required to replace boric acid for this use as expected in the authorization process. Boric acid is also used for its neutron absorbing capacities within the fuel cycle and during dismantling. Moreover boric acid is used in the glass for nuclear waste in Germany. The uses containing boric acid that are applied in the nuclear power plants are mostly via closed systems inside controlled area as defined by EU Directive 2013/59/EURATOM. The only process with intrinsic personnel contact is during the fabrication of the solution. To protect worker health both technical measurements are installed and personal protection equipment, like protection gloves and dust masks FFP3, is used. Boric acid is classified as toxic for reproduction Category 1B according to EU Regulation 790/2009 (belongs since then to the CMR substances) and therefore requires a safety data sheet according to Regulation 1907/2006 also defining it´s content and the personnel safety measures when dealing with this substance. The safety data sheets are used for establishing operator´s guidelines for handling chemicals following a mandatory risk assessment in hazardous working environments. This process is required by national labor protection law which is implementing the EU Council Directive 89/391/EEC. Consequently the uses of boric acid on nuclear sites are established following EU regulation. Consequently, if the above arguments for the re-evaluation of boric acid as member of the candidate list is not followed it is suggested to exempt nuclear uses from authorization, as EU legislation (and subsequent German and Swedish law) is applied to secure the uses of boric acid in nuclear power plants and therefore could be regarded as a candidate to fulfill the criteria for an exemption for nuclear industry mentioned in article 58 (2) of EU Regulation 1907/2006: "Uses or categories of uses may be exempted from the authorization requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled."	**C.2. Responses to exemption requests referring to other legislation**
2843	Freiberger Compound		Please see references to

2014/11/28	Materials GmbH, Company, Germany	2843_Freiberger - comment for boric acid to the ECHA consultation on the 6th priority list.pdf	responses in section I
2848 2014/11/28	Company, United Kingdom	 *Confidential attachment removed*	
2850 2014/11/28	European Diagnostic Manufacturers Association, Industry or trade association, Belgium	The use of boric acid in biological fermentation should be exempted from authorisation requirements on the basis that boron is an essential micronutrient which can never be substituted. Minute amounts are used annually for this purpose. Authorisation is not an appropriate regulatory mechanism to address the risk of exposure for use of a substance as an essential nutrient.	**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**
2858 2014/11/28	Company, France	The formulation of mixtures containing Boric Acid below the Specific Concentration Limit should not be subjected to authorization because their use is exempted.	**C.2. Responses to exemption requests referring to other legislation** **C.3.1: Claim that solutions below the specific concentration limit should be exempt from authorisation**
2864 2014/11/28	Company, Spain	For the application of intermediate that the sustance takes part of chemical reaction or other aplications where the material is included in articles for friction material, abrasive products ... we have any evidence of any small problem that the substance had produced. Based on ecomics reasons, there are not alternatives to replace this substance in our formulas in order to abtain the same reults and continuing having good health conditions.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 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**
2870	European Borates		Please see references to

2014/11/28	Association, Industry or trade association, Belgium	2870_EBA comments - ECHA PC - 6th priority list - glass-frits.pdf	responses in section I
2875 2014/11/28	Company, France	 2875_EBA comments - 6th priority list (final).pdf	Please see references to responses in section I
2878 2014/11/28	Company, France	SU3 - SU24 PC0 : Use as micronutrient in plant cell culture 2878_Additional non Condidential information.doc	**C.2. Responses to exemption requests referring to other legislation**
2879 2014/11/28	Company, Sweden	Boric Acid serves an important role in radiation protection and promoting global healthcare, by enabling production of Positron Emission Tomography (PET) radio isotopes. GEMS Pet Systems AB uses Boric Acid for radiation protection/attenuation. Boric acid is essential for nuclear safety which requires the Boron isotopes. The cross section of the Boron is many times greater for neutron capture than other elements. This is also the reason why nuclear plants use Borate mixtures as an emergency protection to stop a potential non-controlled reactor activity. Boric acid is mixed with Sodium tetra borate and dissolved in water to form a solution. The mixing operation is carried out by trained and authorised personnel. The final solution is then transferred to several large stainless steel tanks, which are then placed strategically around the cyclotron. Finally, panels of lead are mounted in the water tanks. This completes the assembly of the radiation shield around the cyclotron providing radiation protection. The mixed Water/Boron solution remains sealed inside the tanks throughout the lifetime of the cyclon which is a minimum of 20 year. The annual volume used in this application is estimated to 7500 kg. Currently, there is no viable substitute for Boric acid that is available with the same properties as Boron for the attenuation – neutron capture. Boron is used for its efficiency in neutron shielding, capture and attenuation, and providing radiation protection for workers and environment. There are currently no known technically viable alternatives to the use of boric acid for the neutron capture in the shielding required for radiation protection in the application of a cyclotron. We believe the use highlighted above should be specifically exempted from any future provisions of REACh Annex XIV. For its efficiency in neutron shielding, capture and attenuation, and providing	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 5. Availability of suitable alternatives **B.2.4: Investment cycles should be taken into account** **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**

		radiation protection for workers and environment, GEMS Pet Systems AB requests ECHA exclude this use application from the requirements of authorization in Annex XIV. If ECHA decides not to exempt this essential use of Boric Acid and recommends the "Authorisation" route as the preferred risk management option, then we strongly believe that this would negate the current safety measures afforded by the use of Boric Acid. It would further compromise human safety and result in highly technical challenges which cannot be overcome given the current technologies available to the nuclear industry. In case this use ECHA does not exempt this use from the authorization requirement, taking into account the scientific and technical requirements to develop, validate and qualify a change a replacement technology, We request ECHA set a review period not less than 40 years for this use of boric acid in the neutron capture in the radiation shielding with the cyclotron technology.	
2882 2014/11/28	EDF Energy, Company, United Kingdom	Please see the attachmed document for EDF Energy's full set of comments on the recommendation to include the substance in Annex XIV. 2882_28112014 ECHA Boric Acid Position FINAL.pdf	Please see references to responses in section I
2889 2014/11/29	ECIA European Cellulose Insulation Association, Industry or trade association, Belgium	The use of boric acid as a fire retardant in cellulose insulation shall be exempt from authorisation. The use in this case is absolutely safe: The exposure amounts for workers are much lower that any amount which could have reprotoxic effect. Please see the document provided by EBA regarding the risk. According to REACH, it is possible to go for authorisation, restriction or to limit the exposure. As the exposure is already limited and the use of boric acid is safe, it is not necessary to go for authorisation.	Please see response to comment #2524 (EBA comment) **A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks **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
2905 2014/11/30	ZVO/ VECCO, Industry or trade association, Germany	Please read: IV. Attachment (additional non-confidential information) to comments on ECHA's draft recommendation 2905_2014-11-30 Comment on Boric Acid Joint Application Surface technology.pdf	Please see references to responses in section I
2906 2014/11/30	Individual, Netherlands	Use as micronutrient/ingredient of fertilisers can be exempted from the authorisation requirement: It concerns application to correct a low background boron concentration in agriculture setting, needed for optimal plant growth. The application is done by professionals only, under risk controlled conditions, ensuring that exposures will never be sufficient to lead to a risk.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks **C.2. Responses to exemption requests referring to other legislation**
2923 2014/11/30	Company, Belgium	*Confidential attachment removed*	Please see references to responses in section I
2926 2014/11/30	Individual, Poland	Boric acid (as well as sodium borates) are used as „mineralizers" during synthesis of ceramic pigments. The amount of boric acid in charge is usually 0.1-3%. Boric acid is very effective in lowering of temperature synthesis and has smaller influence on environment then alternatives (halides).	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 5. Availability of suitable alternatives **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**
2930 2014/11/30	Association of European Airlines, Industry or trade association,	Some uses of boron compounds are covered by BPR regulation (EU) 528/2012	**C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other**

	Belgium		**legislation**
2948 2014/12/01	European Federation of Pharmaceutical Industries and Associations, Industry or trade association, Belgium	Please refer to the attachment. 2948_EFPIA comments_Boric Acid_Inclusion into ANNEX XIV_REACH.pdf	Please see references to responses in section I
2950 2014/12/01	ASD, Industry or trade association, Belgium	2950_ASD answer to ECHA consultation_General Conclusions for all Boron and lead compounds_281114.pdf	Please see references to responses in section I
2951 2014/12/01	Savroc Oy, Company, Finland	Without disputing the health and environmental risks associated with boric acid we request exemption to be made for the use of boric acid in metal plating processes in general and specifically in chrome (III) plating process. Also, we do agree that suitable protective measures has to be taken to protect the employees, especially regarding the inhalation of the dust. The reasons why we believe the plaiting industry should not be subject to authorization are that the usage of boric acid takes place in controlled industrial environment where risks can be minimized by using good industrial practices. Also, the amounts used are relatively small and it is not part of the end product. Additional reasons why we believe the chrome (III) plaiting industry should not be subject to authorization are that chrome (III) plating is much safer than chrome (VI) plating. As chrome (VI) is going to be subject to authorization it is giving incentive for the industry to switch to chrome (III) where possible, but only if authorization is not required for the chrome (III) plating process. If the authorization is required for both processes, the incentive is gone. To our knowledge boric acid is part of all commercial chrome (III) plating processes. At the present chrome (III) is suitable only for decorative plating. Hard chrome can be made only by using chrome (VI). That will change as we have developed a technology for making hard chrome plating based on commercial chrome (III) chemistries. Again, there is incentive to switch from chrome (VI) process to chrome (III) process only if chrome (III) process doesn't require authorization. Even if boric acid free plating processes become available for decorative chrome (III) plating it is not necessarily suitable for our technology.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks **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)** **C.3.4: Claim that uses which can replace Cr(VI) should be exempt from authorisation** **C.3.5: Claim that products not containing the substance in the final product should be exempt from authorisation**

		We believe that chrome (VI) is more dangerous than boric acid and the consumption of chrome in chrome (VI) process is much higher (being the component that is consumed in the plating process) than consumption of boric acid (being non consumed buffer component in the bath, losses being only due to drag-out) in chrome (III) process. Therefor it would support ECHA's goal of reducing hazards from dangerous chemicals to exempt boric acid used in chrome (III) plating processes from authorization. Naturally ECHA can later include boric acid used in chrome (III) in authorization if there will not be reasons for exemption in the future. 	
2956 2014/12/01	ASD, Industry or trade association, Belgium	 2956_ASD answer to ECHA consultation on BORICACID_281114.pdf	Please see references to responses in section I
2963 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 section I
2964 2014/12/01	CEA, Company, France	 2964_PC-ECHA-boric_acid-comment_CEA_nov2014.pdf	Please see references to responses in section I
2973 2014/12/01	GIFAS, Industry or trade association, France	Please refer to attached letter 2973_20010_ECHA_Annex XIV_Boron_substances.pdf	Please see references to responses in section I
2988 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,	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 5. Availability of suitable alternatives **A.2.19: Alternative substances are usually less well known and might have a higher risk** **A.2.20 Claim that the socio-**

		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 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.	**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**
2990 2014/12/01	Company, Netherlands	Some uses of boron compounds are covered by BPR regulation (EU) 528/2012.	**C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation**
2991 2014/12/01	EURELECTRIC, Industry or trade association, Belgium	2991_EURELECTRIC-statement boric acid-final.pdf	Please see references to responses in section I
3001 2014/12/01	FORATOM, Industry or trade association, Belgium	3001_FORATOM-boric acid-ECHA-VF.docx	**C.2. Responses to exemption requests referring to other legislation**
3002 2014/12/01	European Semiconductor Industry Association, Industry or trade	Preferred Alternative to Authorization under REACH There is extensive EU Community wide legislation that the semiconductor industry sector is subject to which governs the risk of exposure to chemicals. ESIA believes that the most efficient and practical way of managing the risk of	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 5. Availability of suitable

	association, Belgium	occupational exposure to chemicals critical to the semiconductor sector would be through the continued application of work place legislation such as the Chemical Agents Directive and the IEOL Directive in conjunction with all the elements of the REACH regulation outside the authorization provision such as the use of DNELs and exposure scenarios backed by solid communication in the supply chain which is all geared towards the control of the risk. ESIA would recommend that work place legislation such as the Chemical Agents Directive and the IEOL Directive is continuously amended so that the latest scientifically derived data is applied in order to derive indicative or binding occupational exposure limits as appropriate. Currently no such limit exists for boric acid. Nevertheless the semiconductor industry companies diligently research to determine the most up to date applicable threshold limits to apply based on national and international guidelines and standards in the absence of Community legislation in order to ensure worker protection. In this way ESIA member companies would be able to put forward a cogent argument for exemption from authorization. ESIA would welcome that EU Commission, Member States and ECHA when assessing cases for authorization exemption and indeed when conducting Risk Management Options Analysis, consider the rigorous application of the existing workplace legislation OELs as well as REACH DNELs as viable measures to manage risks in an industry such as the semiconductor industry which has tightly controlled manufacturing process with closed system processing as well as a highly complex and integrated manufacturing process where material substitution is technically and economically challenging. 3002_ESIA Input to the ECHA Public Consultation_BoricAcid_PDF Dec 1 2014.pdf	alternatives **A.2.11: Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV** **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)
3007 2014/12/01	Bundesverband Keramische Industrie e.V., Industry or trade association, Germany	Cerame-unie has attached in section IV a response requesting the exemption Borates from the authorization requirement for the industrial use of this substance in the manufacture of piezo ceramic materials and in the production of other ceramic materials or glazes.	Please see response to comment #3011 (Cerame-Unie)
3011 2014/12/01	Cerame-Unie - the European Ceramics Industry Association,	The use of borates in the manufacture of frits is exempted from authorisation as it is used as an intermediate. Cerame-Unie refers to the input provided by the Frits consortium in this respect.	Please see response to comment #2633 (Frits consortium)

	Industry or trade association, Belgium	Borates are also used as an intermediate in the manufacturing process of boron carbide, boronitride, titanium boride, zirconium boride and calcium boride.	**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** **C.1.2. Generic exemptions**
3018 2014/12/01	Ministry of Foreign Affairs, National Authority, Chile	COMMENTS FROM CHILE RELATING TO THE PUBLIC CONSULTATION FROM ECHA: RECOMMENDATION FOR INCLUSION IN THE AUTHORISATION LIST First of all, we would like to thank EU for providing the opportunity to make comments. Boron (B) is an essential micronutrient for several crops. Essential micronutrients may be defined as those without which plants cannot complete their life cycle, irreplaceable by other elements (Fageria et al., 2002). Specifically, Boron is involved in the process of uptake and metabolism of cationic plant nutrients, particularly Calcium. It is also essential for cell wall rigidity (Findeklee, and Goldbach, 1996; Goldbach et al., 2001; Yu et al., 2003, cited by Marscher (2012)), pectin, nucleic acid and protein synthesis and in phloem translocation of carbohydrates (Broadley et al., 2012). Boron plays a critical role in pollen germination and pollen tube growth, thus directly affecting crop production (Razeto, 1993). The incidence of micronutrient deficiency has increased due to an intensive production and soil conditions. Crops known as being sensitive to B-deficiency include a wide range such as apple, cotton, grape, citrus, olive, oilseed rape, celery, and carrot. In Table Grapes, signs of deficiency include necrosis in the bud tip, apex and leaf, interveinal chlorosis, and swollen internodes, deformed roots (choral like) and in Tomato it is evidence by corky areas near the calyx or on the shoulders of the fruit on plants. Differences between Boron sufficiency and toxicity to plants are narrow (Fageria	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.2.8: 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** **C.2. Responses to exemption requests referring to other legislation**

		et al., 2002); therefore its application requires a control. Boric acid is one of the main commercial sources of Boron, commercially available as such and also available for soil and foliar application as micronutrient in EC fertilisers containing primary and/or secondary nutrient(s). According to Regulation (EC) 2003/2003, the minimum content of Boron in EC fertilisers (to be declared as B containing) is 0,01 % for crops or grassland, horticultural use and leaf sprays. Within the EC, boric acid is classified as Toxic for Reproduction, Category 1B, H360-FD. The harmonised classification has assigned an specific concentration limit (SCL) of 5,5 %. This implies that mixtures containing less than 5,5 % are not classified as toxic to reproduction according to Annex VI to Regulation (EC) No 1272/2008 (CLP). ECHA's Generic Exemption from the Authorisation Requirement (dated 21 August 2014) includes "the use of substances when present in mixtures below the lowest concentration limits specified in….Part 3 of Annex VI to Regulation (EC) No 1272/2008 which results in the classification of the mixture as dangerous…". Accordingly if the substance is to be included in REACH Annex IV, we kindly request to explicitly include the exemption from authorisation requirements to those "EC fertiliser mixtures containing boric acid in a concentrations lower than 5,5% boric acid" . Chile would be grateful if the above-mentioned comments could be taken into account. Thanks. References Fageria, N.K., Baligar, V.C., Clark, R.B. 2002. Micronutrients in crop production. Advances in agronomy 77. Broadley, M., Brown, P., Cakmak, I., Rengel, Z y Zhao, F. 2012. Function of nutrients: Micronutrients. pp.233-243. In: Marschner, P. (Ed.). Marschner´s Mineral Nutrition of Higher Plants. 3rd Ed. Academic Press of Elsevier Ltd., San Diego, California, EEUU. 651p. Marschner, P. 2012. Marschner´s Mineral Nutrition of Higher Plants. 3rd Ed. Academic Press of Elsevier Ltd., San Diego, California, EEUU. 651p. Razeto, B. 1993. La nutrición mineral de los frutales. Deficiencias y excesos. Editorial Eves S.A. Santiago, Chile. 105p.	

3022 2014/12/01	LightingEurope, Industry or trade association, Belgium	1) Boric acid is used as a raw material and is an intermediate in the production of boron containing glass. E.g.: - BORO-SILICATE GLASS USED IN HIGH TEMPERATURE LAMPS IN GENERAL AND SPECIAL LIGHTING APPLICATIONS AND OTHER HIGH TEMPERATURE GLASS APPLICATIONS, ETC. - BORATE- AND BOROSILICATE GLASS FOR SPECIAL APPLICATIONS - BORON CONTAINING SODA LIME GLASSES USED IN UV-C AND UV-B TRANSMITTING LAMPS The main function of boron in a borosilicate glass is to increase the mechanical and chemical resistance and thermal shock resistance of the glass – so some of the lamp types where mechanical resistance and thermal stock resistance is essential cannot be manufactured without borosilicate glass components (CAS number is 65997-17-3) 2) Boric acid is used as a raw material and is an intermediate in the production of borate- and borosilicate frit glass. E.g.: - FRIT GLASS E.G. FRIT RINGS FOR CERAMIC LAMPS FOR SEALING OF OUTER BULBS - FRIT GLASS E.G. FRIT RINGS FOR AUTOMOTIVE LAMPS FOR SEALING OF OUTER BULBS TO THE BASE PLATE - FRIT GLASS IN STAMP PAD INK E.G. FOR GLS/TL /HID LAMPS, LIGHTING APPLICATIONS If the alkali content in the glass needs to kept at a low level, the boron containing ingredient to be used is boric acid. Addition of boron acid enables the reduction of the alkaline or earth alkaline contents of the glass. This results in improved chemical durability, lower electrical conductivity, higher mechanical strength, higher thermal shock resistance and thermally resistant glasses. Boric Acid is an essential and irreplaceable ingredient in the manufacture of borate, borosilicate glass and (ceramic) frit glass. 3) Boric acid is used as a raw material and is an intermediate and mixture in the	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. Please see response to comment #3022 in Section I

		production of Fluorescent coating of lamps for lighting applications. The raw materials will transform into glass material, Raw materials used in the manufacture of this glass meet the definition of intermediates as much as they are transformed into a new substance, namely glass. They are transported isolated intermediates, since they are produced elsewhere and transformed at the sites of Lighting Europe member companies Today, on the market, there is no alternative known with the same performance levels 4) Boric acid is used in a mixture in the Nickel plating bath for surface treatment for metal components used by Lighting industry. Boric acid is widely used as a donor of protons in the Watt-type Nickel plating baths in surface treatment industry. The use of Boric acid in the process make it possible to produce energy efficient lamps LED lamps with long lifetimes. Today, on the market, there is no alternative known with the same performance levels	
		3022_LE_consultation_Boric Acid_20141201_final_final.pdf	