01/07/2015

Comments and references to responses on ECHA's Draft 6th Recommendation for Diboron trioxide (EC number: 215-125-8)

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 Diboron trioxide (EC number: 215-125-8). 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_diboron_trioxide_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
2512 2014/10/15	European Catalyst Manufacturers Association (ECMA),	a. Use of diboron trioxide in hydrotreating catalysts Diboron trioxide contained in hydrotreating catalysts is produced during the calcination step and results in the full transformation of boric acid. Diboron	Thank you for your comment and the additional information provided. This will be taken into

	Industry or trade association, Belgium	trioxide can also be imported directly in catalyst mixtures. Diboron trioxide is also used as an intermediate in the generation other boron species in catalyst mixtures. Hydrotreating catalysts containing diboron trioxide are used in the petrochemicals industry. The function of a catalyst is to enable absorption of contaminants, thus facilitating the desired chemical reaction. Catalytic hydrotreating is a critical process in petroleum refining used to remove over 99% of contaminants such as sulphur, nitrogen, oxygen and metals from liquid petroleum fractions. In a typical refinery, the hydrotreating process takes place in a fixed-bed reactor that is packed with a series of hydroprocessing catalysts layers; each layer provides a different level of contaminant removal for the creation of cleaner burning fuels. Transitional arrangements b. Description of the supply chain Boric acid is bought or imported into the EU by catalysts manufacturers. The catalysts manufacturers produce or import Ni or Co catalysts and catalyst mixtures 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. Therefore, should borates be prioritized for authorisation, ECMA welcomes the proposal to assign borates to the latest LAD slots. 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 recommendation. 2512_20141015- Diboron ECHA consultation final (ECMA) Supply Chain .docx	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)
2523 2014/10/31	European Borates Association (EBA),		Thank you for your comment and the additional information

	Industry or trade association, Belgium	*Confidential attachment removed*	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**
2525 2014/10/31	European Borates Association (EBA), Industry or trade association, Belgium	2525_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**
2530 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). Diboron trioxid is used in several ready to use water quality tests. Total annual consumption is much less than one tone per year.	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

		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). 2530_ECHA attachments.zip *Confidential attachment removed*	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**
2535 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.	Thank you for providing your opinion. **A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban **A.2.15: Claim that exposure data shows low/no risks**
2539 2014/11/14	Company, Germany	Re-Classification of Diboron trioxide Re-Classification of Sodium Tetraborate Re-Classification of Boric Acid 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	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

		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 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	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**

		(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	

2577 2014/11/21	I&P Europe - Imaging and Printing Association e.V., Industry or trade association, Germany	The substance is classified as reprotoxic on the basis of animal studies. But epidemiological studies of borate mining and processing workers, and of 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.	**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 **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**
2588 2014/11/24	AREVA, Company, France	See comments on boric acid	Please see references to responses in comment # 2587 in the comments and references to responses document for boric acid.
2611	PROBELTE S.A.,	boron is considered as essential micro-nutrient for plants, and it can not be	Thank you for your comment and

2014/11/24	Company, Spain	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.	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**
2639 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**
2644 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 Diboron trioxide (EC 215-125-8), which make specific reference to the use of this substance in the manufacture of frits. 2644_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 also responses given to comments by European Borates Association (EBA) (#2525 and 2868). **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**
2645 2014/11/25	Asociación Nacional de Fabricantes de Fritas, Esmaltes y Colores Cerámicos (ANFFECC), Industry or trade association, Spain	The "Asociación Nacional de Fabricantes de Fritas, Esmaltes y Colores Cerámicos (ANFFECC)" would like to express its support to the comments issued by the Frit Consortium for substance diboron trioxide.	Please see responses given to comments by Frit Consortium (#2644).
2649 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
2654 2014/11/25	N.V. EPZ, Company, Netherlands	Diboron trioxide can be used to produce Boric acid, because Diboron trioxide reacts with water to Boric acid, which 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 7100ppm) 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 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 5 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**
2672 2014/11/26	UNIFA, Industry or trade association,	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.	Thank you for your comment and the additional information provided. This will be taken into

	France	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 recommendation included to the annex 14 of REACH regulation and that a Risk Management Option (RMO) is led. (See my attachment) 2672_Commentaires UNIFA_Novembre 2014_EN_VF.pdf	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, 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**

2682 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.	Thank you for providing your opinion. **A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban **A.2.15: Claim that exposure data shows low/no risks**
2698 2014/11/27	European Special Glass Association and European Domestic Glass Association, Industry or trade association, Belgium	2698_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**
2708 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*	Please see also responses given to comments by European Borates Association (EBA) (#2525 and 2868). **C.2. Responses to exemption requests referring to other legislation**
2724 2014/11/27	Wieland-Werke AG, Company, Germany	2724_Comments to 6th priority list of substances for inclusion in Annex XIV _ Wieland-Werke.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.1.1. 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 4. Control of risks **A.2.12: ECHA should not proceed with the 6th recommendation, when the 5th is still open** **A.2.13: Claim that risks for workers are controlled by other legislation** **C.2. Responses to exemption requests referring to other legislation**
2736 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.	Thank you for providing your opinion.
2746 2014/11/28	CMK, s.r.o., Company, Slovakia	2746_CMK's comments 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.1.1. General, recommendation process:** 3. Prioritisation approach applied

			A.1.2. Prioritisation: Volume **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:** 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.2.15: Claim that exposure data shows low/no risks**
2749 2014/11/28	Individual, Poland	Boric trioxide 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),	**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

		- volume used in the scope of authorization (score: 9), - wide dispersiveness of uses (disodium tetraborate, anhydrous is used at industrial sites and by professional workers, score: 12). Boric trioxide is nonorganic substance one of a lot of boron compounds. Similarly to 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 trioxide. Firstly we believe that all users of boric trioxide are adequately protected. - consumers are adequately protected through the restriction (REACH Annex XVII): boric trioxide 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 trioxide in concentration equal to or higher than 3.1% 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 trioxide or mixtures contained boric trioxide 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 trioxide or mixtures contained boric trioxide in such concentration which lead to classification of mixture as toxic to reproduction, Secondly, major uses of boric trioxide in the EU are outside the scope of authorization: □ boric trioxide is mainly used in the manufacturing of glass and frits (in these	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 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**

		uses the boric trioxide is qualifies as intermediate since is completely consumed and transformed into another substance - glass and frits) ☐ boric trioxide (and other borates) is used in mixtures below specific concentration limits ☐ boric trioxide 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 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 (boric trioxide) 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	**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**

		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 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 (boric trioxide) 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 trioxide at this time does not represent regulatory effectiveness and is not proportional.	
2809 2014/11/28	STMicroelectronics, Industry or trade association, France	1) General comments on the recommendation to include the substance in Annex XIV a. General context b. Use of the substance c. Diboron Trioxide doping process d. About Thyristors and Triacs e. Process description and exposure f. Quantity used / Quantity dispersed g. Limited Number of Employees involved h. Employees' exposure i. Absence of substance in article j. Absence of consumer's exposure k. Non applicability of the wide dispersive criteria	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

		l. Adequate control of the risk during the substance's lifecycle m. Strategic consequences of inclusion in Annex XIV for EU Thyristors & Triacs 2) Transitional arrangements Comments on the proposed dates Arrangements wished by our company. 3) Uses (or categories of uses) exempted from the authorisation requirement Applicability of art 58.2 criteria 1) General comments on the recommendation to include the substance in Annex XIV a. General context Semiconductor manufacturing uses highly sophisticated technologies and relies on a complex global supply chain in the world. Manufacturing takes place in a highly controlled environment, ensuring minimization of product contamination risks and employees' exposure control. Various chemicals and gases are used in processes because of their unique properties and functionality. b. Use of the substance In semiconductor production, doping intentionally introduces impurities into an extremely pure (also referred to as intrinsic) semiconductor for the purpose of modulating its electrical properties. The impurities are dependent upon the type of semiconductor. The chemical used is a solution of Diboron Trioxide in an organic solvent. The Boron solution is deposited on the surface of the wafer and the diffusion process occurs at a certain temperature in a controlled atmosphere, the Boron becoming a dopant of the silicon. The Boron migration takes place from the article's surface, the Boron atoms diffusing inside the Silicon wafer. At the end of the process, the maximum Boron concentration in the silicon wafer is inferior to 1000 ppm and is established in average at 70-80 ppm Boron in atomic ratio in the wafer considered as the article. Very small quantities of the Diboron Trioxide are used to get such concentration in the silicon die which is the core of the component. The component itself has a volume inferior to 0.5 cm3 and weighs less than 2 grams. The silicon die has a volume inferior to 10 mm3 (0.01 cm3) in most cases, e.g. less than 1% of the volume of a standard 55 x 85 mm business card. So, the total quantity of Boron Trioxide used by our company in Europe is about 8kg/year at a concentration of 40g/l in solvent (4.2 % in weight), representing an average of 22 g/day.	**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:** 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)** **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:** 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

		c. Diboron Trioxide doping process The process takes place within industrial manufacture of semiconductor devices ("chips") on silicon wafers in fabrication areas (fab) called "clean rooms" in which the temperature, humidity and airborne particle contamination are strictly controlled. The Fab environment is thousands of times cleaner than a hospital operating room (ECHA exposure scenarios for the semiconductor industry examples, ref ECHA-10-R-005-EN, date 5 August 2010). STMicroelectronics employs stringent risk management measures and safety procedures to control any substance release at a manufacturing process level and reduce workers' exposure. Boron is the p-type dopant of choice for silicon integrated circuit production because it diffuses at a rate that makes junction depths easily controllable. The result is an electrically conductive p-type semiconductor. This is a key concept in the physics of diodes and other discrete components such as Thrystors and Triacs. d. About Thyristors and Triacs Thyristors and Triacs are solid-state semiconductor devices with four layers of alternating N and P-type material. They act as bistable switches, conducting when their gate receives a current trigger, and continue to conduct while they are forward biased (that is, while the voltage across the device is not reversed). Once triggered, the device continues to conduct until the gate current drops below a certain threshold, called the holding current. The bidirectionality makes TRIACs very convenient switches for AC circuits, also allowing them to control very large power flows with milliampere-scale gate currents. They often replace relays with the advantage of a much longer life cycle. Low & medium power TRIACs are used in many applications such as computerized control circuits of many household small and major appliances, switching and dimming for AC lamps, speed controls for appliances with electric motors, switching on and off heating or cooking devices, compressors, motors and valves in “white goods”… The Top Glass technology was developed 20 years ago to manufacture such products with the high reliability required by their switching function and in a very cost effective way. This is why such component manufacture can be maintained in Europe while our competitors have their diffusion plants for	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**

		similar products outside Europe. e. Process description uses and exposure Diboron Trioxide is used for the manufacturing of components in Top Glass technology, the most advanced and cost effective technology, highly reliable thanks to its fully isolated assembly on the back side of the die and largely used for Triacs and Thyristors as a proprietary technology by STMicroelectronics in Europe (in France actually). To manufacture Top Glass structures, it is of the most importance to proceed to ultra-deep diffusions across the whole silicon plate, like the "P" areas on the component figure. To achieve such structures, our industry realizes diffusions based upon Boron atoms that permit an accurate localization in the structure. This is achieved, up to now in an industrial scale, using Diboron Trioxide dissolved in a liquid form. These diffusions are processed at very high temperature (1280°) during a 10 day period or more. The key parameter to obtain such diffusions is the critical surface density in Boron on the surface of the wafer before the diffusion. A small volume of about 4 ml (0.16 g of Diboron Trioxide) of the solution is spun on the surface of each wafer. The solvent is evacuated by overheating while the Diboron Trioxide is kept on the surface of the wafer. The spent solvent is collected and sent for incineration. Industrial hygiene measurements performed in all working areas showed that all values are within threshold limit values (see the employee's exposure section for the actual values). Also, equipment design minimizes risk to workers during normal operation and maintenance procedures are in place to prevent employees' exposure. f. Quantity used, quantity dispersed Previous year consumptions, since 2010 are almost aligned to the formerly given values, e.g. 8kg/year at a concentration of 40 g/l in solvent (4.2 % in weight). Therefore the substance is not registered for the specific use in the semiconductor manufacturing. In the process, further to the Diboron Trioxide deposition while dissolved in the solvent and the 5-6 hours overheating to remove the solvent, the wafers with pure Diboron Trioxide left on their surface are introduced into the furnace for high temperature diffusion. The thin layer of Diboron Trioxide provides elemental Boron for the diffusion into the silicon via the reaction: 2 B2O3 + 3 Si -> 4 B + 3 SiO2	

		Consequently, at the end of the process, all available Boron Trioxide is completely consumed and no unreacted Boron Trioxide can be found on the wafer and in the spent solvent. Only the Boron is included into the wafer considered as article, the so-called semiconductor device, the Oxygen and the solvent molecules being released in the exhaust. In the semiconductor device, the Boron atoms are embedded into the silicon matrix and cannot be released from the article. g. Limited number of employees involved Only 13 people are directly working in the area of a manufacturing line counting 150 people, in a site of 1 400 employees. One person only by shift is working on the spin-coating equipment, so that we can operate 24 hrs a day, 7 days a week. This explains that not more than 13 different persons are directly manipulating Diboron Trioxide dissolved in a liquid along the year. However, it should be noted that a person working on the spin coating equipment spends in average 3 hours per shift on this station, e.g. approximately 40% of all his(her) time while also affected to other tasks during the shift. By precaution pregnant female employees are not authorized to access to the work station as soon as their pregnancy is known by the labour doctor. All operators follow a specific training program for process and safety rules, they are regularly certified on a 3 years pace. h. Employees' exposure The Industrial hygiene measurements performed in all working areas show all values below 0.0443mg/m3 while applicable TLV (threshold limit value) is 10mg/m3. The here below table reports the relevant descriptor as per Appendix R.12.1 to R.12.6 of the ECHA Guidance on Use Descriptor System (R12) and based on the ECHA-10-R-005-EN publication EXPOSURE SCENARIOS FOR THE SEMICONDUCTOR INDUSTRY EXAMPLES – August 2010 Sector of use (SU) SU 3 Industrial manufacturing SU 16 Manufacturing of computer, electronic and optical product, electrical equipment Chemical product category (PC) PC 33 Semi-conductor PC 15 Non-metal-surface treatment products Process category (PROC) PROC 2 Use in closed, continuous process with	

		occasional controlled exposure (e.g. sampling) - Industrial setting ; PROC 13 Treatment of articles by dipping and pouring Article category (AC) Not applicable Environmental release category ERC 4 Industrial use of processing aids in processes and products, not becoming part of articles i. Absence of substance in article No Boron Trioxide substance is available in the finished article as only Boron diffuses into the silicon. In the semiconductor device, Boron is embedded into the silicon matrix therefore no Boron can be released from the article. Only a very small amount of dopant is required. Weakly doped silicon crystals contain only 1 impurity per 1,000,000,000 silicon atoms, highly doped semiconductors for contain 1 foreign atom per 1,000 silicon atoms, that is to say 0.1% maximum Boron (1000 ppm) in the silicon die. j. Absence of consumer's exposure There is strictly no exposure of the consumer, while no more Diboron Trioxide is still present in the assembled component. Only Boron can be found at a concentration < 1000 ppm level in the silicon part of the component (the die), this silicon part being assembled inside a package which is sealed with an epoxy compound (see figure besides). Such component is then soldered on the printed circuit boards of the electronics of final appliances. Even Boron is fully embedded into the silicon material, which is not accessible to the consumer for obvious reason of electrical safety. Therefore no consumer exposure is possible. k. Non applicability of the wide dispersive criteria The wide dispersive criteria cannot apply to Diboron Trioxide used as dopant for semiconductors because: 1. Total quantity of substance used is below 10 kg/year, e.g. 0.0001 % (1 ppm) of total quantity put on the market according to the ECHA document "Draft background document for Diboron trioxide" of Sept 2014 2. The substance is used in one site only involving 13 different workers in average over the year 3. The substance is not present in products or articles available to the public. l. Adequate control of the risk during the substance's lifecycle Referring to:	

		- the risk mitigation measures implemented during the manufacturing process, - the absence of substance in the product or article, - the absence of possible exposure of consumers, - the non-applicability of the wide dispersive criteria, it is believed that the risk is adequately managed during the complete substance's lifecycle: the risks related to the use of Diboron Trioxide in the manufacturing process are adequately controlled, ensuring environmental release control, manufacturing employees are adequately protected and article users are not exposed to the substance. Moreover electric and electronic equipment at their end of life are managed according to the WEEE Directive requirements. m. Strategic consequences of inclusion in Annex XIV for EU Thyristors & Triacs Semiconductors are the building blocks of most all consumer electronics, including PCs, mobile phones, MP3 players, etc. However, this industry features a number of distinct characteristics that position it uniquely in the global competitive arena. These include: 1. The role of the industry as technology enabler, while the semiconductor industry is widely recognized as a key driver for the whole electronics value chain, 2. Continuous growth but in a cyclical pattern with high volatility, 3. The need for high degrees of flexibility and innovation in order to constantly adjust to the rapid pace of change in the market. As a consequence, changes in the semiconductor market not only occur extremely rapidly but also anticipate changes in related industries which evolve at a slower pace. Yet another consequence of this rapid pace is that established market strongholds can be displaced very quickly. The semiconductor industry generates over 5 times its revenues in electronics systems business and about 20 times its revenues in services, representing close to 10% of world GDP. This correlation to the global economy and its own business cycles is a main driver for semiconductor cyclicality. The semiconductor industry's operating costs and capital expenditures are uniquely high because new manufacturing plants, or fabs, can cost them up to 25% of annual revenues, or as much as $3-5B. Large capital expenditures are a continuous pain point for this industry because advances in technology require expensive machinery.	

		Also, compared to every other industry, the semiconductor industry is perennially one major factor of economy growth and every year, chip makers and designers dramatically increase the performance of their products while decreasing prices, making high-end technology goods increasingly productive and affordable for consumers. This constant trend for price decrease obliges semiconductor manufacturer to yearly cost effectiveness improvements, prioritizing R&D which maintain competitiveness through the required time to market and avoiding unnecessary expenses. As already stated, the manufacture of Thyristors and Triacs made with the Top Glass technology can be maintained in EU as long as their costs can keep competitive in front of similar products manufactured in other places of the world, specifically Asia. This is why the best approach would be an exemption from authorization justified by low volumes and absence of the criteria of wide dispersive use, the used quantities (8 kg/year) representing less than 0.0001 % (1 ppm) of the total quantity put on the market, according to the ECHA document "Draft background document for Diboron trioxide" of Sept 2014 (e.g. 1,000 – 10,000 t/year). Such an exemption from authorization would be highly justified with respect to the economic risks incurred by the elimination of the substance. 2809_B2O3 autho template prop 2014 11 28final.pdf	
2826 2014/11/28	Norway, Member State	The Norwegian CA supports the prioritisation of diboron trioxide for inclusion in Annex XIV.	Thank you for providing your opinion.
2839 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. 2839_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) **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.**
2840 2014/11/28	Freiberger Compound Materials GmbH, Company, Germany	From our perspective an inclusion of diboron trioxide for the special and limited use in semiconductor industry would not be the appropriate option for further regulation beside the already existing legislation. 2840_Freiberger - comments for diboron trioxide to the ECHA consultation on the 6th priority list for annex XIV.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.1.1. General, recommendation process:** 3. Prioritisation approach applied

			A.1.2. Prioritisation: Volume **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:** 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.2.11: 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.2.13: Claim that risks for workers are controlled by**

			other legislation **A.2.15: Claim that exposure data shows low/no risks** **A.2.16: Risks should be managed using risk management measures like PPE, LEV, exposure tracking, training** **C.2. Responses to exemption requests referring to other legislation**
2842 2014/11/28	Freiberger Compound Materials GmbH, Company, Germany	From our perspective an inclusion of diboron trioxide for the special and limited use in semiconductor industry would not be the appropriate option for further regulation beside the already existing legislation. 2842_Freiberger - attachment to comments for diboron trioxide to the ECHA consultation on the 6th priority list for annex XIV.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.2.21 Boron is a critical raw material**
2849 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.	Thank you for providing your opinion.

	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.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban **A.2.13: Claim that risks for workers are controlled by other legislation**
2868 2014/11/28	European Borates Association, Industry or trade association, Belgium	2868_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**
2886 2014/11/28	Company, Italy	General context Semiconductor manufacturing uses highly sophisticated technologies and relies on a complex global supply chain in the world. Manufacturing takes place in a highly controlled environment, ensuring minimization of product contamination risks and employees' exposure control. Glass frits description Glass frits paste is a mixture of an extremely finely grinded glass, with an inert filler material, together with a binding resin and solvent. These components mixed together form a glass frits paste. Lead monoxide and Diboron trioxide are among the constituents of 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. **A.1.3. Prioritisation: Wide-dispersiveness of uses:**

		formulation of a Low-Temperature (Low-T) melting glass (i.e. the glass component in the glass frits paste). Lead monoxide lowers the melting Temperature of the glass, rendering the glass compatible with the Aluminium metal in the device. Diboron trioxide gives the glass properties of chemical and mechanical resistance. Based on the chemical reactions for production of glass and frits, Lead monoxide and Diboron trioxide are used specifically in order to be transformed into another substance (i.e. the glass or frits), rather than being added to other substances to modify their properties. Therefore, the use is in line with the definition of intermediates and exempt from authorization. www.glassallianceeurope.eu During the glass "melting" process, the different raw materials react chemically to produce the substance glass, which is an amorphous network of elements bonded together with oxygen ions between cations. For practical reasons, the elemental analyses of glass are expressed in the form of their oxides, but this must not be confused with a mixture of the different oxides. In conclusion, the substance glass does not contain any raw material used as starting materials and particularly does not contain any Lead monoxide or Diboron trioxide. Glass frits used in Semiconductor Manufacturing Industry may be described, however, in terms of Diboron trioxide (CAS 1303-86-2). In the Draft background document for Diboron trioxide the use of technical glass frits is not mentioned at all, thus implying that those uses are irrelevant for the whole authorization scope due to very limited volumes used for this selected electronic application (Draft background document for Diboron trioxide - ECHA 01/09/2014). Anyhow a response to the current consultation is submitted to inform ECHA and the Commission on the relevance of this specific industrial use. In conclusion, due to the above described "melting" process, the SVHC Diboron trioxide is not present in the glass as such and Boron, only, is chemically bonded in the glass amorphous structure. For this reason, it is believed that the use of frits in the specific application of MEMS manufacturing in the semiconductor industry is to be considered out of the scope of the authorization. Conditions of use Glass frits are used in semiconductor manufacturing, with the scope of hermetically sealing microelectronic devices.	1. Scope of the assessment of wide-dispersiveness of uses 2. Assignment of WDU score based on use types and their associated volumes **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.1.5. Aspects not considered in ECHA's prioritisation:** 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** **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**

		Low Temperature (Low-T) Boron trioxide based glass frits are used in wafer-to-wafer bonding process of MEMS (Micro Electro Mechanical Systems) devices. MEMS devices, such as accelerometers or gyroscopes, are well-known components of smartphones, tablets and several games consoles. In the table below, a simplified MEMS process flow is presented, with wafer-to-wafer bonding. All processes are performed in clean room environment and in controlled equipment. Process step Description Image Make Sensor wafer Where actual Sensor device is built. Make Cap wafer Role: protect Sensor device from environment; Glass Frits application via Screen Printing Bond Sensor wafer with Cap wafer Bonding Technology: Glass Frit Dice & Assemble In package with electronics driver chip (ASIC) In terms of processing, glass frits paste is screen printed on the wafer, transformed into melted glass at high temperature and used to bond 2 wafers together). Process step Description Image Screen Printing Glass Frits Paste Pattern transfer Firing Thermal treatment in batch oven Transform Glass Frits Paste (Binder + solvent + Glass powder) --> Glass Bonding Thermal Treatment on Bonder Equipment	**should be considered)** **C.2. Responses to exemption requests referring to other legislation**

		"Soften" Glass --> squeeze wafers together Dice & Assemble In package with electronics driver chip (ASIC) The used screens are cleaned in dedicated closed circuit screen cleaner equipment. The solvent used for cleaning the screens is filtered and re-circulated. The spent solvent is collected separately in a dedicated solvent drain, and sent for incineration. The glass frit contaminated filters are collected separately and sent for incineration. All operations take place under local exhaust ventilation and ensuring appropriate solvent containment. The whole process takes place in a controlled environment applying strict risk management measures, ensuring no release to the environment and controlled employees' exposure. Exhaust are installed in all relevant area and air emissions are regularly monitored ensuring all results for B < 0.132 mg/m3 Controlled discharge to water is expected being plant waste water regularly monitored ensuring all results for B < 0.1 mg/l while applicable emission limit is 4 mg/l. Boron being present in the glass paste is not expected to be re combined into Diboron trioxide during the process, while it is found embedded in a glass matrix in the final product. Glass frits is used for a total quantity of 450 Kg/year in one site, equivalent to a theoretical consumption of 60 Kg/year of Diboron trioxide, to the 0.007 % of the total quantity of Diboron trioxide in the authorization scope (Draft background document for Diboron trioxide - ECHA 01/09/2014). This quantity is relevant to the production of 500 Million unit/y electronics components. Each electronic component may contain about 0.001 mg of Boron in a concentration up to 0.009 %, depending on the component weight. Here below picture of MEMS plastic packages with thickness of less than 1.0 mm ranging from 7x5 mm2 , 5x5 mm2 , 3x5 mm2 , 4x4 mm2 ,3x3 mm2 Glass frits are imported into Europe and, due to low quantity used, are not registered for the specific use in the semiconductor industry. Use descriptor The here below table reports the relevant descriptor as per Appendix R.12.1 to	

		R.12.6 of the ECHA Guidance on Use Descriptor System (R12) and based on the ECHA-10-R-005-EN publication EXPOSURE SCENARIOS FOR THE SEMICONDUCTOR INDUSTRY EXAMPLES – August 2010 Sector of use (SU) SU 3 Industrial manufacturing SU 16 Manufacturing of computer, electronic and optical product, electrical equipment Chemical product category (PC) PC1 Adhesives, sealants Process category (PROC) PROC 2 Use in closed, continuous process with occasional controlled exposure (e.g. sampling) - Industrial setting; (1) Article category (AC) AC2 Electric and electronic articles included (2) Environmental release category ERC5 Industrial use resulting in inclusion into or onto a matrix (2) (1) Some process could take place not only in continuous process but also in batch operations with occasional control exposure, only (2) Article category and Environmental release category are relate to glass frits Non applicability of the wide dispersive criteria With reference to the Draft background document for Boron trioxide - ECHA 01/09/2014 - there is a further clarification need: the total quantity of glass frit paste used in one industrial site is 450 Kg/y, only, and the number of potentially exposed employees is very limited (40 employees) therefore the use of frits in the specific application of MEMS manufacturing in the semiconductor industry cannot be considered to contribute to the wide dispersive use criteria for prioritization. There is no release to the environment from the article (semiconductor device) since the Boron trioxide, as already explained, is not present in the glass as such and Boron is chemically bonded in the glass amorphous structure. Moreover the semiconductor device is assembled into a matrix resin, to produce the semiconductor component, finally used in the electric or electronic equipment. Waste of electric and electronic components are managed according to the WEEE Directive, therefore there is no consumers exposure.	

		2886_boroglassfrit autho template prop 2014 11 28.pdf	
2891 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 diboron trioxide 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 diboron trioxide in crucibles and in the majority of mixtures is below the specific concentration limit of diboron trioxide. Refractories are not consumer products; they are only used for industrial purposes. The exposure of workers during the manufacturing of crucibles or mixtures is well below the DNEL for diboron trioxide of 4,66mg/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 diboron trioxide, 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 diboron trioxide will not cause any improvement in safety at work and a substitution of diboron trioxide with boron-free substances is not feasible.	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 **.**
2922 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 with the substances on te 6th list.	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

		Confidential attachment removed	corresponding background documentation. Please see also responses given to comments by European Borates Association (EBA) (#2525 and 2868). **A.2.12: ECHA should not proceed with the 6th recommendation, when the 5th is still open** **C.1.2. Generic exemptions**
2942 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. 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	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 also responses given to comments by European Borates Association (EBA) (#2525 and 2868) and by Frit Consortium (#2644). **A.1.3. Prioritisation: Wide-dispersiveness of uses:** 2. Assignment of WDU score based on use types and their associated volumes

		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 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	**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** **- 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.**

		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.	**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**
2943 2014/11/30	Austrian workers' compensation board, National Authority,	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 providing your opinion.

	Austria		
2955 2014/12/01	ASD, Industry or trade association, Belgium	1.3. Diboron trioxide (CAS 1303-86-2) Diboron trioxide is used in a number of commercially available brazing fluxes and flux solutions. The substance provides a number of functionalities to the mixture, including wetting and melting pOint and these fluxes are used in a wide variety of applications. Production of borosilicate glass requires the use of diboron trioxide. The importance to the aerospace and defence industries is in its use in optical products such as lenses, mirrors as well as glass enclosures, some forms of fiberglass and ceramic coatings. Diboron trioxide is an intermediate chemical that is formed during the production of boron nitride. Boron nitride itself is a very important high temperature lubricant for forming aluminium and titanium structures. It is also useful as a high temperature lubricant for superplastic forming of titanium. Other methods of forming boron nitride are noted in the literature, but it is not clear at this time whether these are commercially viable and if the particle morphology resulting from the process will work in these high temperature lubrication applications.	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.2.4: 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** **B.1.1. General principles for setting latest application dates / sunset dates** **B.1.2. Aspects not considered**
		2955_ASD answer to ECHA consultation_General Conclusions for all Boron and lead compounds_281114.pdf	

			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.**
2962 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 (#2955).
2966 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. 2966_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 timelines (e.g. with regard to nominal lifetime and**

			decommissioning) 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**
2975 2014/12/01	GIFAS, Industry or trade association, France	Please refer to attached letter 2975_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. Please see responses given to comments by ASD (#2955). **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.**
3012 2014/12/01	Cerame-Unie - the European Ceramics Industry Association,	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	Thank you for your comment and the additional information provided. This will be taken into

	Industry or trade association, Belgium	enamels. It accounts for more than 200.000 direct employments and a turnover 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	account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. Please see also responses given to comments by European Borates Association (EBA) (#2525 and 2868) and by Frit Consortium (#2644). **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**

		industry. 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	**- 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** **A.2.21 Boron is a critical raw material**

		Association (EBA).	
3013 2014/12/01	European Semiconductor Industry Association, Industry or trade association, Belgium	a. General context Semiconductor manufacturing uses highly sophisticated technologies and relies on a complex global supply chain in the world. Manufacturing takes place in a highly controlled environment, ensuring minimization of product contamination risks and employees' exposure control. Various chemicals and gases are used in processes because of their unique properties and functionality. b. Use of the substance In semiconductor production, doping intentionally introduces impurities into an extremely pure (also referred to as intrinsic) semiconductor for the purpose of modulating its electrical properties. The impurities are dependent upon the type of semiconductor. The chemical used is a solution of Diboron Trioxide in an organic solvent. The Boron solution is deposited on the surface of the wafer and the diffusion process occurs at a certain temperature in a controlled atmosphere, the Boron becoming a dopant of the silicon. The Boron migration takes place from the article's surface, the Boron atoms diffusing inside the Silicon wafer. At the end of the process, the maximum Boron concentration in the silicon wafer is below 1000 ppm and is established in average at 70-80 ppm Boron in atomic ratio in the wafer considered as the article. Very small quantities of the Diboron Trioxide are used to get such concentration in the silicon die which is the core of the component. The component itself has a volume inferior to 0.5 cm3 and weighs less than 2 grams. The silicon die has a volume inferior to 10 mm3 (0.01 cm3) in most cases, e.g. less than 1% of the volume of a standard 55 x 85 mm business card. The total quantity of Boron Trioxide in industrial use in Europe is in the region of 8kg/year at a concentration of 40g/l in solvent (4.2 % in weight), representing an average of 22 g/day. c. Diboron Trioxide doping process The process takes place within industrial manufacture of semiconductor devices ("chips") on silicon wafers in fabrication areas (fab) called "clean rooms" in which the temperature, humidity and airborne particle contamination are strictly controlled. The Fab environment is thousands of times cleaner than a	Please refer to responses given to comments by STMicroelectronics (#2809).

		hospital operating room (ECHA exposure scenarios for the semiconductor industry examples, ref ECHA-10-R-005-EN, date 5 August 2010). The industry employs stringent risk management measures and safety procedures to control any substance release at a manufacturing process level and reduce workers' exposure. Boron is the p-type dopant of choice for silicon integrated circuit production because it diffuses at a rate that makes junction depths easily controllable. The result is an electrically conductive p-type semiconductor. This is a key concept in the physics of diodes and other discrete components such as Thrystors and Triacs. d. About Thyristors and Triacs Thyristors and Triacs are solid-state semiconductor devices with four layers of alternating N and P-type material. They act as bistable switches, conducting when their gate receives a current trigger, and continue to conduct while they are forward biased (that is, while the voltage across the device is not reversed). Once triggered, the device continues to conduct until the gate current drops below a certain threshold, called the holding current. The bidirectionality makes TRIACs very convenient switches for AC circuits, also allowing them to control very large power flows with milliampere-scale gate currents. They often replace relays with the advantage of a much longer life cycle. Low & medium power TRIACs are used in many applications such as computerized control circuits of many household small and major appliances, switching and dimming for AC lamps, speed controls for appliances with electric motors, switching on and off heating or cooking devices, compressors, motors and valves in “white goods”… e. Process description uses and exposure Diboron Trioxide is used for the manufacturing of components in Top Glass technology, the most advanced and cost effective technology, highly reliable thanks to its fully isolated assembly on the back side of the die and largely used for Triacs and Thyristors in Europe. To manufacture Top Glass structures, it is of the most importance to proceed to ultra-deep diffusions across the whole silicon plate, like the "P" areas on the component figure. To achieve such structures, our industry realizes diffusions based upon Boron atoms that permit an accurate localization in the structure.	

		This is achieved, up to now in an industrial scale, using Diboron Trioxide dissolved in a liquid form. These diffusions are processed at very high temperature (1280°) during a 10 day period or more. The key parameter to obtain such diffusions is the critical surface density in Boron on the surface of the wafer before the diffusion. A small volume of about 4 ml (0.16 g of Diboron Trioxide) of the solution is spun on the surface of each wafer. The solvent is evacuated by overheating while the Diboron Trioxide is kept on the surface of the wafer. The spent solvent is collected and sent for incineration. Industrial hygiene measurements performed in all working areas showed that all values are within threshold limit values. Also, equipment design minimizes risk to workers during normal operation and maintenance procedures are in place to prevent employees' exposure. f. Quantity used, quantity dispersed Substance used in the region of 8kg/year at a concentration of 40 g/l in solvent (4.2 % in weight). Therefore the substance is not registered for the specific use in the semiconductor manufacturing. In the process, further to the Diboron Trioxide deposition while dissolved in the solvent and the 5-6 hours overheating to remove the solvent, the wafers with pure Diboron Trioxide left on their surface are introduced into the furnace for high temperature diffusion. The thin layer of Diboron Trioxide provides elemental Boron for the diffusion into the silicon via the reaction: 2 B2O3 + 3 Si -> 4 B + 3 SiO2 Consequently, at the end of the process, all available Boron Trioxide is completely consumed and no unreacted Boron Trioxide can be found on the wafer and in the spent solvent. Only the Boron is included into the wafer considered as article, the so-called semiconductor device, the Oxygen and the solvent molecules being released in the exhaust. In the semiconductor device, the Boron atoms are embedded into the silicon matrix and cannot be released from the article. g. Employees' exposure The Industrial hygiene measurements performed in all working areas show all values below applicable DNELS. The relevant descriptor as per Appendix R.12.1 to R.12.6 of the ECHA Guidance	

		on Use Descriptor System (R12) and based on the ECHA-10-R-005-EN publication EXPOSURE SCENARIOS FOR THE SEMICONDUCTOR INDUSTRY EXAMPLES – August 2010 Sector of use (SU) SU 3 Industrial manufacturing Chemical product category (PC) PC 33 Semi-conductor PC 15 Non-metal-surface treatment products Process category (PROC) PROC 2 Use in closed, continuous process with occasional controlled exposure (e.g. sampling) - Industrial setting ; PROC 13 Treatment of articles by dipping and pouring Article category (AC) Not applicable Environmental release category ERC 4 Industrial use of processing aids in processes and products, not becoming part of articles h. Absence of substance in article No Boron Trioxide substance is available in the finished article as only Boron diffuses into the silicon. In the semiconductor device, Boron is embedded into the silicon matrix therefore no Boron can be released from the article. Only a very small amount of dopant is required. Weakly doped silicon crystals contain only 1 impurity per 1,000,000,000 silicon atoms, highly doped semiconductors for contain 1 foreign atom per 1,000 silicon atoms, that is to say 0.1% maximum Boron (1000 ppm) in the silicon die. i. Absence of consumer's exposure There is strictly no exposure of the consumer. Only Boron can be found at a concentration < 1000 ppm level in the silicon part of the component (the die), this silicon part being assembled inside a package which is sealed with an epoxy compound (see figure besides). Such component is then soldered on the printed circuit boards of the electronics of final appliances. Even Boron is fully embedded into the silicon material, which is not accessible to the consumer for obvious reason of electrical safety. Therefore no consumer exposure is possible. j. Non applicability of the wide dispersive criteria The wide dispersive criteria cannot apply to Diboron Trioxide used as dopant for semiconductors because:	

		1. Total quantity of substance used is below 10 kg/year, e.g. 0.0001 % (1 ppm) of total quantity put on the market according to the ECHA document "Draft background document for Diboron trioxide" of Sept 2014 2. The substance is not present in products or articles available to the public. k. Adequate control of the risk during the substance's lifecycle Referring to: - the risk mitigation measures implemented during the manufacturing process, - the absence of substance in the product or article, - the absence of possible exposure of consumers, - the non-applicability of the wide dispersive criteria, it is believed that the risk is adequately managed during the complete substance's lifecycle: the risks related to the use of Diboron Trioxide in the manufacturing process are adequately controlled, ensuring environmental release control, manufacturing employees are adequately protected and article users are not exposed to the substance. Moreover electric and electronic equipment at their end of life are managed according to the WEEE Directive requirements. l. Strategic consequences of inclusion in Annex XIV for EU Thyristors & Triacs Semiconductors are the building blocks of most all consumer electronics, including PCs, mobile phones, MP3 players, etc. However, this industry features a number of distinct characteristics that position it uniquely in the global competitive arena. These include: 1. The role of the industry as technology enabler, while the semiconductor industry is widely recognized as a key driver for the whole electronics value chain, 2. Continuous growth but in a cyclical pattern with high volatility, 3. The need for high degrees of flexibility and innovation in order to constantly adjust to the rapid pace of change in the market. As a consequence, changes in the semiconductor market not only occur extremely rapidly but also anticipate changes in related industries which evolve at a slower pace. Yet another consequence of this rapid pace is that established market strongholds can be displaced very quickly. The semiconductor industry's operating costs and capital expenditures are uniquely high because new manufacturing plants, or fabs, can cost them up to	

		25% of annual revenues, or as much as $3-5B. Compared to other industries, the semiconductor industry annually increases the performance of semiconductor products making high-end technology goods increasingly productive and affordable for consumers. This constant trend for price decrease obliges semiconductor manufacturer to yearly cost effectiveness improvements, prioritizing R&D which maintain competitiveness through the required time to market and avoiding unnecessary expenses. The manufacture of Thyristors and Triacs made with the Top Glass technology can be maintained in EU as long as their costs can keep competitive in front of similar products manufactured in other places of the world, specifically Asia. This is why the best approach would be an exemption from authorization justified by low volumes and absence of the criteria of wide dispersive use, the used quantities (8 kg/year) representing less than 0.0001 % (1 ppm) of the total quantity put on the market, according to the ECHA document "Draft background document for Diboron trioxide" of Sept 2014 (e.g. 1,000 – 10,000 t/year). Such an exemption from authorization would be highly justified with respect to the economic risks incurred by the elimination of the substance.	

II - Transitional arrangements. Comments on the proposed dates

Number / Date	Submitted by (name, submitter type, country)	Comment	Reference to responses
2512 2014/10/15	European Catalyst Manufacturers Association (ECMA), Industry or trade association, Belgium	2512_20141015- Diboron ECHA consultation final (ECMA) Supply Chain .docx	Please see references to responses in section I
2523 2014/10/31	European Borates Association (EBA), Industry or trade association, Belgium	*Confidential attachment removed*	Please see references to responses in section I

2525 2014/10/31	European Borates Association (EBA), Industry or trade association, Belgium	 2525_EBA comments - ECHA PC - 6th priority list (final).pdf	Please see references to responses in section I
2530 2014/11/10	Individual, Germany	 2530_ECHA attachments.zip *Confidential attachment removed*	Please see references to responses in section I
2539 2014/11/14	Company, Germany	- 	-
2577 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. 	-
2588 2014/11/24	AREVA, Company, France	See comment on boric acid 	Please see references to responses in section I
2644 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 Diboron trioxide (EC 215-125-8) 2644_Frit Consortium - borates intermediate in frits.pdf	Please see references to responses in section I
2672 2014/11/26	UNIFA, Industry or trade association, France	 2672_Commentaires UNIFA_Novembre 2014_EN_VF.pdf	Please see references to responses in section I
2698 2014/11/27	European Special Glass Association and European Domestic Glass Association, Industry or trade association, Belgium	 2698_FINAL EDG-ESGA - Use of borates as intermediates in the manufacture of borosilicate glass.docx	Please see references to responses in section I
2708 2014/11/27	Vesuvius Group, Company, United Kingdom	 *Confidential attachment removed*	Please see references to responses in section I

2724 2014/11/27	Wieland-Werke AG, Company, Germany	 2724_Comments to 6th priority list of substances for inclusion in Annex XIV _ Wieland-Werke.pdf	Please see references to responses in section I
2746 2014/11/28	CMK, s.r.o., Company, Slovakia	 2746_CMK's comments to ECHA.pdf	Please see references to responses in section I
2809 2014/11/28	STMicroelectronics, Industry or trade association, France	2) Transitional arrangements Comments on the proposed dates Although it is believed that the use of Diboron Trioxide in the Semiconductor sector should benefit of an exemption from authorization due to the low volume usage and the inapplicability of the wide dispersive criteria, being this option currently unavailable in the regulation text, here are the arrangements that are requested by our company: 1) To have the latest application date after 48 months the Annex XIV publications date, instead of the actual proposal of 24 months, this option request being supported by the fact that the substance was not registered for the intended use and that our company needs time to develop the relevant dossier. 2) To be given a 7 years authorization review period, this option request being supported by the fact that there is no current industrial substitution available since other boron sources are not as efficient as the one currently used. 2809_B2O3 autho template prop 2014 11 28final.pdf	**A.1.5. Aspects not considered in ECHA's prioritisation:** 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** **B.1.3. Review periods** **C.1.3. Aspects not justifying an exemption from authorisation** **C.2. Responses to exemption requests referring to other legislation**
2826 2014/11/28	Norway, Member State	In general, we are in favour that a regulation should enter into force as soon as possible. Hence we are in favour of the shortest LAD slot. 	**B.1.1. General principles for setting latest application dates / sunset dates:** 3. ECHA's proposal for latest application dates

2839 2014/11/28	ACEA, Industry or trade association, Belgium	2839_20141128_Proposal for annex XIV recommendation on Borates Final.pdf	Please see references to responses in section I
2840 2014/11/28	Freiberger Compound Materials GmbH, Company, Germany	In case an authorization would really started the dates should be as long as possible, min. 20 years 2840_Freiberger - comments for diboron trioxide to the ECHA consultation on the 6th priority list for annex XIV.pdf	**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**
2842 2014/11/28	Freiberger Compound Materials GmbH, Company, Germany	In case an authorization would be really started these dates should be as long as possible, min. 20 years 2842_Freiberger - attachment to comments for diboron trioxide to the ECHA consultation on the 6th priority list for annex XIV.pdf	**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**
2868 2014/11/28	European Borates Association, Industry or trade association, Belgium	2868_EBA comments - ECHA PC - 6th priority list - glass-frits.pdf	Please see references to responses in section I
2886 2014/11/28	Company, Italy	Time line for glass frits substitution As of today, all alternative glass frits materials contain Boron. As for all changes in the semiconductor industry, implementation implies long time research project with associated costs and investments. Alternative technologies exist, but not all technologies are compatible with the processing of MEMS devices. Phosphorus, zinc, tin, bismuth, etc. and their relatives oxides have been investigated as materials to be used as a constituent element of glass frits used	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives **B.1.1. General principles for setting latest application dates / sunset dates**

		as a wafer-to-wafer bonding and sealing layers for MEMS devices. Up to now, the presence of Boron is needed to ensure the relevant mechanical characteristics as of those Boron containing glass frits. However, these new type of glasses and glass frits are still in the investigation phase and have to fully demonstrate to meet the requirements necessary for substituting adequately the described Boron-based glass frits application. Among the requirements to meet, some must be taken into account: the sealing properties (MEMS gyroscopes sensors, in order to work, must operate in a strict vacuum environment) and the excellent mechanical resistance. This point is especially important to note, being the market of MEMS sensors one of the fastest growing markets of the last years (for example, the incorporation of MEMS sensors, such as accelerometers, gyroscopes, pressure sensors, into smartphones). More over the use of Boron containing glasses (obtained from Boron trioxide) has been recently investigated as possible replacement material of Lead containing glasses. A typical time frame for a substitution process in the semiconductor industry would be as described in fig 1 Figure 1 Assuming that after 2 years of new process trials, a suitable candidate is considered for the manufacturing of components and positively qualified (after almost 2 years), then the product is tested for acceptance by customers selected for the criticality of their applications (which will take about another 2 years). After the selected customers' acceptance, a PCN (product/process change notification) will be issued (high level classification) for global customers' acceptance and the mass production will start only after positive returns. There is no clear visibility of a possible substitute availability and, therefore, of authorization needs in less than 4 years' timeframe. Although it is believed that the use of frits in the specific application of MEMS manufacturing in the semiconductor industry is to be considered out of the scope of the authorization, in case this position is not agreed upon, it would be suitable to have the latest application date 48 months after the Annex XIV publication date, instead of the actual proposal of 24 months.	**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates**

		2886_boroglassfrit autho template prop 2014 11 28.pdf	
2922 2014/11/30	Company, Belgium		Please see references to responses in section I
		Confidential attachment removed	
2955 2014/12/01	ASD, Industry or trade association, Belgium	Not workable for our industry-see VComments on Boric Acid	Please see references to responses in section I
		2955_ASD answer to ECHA consultation_General Conclusions for all Boron and lead compounds_281114.pdf	
2962 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
2966 2014/12/01	CEA, Company, France		Please see references to responses in section I
		2966_PC-ECHA-boric_acid-comment_CEA_nov2014.pdf	
2975 2014/12/01	GIFAS, Industry or trade association, France		Please see references to responses in section I
		2975_20010_ECHA_Annex XIV_Boron_substances.pdf	
3013 2014/12/01	European Semiconductor Industry Association, Industry or trade association, Belgium	Although it is believed that the use of Diboron Trioxide in the Semiconductor sector should be considered for an exemption from authorization due to the low volume usage and the inapplicability of the wide dispersive criteria, if this option is not followed the industry would make the following comments relating to transitional arrangements: 1) To have the latest application date after 48 months the Annex XIV publications date, instead of the actual proposal of 24 months, this option request being supported by the fact that the substance was not registered for the intended use and that our company needs time to develop the relevant dossier. 2) To be given a 7 years authorization review period, this option request being supported by the fact that there is no current industrial substitution available since other boron sources are not as efficient as the one currently used.	Please refer to responses given to comments by STMicroelectronics (#2809).

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
2504 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**
2512 2014/10/15	European Catalyst Manufacturers Association (ECMA), Industry or trade association, Belgium	2512_20141015- Diboron ECHA consultation final (ECMA) Supply Chain .docx	Please see references to responses in section I
2523 2014/10/31	European Borates Association (EBA), Industry or trade association, Belgium	*Confidential attachment removed*	Please see references to responses in section I
2525 2014/10/31	European Borates Association (EBA), Industry or trade association, Belgium	2525_EBA comments - ECHA PC - 6th priority list (final).pdf	Please see references to responses in section I
2530	Individual,		Please see references to

2014/11/10	Germany	2530_ECHA attachments.zip *Confidential attachment removed*	responses in section I
2539 2014/11/14	Company, Germany	-	Please see references to responses in section I
2577 2014/11/21	I&P Europe - Imaging and Printing Association e.V., Industry or trade association, Germany	Member companies use the substance to formulate some photographic processing chemicals, specifically developers. 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 processing. Thus the only aspect of this photographic use that would require authorisation is the industrial formulation of the processing chemicals. 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.	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.1.3. Aspects not justifying an exemption from authorisation**
2644 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. 2644_Frit Consortium - borates intermediate in frits.pdf	Please see references to responses in section I
2672 2014/11/26	UNIFA, Industry or trade association, France	Fertilizers must be exempted because it's essential for crops. 2672_Commentaires UNIFA_Novembre 2014_EN_VF.pdf	**C.2. Responses to exemption requests referring to other legislation**
2698 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. 2698_FINAL EDG-ESGA - Use of borates as intermediates in the manufacture of borosilicate glass.docx	Please see references to responses in section I

2708 2014/11/27	Vesuvius Group, Company, United Kingdom	Mixing/blending and transfer operations intended to manufacture mixtures where the diboron trioxide 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*	Please also see references to responses in section I **C.3.7: Claim that articles should be exempt from authorisation.**
2724 2014/11/27	Wieland-Werke AG, Company, Germany	Use to be exempted: Metallurgy. The use of diboron trioxide within metallurgical processes (e.g. as component of a casting salt) is a pure industrial use. The substance is not incorporated in the product. Authorization is not the right instrument to regulate the risk for the use of diboron trioxide within metallurgy processes. In many European countries, like e.g. in Germany, OELs exists, which provide safe conditions for use. The alignment of working regulation within Europe would be the more feasible way to cover potential risks than inclusion in Annex XIV. 2724_Comments to 6th priority list of substances for inclusion in Annex XIV _ Wieland-Werke.pdf	Please also see references to responses in section I Please also see references to responses in section I **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.**
2746 2014/11/28	CMK, s.r.o., Company, Slovakia	 2746_CMK's comments to ECHA.pdf	Please see references to responses in section I
2749 2014/11/28	Individual, Poland	Major uses of boric trioxide in the EU are outside the scope of authorization: ☐ boric trioxide is mainly used in the manufacturing of glass and frits (in these uses the boric trioxide is qualifies as intermediate since is completely consumed and transformed into another substance - glass and frits) ☐ boric trioxide (and other borates) is used in mixtures below specific concentration limits ☐ boric trioxide 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 (boric trioxide) 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 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	**C.1.3. Aspects not justifying an exemption from authorisation** **C.2. Responses to exemption requests referring to other legislation** Please see references to responses in section I

		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 (boric trioxide) will cause reproductive or developmental effects in humans.	
2809 2014/11/28	STMicroelectronics, Industry or trade association, France	3) Uses (or categories of uses) exempted from the authorisation requirement Applicability of art 58.2 criteria Use of Diboron Trioxide in the semiconductor sector in Europe is subject to the following EU wide regulation EU. Indicative Exposure Limit Values in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU, thru OJ (L 338) 87, 17 Dec 2009) EU. Directive 98/24/EC on the protection of workers from the risks related to chemical agents, Art. 2(b)(i), OJ (L 131) 11, 5 May 1998 (updated thru table 3.2 of Annex VI to CLP, 3 Oct 2013) EU. Directive 92/85/EEC on pregnant workers and workers who have recently given birth or are breastfeeding, O.J. (L 348) 1, 28 Nov 1992 (updated thru table 3.2 of Annex VI to CLP, 3 Oct 2013) EU. Directive 94/33/EC on young people at work, OJ (L 216) 12, 20 Aug 1994, as amended by Directive 2007/30/EC, OJ (L 165) 21, 27 Jun 2007 (updated thru table 3.2 of Annex VI to CLP, 3 Oct 2013). Tours Site holds a valid authorization from Prefecture : "ARRETE PREFECTORAL N°18938 Bis du 11 Mars 2011 modifié"	Please see references to responses in section I
		2809_B2O3 autho template prop 2014 11 28final.pdf	
2826 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 providing your opinion.
2839 2014/11/28	ACEA, Industry or trade association,		Please see references to responses in section I
		2839_20141128_Proposal for annex XIV recommendation on Borates Final.pdf	

	Belgium		
2840 2014/11/28	Freiberger Compound Materials GmbH, Company, Germany	Use of diboron trioxide to cover the melt of semiconductor materials in order to avoid the outgassing of a component 2840_Freiberger - comments for diboron trioxide to the ECHA consultation on the 6th priority list for annex XIV.pdf	Please also see references to responses in section I **C.1.3. Aspects not justifying an exemption from authorisation**
2842 2014/11/28	Freiberger Compound Materials GmbH, Company, Germany	use of diboron trioxide to cover the melt of semiconductor materials in order to avoid the outgassing of a component 2842_Freiberger - attachment to comments for diboron trioxide to the ECHA consultation on the 6th priority list for annex XIV.pdf	Please also see references to responses in section I **C.1.3. Aspects not justifying an exemption from authorisation**
2868 2014/11/28	European Borates Association, Industry or trade association, Belgium	 2868_EBA comments - ECHA PC - 6th priority list - glass-frits.pdf	Please see references to responses in section I
2886 2014/11/28	Company, Italy	 2886_boroglassfrit autho template prop 2014 11 28.pdf	Please see references to responses in section I
2922 2014/11/30	Company, Belgium	 *Confidential attachment removed*	Please see references to responses in section I
2955 2014/12/01	ASD, Industry or trade association, Belgium	 2955_ASD answer to ECHA consultation_General Conclusions for all Boron and lead compounds_281114.pdf	Please see references to responses in section I
2962 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
2966 2014/12/01	CEA, Company, France	 2966_PC-ECHA-boric_acid-comment_CEA_nov2014.pdf	Please see references to responses in section I
2975	GIFAS,		Please see references to

2014/12/01	Industry or trade association, France	2975_20010_ECHA_Annex XIV_Boron_substances.pdf	responses in section I
2987 2014/12/01	Company, United Kingdom	Use as fluxing agent in metallurgical processes. Britannia Refined Metals used calcium chloride as a fluxing agent in refining of silver separated from lead metal in primary metal refining. This caused issues with health and safety and posed an environmental risk. Health and safety issues arose due to calcium chloride capturing moisture from the air, giving a risk of explosion due to moisture being charged to molten metal, to the formation of a slippery film on plant, floors, stairs, etc., and to excessive corrosion of steel structures in the vicinity. Environmental risks arose from the solubility of the slag formed which required a leaching step with subsequent water treatment issues. In 1990 a research project revealed that use of borates, in this instance borax, although other borates would also be effective, produced a slag with none of these problems and also produced savings of about £67 000 (equivalent to about £158 000 today). Research was also conducted into other potential fluxing agents, without success. Shortly afterwards, the use of borates as a metallurgical fluxing 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.	**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-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**
3012 2014/12/01	Cerame-Unie - the European Ceramics Industry Association, Industry or trade 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. Borates are also used as an intermediate in the manufacturing process of	**A.2.4: Claim of use as intermediate:** **- in manufacture of boron glass** **- in manufacture of frits**

	Belgium	boron carbide, boronitride, titanium boride, zirconium boride and calcium boride. 	**- 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**
3013 2014/12/01	European Semiconductor Industry Association, Industry or trade association, Belgium	Applicability of art 58.2 criteria Use of Diboron Trioxide in the semiconductor sector in Europe is subject to the following EU wide regulations EU. Indicative Exposure Limit Values in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU, thru OJ (L 338) 87, 17 Dec 2009) EU. Directive 98/24/EC on the protection of workers from the risks related to chemical agents, Art. 2(b)(i), OJ (L 131) 11, 5 May 1998 (updated thru table 3.2 of Annex VI to CLP, 3 Oct 2013) EU. Directive 92/85/EEC on pregnant workers and workers who have recently given birth or are breastfeeding, O.J. (L 348) 1, 28 Nov 1992 (updated thru table 3.2 of Annex VI to CLP, 3 Oct 2013) EU. Directive 94/33/EC on young people at work, OJ (L 216) 12, 20 Aug 1994, as amended by Directive 2007/30/EC, OJ (L 165) 21, 27 Jun 2007 (updated thru table 3.2 of Annex VI to CLP, 3 Oct 2013). 	Please refer to responses given to comments by STMicroelectronics (#2809).