01/07/2015

Comments and references to responses on ECHA's Draft 6th Recommendation for Disodium tetraborate, anhydrous (EC number: 215-540-4)

The present document compiles the comments received during the public consultation on the draft 6th recommendation for inclusion of substances in Annex XIV of REACH for Disodium tetraborate, anhydrous (EC number: 215-540-4). The public consultation took place between 1 September and 1 December 2014. Some of the comments submitted contained additional attachment(s), accessible at http://echa.europa.eu/documents/10162/13640/6th_rec_comref_attachments_disodium_tetraborate_anhydrous_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
2516 2014/10/28	Individual, United Kingdom	As a formulator I can only comment on the use of Borax in my field of products. Borax is used in a cleanser for it's effective pH buffering and stain removal properties at a low percentage of the formulation. The low percentage use of this product ensures that there are no hazardous effects to the user or the environment. No suitable alternative has been found that performs as well as	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of

		Borax at such low incorporation levels of use. The product we manufacture which includes Borax is Sugar Soap powder, an old traditional decorator's cleanser.	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
2517 2014/10/29	Company, Switzerland	Despite the classification as Toxic for Reproduction, Category 1B, H360-FD (May damage fertility. May damage the unborn child) the disodium tetraborate is used safely in our facilities (controlled closed system). Moreover, we don't have in our company a replacement agent, we surely won't have the funds to request an authorization and if the disodium tetraborate will be included in Annex XIV it's a ~2000 employees company which will be in a serious socio-economic situation.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 5. Availability of suitable alternatives 7. Burden for industry and potential competitive disadvantage
2522 2014/10/31	European Borates Association (EBA), Industry or trade association, Belgium	2522_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**
2531 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). Disodium tetraborate, anhydrous is used in several ready to use water quality tests. Total annual consumption is much less than one tone per year. Nevertheless downstream use is exempted; Hach Lange is forced to apply for Authorization for the production steps. Analog to the ongoing discussion at Commission site about implementation of pre	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**

		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). 2531_ECHA attachments.zip *Confidential attachment removed*	**ECHA's prioritisation:** 1. Potential other regulatory actions **C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation**
2533 2014/11/13	British Jewellers' Association, 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 boarates would not be proportional and not contribute to regulatory effectiveness	Thank you for 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**
2538 2014/11/14	Company, Germany	Re-Classification of Sodium Tetraborate Re-Classification of Boric Acid Re-Classification of Boron Oxide As a "Downstream user" involved in development and manufacturing of boron base protective paints for heat treated steel parts for more than 60 years - without having faced any problems regarding boric compounds hazards, neither in respect of our workers nor our customers - we strongly support the considered re-classification of boric compounds to Category 2. In fact we think it was overdue to introduce the investigations carried out on	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

		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 (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.	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**

		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	
2549 2014/11/18	ANASTA/ANIMA, Industry or trade association, Italy	Soft soldering, brazing and braze welding are industrial processes to join ferrous and non ferrous metals (steels, copper, nickel, titanium alloys, etc.) that are executed without melting the base metal, but only the added metal. They are based on the wetting of the base metal, that is possible only on metals free of	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

		oxides because properly de oxidized by using mixtures containing boric acid, disodium tetraborate and boric oxide	XIV and the corresponding background documentation.
2552 2014/11/18	Manufacture Française des Pneumatiques Michelin, Company, France	Disodium tetraborate is classically used as a lubricant for dry steel cord drawing of metal reinforcements used in tires. Dry steel cord drawing process enables to manufacture steel cords at the right diameter. The borate is essential for the majority of steel cord manufacturers. It is used as a process facilitator and does not enter into the composition of the tire. The borate does not enter into the composition of the metal part either. And this is not an intermediate use because it is not transformed into another substance. Michelin uses disodium tetraborate decahydrate (CAS n°1303-96-4) for steel cord dry drawing. This is a two-step process: First the wire is surface treated with borax and then it is dry drawn with powder soap. The metallic reinforcements produced by Michelin are only for internal use. In 2013, Michelin Europe consumed 142 T disodium tetraborate decahydrate for a production of more than 186 000 T of metallic reinforcements. This represents about 60% of Michelin worldwide production of metallic reinforcements. Therefore, Michelin use of disodium tetraborate decahydrate represents very low tonnages of consumption but high production volumes of steel cord. The metallic reinforcements manufactured via dry drawing are used in the production of bead wires, rubber steel cord fabrics and truck tires metallic carcasses. Bead wires enable maintaining the tire on the wheel, rubber steel cord fabrics provide rigidity to the top of the passenger car tires. All are necessary for the tire performances and the security. As the substance is eliminated during the process this use of disodium tetraborate decahydrate does not imply any risk for consumers and there is no possibility of emission of borate in the environment during tires service life. For Michelin, the use is specific to dry drawing process and this takes place in our steel cord plants without any other exposure risks. 78 persons operate on dry steel cord drawing process in Europe. The risk management measures for these workers include mandatory personal protective equipments. The workers exposure is monitored and a Michelin group exposure limit is fixed to 2 mg/m3, whereas, for example in France, the binding occupational exposure limit for disodium tetraborate decahydrate is 5 mg/m3. On last 5 years, 100% of the exposure measurements were below 2 mg/m3 and more than 75% were below 0,6 mg/m3. The borax is eliminated during the drawing process and effluents are treated in a	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 5. Availability of suitable alternatives 6. Socio-economic benefits of continued use **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** Please also see response to comment #2522 (EBA comment)

		sewage treatment plant (STP). All Michelin plants having steel cord drawing activities are equipped with STP. Between 2007 and 2012, Michelin invested in a research program of substitution of bore in steel cord drawing. It was only partially a success: the soap which was initially bore-based was replaced by a bore-free soap, but no solution was found for disodium tetraborate decahydrate used in bath, despite 67 alternative products tested in collaboration with 4 major suppliers of lubricants. Therefore, the risk of exposure was highly lowered by the replacement of soaps by bore-free soaps but for the moment, there is no alternative solution in perspective for the bath of disodium tetraborate decahydrate. European Borates Association (EBA) comments: "using the REACH authorisation process to control borates would not be proportional and would not contribute to regulatory effectiveness", because "nearly 79% of diboron trioxide, the boric acid and disodium tetraborates used in Europe is outside the scope of authorization". A "Risk Management Options Analysis (RMOA) should be conducted for borates before a decision can be taken on the appropriate regulatory instruments." Michelin fully supports EBA comments.	
2559 2014/11/20	Company, Poland	Disodium tetraborate, anhydrous is used to produce various haematology reagents. Borate buffer (composed from boric acid and Disodium tetraborate, anhydrous) enables to maintain pH of the solutions within the specific range: 7.8 to 10.6. Borate buffer has bacteriostatic properties and it is also an inhibitor of enzymes. Its use minimizes the need for the use of bacteriostatics and fungistatics. Buffers based on borate compounds have good conductivity properties. Moreover, they are less sensitive to overheating, what facilitates transport and storage of haematology reagents. This issue is especially important during using the reagents in African countries and in Asia, which are the main recipients of the reagents. Haematology reagents containing in its composition borate buffer, dedicated to clinical diagnostics are used only by qualified medical personnel. The reagents are not widely available. Haematology reagents based on borate buffer are stored in properly labelled, tightly closed containers.	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**

		Disposal of used up reagents is performed in accordance with the requirements applicable in hospitals and diagnostic laboratories. Application in haematology reagents raw materials other than boric acid and its salts may lead to reduction of reagent's stability. It may increase their sensitivity to high temperatures and cause abnormal functioning , which in turn may lead to receiving abnormal blood count for patients.	
2565 2014/11/20	British Jewellers Association, Industry or trade association, United Kingdom	The BJA does not support the inclusion of borates in the draft ECHA 6th prioritisation list for Annex XIV. In our opinion borates are safe for workers with no epidemiology studies proving otherwise. Additionally, using the REACH authorisation process to control borates would not be proportional and not contribute to regulatory effectiveness.	Thank you for 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**
2576 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.2.8: Claim that formulation of mixtures where the final concentration of the substance is below the specific concentration limit for classification should fall under the generic exemption of such mixtures**

			A.2.13: Claim that risks for workers are controlled by other legislation **A.2.14: Claim that authorisation is not necessary as consumers are protected through the restriction in place** **A.2.15: Claim that exposure data shows low/no risks** **22: Disputing the harmonised classification** **C.2. Responses to exemption requests referring to other legislation**
2584 2014/11/21	Company, Portugal	The substance Disodium tetraborate shouldn't be included in Annex XIV because of the following points: a) Consumers are adequately protected through the restrictions (REACH Annex XVII)and the risk management measures detailed in the exposure scenarios of the registration dossiers; b)Risks for workers are adequately controlled through the risk management measures detailed in the exposure scenarios of the registration dossiers and other chemical management legislation; c)Boron is an essential micronutrient for normal, productive plant growth and is one of seven essential micronutrients for plants according to the EU Fertiliser Regulation	**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.2.16: Risks should be managed using risk management measures like PPE, LEV, exposure tracking, training** **C.2. Responses to exemption requests referring to other legislation**

2589 2014/11/24	AREVA, Company, France	See comment on boric acid and borates	Please see references to responses in comment # 2587 in the comments and references to responses document for boric acid.
2592 2014/11/24	N.V. EPZ, Company, Netherlands	Disodium tetraborate anhydrous is used in boiling water reactors in nuclear power plants together with boric acid. This substance is part of the nuclear safety system. It acts as a kind of pollutant of the primary system to stop the chain reaction immediately. Without disodium tetraborate anhydrous and boric acid some of the main reactor protecting system are missing and a safe operation of nuclear power plants is impossible. Disodium tetraborate anhydrous is stored in a special tank together with boric acid. It will only be used in emergency situations. The risks for workers are only, while measuring the boron concentration and when it is necessary to mix new substances.	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 .
2595 2014/11/24	Company, Germany	see attachment 2595_Comment_K+S_KALI_GmbH_boron2.doc *Confidential attachment removed*	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 1. Potential other regulatory actions 2. Aim & proportionality of

			authorisation system - Authorisation is not a ban 4. Control of risks 5. Availability of suitable alternatives 7. Burden for industry and potential competitive disadvantage **A.2.1: Borates are naturally present in the environment (water, soil, plants). The use of eco-toxicological data obtained in the laboratory claimed to be not relevant given the natural levels of boric acid.** **A.2.8: Claim that formulation of mixtures where the final concentration of the substance is below the specific concentration limit for classification should fall under the generic exemption of such mixtures.** **A.2.20: Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **C.2. Responses to exemption requests referring to other legislation**

2609 2014/11/24	PROBELTE S.A., Company, Spain	boron is considered as essential micro-nutrient for plants, and it can not be substituted for this particular use. Probelte is manufacturing mixture as fertilizer, including boron in the formulation and in different concentration range (from 1 to 50% depend on the mixture, liquid or solid), and according to EU Regulations on fertilizer. It would be a non sense to limit so far the use of this natural element.	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **C.2. Responses to exemption requests referring to other legislation**
2631 2014/11/25	Asociacion Nacional de Fabricantes de Fritas, Esmaltes y Colores Ceramicos (ANFFECC), Industry or trade association, Spain	The "Asociacion Nacional de Fabricantes de Fritas, Esmaltes y Colores Ceramicos (ANFFECC)" would like to express its support to the position stated by the Frit Consortium regarding substance Disodium tetraborate, anhydrous	Please see response to comment #2632 (Frits consortium)
2632 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 Disodium tetraborate, anhydrous (EC 215-540-4), which make specific reference to the use of this substance in the manufacture of frits. 2632_Frit Consortium - borates intermediate in frits.pdf	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation Please see response to comment #2522 (EBA comment) **A.2.4: Claim of use as intermediate:**

			- in manufacture of boron glass **- in manufacture of frits** **- manufacture of starch glues** **- production of fluoroboric acid (CAS 16872-11-0** **- in manufacture of boron carbide, boron nitride, titanium boride, zirconium boride and calcium boride**
2648 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**
2652 2014/11/25	Company, Germany	Our company supports the general comments submitted by The European Borates Association (EBA). Our company requests that Disodium tetraborate, anhydrous (Borax) is removed from the recommendation of ECHA for inclusion in Annex XIV of REACH. For many years, we have attempted substitution of Borax. However, costs and expensive product certifications were restrictive plus technically effective solutions are not yet fully available; time is needed both for developing these solutions and to implement the necessary financial resources without impairing the competitiveness of our industry. Since our use of Borax (4,000Kg per annum) is within an article, where it is encapsulated in the finished product matrix plus there is no intended release of the substance during product use, an Annex XIV listing will not be an efficient	Please see response to comment #2522 (EBA comment) **A.1.5. Aspects not considered in ECHA's prioritisation:** 1. Potential other regulatory actions 2. Aim & proportionality of authorisation system - Authorisation is not a ban 4. Control of risks 5. Availability of suitable alternatives **A.2.20: Claim that the socio-economic impact of inclusion of**

		mean to achieve the goal of the legislation. In our industry, technical solutions are available to adequately control the exposure of workers during article manufacturing. They are sufficiently protected through the restrictions (REACH Annex XVII) and the risk management measures detailed in the exposure scenarios of the registration dossiers. Additionally other downstream legislation specifically protects certain vulnerable workers from exposure to substances toxic to reproduction, such as pregnant workers (Directive 92/85/EC) and young workers (Directive 94/33/EC). We are of the opinion that existing regulations, controls and restrictions provide the necessary safeguards for workers and consumers. In addition, we note that ECHA's draft 5th priority list was stopped by the European Commission and it does not make sense to skip the substances on that 5th list (which presumably have a higher priority) and instead proceed with these substances on the 6th list. Prioritising borates at this time does not represent regulatory effectiveness and is not proportional.	**the substance in Annex XIV would be very high and result in a high burden for industry** **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.2.14: Claim that authorisation is not necessary as consumers are protected through the restriction in place** **C.2. Responses to exemption requests referring to other legislation**
2659 2014/11/25	Company, United Kingdom	Disodium tetraborate, anhydrous is a key process ingredient in a wide range of industrial processes. Studies have shown that boron exposure in rats etc can have adverse reproductive effects and that these effects could be extrapolated to be similar in humans. However these studies have been carried out at extreme exposure levels, far in excess of those that have been observed in studies looking at workers in industries with significant exposure levels such as the study by Duydu et al. in 2011 looking at workers in a Turkish borax processing plant. Since the level of bioaccumulated boron in these workers is more than an order of magnitude lower than the minimum amount required to induce reproductive effects in lab animals it makes no sense to proceed with this material to authorisation on the basis of the existing science. The effect of proceeding to authorisation on industrial users such as ourselves will be two-fold.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban 5. Availability of suitable alternatives **A.2.20 Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry**

		Firstly this action will put a significant cost and admin burden on the affected industries so that they can carry out more studies to verify just how far below the significant exposure their processes are. Secondly the affected industries will need to re-direct product development efforts away from pulling ahead of their competitors and instead direct their energies into changing process ingredients to alternative materials. Selection of suitable alternative materials will need to be on the basis of there being no reasonable scientific evidence that workers in industrial processes such have suffered, or will in the future suffer exposure that would be detrimental to their health. However if we had taken this development approach several years ago we would have selected Disodium tetraborate, anhydrous as no studies have shown detrimental effects to humans at the exposure levels that could be anticipated in industry.	**A.2.22: Disputing the harmonised classification**
2662 2014/11/26	Individual, France	Consumers, industrial and professional workers are adequately protected by virtue of existing REACH restrictions or other EU regulations. a. Consumers are adequately protected through the restrictions (REACH Annex XVII) and the risk management measures detailed in the exposure scenarios of the registration dossiers. In February 2012, the Commission adopted restrictions on borates. Consequently, the use of borates in mixtures above the specific concentration limits is prohibited in consumer markets since 1 June 2012. An assessment of the impact of these restrictions should be conducted first before considering other regulatory options such as authorisation. The use of mixtures containing borates below the specific concentration level does not raise concern as consumers are not subject to prolonged exposure to borates and the threshold level for health effects observed in animals cannot be reached. b. Risks for workers are adequately controlled through the risk management measures detailed in the exposure scenarios of the registration dossiers and other chemical management legislation	**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.2.14: Claim that authorisation is not necessary as consumers are protected through the restriction in place** **A.2.13: Claim that risks for workers are controlled by other legislation** **A.2.15: Claim that exposure data shows low/no risks** **C.2. Responses to exemption requests referring to other legislation**

		The REACH registration dossiers for diboron trioxide, boric acid and disodium tetraborates identified Risk Management Measures (RMM) where appropriate to ensure that health risks to workers are adequately controlled. RMM are communicated via the eSDS, which allows the site risk assessment to be carried out as required by the Chemical Agents Directive (98/24/EC); these mechanisms assist in ensuring worker safety. Additionally other downstream legislation specifically protects certain vulnerable workers from exposure to substances toxic to reproduction, such as pregnant workers (Dir. 92/85/EC) and young workers (Dir. 94/33/EC). compliance with the DNELs can be achieved with common hygiene measures, i.e. without a need to use Personal Protective Equipment (PPE). This results from the low potency hazard of borates. c. Total weight of evidence, including worker exposure data, shows that it is improbable that borates will cause reproductive and developmental effects in humans Although reproductive and developmental effects have been demonstrated in laboratory animals exposed to abnormally high doses of boric acid, similar effects have not been observed in highly exposed human populations or workers. The absence of adverse reproductive effects in extensive investigations of borate workers in the United States, Turkey and China chronically exposed to high levels of borates and in populations living in high boron areas demonstrate that the actual health risk from exposure to borates is small. Workers in boron mining and processing industries represent the maximum possible human exposure. Based on the total weight of evidence that includes worker exposure data, epidemiological studies and mechanistic data, the data show that it is improbable that boric acid will cause reproductive or developmental effects in humans.	

		Aythorisation shall help to improve the risk management of SVHCs; However, risks are adequaltely controlled Under the current regulation, therefore autorisation will not provide a further improvement, but only provide a bureaucratic burden.	
2665 2014/11/26	Individual, Poland	Disodium tetraborate has been identified as a Substance of Very High Concern (SVHC) for its effect on reproduction and subsequently included in ECHA's 6th draft recommendation of priority substances for inclusion in Annex XIV (list of substances subject to authorisation), for which a public consultation is on-going. PPC ADOB do not support the inclusion of Ddisodium tetraborate in the draft ECHA6th prioritisation list for Annex XIV. Despite the identification of certain borates as SVHCs, borates are safe for the general public and for workers. Several epidemiology studies show the absence of health effects for the general public and for highly exposed workers. In our view, using the REACH authorisation process to control borates would not be proportional and would not contribute to regulatory effectiveness. We strongly suggest that the use of boron, one of critical element in fertilizer industry should be excluded from the scope of authorization as it has no alternatives to secure both, high yields and quality of agricultural products. There is known evidence that in case of boron deficiency there is no other element (product) substance that could replace boron, as it plays important role in all metabolic processes during growing period. ARGUMENTS AND RATIONALE 1. A Risk Management Options analysis (RMOa) should be conducted for borates before a decision can be taken on the appropriate regulatory instruments. The implementation of the SVHC Roadmap allows substances with potential concerns to benefit from an RMOa in order to identify the most appropriate risk management options. This is welcomed by industry as it would improve regulatory effectiveness. To our knowledge, for borates an RMOa has not been carried out. Recognizing the experience from the (ex)- 5th list proposal, we would strongly recommend assessing the efficiency of authorisation in order to consider whether	**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**

		this is the right RMM option for borates. 2. Grouping is only effective when all substances of the group are prioritised at the same time. In previous evaluations (2011, 2012) on prioritisation of SVHCs, ECHA suggested "grouping other boron compounds from the candidate list to prevent replacement of the authorised substances by other similar substances". The EBA agrees that the grouping approach should be used to (i) avoid duplicating the administrative burden and (ii) ensure an equal playing field. Should borate substances be recommended for prioritisation in the future (despite our arguments against this step), we consider it appropriate to suggest that all borate substances classified as Repr 1B H360FD be grouped. Today diboron trioxide, boric acid and disodium tetraborates are identified as SVHCs. In March 2014, the RAC recommended the classification & labelling of disodium octaborate and disodium octaborate tetrahydrate as Repr 1B H360FD, yet these are not considered SVHCs at this point. We believe these substances could replace diboron trioxide, boric acid and disodium tetraborates in a number of end uses. This situation should be clarified before considering prioritisation of other borates for inclusion in Annex XIV. 3. The major uses of the borate substances in the EU are outside the scope of authorization, either as intermediates or as mixtures below the specific concentration limit (SCL), or covered by other legislation. Nearly 79% of boron trioxide, the boric acid and disodium tetraborates used in Europe is outside the scope of authorisation, as these substances are mainly used in: - the manufacture of glass and frits or for the synthesis of new substances: in these uses, the substances qualify as an intermediate since they are completely consumed and transformed into another substance. In the new substance formed, boron is part of the chemical structure and thus, these uses fall outside the scope of authorisation. - mixtures below the specific concentration limits - covered by other sector- specific legislation (e.g. biocides, medicinal products for human or veterinary use), again, falling outside the scope of authorization. Boric acid and other borates have used as an antiseptics from over hundred years.	**concentration limit for classification should fall under the generic exemption of such mixtures.** **A.2.9: ECHA should group the borates on the Candidate List with borates with a harmonised classification that are not yet identified as SVHC. Recommendation should be postponed until all classified boron compounds are included in the Candidate List.** **A.2.11: Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV** **A.2.15: Claim that exposure data shows low/no risks** **A.2.20 Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **C.2. Responses to exemption requests referring to other legislation**

		The most common are aqueous solutions (usually 3%) but they are also available in consistency of gel or ointment (10%). Medicinal products containing borates are popular in treatment for mouth ulcer, inflammation of the skin, eczema, burns, bruises, swelling, superficial damage to the epidermis. Those products are efficient, safe, commonly available (over-the-counter drugs) and not expensive. Please see attached leaflets of some medicines registered in Poland.	
2671 2014/11/26	UNIFA, Industry or trade association, France	The BORON, absorbed by plants in the form of borate, is essential to vegetables. It plays a role in the meristematic growth, the migration of carbohydrates, synthesis of nucleic acids and proteins. The boron deficiency is linked to the availability of this nutrient in the soil, that can be influenced by the soil pH and by various other soil and climate conditions. This results in anomalies of the leaves extremities, stalks, fruits and roots. This deficiency is corrected by precise applications of boron to the soil or in foliar spraying, knowing that an 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. The boron is substitutable by no other chemical element. The industry of the fertilization did not find alternative to boron substances listed in the draft 6th recommendation. An absence of borated fertilization would engender in the short term in France more than 800 million euros per year of yield loss, including the quality of the crops, knowing that certain crops like sugar beet, sunflower and rape are more sensitive to boron deficiency than others. Furthermore, if this deficiency cannot be corrected because of the absence of borated fertilizer, the issue would remain in the following years with increased concern. It is important to underline that these crops are grown in all Europe and they are not specific to France. It would also have an impact in term of employment in the whole supply chain of	**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**

		fertilizers, which has already 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 are not included to the annex 14 of REACH regulation and that a Risk Management Option (RMO) is led. (See my attachment) 2671_Commentaires UNIFA_Novembre 2014_EN_VF.pdf	
2675 2014/11/26	Company, Germany	Dear Sir or Madam, We do appreciate and understand ECHA's approach to identify SVHC and ban these from the EU market in order to protect the human life and the environment. Our company is absolutely in line with this approach. Effect on chromium trioxide authorization process However it is to point out that the electroplating industry is currently facing a major challenge with respect to REACH authorization due to the substitution of hexavalent chromium compounds (e.g. chromium trioxide) in a significant number of applications. Such applications comprise, but are not limited to: transportation (cars, trucks, trains, airplanes), sanitary or furniture. The switch to new technologies is complex and costly for plating companies as it requires revamping of existing equipment, investment into new equipment and the product approval at final customer level, e.g. Automotive OEM. The substitution process has already started but will take several years for the complete market to switch. Use in industrial setting/environment regulated Furthermore disodium tetraborate is deemed to be toxic to reproduction 1B, i.e. "may damage fertility/the unborn child". Consequently consumers as well as professional users should not be able to get in contact with such substance as they might not be able to handle the substance according to its hazard. In contrast to that industrial users are well trained in the handling of hazardous substances. In addition to that plating facilities are falling under numerous local, federal and EU regulations that strictly restrict the handling and define the waste and waste water quality. Examples of such regulations are (non-exhaustive list): Directive 2010/75/EU, Directive 96/82/EC (resp. 2012/18/EU), ADR, Bundesimmissionsschutzgesetz (German immission control law), Arbeitsschutzgesetz (German occupational safety law).	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 1. Potential other regulatory actions 2. Aim & proportionality of authorisation system - Authorisation is not a ban 4. Control of risks **A.2.11: Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV** **A.2.13: Claim that risks for workers are controlled by other legislation** **A.2.16: Risks should be**

		Risk Management Option Assessment missing The high scoring leading to the current prioritization proposal of disodium tetraborate is based on the high volumes with a score of 15 and the wide dispersiveness of uses (WDU) in combination with article service-life (ASL) with a score of 12. The high score of the WDU is mainly based on uses by professionals (+5) and the uncertainty on releases from articles (+2). Here it is to point out that professional users as well as consumers are less well trained than industrial workers that are working in a strongly regulated and controlled environment like already mentioned before. If the EU bodies see risks in the handling of disodium tetraborate in specific sectors or user groups like professionals or consumers we would ask you to tackle these by specific restrictions in those sectors with risks. Furthermore in our opinion it is questionable why substances falling in the scope of REACH, meaning industrial chemicals, that are strictly regulated, may still be used as food ingredients. Disodium tetraborate is considered an approved food ingredient, E285. In our opinion, this is a strong contradiction to the proposal of this substance being SVHC. To date the authorization of disodium tetraborate would lead to a heavy burden for the plating industry, its suppliers and its customers as it would clearly interfere with the ongoing hexavalent chromium substitution process. We ask you to postpone the authorization of disodium tetraborate in order to allow for a smooth substitution of chromium trioxide. Best regards,	**managed using risk management measures like PPE, LEV, exposure tracking, training** **A.2.23: Claim that authorisation requirement for borates would be in conflict with the EU food law (including food contact materials and food or feedingstuffs legislation)** **B.2.2: Concerns about workload, timelines and resources needed for those companies already dealing with Cr(VI) applications** **C.2. Responses to exemption requests referring to other legislation**
2681 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 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**

2684 2014/11/26	Company, Portugal	The authorization should help to improve the risk management of SVHC's. However, risks are already adequately controlled under the current legislation, so the authorization will not provide a further improvement, but will only provide a bureaucratic burden.	**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**
2688 2014/11/26	CooperVision, Company, United States	CooperVision is a manufacturer of globally trusted brands of vision correction devices. It is a world leader in the manufacture of soft contact lenses, related products and services. The sale of these devices is regulated to the utmost standards worldwide to ensure the highest level of protection to end users. The use of disodium tetraborate in the manufacture, validation, packaging and use of these devices is critical to the continuing production of these devices within the EU. Should disodium tetraborate be included onto Annex XIV of REACH, global supply of these lenses could be impacted. It is estimated that over 30% of all soft contact lenses placed on the market globally contain disodium tetraborate buffering solution. CooperVision therefore expresses its concern over the potential inclusion of disodium tetraborate on to Annex XIV of REACH. Disodium tetraborate is widely used in the manufacture of ophthalmic care products and in the manufacture, validation and packaging of soft contact lenses, regulated under Council Directive 93/42/EEC. The principle function of the substance is to help maintain a hydrating and biocompatible environment for the lenses to ensure its safe operation as a vision correction device. The use of such buffering solutions is important for many contact lens wearers. These solutions must have a stable pH within the physiologic range and at approximately the pH of the tears. The normal range reported in the literature since 1921 on human tear pH has a span of values from 6.6 – 7.8. Disodium tetraborate buffers exhibit microbiocidal properties thereby reducing the risk of contamination during the contact lens manufacturing process, additionally disodium tetraborate buffers provide a compatible environment with the contact lens polymer, thereby helping to assure the stability of the device over the entire shelf life. The ability of the substance to function in a dual role, renders substitution very	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives 7. Burden for industry and potential competitive disadvantage **A.2.12: ECHA should not proceed with the 6th recommendation, when the 5th is still open** **A.2.20: Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry**

		challenging. There are currently no clear, single substitutes for this substance in ophthalmic care products. It is likely that a combination of substances would be required in order to achieve an equivalent level function. Should substitutes be identified, the device would be required to go through approximately 45 different validation and notification systems before being placed on the market for global sales. The impact of listing this substance onto Annex XIV will be detrimental to the sector in the EU. Such an action would result in significant economic losses to the Company and the EU as approximately 50% of its global sales of soft lenses are manufactured within the EU. This industry cannot depend upon a successful authorisation application to continue to meet global demand for these devices, rather it will require to have fully validated substitutes in place prior to the sunset date in order to meet global demand. Given the timeframe and complexity of meeting global validation assessments it is possible that production and packaging of such lenses will move to sites outside of the EU as importation of the finished devices could continue without restriction. Finally, as the EU Commission is currently carrying out a full review of the Authorisation process resulting in a delay of the finalisation of the 5th Recommendation. It would be prudent to delay this 6th Recommendation until this review has been completed and the outcome is known.	**C.2. Responses to exemption requests referring to other legislation**
2689 2014/11/26	Comité Européen de la Tréfilerie (CET), Industry or trade association, United Kingdom	Description of the European Wire Industry The European steel wire-drawing industry is downstream from the steelmaking industry and CET estimates it produces some 6 million tonnes per annum of drawn wire. Wire is used in a wide variety of applications from high quality grades which go into the automotive industry, ropes for mining and bridges, specialised wires for oil and gas, springs for car seats and mattresses to 'commodity' grades which are used in fencing, nails, staples and a million other uses. The European wire drawing industry comprises some 300 companies with about 25,000 employees. Some larger wire producing companies are integrated with steel producers, some are independent and some are small, family-owned, particularly in Germany and Italy. The estimated turnover of the industry is 6-7 bn euros per annum. The wire industry plays a key role in a number of essential manufacturing supply	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

		chains, particularly automotive, construction, telecoms and agriculture. Wire Drawing Process Wire is made by drawing rod through a number of drawing dies to reduce its diameter (which also increases its length). The wire may need to be drawn a number of times, and this is done at room temperature and so is classified as a cold working process. However to enable the wire to be further worked, or to change its metallurgical properties sometimes the wire has to be annealed (ie heated to a high temperature) between drawing processes. This re-heating process is energy intensive. In Europe, the wire drawing process is a highly automated, productive and efficient process. Competition Wire imports come from all over the world including China. Closer to home Turkey is significant wire producer. Use of Borates Borates in the wire drawing industry have already been partly substituted in soaps, but substitution is not feasible as a coating carrier for lubricants for both technical and economic reasons. Use of borates in soaps and use as coating carriers are the two main uses within the wire industry which are being investigated at the moment. The total volume used as a coating carrier is rather low in the European wire industry compared to the global use of borax. Best guess is in the range of 1,000 ton/year. Borax is used exclusively within an industrial environment, in which exposure is limited, and adequate exposure reduction measures restrict this exposure even further. Consumer exposure can be excluded given that the borax is normally removed in further processing and only used as an enabler within the production process for getting a proper product quality. The results of research into substitution which has been going on since 2009 show that: - Borax in soaps can and is being substituted for most applications by low borax to even borax free soaps; - Borax as a coating carrier cannot feasibly be substituted at the moment for technical and economic reasons. Borax is also used in the wire industry, typically in low quantities, in a wide range of smaller applications, not linked to coating carriers and soaps, and for which we have not yet conducted research but which could be crucial in the process and product quality.	

2696 2014/11/27	Outokumpu Stainless ltd., Company, United Kingdom	Disodium tetraborate anhydrous (often referred to as Borax) is used by our company as a slag stabiliser. Based on exposure facts and socioeconomic impacts our organization proposes to: Exempt Disodium tetraborate, anhydrous use as slag stabiliser from authorization 2696_Outokumpu input to EC Socioeconomic consultation on Borax 20141121.docx	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 1. Potential other regulatory actions 5. Availability of suitable alternatives **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**
2697 2014/11/27	European Special Glass Association and European Domestic Glass Association, Industry or trade association, Belgium	2697_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**
2701 2014/11/27	Company, Sweden	Disodium tetraborate anhydrous (often referred to as Borax) is used by our company as a slag stabiliser. Based on exposure facts and socioeconomic impacts our organization proposes to • Remove Disodium tetraborate, anhydrous from final proposal or • Exempt Disodium tetraborate, anhydrous use as slag stabiliser from authorization more, see attachment 2701_Outokumpu input to EC Socioeconomic consultation on Borax 20141121.docx	Please see response to comment #2696 (Outokumpu UK)) **C.2. Responses to exemption requests referring to other legislation**
2706 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 response to comment #2522 (EBA comment). **C.2. Responses to exemption requests referring to other legislation**
2713 2014/11/27	Company, Germany	General remarks The European Commission released its Review of REACH on 5 February 2013 emphasizing the Commission's conception of risk management under REACH. The	**A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of

		European Commission explicitly mentions that "no automatic link is assumed between the classification of a substance as a CMR (carcinogens, mutagens and reproductive toxins) and its inclusion on the Candidate List". This appears to acknowledge that Authorization is not an inevitable consequence of classification as CMR1. Furthermore, the Commission explains that "before considering the inclusion of a substance on the Candidate List, an assessment of the best Risk Management Options under REACH is performed". Similarly to the review of REACH, the Commission, the Member States and ECHA confirm their commitment to the "best RMOs" approach to handle SVHCs. This roadmap is a significant development, because it provides a more transparent and predictable process to consideration of SVHCs. It will also make conducting an RMO study a routine step before a substance is placed on the Candidate List. A RMO study should therefore be performed (which has not been done for disodium tetraborate, anhydrous) before adding and prioritizing a substance on the candidate list following the Review - recommendation: 7.1. "The Member States and ECHA are encouraged to continue discussing and sharing at an early stage RMOs analysis with the view to coordinate activities in relation to identification of SVHCs, including "substances of equivalent concern" for which no guiding criteria are available yet." Disodium tetraborate, anhydrous got the classification "toxic of reproduction" category 1B by the EU Regulation 790/2009 since September 2009 and therefore belongs to the hazardous substances according to the EU Regulation 1272/2008. Prior to this classification, the general rules for handling chemicals were applied when using disodium tetraborate, anhydrous. All specific measures which have been introduced and implemented since the classification (such as substitution, prevention and reduction of exposure as well as the protection of the employees) are therefore a maximum of 5 years old. Already now Europe faces a ban of disodium tetraborate, anhydrous by inclusion in annex XIV (or use has to be authorised). From the downstream user's perspective this timeline is not plausible, especially as there haven't been studies performed recently by the European public authorities on the effectiveness of the measures taken or on any associated evidence of the remaining health risks of the affected employees as well as the remaining environmental risk, which could justify the inclusion of disodium tetraborate, anhydrous in the Annex XIV. The study according to annex XV does	authorisation system - Authorisation is not a ban **A.1.2. Prioritisation: Volume** **A.1.3. Prioritisation: Wide-dispersiveness of uses:** 1. Scope of the assessment of wide-dispersiveness of uses **A.2.2: Disputing the volume score, claiming that the volume figures used for prioritisation are outdated** **A.2.11: Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV** **A.2.20: Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **B.2.6: Check effectiveness of harmonised classification before proceeding with further regulatory risk management activities** **C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other**

		not include these aspects. We regard this as an additional reason for the necessity of an RMO study for disodium tetraborate, anhydrous. The inclusion of disodium tetraborate, anhydrous in the candidate list should therefore be re-evaluated. High volumes and wide dispersive use Since the disodium tetraborate, anhydrous harmonized classification as Toxic for Reproduction, Category 1B, was established some uses have been substituted. Moreover some mixtures have been modified in order to ensure that disodium tetraborate, anhydrous concentration is under the specific classification limit. These evolutions are leading to considerable change within the market and the related exposures. The data concerning the volume and wide dispersive used for prioritization of disodium tetraborate, anhydrous are dating back to 2005 - 2008 and should therefore be revalidated. Any prioritization action should be based on current data – a prioritization based on outdated material can lead to overregulation and might not be in line with the principle of proportionality. The prioritization of disodium tetraborate, anhydrous in the candidate list should therefore be re-evaluated. *Confidential attachment removed*	**legislation**
2717 2014/11/27	Company, Germany	As indicated in Section 2.2. of ECHA background document, the use of boron compounds as raw material to manufacture the substance glass is a use as "intermediate" which is not in the scope of authorization. Therefore, additional comments are not relevant for our use.	**A.2.4: Claim of use as intermediate:** **- in manufacture of boron glass** **- in manufacture of frits** **- manufacture of starch glues** **- production of fluoroboric acid (CAS 16872-11-0** **- in manufacture of boron carbide, boron nitride, titanium boride, zirconium boride and calcium boride**
2721 2014/11/27	Wieland-Werke AG, Company,	2721_Comments to 6th priority list of substances for inclusion in Annex XIV _	Thank you for your comment and the additional information provided.

	Germany	Wieland-Werke.pdf	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**
2730 2014/11/27	Company, Germany	The element B is an essential micronutrient to plants which is not substitutable, the use of Disodium tetraborate for the formulation of fertilizers should be exempted from the authorization scope. 2730_COMPO.pdf	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 5. Availability of suitable alternatives

			A.2.8: Claim that formulation of mixtures where the final concentration of the substance is below the specific concentration limit for classification should fall under the generic exemption of such mixtures. **A.2.20: Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **C.2. Responses to exemption requests referring to other legislation**
2737 2014/11/27	Saint-Gobain ADFORS, Company, France	As indicated in Section 2.2. of ECHA background document, the use of boron compounds as raw material to manufacture another substance – glass – is a use as "intermediate" which is not in the scope of authorization. Therefore, additional comments are not relevant for our use.	**A.2.4: Claim of use as intermediate:** **- in manufacture of boron glass** **- in manufacture of frits** **- manufacture of starch glues** **- production of fluoroboric acid (CAS 16872-11-0** **- in manufacture of boron carbide, boron nitride, titanium boride, zirconium boride and calcium boride**
2741 2014/11/27	Industry or trade association, France	Changes in the market since 2009 Since promulgation of the harmonised classification of disodium tetraborate decahydrate or borax as Toxic for Reproduction, Category 1B, various usages have been substituted. In the same way, numerous mixtures have been	**A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban

		reformulated so as to limit borax concentration to below the classification thresholds. These developments resulted in changes in the market (considerable drop in the volume used by the detergent sector, sector considered as accounting for 23% of the volume used and therefore of exposure to the substance in question). The question of relevance of the data used to prioritise these substances may therefore be raised. Numerous usages outside scope In addition, the authorisation procedure does not seem the best risk management option. Certain usages are outside scope of the authorisation procedure: - covered by the biocide regulations - benefiting from interim status - chemical synthesis of other substances. These usages account for at least 60% of the volumes concerned according to the data in the Annex XV Transitional report of 2009, and for at least 70% if the European Commission Report on critical raw materials for the European Union is referred to*. Critical raw materials for the European economy Certain usages cannot be substituted, such as use as a fertiliser for certain crops. A high number of files requesting authorisation would therefore be justifiably submitted with approval potentially granted. Borates are part of the 20 critical raw materials for the European economy. Substitution of borates is considered as difficult** (the third least substitutable substance out of the 20 critical raw materials for the European economy and even not substitutable for nuclear usages). There is consequently a difference between REACh regulation of these materials and market reality. The recommendation to include borates should be based on RMO analysis so as to clarify the situation, and given the extent of impacts on numerous industrial sectors, support the appropriate regulatory measures.	5. Availability of suitable alternatives **A.2.2: Disputing the volume score, claiming that the volume figures used for prioritisation are outdated** **C.2. Responses to exemption requests referring to other legislation**

		Usage of borax (1303-96-4) EDF plans to use borax to strengthen the arrangements already in place in the event of spillage of reactor coolant in the reactor building at PWR plants. This use was studied by EDF further to operating experience from the Fukushima accident in Japan and will be set up with approval from the Nuclear Safety Authority. Other solutions not using a substance of very high concern or likely to be one have been studied but they incur risks that are incompatible with plant safety. In the event of unavailability of the first emergency system (containment spray with injection of caustic soda), borax would enable pH of the water spilled to be increased so as to limit the corrosion risk for metallic materials and hydrogen release, and trap the iodine in solution in the water thus preventing its transfer in volatile form into the reactor containment building atmosphere. The purpose is to limit the radiological consequences for the local population, as iodine is the main contributor to thyroid dose in accident situations. Compared to other components, borax plays a role of neutron absorber and does not generate any precipitate likely to result in clogging of the containment sump filters thus guaranteeing maintained water recirculation to remove heat from the containment. The system consists of installing baskets filled with borax at the bottom of the reactor building. In the event of accident, the volume of water at the bottom of the containment would dissolve the borax contained in the baskets. The baskets are installed at sufficient height so that the alkalinity-providing component is not dissolved in normal plant operating conditions. The basket walls are composed of wire mesh with sufficiently fine mesh size to retain the solid borax but wide enough to let the water go through. All the situations of worker exposure have been identified and the measures to be taken to manage the risks for the workers have been defined: • Once the baskets have been installed in the reactor buildings, the operations	

		planned on the baskets are sampling for analysis (test of dissolution and measurement of pH in a solution representative of the recirculation solution) and any makeup. • The personnel will have to wear the regulatory suit in the radiologically controlled area (RCA), oversuit, gloves and breathing masks with class P3 filters. • Temporary protection of the system is planned during outage. The purpose of this protection, of waterproof cover type or equivalent, is to protect the system from any inadvertent dissolution of the alkalinity-providing component and prevent worker exposure to any dust from the alkalinity-providing component. This safety system prevents release into the environment. In the event of accident and inadvertent injection of water into the reactor building resulting in immersion of the baskets, the effluent produced can be sent to the Liquid Waste Processing System to be treated with the evaporator. Concentrates are sent to the appropriate waste disposal facility. The total volume installed in the French nuclear power plants is around 336 tonnes of borax. Implementation of this solution on the sites is planned from 2015 to 2017 subject to approval from the Nuclear Safety Authority (ASN). These baskets are designed to stay for the remainder of plant operating lifetime and to be used only in the event of accident. Moreover, this type of passive system has already been set up at nuclear power plants in the US and South Africa and on other foreign sites. *Report on critical raw materials for the EU, EC, 2014. **Communication from the European Commission to the European Parliament, European Council, European Social and Economic Committee and Regional Committee on the revised list of critical raw materials for the European Union and implementation of the raw materials initiative.	
2743 2014/11/27	RWE Power AG, Company,	General remarks The European Commission released its Review of REACH on 5 February 2013	**A.1.2. Prioritisation: Volume**

	Germany	emphasizing the Commission's conception of risk management under REACH. The European Commission explicitly mentions that "no automatic link is assumed between the classification of a substance as a CMR (carcinogens, mutagens and reproductive toxins) and its inclusion on the Candidate List". This appears to acknowledge that Authorization is not an inevitable consequence of classification as CMR1. Furthermore, the Commission explains that "before considering the inclusion of a substance on the Candidate List, an assessment of the best Risk Management Options under REACH is performed". Similarly to the review of REACH, the Commission, the Member States and ECHA confirm their commitment to the "best RMOs" approach to handle SVHCs. This roadmap is a significant development, because it provides a more transparent and predictable process to consideration of SVHCs. It will also make conducting an RMO study a routine step before a substance is placed on the Candidate List. A RMO study should therefore be performed (which has not been done for disodium tetraborate, anhydrous) before adding and prioritizing a substance on the candidate list following the Review - recommendation: 7.1. "The Member States and ECHA are encouraged to continue discussing and sharing at an early stage RMOs analysis with the view to coordinate activities in relation to identification of SVHCs, including "substances of equivalent concern" for which no guiding criteria are available yet." Disodium tetraborate, anhydrous got the classification "toxic of reproduction" category 1B by the EU Regulation 790/2009 since September 2009 and therefore belongs to the hazardous substances according to the EU Regulation 1272/2008. Prior to this classification, the general rules for handling chemicals were applied when using disodium tetraborate, anhydrous. All specific measures which have been introduced and implemented since the classification (such as substitution, prevention and reduction of exposure as well as the protection of the employees) are therefore a maximum of 5 years old. Already now Europe faces a ban of disodium tetraborate, anhydrous by inclusion in annex XIV (or use has to be authorised). From the downstream user's perspective this timeline is not plausible, especially as there haven't been studies performed recently by the European public authorities on the effectiveness of the measures taken or on any associated evidence of the remaining health risks of the affected employees as well as the remaining environmental risk, which could justify the inclusion of disodium	**A.1.3. Prioritisation: Wide-dispersiveness of uses:** 1. Scope of the assessment of wide-dispersiveness of uses **A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban 4. Control of risks **A.2.1: Borates are naturally present in the environment (water, soil, plants). The use of eco-toxicological data obtained in the laboratory claimed to be not relevant given the natural levels of boric acid.** **A.2.2: Disputing the volume score, claiming that the volume figures used for prioritisation are outdated.** **A.2.11: Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV** **A.2.16: Risks should be managed using risk management measures like PPE, LEV, exposure tracking, training**

		tetraborate, anhydrous in the Annex XIV. The study according to annex XV does not include these aspects. We regard this as an additional reason for the necessity of an RMO study for disodium tetraborate, anhydrous. The inclusion of disodium tetraborate, anhydrous in the candidate list should therefore be re-evaluated. High volumes and wide dispersive use Since the disodium tetraborate, anhydrous harmonized classification as Toxic for Reproduction, Category 1B, was established some uses have been substituted. Moreover some mixtures have been modified in order to ensure that disodium tetraborate, anhydrous concentration is under the specific classification limit. These evolutions are leading to considerable change within the market and the related exposures. The data concerning the volume and wide dispersive used for prioritization of disodium tetraborate, anhydrous are dating back to 2005 - 2008 and should therefore be revalidated. Any prioritization action should be based on current data – a prioritization based on outdated material can lead to overregulation and might not be in line with the principle of proportionality. The prioritization of disodium tetraborate, anhydrous in the candidate list should therefore be re-evaluated. 2743_2-2_ECHA_consultation_disodium tetraborate anhydrous paper_final.docx	**A.2.20: Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **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**
2751 2014/11/28	BOCI, CFHM, UFBJOP et Comité Francéclat, Industry or trade association, France	Draft recommendation for inclusion of borax and boric acid in the Authorisation List of the European REACH regulation Submission to the European Chemicals Agency (ECHA) produced by The National Jewellery-making, Gold Jewellery-making and Silversmiths, Gift Makers and Decorative Arts Industries Trade Association (BOCI) The French Association of Watchmaking and Microtechnology (CFHM) The French Union of Jewellery, Silverware, Gems and Pearls (UFBJOP)	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

		& The Francéclat Committee, the French Watchmaking, Jewellery, Silverware and Tableware Committee Within the framework of the authorisation procedure established by the European REACH regulation, the above-mentioned organisations would like to present their input about the draft concerning the integration of borax and boric acid to annex XIV because of the consequences said integration would have on the watchmaking, jewellery and high-jewellery sectors. The use of borax and boric acid in the watchmaking, jewellery and high-jewellery sectors Borax is frequently used in jewellery and high-jewellery, either in smelting for example when preparing alloys or in the remelting of precious metal "waste", or combined with boric acid as a brazing flux. Brazing flux Borax and boric acid have been used for a very long time as fluxes for blowtorch brazing of precious metals in the jewellery and high-jewellery sectors. This technique is one of the most commonly used in assemblies and repairs in these sectors. Suppliers of specific brazing processes on the jewellery market offer complex flux formulas. Their main ingredients are borax and boric acid. Their use is explained by their melting characteristics and their stability at high temperature which makes them particularly suitable for precious metal brazing. The main properties of brazing fluxes are:	5. Availability of suitable alternatives **A.2.13: Claim that risks for workers are controlled by other legislation** **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** **B.2.1: Concerns and uncertainties with respect to the authorisation process, in particular for SMEs** **C.2. Responses to exemption requests referring to other legislation** **C.3.5: Claim that products not containing the substance in the final product should be exempt from authorisation**

		- melting at a temperature at least 100°C lower than the brazing solder solidus; - remaining stable up to the maximum temperature required for brazing; - dissolving metallic oxides that can form before and during brazing; - being sufficiently fluid, even when loaded with dissolved oxides to be easily removed into the capillary gaps of the joint by the brazing solder and to then form a continuous film on the liquid braze; - being easy to remove after brazing. With this process, the borax and boric acid are removed from the brazed parts at the end of the operation. The finished sold products therefore do not contain these two substances and consumers are not exposed to them in any way. Flux in remelting precious metals (waste smelting and alloy preparation) Borax is also used in smelting for the preparation of precious metal alloys and for remelting precious metal "waste". The primary source of precious metals is of course extraction from minerals, but there is an important secondary circuit that involves recycling metals from waste and scraps which, when processed in the appropriate refining channels, can become new metals. Scrap rates from the manufacture of jewellery or jewellery pieces in precious metals are rather high, at least for the two important manufacturing procedures that are lost-wax casting and machining; these scrap rates vary from 50 to 80% of the material used. All manufacturing waste and scraps are collected and recycled. Some recycling is done internally and some is refined by specialised companies. Considering the monetary value of precious metals, this is an essential condition for the financial health of manufacturing companies. This systematic recycling also helps limit the quantity of precious metals from the primary circuit and therefore reduces environmental damage associated with mineral extraction. Jewellery workshops are generally equipped with a more or less advanced system for collecting and processing precious metal waste and scraps. The first level consists in remelting the waste in a crucible containing fluxes that will facilitate	

		fusion and remove some of the impurities. As well as jewellery workshops, major precious metal refining companies use this technique as the first refining operation for cleaning and standardising the batches of waste they receive. Borax is one of the fluxes used systematically because it dissolves common metal oxides and prevents their creation during smelting. Its properties as a flux combined with its stability at high temperature make it indispensable for remelting precious metals. Similarly to its use in brazing fluxes, borax is used in the manufacture and recycling of jewellery, high-jewellery and watchmaking pieces in precious metals but is not in the finished product and consumers are not exposed to it in any way. Alternatives to borax and boric acid in the watchmaking, jewellery and high-jewellery sectors Since borax and boric acid have been classified in Category 1B for reproductive toxicity, they are subject to the European legislation concerning chemical risks in the workplace, governed by the two directives 2004/37/CE and 98/24/CE which protect workers from risks associated with exposure to chemical substances at their workstations. As a CMR, the rules specific to preventing risks of carcinogenic exposure, mutagenic exposure or exposure that is toxic to reproduction apply and in particular obligate, wherever possible, the replacement of the CMR used in the company by a non-dangerous substance or, at least, by a less dangerous one. Research has been carried out and continues on the replacement of borax and boric acid. In the case of their use in brazing fluxes, a replacement product is being integrated by companies. The first results are not satisfactory from a technical point of view as the product does not cover all the uses (in terms of brazing material, types of brazing solder, types of pieces) of brazing fluxes made with borax and boric acid. Furthermore, from a financial point of view, the proposed product costs 7 times more than the brazing fluxes made with borax and boric acid.	

		In the case of using borax in smelting (preparing alloys, remelting precious metals), there is currently no substitute product. Its ban would therefore be extremely problematic for the jewellery and high-jewellery sectors. The use of borax in smelting is only a tiny part of the product's overall use which makes its replacement particularly difficult for this specific application. Replacement efforts provided by borax suppliers are not necessarily focused on this minor use which is nevertheless essential for our sector. Company testimonials and socio-economic impact Most companies that work with precious metals use borax and boric acid and would therefore be affected by its inclusion in annex XIV of REACH. Companies that do not use it outsource the operations involving these substances. The industrial fabric of jewellery and watchmaking is made up of a few large companies and a multitude of small and very small (craftsmen) businesses. A ban on the use of borax and boric acid pending authorisation would cause great prejudice in these sectors which have already had to deal with the implementation of many restrictions on other substances over the last few years (nickel, lead, cadmium, chromium VI and PAH, for example). Considerable efforts have already been made by professionals and a ban on borax and boric acid, two strategically essential substances in the field of precious metals to which consumers are never exposed, would once again have a significant impact on their business. French companies in the watchmaking and jewellery sectors have been contacted for information about their use of borax and boric acid, and the impact their inclusion in annex XIV would have. You will find a sample of their testimonials in the attached document. For companies that supply and/or recycle precious metals and use borax in large quantities (several tons a year), the inclusion of borax in annex XIV of REACH would result in the loss of an important competitive edge which could, quite simply, lead to an end of their precious metal recycling business, for the benefit of non-European companies. Furthermore, banning borax would lead to a higher risk	

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

		Conclusion It seems essential that further studies are carried out to determine the best option for risk management of borax and boric acid to establish proportionate measures that can conciliate the necessary health protection with the companies' technical and socio-economic imperatives. The main risk identified associated with the use of borax and boric acid in the watch, jewellery and high-jewellery sectors involves the exposure of workers as these substances are not in the finished product that is sold. Health and safety legislation in the workplace, and particularly the Directive 2004/37/EC concerning the protection of workers against risks associated with carcinogenic exposure, mutagenic exposure or exposure that is toxic to reproduction which already applies and requires a replacement approach, seems to be the option the most suitable for managing the identified risk. It is, in effect, completely adequate and perfectly proportionate to the required objective. Considering the impact that the integration of borax and boric acid into annex XIV would have on our profession and the uncertainty of the capacity an authorisation process would have for better managing the risks presented by these substances as no study assessing the better management of said risks has been carried out, we ask that the integration of borax and boric acid into REACH's annex XIV be suspended until new information can be explored and discussed. 2751_Sample of testimonials.pdf	
2772 2014/11/28	WKÖ, Other contributor, Austria	See PDF attached. 2772_su_85_WKÖ Borate.pdf	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 1. Potential other regulatory actions

			4. Control of risks 5. Availability of suitable alternatives **A.2.8: Claim that formulation of mixtures where the final concentration of the substance is below the specific concentration limit for classification should fall under the generic exemption of such mixtures** **A.2.11: Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV** **A.2.20: Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 2. Lack of alternatives, socio-economic aspects **C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation**

			C.3.5: Claim that products not containing the substance in the final product should be exempt from authorisation
2776 2014/11/28	Aurubis AG, Company, Germany	Aurubis is the leading integrated copper group and the world's largest copper recycler. We produce some 1 million t of copper cathodes each year and from them a variety of copper products. Production expertise is our strength and the driving force of our success. Aurubis has about 6,500 employees, production sites in Europe and the USA and an extensive service and sales system for copper products in Europe, Asia and North America. Thanks to our wide range of services, we rank among the global leaders in our industry. Our core business is the production of marketable copper cathodes from copper concentrates, copper scrap and recycling raw materials. These are processed within the Group into continuous cast wire rod, shapes, rolled products and strip as well as specialty wire made of copper and copper alloys. Precious metals and a number of other products, such as sulfuric acid and iron silicate, round off our product portfolio. Customers of Aurubis include companies in the copper semis industry, the electrical engineering, electronics and chemical industries as well as suppliers of the renewable energies, construction and automotive sectors. Aurubis is oriented to growth and to increasing corporate value: the main focuses of our strategy are on expanding our leading market position as an integrated copper producer, utilizing growth opportunities and practicing a responsible attitude when dealing with people, resources and the environment. Aurubis shares are part of the Prime Standard Segment of the Deutsche Börse and are listed in the MDAX and the Global Challenges Index (GCX). Summary: Aurubis is using disodium tetraborate as a production aid for the production of brass and as processing aid for the analysis of precious metal content of secondary and complex materials. Regarding our applications disodium tertraborate is only used by industrial users. Exposure assessments have been carried out as well as monitoring campaigns to assess the risk of the substance to workers, which shows that a risk can be reasonably excluded. Also the risk for the environment is adequately controlled	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban 3. Use specific scrutiny foreseen at application stage 4. Control of risks 5. Availability of suitable alternatives 7. Burden for industry and potential competitive disadvantage **A.2.8: Claim that formulation of mixtures where the final concentration of the substance is below the specific concentration limit for classification should fall under the generic exemption of such mixtures.** **C.1.1: General principles for exemptions under Art. 58(2)**

		due to waste water collection as well as treatment and off gas cleaning systems. The substance is not part of a finished article which may be used by consumer and the use in our applications is essential as there is no alternative available. For the use in the production of brass resulting considerable cost for an authorisation would only apply for EU manufacturers whereas imports of brass and brass products from non EU companies would not be affected. For the analytical use, contracting non EU laboratories or the relocation of the analytical department would result in higher costs for products/services. Due to the argumentation described above and in the information attached a listing of the substance would lead to negative effects on cost and price competitiveness as well on the global competitive position of EU companies without a benefit for human health or environment protection. We strongly recommend not to include disodium tetraborate on Annex XIV or to exclude the described uses from authorisation. In order to allow a complete view on all aspects and consequences of such a listing for our industry, please find attached our input based on the list of questions proposed by commission to the socio-economic public consultation. *Confidential attachment removed*	**C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation** **C.3.5: Claim that products not containing the substance in the final product should be exempt from authorisation**
2790 2014/11/28	Industry or trade association, Belgium	Please see attachement 2790_FEFCO comments on uses that should be expemt from the 6th ECHA priority list for authorization_to ECHA.pdf	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 5. Availability of suitable

			alternatives **A.2.20: Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation**
2807 2014/11/28	Norway, Member State	The Norwegian CA supports the prioritisation of disodium tetraborate, anhydrous for inclusion in Annex XIV.	Thank you for your support
2808 2014/11/28	Eurima, Industry or trade association, Belgium	No comments. 2808_Final answer.zip	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 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.2.16: 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**
2836 2014/11/28	Intermag Sp. z .o.o., Company, Poland	 2836_boron consulatation.pdf	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 5. Availability of suitable alternatives 7. Burden for industry and potential

			competitive disadvantage **A.2.8: Claim that formulation of mixtures where the final concentration of the substance is below the specific concentration limit for classification should fall under the generic exemption of such mixtures** **A.2.20: Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **B.2.1: Concerns and uncertainties with respect to the authorisation process, in particular for SMEs** **C.2. Responses to exemption requests referring to other legislation**
2845 2014/11/28	National Associatuon of Goldsmiths, Industry or trade association, United Kingdom	The NAG does not support the inclusion of borates in the draft ECHA 6th prioritisation list for Annex XIV. In our opinion borates are safe for workers with no epidemiology studies proving otherwise. Additionally, using the REACH authorisation process to control borates would not be proportional and not contribute to regulatory effectiveness.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban 4. Control of risks
2851	Agoria,	Description of the European Wire Industry	Thank you for your comment and

2014/11/28	Industry or trade association, Belgium	The European steel wire-drawing industry is downstream from the steelmaking industry and CET (Comité Européen de la Tréfilerie) estimates it produces some 6 million tonnes per annum of drawn wire from which a substantial part is produced in Belgium within the membership of Agoria. Wire is used in a wide variety of applications from high quality grades which go into the automotive industry, ropes for mining and bridges, specialised wires for oil and gas, springs for car seats and mattresses to 'commodity' grades which are used in fencing, nails, staples and a million other uses. The European wire drawing industry comprises some 300 companies with about 25,000 employees. Some larger wire producing companies are integrated with steel producers, some are independent and some are small, family-owned. The estimated turnover of the industry is 6-7 bn euros per annum. The wire industry plays a key role in a number of essential manufacturing supply chains, particularly automotive, construction, telecoms and agriculture. Wire Drawing Process Wire is made by drawing rod through a number of drawing dies to reduce its diameter (which also increases its length). The wire may need to be drawn a number of times, and this is done at room temperature and so is classified as a cold working process. However to enable the wire to be further worked, or to change its metallurgical properties sometimes the wire has to be annealed (ie heated to a high temperature) between drawing processes. This re-heating process is energy intensive. In Europe, the wire drawing process is an automated, productive and efficient process. Competition Wire imports come from all over the world including China. Closer to home Turkey is significant wire producer. Use of Borates Borates in the wire drawing industry have already been partly substituted in soaps, but substitution is not feasible as a coating carrier for lubricants for both technical and economic reasons. Use of borates in soaps and use as coating carriers are the two main uses within the wire industry which are being investigated at the moment. The total volume used as a coating carrier is rather low in the European wire industry compared to the global use of borax. Best guess is in the range of 1,000 ton/year. Borax is used exclusively within an industrial environment, in which exposure is limited, and adequate exposure reduction measures restrict this exposure even further. Consumer exposure can be excluded given that the borax is normally removed in	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

		further processing and only used as an enabler within the production process for getting a proper product quality. The results of research into substitution which has been going on since 2010 show that: - Borax in soaps can and is being substituted for most applications by low borax to even borax free soaps; - Borax as a coating carrier cannot feasibly be substituted at the moment for technical and economic reasons. Borax is also used in the wire industry, typically in low quantities, in a wide range of smaller applications, not linked to coating carriers and soaps, and for which we have not yet conducted research but which could be crucial in the process and product quality. *Confidential attachment removed*	
2852 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. 2852_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.**
2853 2014/11/28	European Diagnostic Manufacturers Association, Industry or trade association, Belgium	In vitro diagnostic (IVD) medical devices are products which are CE-marked under Directive 98/79/EC and provide for the screening, diagnosis, prediction and monitoring of medical conditions in Europe including for infectious, rare or genetic diseases and medical conditions. IVDs are also used to ensure the safety of the European population blood supply. EDMA (the European Diagnostic Manufacturers Association) is the trade association that represents the IVD industry active in Europe. NB: the information submitted by EDMA in this contribution covers Boric Acid, Disodium tetraborate, anhydrous and Tetraboron disodium heptaoxide, hydrate, hereafter "borates". References to borates in this contribution should be understood as references to the three aforementioned substances. This is justified as one of the most important uses of borates within the IVD industry is the generation of buffer solutions in which both kinds of borates are in fact used (whereas Disodium tetraborate (anhydrous) and Tetraboron disodium heptaoxide are two different salts, when in aqueous solution they dissolve to a single substance – thus in fact there are only two substances concerned when assessing the impact of these three submissions in solution). The IVD industry uses borates for a number of applications both to manufacture IVD and as a component of the final IVD. Use of borates in IVD will be exempted from the requirement to apply for authorisation where borates are found in the final product. Therefore this input by EDMA considers uses of borates as a 'process chemical' only (i.e. where the borates are not found in the final IVD. The main uses by our sectors of borates as 'process chemicals' are as an essential micronutrient and in buffer solutions. EDMA notes that these uses for manufacturing of IVD are likely to be similar for other sectors relying on biotechnology, such as veterinary 'IVD', forensics, biopharmaceuticals and 'in-	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.1. General, recommendation process:** 3. Prioritisation approach applied **A.1.5. Aspects not considered in ECHA's prioritisation:** 1. Potential other regulatory actions 2. Aim & proportionality of authorisation system - Authorisation is not a ban 5. Availability of suitable alternatives **A.2.6: Substance is used in very low volumes in specific use (and therefore these uses should be exempted, or other risk management activities should be considered)**

		house' laboratory medicine. The main properties of borates are described here below: • Boron (introduced in the form of boric acid) – is an essential micronutrient in biological fermentation processes for the manufacture of proteins, recombinant proteins, monoclonal antibodies, polyclonal antibodies, viruses, etc. • Biocidal activity – Borates are known to have a mild biocidal activity which is of importance in preparations which contain substances of biological origin or which are used to analyse biological samples. IVD reagent products typically require biocides in their formulations to prevent reagent deterioration during their storage that could result in potential misdiagnosis and harm to patients. Boric acid and sodium borate support the biocide function in certain reagents, while also maintaining compatibility with the chemistry of the product formulations (i.e. proteins and other biological substances remain stable). Depending on the nature of the specific application the biocidal activity of the borates will be sufficient or may need to be supplemented with additional biocidal activity. • Buffer solution – Borates buffers provide excellent buffering properties over a pH range adequate for biochemical investigations. Furthermore borate buffers allow for stable relatively high salinity buffers and are very commonly used as ionic strength adjustment buffers in biological preparations. • Proteins and other biological substances remain stable and thus suitable for analysis within a borate buffer even under strong buffering conditions. It is the combination of the above properties, as well as additional ones (e.g. stability under high voltage conditions) which have allowed a number of key biochemical applications to be developed based on the use of borates, for instance in the fields of immunodiagnosis, blood screening, cytochemistry, protein electrophoresis, etc. The IVD industry is not aware of an alternative to boric acid and disodium tetraborate which would deliver all these properties. The original formulation of borate-containing products and the use of borates as process chemicals have taken the industry many years to develop and no other viable options have been available to date which will achieve the parallel goals of stability and reagent function. There is no alternative to the use of boron as an essential micronutrient. Socioeconomic considerations (these will also be addressed in the socioeconomic consultation): REACH authorisation requirements would be expected to cause considerable disruption to the uses by our industry as 'process chemicals' because	**A.2.20: Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** **C.2. Responses to exemption requests referring to other legislation** **C.3.6: Claim that uses in healthcare sector in small quantities should be exempt from authorisation**

		of the role which borates play in the functioning and reliability of in vitro diagnostic tests. Authorisation intrinsically pushes industry toward substitution and the application for authorisation itself would represent a significant cost and resource burden for our industry. EDMA believes that it would be disproportionate to subject the use of borates for the manufacture of various assays to REACH authorisation because: • Borates as 'process chemicals' are an industrial use only. Risks associated to the use of borates in IVDs are adequately covered by the IVD industry which regularly uses borates and other biologically active substances under strictly controlled manufacturing conditions and in adherence to their safety data sheets. • Neither fermentation processes nor borate buffers triggered ECHA to prioritise borates for Annex XIV and are not the basis of concern. Rather, other applications have raised concerns which are now being addressed, catching biological fermentation processes and buffers within them. • Substitution for use of borates in biological fermentation will be impossible, given that boron is an essential micronutrient. With regards to borate buffer solutions, though a number of other buffers do exist and are used in biochemical applications, EDMA has not been made aware of any one substance which could substitute for all of the essential properties of borates in the IVD field. • The quantity of borates used as process chemical in the IVD industry is extremely low and likely amounts to around 5-6 tonnes per year in total (conservative estimate), or 0.003% of the total maximum quantity of Boric Acid and Disodium tetraborate, anhydrous (100,000 tonnes each) estimated by ECHA as being used in the EU. The use of boric acid for biological fermentation is around 10 kg per year (conservative estimate). This amount of material is simply too small to justify the cost of authorisation for upstream suppliers, thus the responsibility for authorisation would fall on the users of borates, which would not benefit from an upstream authorisation process. Moreover, over 90% of our industry is made up of small and medium sized enterprises. • REACH requires an R&D effort to determine if substitution is possible, however the cost and time envisioned to reformulate and re-validate each impacted assay which is manufactured using borates (e.g. to purify proteins, buffer for synthesis of protein conjugates, storage buffer etc.) would not be trivial. An estimate is that costs of substitution (if an alternate would be possible) may reach 750 thousand to 1.5 million euros per assay. Given that IVD manufacturers can place on the market several dozens of assays, these are significant costs when compared to	

		the total European IVD market revenue of €10.5 billion in 2013. • The costs for developing an alternative for borate buffers are not justified by the commercial value of the tests (if it would even be possible to find a substitute). Incurring such prohibitive costs would lead to many tests (particularly those which are older or produced in smaller volume) being taken off the EU market where hospitals, clinical laboratories and Member State payers would not cover these costs due to their own tight budgets. • Authorisation would hurt the competitiveness of the IVD business. Given that in the case of the IVD industry it is the use of borates as process chemical which is being regulated, the authorisation measure would have no impact on the import of devices from outside the EU but would impact manufacturing facilities within the EU. Authorisation is not considered to be an efficient and resource-effective regulatory measure in the case of borates. Indeed it would be expected to have a disruptive and significant impact on thousands of IVDs and present a considerable burden on our industry. Other more efficient and targeted regulatory options should be considered for managing risks arising from the use of borates and which take into account the cost to industry arising from their implementation.	
2867 2014/11/28	European Borates Association, Industry or trade association, Belgium	2867_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**
2877 2014/11/28	Japan Business Council in Europe (JBCE), Industry or trade	See an attached file. 2877_JBCE response for REACH authorization_RM.pdf	**A.2.7: Claim that uses and precursor uses of (Certified) Reference Materials should be considered as being covered by**

	association, Belgium		**provisions for scientific research and development and such uses should therefore be exempted** **C.2. Responses to exemption requests referring to other legislation**
2880 2014/11/28	Company, France	We fully share the position of our supplier EBA (European Borates Association). We join the EBA comments on the 6th priority list of substances for inclusion in Annex XIV. 2880_EBA comments - 6th priority list (final).pdf	Please see response to comment #2522 (EBA comment) **C.2. Responses to exemption requests referring to other legislation**
2884 2014/11/28	Company, Sweden	We manufacture, develop, and services particle accelerators such as cyclotrons. The cyclotrons are used to produce short-lived radioactive nuclides for medical imaging and diagnostic purposes, using Positron Emission Tomography (PET) technology. The radioactive nuclides produced by the cyclotron are used to label biomarkers that can be injected into patients to early diagnose cancer tumors and follow up therapy results via a PET scanner. Using PET technique significantly improves the selection of efficient therapy. Disodium tetraborate is mixed with Boric Acid and dissolved in water to form a solution. The mixing operation is carried out by trained and authorised personnel. The final solution is then transferred into several large stainless steel tanks, which are then placed strategically around the cyclotron. Finally, panels of lead are mounted in the water tanks. This completes the assembly of the radiation shield around the cyclotron providing radiation protection. The purpose of submitting these comments is to ensure that ECHA is fully informed with this essential and safety critical use of Disodium tetraborate in providing radiation protection. In this case, we consider our use of Disodium tetraborate serves an important role in radiation protection and promoting global healthcare, by enabling production of	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.1.3. 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

		Positron Emission Tomography (PET) radio isotopes. A Restricted usage of Disodium tetraborate will impact negatively on healthcare diagnostics, reducing or even eliminating the availability of PET isotopes and tracers in the EU. Some customer with existing facilities are forced to the Cyclotron self-shield with boron loaded water stainless steel container. The alternative would be building a new facility with a concrete bunker to house the cyclotron. This bunker consist of two meter concrete walls which leads to significant infrastructure investments, often forcing the customer to abandon the plans for a cyclotron facility and hence the isotope production. We would strongly encourage ECHA to exempt this particular use of Disodium tetraborate from the Authorization process in order to avoid a serious disruption to the global healthcare diagnostics development and availability and compromise radiation protection measures. We understand the importance of human health risks such as inhalation & skin contact exposures for Boric Acid. We also recognize the importance of curtailing the use of Boric Acid in applications whereby inhalation & skin contact are potential exposure routes. However, if Disodium tetraborate was to be added to REACH Annex XIV, without appropriate exemptions for our use or if an authorisation is not granted in the future, then there would be a serious disruption both to scientific research & development and the manufacture of medical products within the European Union using nuclear technology for medical purposes. We recommend that the use of Disodium tetraborate for neutron shielding is exempted from the obligations imposed by REACH Annex XIV. • The level of environmental protection is not hindered by this exclusion as EU legislation (98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work and 2004/37/EC on the protection of workers from the risks, national law and internationally recognized industrial hygiene practices are followed for these processes. The annual quantity used in this application is estimated to 7500 kg.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks 5. Availability of suitable alternatives **A.2.20: Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **C.2. Responses to exemption requests referring to other legislation** **C.3.6: Claim that uses in healthcare sector in small quantities should be exempt from authorisation**

2892 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 disodium tetraborate 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 disodium tetraborate in crucibles and in the majority of mixtures is below the specific concentration limit of disodium tetraborate. 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 disodium tetraborate of 6,7 mg/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 disodium tetraborate, 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 disodium tetraborate will not cause any improvement in safety at work and a substitution of disodium tetraborate 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
2911 2014/11/30	Company, France	With respect to point 2.2 on the volume using in adhesives applications : For industrial and professional uses in adhesive production, borates are mixed with alkalizing agents and starch to provide for ready-made glues after mixing with water. Borax is needed to provide for optimal physical properties to allow corrugated board application to run in an economical way. The volume of borates that are used in corrugated board is < 10 000 MT/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 corresponding background documentation.

		Although during formulation the amount of borates can exceed the SCL as set out in Regulation 1272/2008, the mixes are provided in levels below SCL as set out in Part 3 of Annex VI to Regulation (EC) No1272/2008 which results in the classification of the mixture as dangerous (Art. 56(6)(b) REACH). An Authorisation is only required for the use of borates in adhesives (industrial and professional users only) above SCL. Annex XVII of the REACH regulation is mentioning under entry 30 that SVHC are only required to be used for professional use if they are used in levels below SCL. Boric acid and borates have SCL between 3 to 8.5 % - so if mixtures are made with starches in this range, then most of the starch producers are providing their downstream users with mixtures meeting a generic exemption for authorisation. The starch industry and chemical suppliers are providing borates in liquid form which are clearly above the SCL. An authorisation is required for the formulation of these products. However, this happens in closed systems using proper ventilation. With respect to paragraph 2.3 and 2.4 in the draft background document from ECHA on justification for the WDU score : following the specific use in the starch industry and the corrugating board of borates/starches or ready-made mixes, it is clear that the borates are intermediates which are after reaction with alkalizing agents and starch give rise to glue containing boron as a non SVHC. Based on the approach on determining the WDU score has described in http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf it would be fair to state we have only industrial and professional uses (WDU is average of 5 and 10) since in the articles boron is present as non SVHC. 2911_Attach IV ECHA.docx *Confidential attachment removed*	**A.1.2. Prioritisation: Volume** **A.1.3. Prioritisation: Wide-dispersiveness of uses:** 1. Scope of the assessment of wide-dispersiveness of uses **A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks **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** *Responses referring to the confidential attachment removed.*
2924 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.	Please see response to comment #2522 (EBA comment) **A.2.12: ECHA should not proceed with the 6th recommendation, when the 5th is still open**

		Confidential attachment removed	**C.1.2. Generic exemptions**
2927 2014/11/30	Austrian workers' compensation board, National Authority, Austria	We support the inclusion of anhydrous Disodium tetraborate in REACH Annex XIV. This substance is widely used and The further authorisation process will lead to the extensive search for new substitutes or the use of already partly possible alternatives.	Thank you for your support
2928 2014/11/30	Association of European Airlines, Industry or trade association, Belgium	This comment is handed in by the European Association of Airlines (AEA) as a common concern shared by all 30 AEA members: the European Aviation industry, the airlines who are responsible for an airworthy fleet, and maintain the aircraft according to their EASA and FAA licenses. These comments also concern independent MRO (maintenance, repair and overhaul) services in Europe. Both airlines and independent MRO companies guarantee a whole raft of requirements ranging from safeguarding air safety, properly managing aircraft operation, and minimizing costs. The statement is made in close cooperation with several AEA members and with ASD (Aerospace and Defence Industries Association of Europe), the national trade organization in Europe who represent a.o. the Original Equipment Manufacturers (OEMs), and the AIA (Aerospace Industries Association), who represent the OEMs outside Europe (US). Therefore the following statement refers to the official ASD statement and the paper from the AIA () which was handed in to this public consultation as well. Boron compounds are used for an extensive range of applications during maintenance, repair and overhaul. Examples of uses are electroplating processes like nickel plating or anodizing, cleaning materials / processes, corrosion inhibitors or fluxes. Aviation materials must be able to withstand extreme conditions including temperatures, humidity, altitude, pressure, friction, and rapid, repeated cycling during normal use. In addition, they must resist attack by aggressive fluids such as hydraulic fluids and de-icing agents. Many components that use boron compounds are inaccessible and difficult to inspect for damage following product delivery without disassembly. These components are expected to last for the anticipated product lifespan which can exceed 25 years. See for a more detailed description of the use the ASD input and AIA input from OEMs. Today there are no qualified commercially available alternatives that meet the	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives **B.2.2: Concerns about workload, timelines and resources needed for those companies already dealing with Cr(VI) applications**

		aerospace performance criteria of longevity, reliability and compatibility exhibited by some boron compounds for a range of applications. Authorisation of these products is creating a severe disadvantage for the European airline industry. The aviation industry and especially the companies who perform the MRO services are directly dependent on processes, products and maintenance procedures developed by the OEMs and certified by the airworthiness authorities (European Aviation Safety Agency (EASA) and United States Federal Aviation Administration (FAA)). Due to the strict airworthiness requirements OEMs are responsible for the safety of the aircraft system as well as for stringent maintenance procedures. Therefore airlines and MRO providers are in the first place bound to the research and developments done by OEMs. AEA members and MRO companies are not in the position to perform the important REACH process of "Analysis of Alternatives". Nevertheless – looking at on-going REACH authorization processes for e.g. Chromium Trioxide many AEA members are heavily burdened by securing the product availability and handling the unknown and inexperienced REACH authorization process. For further details of the certification and qualification and industrialization process we refer to the joint paper developed between industry EASA and ECHA "An elaboration of key aspects of the authorisation process in the context of aviation industry". 	
2933 2014/11/30	Company, United Kingdom	OVERVIEW Johnson Matthey 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, Johnson Matthey 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.	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) (#2522) **A.1.3. Prioritisation: Wide-dispersiveness of uses:** 2. Assignment of WDU score based

		ARGUMENTS AND RATIONALE 1. Industrial and professional workers are adequately protected by virtue of existing REACH restrictions and other EU regulations. a. Risks for workers are adequately controlled through the risk management measures detailed in the exposure scenarios of the registration dossiers and other chemical management legislation The REACH registration dossiers for diboron trioxide, boric acid and disodium tetraborates identified Risk Management Measures (RMMs), where appropriate, to ensure that health risks to workers are adequately controlled. RMMs are communicated via the eSDS, which allows the site risk assessment to be carried out as required by the Chemical Agents Directive (98/24/EC); these mechanisms assist in ensuring worker safety. Additionally, other downstream legislation specifically protects certain vulnerable workers from exposure to substances toxic to reproduction, such as pregnant workers (Dir. 92/85/EC) and young workers (Dir. 9433/EC). Furthermore, for all identified uses, Risk Characterisation Ratios (RCRs) <1 were determined and compliance with the DNELs can be achieved with common hygiene measures, i.e. without a need to use Personal Protective Equipment (PPE). This results from the low potency hazards of the listed borates. b. The major uses of the listed borate substances in the EU are outside the scope of authorization, either as intermediates or as mixtures below the specific concentration limit (SCL), or covered by other legislation. Nearly 79% of the diboron trioxide, the boric acid and disodium tetraborates used in Europe is outside the scope of authorization, as these substances are mainly used in: • The manufacture of glass and frits or for the synthesis of new substances in 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	on use types and their associated volumes **A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban 4. Control of risks 5. Availability of suitable alternatives **A.2.3: As a high fraction of the volume of the substance seems to be used in uses that are out of the scope of Authorisation, the substance should not be prioritised.** **A.2.4: Claim of use as intermediate:** **- in manufacture of boron glass** **- in manufacture of frits** **- manufacture of starch glues** **- production of fluoroboric acid (CAS 16872-11-0** **- 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**

		before a decision can be taken on the appropriate regulatory instruments. The implementation of the SVHC Roadmap allows substances with potential concerns to benefit from an RMOa in order to identify the most appropriate risk management options. This is welcomed by Industry as it should improve regulatory effectiveness. To our knowledge, for thelisted borates, an RMOa has not been carried out. Based on experience from the (ex-) 5th list proposal, we would strongly recommend assessing the efficiency of authorization in order to consider whether this is the most appropriate RMM option for borates. 3. Boron is not replaceable in certain uses We are not aware of any SVHC-free alternatives to borate-containing high temperature brazing fluxes that offer the required time and temperature stability over the life of the flux. These properties are critical to their niche applications, in particular in the oil and gas industry, e.g. in the (EU-based) manufacture of oil well drilling pipe centralisers. Notwithstanding the lack of viable alternatives, the complexities of qualifying new substances / products for application in these industry, in addition to recognising the importance of these specialized engineering industries to EU competitiveness, suggests that the authorization would have to be granted for these uses, and would not achieve the aim of authorization. In conclusion, it is the position of Johnson Matthey 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.	**classification should fall under the generic exemption of such mixtures.** **A.2.11: Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV** **A.2.13: Claim that risks for workers are controlled by other legislation** **A.2.14: Claim that authorisation is not necessary as consumers are protected through the restriction in place** **A.2.15: Claim that exposure data shows low/no risks** **A.2.20: Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **A.2.22: Disputing the harmonised classification** **C.2. Responses to exemption requests referring to other legislation**
2952 2014/12/01	Company, Ireland	For over 20 years, borates, such as disodium tetraborate, have been used in a range of medical devices such as contact lenses. Borates are also commonly used	Thank you for your comment and the additional information provided.

		in ophthalmic solutions, such as over-the-counter eye drops and multi-purpose solutions used for disinfecting and storage of soft contact lenses. We use disodium tetraborate in the manufacturing process of a category of silicone hydrogel daily disposable contact lenses. The use of disodium tetraborate in this step of the manufacturing process is essential. We have not identified alternative substances which could guarantee the same properties as disodium tetraborate, while maintaining the same safety and environmental profile. *Confidential attachment removed*	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 **C2: Responses to exemption request under Art. 58(2) referring to specific Community legislation**
2954 2014/12/01	ASD, Industry or trade association, Bulgaria	1.2. Disodium tetraborate, anhydrous (CAS 1330-43-4, 12179-04-3,1303-96-4) Disodium tetra borate is used in a number of commercially available brazing fluxes and flux solutions. The substance improves a number of functionalities of the mixture, including wetting and melting point and these fluxes are used in a wide variety of applications. Cleaning solutions require disodium tetraborate and these solutions are used in a large number of applications. Validation and deployment of alternatives will require application specific investigation and this can take considerable time and resource 2954_ASD answer to ECHA consultation_General Conclusions for all Boron and lead compounds_281114.pdf	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban 5. Availability of suitable alternatives **B.1.1. General principles for setting latest application dates / sunset dates**

			B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates 1. Extensive time needed in the supply chain to getting organised for preparing application (e.g. due to high number of users) 2. Lack of alternatives, socio-economic aspects **B.2.2: Concerns about workload, timelines and resources needed for those companies already dealing with Cr(VI) applications**
2961 2014/12/01	ADS Group, Industry or trade association, United Kingdom	ADS fully supports the comments made by ASD	Please see response to comment #2954 (ASD comment)
2965 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. 2965_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.2.21 Boron is a critical raw material** **A.2.20 Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **B.2.4: Investment cycles should be taken into account** **B.2.3: Regulations and regulatory timelines for the nuclear industry 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**
2968 2014/12/01	Company, Germany	2968_Comments ECHA 01.12.14.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.1.3. 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.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
2969 2014/12/01	Company, Germany	 2969_Comments ECHA 01.12.14.pdf	*Please see* response to comment #2969 (AGREX comment)
2972 2014/12/01	Outokumpu, Company, Finland	Disodium tetraborate anhydrous (Na2B4O7) is a relatively benign substance whose classification as "toxic for reproduction" has been disputed on a number of occasions due to different scientific data. We are thus questioning the classification in section 2.1 Intrinsic Properties: "Disodium tetraborate, anhydrous was identified as a Substance of Very High Concern (SVHC) according to article 57 (c) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1B, H360-FD (May damage fertility. May damage the unborn child) and was therefore included in the candidate list for authorisation on 18 June 2010, following ECHA's decision ED/30/2010." Outokumpu believes that risks related to borates should be subject to a Risk Management Option (RMO) Analysis which had been announced but never conducted, and could be better managed through binding Occupational Exposure Limits (OELs). This assumption is based on own experience as well as experiences from the industry as already indicated to ECHA by the European Borates Association (Please see attachment: European Borates Association - Comments on Annex XV dossiers). To conclude: The qualitative selection procedure that is currently used by ECHA should be carefully reviewed in order to ensure that the substances on the authorisation list are proportional to the potential exposures and subsequent risks they may pose to public health and the environment. 2972_Illustration of effect of Disodium Tetraborate addition.pdf	**A.1.5. Aspects not considered in ECHA's prioritisation:** 1. Potential other regulatory actions **A.2.11: Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV** **A.2.22: Disputing the harmonised classification** **C.2. Responses to exemption requests referring to other legislation**
2974 2014/12/01	GIFAS, Industry or trade association, France	Please refer to attached letter 2974_20010_ECHA_Annex XIV_Boron_substances.pdf	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding

			background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives 7. Burden for industry and potential competitive disadvantage **B.1.1. General principles for setting latest application dates / sunset dates:** 3. ECHA's proposal for latest application dates **B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 1. Extensive time needed in the supply chain to getting organised for preparing application (e.g. due to high number of users) 2. Lack of alternatives, socio-economic aspects **B.2.1 Concerns and uncertainties with respect to the authorisation process, in particular for SMEs** **B.2.2: Concerns about workload, timelines and resources needed for those companies already dealing with Cr(VI) applications** **B.2.4: Investment cycles should**

			be taken into account
2992 2014/12/01	Company, Netherlands	This comment is handed in by the European Association of Airlines (AEA) as a common concern shared by all AEA members: the European Aviation industry, the airlines who are responsible for an airworthy fleet, and maintain the aircraft according to their EASA and FAA licenses. These comments also concern independent MRO (maintenance, repair and overhaul) services in Europe. Both airlines and independent MRO companies guarantee a whole raft of requirements ranging from safeguarding air safety, properly managing aircraft operation, and minimizing costs. The statement is made in close cooperation with several AEA members and with ASD (Aerospace and Defence Industries Association of Europe), the national trade organization in Europe who represent a.o. the Original Equipment Manufacturers (OEMs), and the AIA (Aerospace Industries Association), who represent the OEMs outside Europe (US). Therefore the following statement refers to the official ASD statement and the paper from the AIA () which was handed in to this public consultation as well. Boron compounds are used for an extensive range of applications during maintenance, repair and overhaul. Examples of uses are electroplating processes like nickel plating or anodizing, cleaning materials / processes, corrosion inhibitors or fluxes. Aviation materials must be able to withstand extreme conditions including temperatures, humidity, altitude, pressure, friction, and rapid, repeated cycling during normal use. In addition, they must resist attack by aggressive fluids such as hydraulic fluids and de-icing agents. Many components that use boron compounds are inaccessible and difficult to inspect for damage following product delivery without disassembly. These components are expected to last for the anticipated product lifespan which can exceed 25 years. See for a more detailed description of the use the ASD input and AIA input from OEMs. Today there are no qualified commercially available alternatives that meet the aerospace performance criteria of longevity, reliability and compatibility exhibited by some boron compounds for a range of applications. Authorisation of these products is creating a severe disadvantage for the European airline industry. The aviation industry and especially the companies who perform the MRO services are directly dependent on processes, products and maintenance procedures	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives **B.2.2: Concerns about workload, timelines and resources needed for those companies already dealing with Cr(VI) applications**

		developed by the OEMs and certified by the airworthiness authorities (European Aviation Safety Agency (EASA) and United States Federal Aviation Administration (FAA)). Due to the strict airworthiness requirements OEMs are responsible for the safety of the aircraft system as well as for stringent maintenance procedures. Therefore airlines and MRO providers are in the first place bound to the research and developments done by OEMs. AEA members and MRO companies are not in the position to perform the important REACH process of "Analysis of Alternatives". Nevertheless – looking at on-going REACH authorization processes for e.g. Chromium Trioxide many AEA members are heavily burdened by securing the product availability and handling the unknown and inexperienced REACH authorization process. For further details of the certification and qualification and industrialization process we refer to the joint paper developed between industry EASA and ECHA "An elaboration of key aspects of the authorisation process in the context of aviation industry".	
3014 2014/12/01	Cerame-Unie - the European Ceramics Industry Association, Industry or trade association, Belgium	The European Ceramic Industry, Cerame-Unie, covers a wide range of products including brick & roof tiles, clay pipes, wall & floor tiles, refractory products, sanitary ware, table & decorative ware, technical ceramics, abrasives and enamels. It accounts for more than 200.000 direct employments and a turnover 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.	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. Please see response to comment #2632 (Frits consortium) Please also see response to comment #2522 (EBA comment) **A.1.5. Aspects not considered in ECHA's prioritisation:** 1. Potential other regulatory actions 2. Aim & proportionality of authorisation system - Authorisation is not a ban

		Borates are also used as a raw material in ceramic articles like tiles where its application reduces both the firing time and temperature needed and at the same time increases the dry mechanical strength of the product, allowing for thinner and more light-weight products. In the refractory industry, borates are used in the production of refractory articles (such as heat resistant crucibles) as well as in mixtures (unshaped refractory products). These refractory products are only used in industrial applications, with no consumer exposure. The content of boric acid in crucibles and in the majority of mixtures is below the specific concentration threshold applicable to boric acid. Boron free substitutes for this application are not yet known in that quality. Moreover, without the addition of boric acid, the refractory materials will undergo a certain type of corrosion, which - in the worst case - will lead to an uncontrolled released of hot, liquid metal due to a perforation/deterioration of the furnace wall. Boric acid is also used as an intermediate in the high volume manufacturing of boron carbide, boron nitride, titanium boride, zirconium boride and calcium boride. These substances are important for the refractory and technical ceramic industry. 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	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.2.9: 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**

		options assessment (RMOa) was carried out. We consider such RMOa to be an essential step that should take place before a substance is added to REACH Annex XIV. Such approach is also reflected in the SVHC Roadmap. Disodium octaborate and disodium octaborate tetrahydrate have been recommended by the RAC to be classified and labelled as Repr 1B H360FD. This is the same classification and labelling as the borates currently under consideration. In many ceramic applications described above, the borates which are proposed for authorisation can be replaced by Disodium octaborate and disodium octaborate tetrahydrate, that are not yet on the candidate list, although they have the same classification. Cerame-Unie strongly believes that an authorisation of borates in general is not the best risk management option. Furthermore, a grouping approach is essential and the authorisation requirement at this stage for only boric acid, diboron trioxide and disodium tetraborates is meaningless. Cerame-Unie also fully supports the input given by the European Borates Association (EBA).	**the substance for Annex XIV** **A.2.21: Boron is a critical raw material**
3021 2014/12/01	LightingEurope, Industry or trade association, Belgium	Disodium tetraborate is used as a raw material and is an intermediate in the production of boron containing glass. Disodium tetraborate is used to manufacture the glass article, they are not present in the final article anymore as glass is a non-crystalline or virtuous inorganic macromolecular structure, which does not contain the chemical components of the different raw materials. The original substance is not present anymore in the glass as it is transformed in another chemical substance. Today, the substance is an essential ingredient and there is no alternative known on the market with the same performance levels. 3021_LE_consultation_Disodium tetraborate_anhydrous_20141201_final.pdf	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban **A.2.4: Claim of use as intermediate:** **- in manufacture of boron glass**

			- in manufacture of frits **- manufacture of starch glues** **- production of fluoroboric acid (CAS 16872-11-0** **- in manufacture of boron carbide, boron nitride, titanium boride, zirconium boride and calcium boride** **C.1.1. General principles for exemptions under Art. 58(2)** **C.1.2. Generic exemptions** **C.1.3. Aspects not justifying an exemption from authorisation** You might also be interested in response: **C.2: Responses to exemption requests referring to other legislation**
3023 2014/12/01	LightingEurope, Industry or trade association, Belgium	Disodium tetraborate is used as a raw material and is an intermediate in the production of boron containing glass. 3023_LE_consultation_Disodium tetraborate_anhydrous_20141201_final.pdf	Please see response to comment #3021 (LightingEurope comment)

II - Transitional arrangements. Comments on the proposed dates

Number / Date	Submitted by (name, submitter type, country)	Comment	Reference to responses
2516 2014/10/28	Individual, United Kingdom	The sooner that this product is added to the authorisation list the better.	Thank you for your opinion

2522 2014/10/31	European Borates Association (EBA), Industry or trade association, Belgium	 2522_EBA comments - ECHA PC - 6th priority list (final).pdf	Please see references to responses in section I
2531 2014/11/10	Individual, Germany	 2531_ECHA attachments.zip *Confidential attachment removed*	Please see references to responses in section I
2538 2014/11/14	Company, Germany	- 	Please see references to responses in section I
2576 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. 	
2595 2014/11/24	Company, Germany	 2595_Comment_K+S_KALI_GmbH_boron2.doc *Confidential attachment removed*	Please see references to responses in section I
2632 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 Disodium tetraborate, anhydrous (EC 215-540-4) 2632_Frit Consortium - borates intermediate in frits.pdf	Please see response to comment #2522 in Section I (EBA comment)
2659 2014/11/25	Company, United Kingdom	no comment 	
2665 2014/11/26	Individual, Poland	Although we do not support the inclusion of Disodium tetraborate in the draft ECHA 6th prioritisation list for Annex XIV, in case of inclusion we propose (apply) to use the longest possible period of transition. 	**B.1.1. General principles for setting latest application dates / sunset dates:** 2. ECHA's proposal for sunset dates 3. ECHA's proposal for latest application dates See also references to responses in section I.

2671 2014/11/26	UNIFA, Industry or trade association, France	2671_Commentaires UNIFA_Novembre 2014_EN_VF.pdf	Please see references to responses in section I
2689 2014/11/26	Comité Européen de la Tréfilerie (CET), Industry or trade association, United Kingdom	None	
2696 2014/11/27	Outokumpu Stainless ltd., Company, United Kingdom	No comments 2696_Outokumpu input to EC Socioeconomic consultation on Borax 20141121.docx	Please see references to responses in section I
2697 2014/11/27	European Special Glass Association and European Domestic Glass Association, Industry or trade association, Belgium	2697_FINAL EDG-ESGA - Use of borates as intermediates in the manufacture of borosilicate glass.docx	Please see references to responses in section I
2701 2014/11/27	Company, Sweden	- 2701_Outokumpu input to EC Socioeconomic consultation on Borax 20141121.docx	Please see references to responses in section I
2706 2014/11/27	Vesuvius Group, Company, United Kingdom	*Confidential attachment removed*	Please see references to responses in section I
2713 2014/11/27	Company, Germany	Dates proposed until now when substances are added to Annex XIV are leading to a very short implementation time, compared to design, build and operation cycles for certain industrial activities as well as related investments. Concerning disodium tetraborate, anhydrous, some uses (as for nuclear power plants) are relying on long term investments (60 years for an EPR without taking into account time frames for dismantling activities and spent fuel treatment). Therefore, the proposed dates do not conform with article 58.1.c.i, indicating that these dates « should take into account, where appropriate, the production cycle specified for that use ».	**B.2.4: Investment cycles should be taken into account.**

		Confidential attachment removed	
2721 2014/11/27	Wieland-Werke AG, Company, Germany		Please see references to responses in section I
		2721_Comments to 6th priority list of substances for inclusion in Annex XIV _ Wieland-Werke.pdf	
2730 2014/11/27	Company, Germany		Please see references to responses in section I
		2730_COMPO.pdf	
2743 2014/11/27	RWE Power AG, Company, Germany	Dates proposed until now when substances are added to Annex XIV are leading to a very short implementation time, compared to design, build and operation cycles for certain industrial activities as well as related investments. Concerning disodium tetraborate, anhydrous, some uses (as for nuclear power plants) are relying on long term investments (60 years for an EPR without taking into account time frames for dismantling activities and spent fuel treatment). Therefore, the proposed dates do not conform with article 58.1.c.i, indicating that these dates « should take into account, where appropriate, the production cycle specified for that use ».	**B.2.4: Investment cycles should be taken into account.**
		2743_2-2_ECHA_consultation_disodium tetraborate anhydrous paper_final.docx	
2748 2014/11/28	Poland, Member State	Disodium tetraborate, anhydrous was identified as a Substance of Very High Concern (SVHC) according to article 57 (c) of REACH Regulation as it is classified as Toxic for Reproduction Category 1B and follow entered in Annex VI (list of substances with harmonized classification and labeling) of Regulation (EC) No 1272/2008 (CLP). During prioritization of boric acid the following criteria was taken into account: - intrinsic properties (score: 1), - volume used in the scope of authorization (score: 15), - wide dispersiveness of uses (disodium tetraborate, anhydrous is used at industrial sites and by professional workers, score: 12). Disodium tetraborate, anhydrous 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 acid.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban 4. Control of risks 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**

		Firstly we believe that all users of disodium tetraborate, anhydrous are adequately protected. - consumers are adequately protected through the restriction (REACH Annex XVII): disodium tetraborate, anhydrous is classified as Toxic for Reproduction Category 1B and according to point 30 of Annex XVII of REACH, mixtures and other substances which contains disodium tetraborate, anhydrous in concentration equal to or higher than 4.5% are prohibited for supply to the general public. - risk for workers are adequately controlled through chemical management legislation: the Chemical Agent Directive (98/24/EC) lays down minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents, - other downstream legislation protects certain vulnerable workers from exposure to substances/mixtures classified as toxic to reproduction. o Directive 92/85 protects the health and safety of women in the workplace when pregnant or after they have recently given birth and women who are breastfeeding from exposure to disodium tetraborate, anhydrous or mixtures contained disodium tetraborate, anhydrous 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 disodium tetraborate, anhydrous or mixtures contained disodium tetraborate, anhydrous in such concentration which lead to classification of mixture as toxic to reproduction, Secondly, major uses of disodium tetraborate, anhydrous in the EU are outside the scope of authorization: ☐ disodium tetraborate, anhydrous is mainly used in the manufacturing of glass and frits (in these uses the boric acid is qualifies as intermediate since is completely consumed and transformed into another substance - glass and frits) ☐ disodium tetraborate, anhydrous (and other borates) is used in mixtures below specific concentration limits ☐ disodium tetraborate, anhydrous 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	**glass** **- in manufacture of frits** **- manufacture of starch glues** **- production of fluoroboric acid (CAS 16872-11-0** **- in manufacture of boron carbide, boron nitride, titanium boride, zirconium boride and calcium boride** **A.2.8: Claim that formulation of mixtures where the final concentration of the substance is below the specific concentration limit for classification should fall under the generic exemption of such mixtures.** **A.2.13: Claim that risks for workers are controlled by other legislation** **A.2.14: Claim that authorisation is not necessary as consumers are protected through the restriction in place** **A.2.15: Claim that exposure data shows low/no risks** **A.2.21 Boron is a critical raw material** **A.2.22: Disputing the harmonised classification**

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

		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 (disodium tetraborate, anhydrous) 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 disodium tetraborate, anhydrous at this time does not represent regulatory effectiveness and is not proportional.	
2751 2014/11/28	BOCI, CFHM, UFBJOP et Comité Francéclat, Industry or trade association, France	2751_Sample of testimonials.pdf	Please see references to responses in section I
2772 2014/11/28	WKÖ, Other contributor, Austria	See PDF attached. 2772_su_85_WKÖ Borate.pdf	Please see references to responses in section I
2776 2014/11/28	Aurubis AG, Company, Germany	*Confidential attachment removed*	Please see references to responses in section I
2790 2014/11/28	Industry or trade association, Belgium	Please see attachement 2790_FEFCO comments on uses that should be expemt from the 6th ECHA priority list for authorization_to ECHA.pdf	Please see references to responses in section I
2807 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.	Thank you for your support **B.1.1. General principles for setting latest application dates / sunset dates:** 3. ECHA's proposal for latest application dates
2808	Eurima,	Not applicable, see section below.	Please see references to

2014/11/28	Industry or trade association, Belgium	2808_Final answer.zip	responses in section I
2836 2014/11/28	Intermag Sp. z .o.o., Company, Poland	2836_boron consulatation.pdf	Please see references to responses in section I
2851 2014/11/28	Agoria, Industry or trade association, Belgium	none *Confidential attachment removed*	Please see references to responses in section I
2852 2014/11/28	ACEA, Industry or trade association, Belgium	2852_20141128_Proposal for annex XIV recommendation on Borates Final.pdf	Please see references to responses in section I
2853 2014/11/28	European Diagnostic Manufacturers Association, Industry or trade association, Belgium	With regards to setting a latest application date – EDMA notes that ECHA has a truly diverse set of registered uses for borates (for example, see Section 2.3 of Draft background document for Boric acid). Given the complex supply chains involved, EDMA strongly suggests that ECHA put in place a later 'latest application date' to help both applicants and ECHA manage the process to apply for authorisation. A later 'latest application date' has been established for other substances with complex supply chains, such as for chromates. With regards to review periods – according to Article 58(1) of REACH it is possible to set review periods for certain uses, if appropriate, in Annex XIV. EDMA notes that the use of borates in the IVD industry fulfils many of the criteria established by ECHA SEAC and RAC for setting an exceptionally long review period: • The IVD industry has exceptionally long development cycles which can be up to 10 or 12 years, depending on the complexity of the test being developed. This time period includes EU regulatory requirements to perform a conformity assessment process and gain certification by a notified body. Substitution for borates (where at all possible) would trigger re-registration of each devices where there could be an impact on the sensitivity or specificity of a test. • The use of borates for biological fermentation cannot be substituted. • Although the industry has tried different buffers, borate buffers offer a unique combination of properties which are difficult to substitute. Because each test varies according to what is being tested for (i.e. the analyte), the technology	**A.1.5. Aspects not considered in ECHA's prioritisation:** 1. Potential other regulatory actions 5. Availability of suitable alternatives **B.1.1. General principles for setting latest application dates / sunset dates:** 1. Legal background 2. ECHA's proposal for sunset dates 3. ECHA's proposal for latest application dates **B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 1. Extensive time needed in the supply chain to getting organised for preparing application (e.g.

		being used and the properties of the biological specimen on which the test is being performed, the use of alternate buffers may impact each test differently. Therefore data for the application for authorisation would need to come from substitution trials performed on an individual assay-by-assay basis for thousands of impacted assays on the market. The costs for doing so are prohibitive and disproportionate to the quantity of borates involved and their risk of exposure when used for this purpose. • Any impact of substitution on in vitro diagnostic (IVD) medical device tests would require extensive re-validation of according to EU regulatory requirements under IVD Directive 98/79/EC. • The IVD industry uses low quantities of use of borates: around 0.003% of the total maximum quantity of borates (100,000 tonnes each for boric acid and tetraboron disodium) estimated by ECHA as being used in the EU. Risks associated to the use of borates in IVDs are adequately covered by the IVD industry which regularly uses borates and other biologically active substances under strictly controlled manufacturing conditions and in adherence to their safety data sheets. 	due to high number of users) 2. Lack of alternatives, socio-economic aspects **B.2.5: Claim that the use fulfils the RAC/SEAC conditions for longer review period**
2867 2014/11/28	European Borates Association, Industry or trade association, Belgium	 2867_EBA comments - ECHA PC - 6th priority list - glass-frits.pdf	Please see references to responses in section I
2877 2014/11/28	Japan Business Council in Europe (JBCE), Industry or trade association, Belgium	No comment 2877_JBCE response for REACH authorization_RM.pdf	Please see references to responses in section I
2880 2014/11/28	Company, France	 2880_EBA comments - 6th priority list (final).pdf	Please see references to responses in section I
2884 2014/11/28	Company, Sweden	There are currently no known technically equivalent substitutes for our use of Disodiumtetratborate and if ECHA were to pursue the Authorisation route as the preferred risk management option, then it would be appropriate to set the authorisation renewal period at 40 years or more to allow sufficient	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives

		development period for new technologies to be researched, developed and tested, prior to any implementation. 	**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 2. Lack of alternatives, socio-economic aspects
2911 2014/11/30	Company, France	Our company has no comments on the planned application and sunset date. [ECHA has opted for a group approach on a number of substances – for the boron containing substances the LAD [Latest application date] based on Art 58 (1)[c] (ii)] will be August 2018. The sunset date will be February 2020 (provided the Commission amendment for getting these substances into Annex XIV will enter into force in the Summer of 2016).] 2911_Attach IV ECHA.docx *Confidential attachment removed*	Please see references to responses in section I
2924 2014/11/30	Company, Belgium	 *Confidential attachment removed*	Please see references to responses in section I
2928 2014/11/30	Association of European Airlines, Industry or trade association, Belgium	We clearly ask for the refusal of the inclusion of boric acid and boron compounds to the authorization list, recognizing 5th recommendation is still open and a huge burden on the whole industry which is struggling by the on-going authorization procedures. Due to the industry's characteristics the search for alternatives requires at least more than 10 years for every substance and use combination. Therefore - in line with the ASD and AIA position - including boron compounds in the authorization list seems to be not proportional. Postpone 6th recommendation, because the 5th recommendation is not even final yet. 	**A.2.12: ECHA should not proceed with the 6th recommendation, when the 5th is still open** **B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 2. Lack of alternatives, socio-economic aspects **B.2.1: Concerns and uncertainties with respect to the authorisation process, in particular for SMEs**
2952 2014/12/01	Company, Ireland	ECHA's draft background documents for disodium tetraborate, at page 4, clarify that the Latest Application Date (DAT) slots are set in 3 months intervals (i.e.,	Thank you for your support

		18, 21 and 24 months after inclusion of a substance in Annex XIV), and recommend to assign borates (including disodium tetraborate), to the latest LAD slot (i.e. 24 months), due to the high number of uses and overall complexity of supply chain. We support this recommendation, particularly in view of the complex product development and production cycle which precedes the commercial manufacture of medical devices, such as contact lenses. *Confidential attachment removed*	
2954 2014/12/01	ASD, Industry or trade association, Bulgaria	See comments on Boric Acid 2954_ASD answer to ECHA consultation_General Conclusions for all Boron and lead compounds_281114.pdf	Please see references to responses in section I
2960 2014/12/01	Company, Germany	We, BK Giulini GmbH, Ludwigshafen develop Borax substitutes (Gilunal) for starch and dextrin glues in paper processing (Paper tube winding and corregated boards) Please contact us for further information.	Thank you for the information
2961 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
2965 2014/12/01	CEA, Company, France	2965_PC-ECHA-boric_acid-comment_CEA_nov2014.pdf	Please see references to responses in section I
2968 2014/12/01	Company, Germany	2968_Comments ECHA 01.12.14.pdf	Please see references to responses in section I
2969 2014/12/01	Company, Germany	2969_Comments ECHA 01.12.14.pdf	Please see references to responses in section I
2972 2014/12/01	Outokumpu, Company, Finland	2972_Illustration of effect of Disodium Tetraborate addition.pdf	Please see references to responses in section I
2974 2014/12/01	GIFAS, Industry or trade association, France	2974_20010_ECHA_Annex XIV_Boron_substances.pdf	Please see references to responses in section I
2992	Company,	We clearly ask for the refusal of the inclusion of boric acid and boron	**A.2.12: ECHA should not**

2014/12/01	Netherlands	compounds to the authorization list, recognizing 5th recommendation is still open and a huge burden on the whole industry which is struggling by the on-going authorization procedures. Due to the industry's characteristics the search for alternatives requires at least more than 10 years for every substance and use combination. Therefore - in line with the ASD and AIA position - including boron compounds in the authorization list seems to be not proportional. Postpone 6th recommendation, because the 5th recommendation is not even final yet.	**proceed with the 6th recommendation, when the 5th is still open** **B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 2. Lack of alternatives, socio-economic aspects **B.2.1: Concerns and uncertainties with respect to the authorisation process, in particular for SMEs**
3021 2014/12/01	LightingEurope, Industry or trade association, Belgium	3021_LE_consultation_Disodium tetraborate_anhydrous_20141201_final.pdf	Please see references to responses in section I
3023 2014/12/01	LightingEurope, Industry or trade association, Belgium	3023_LE_consultation_Disodium tetraborate_anhydrous_20141201_final.pdf	Please see references to responses in section I

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

Number / Date	Submitted by (name, submitter type, country)	Comment	Reference to responses
2507 2014/10/02	European Borates Association (EBA), Industry or trade association, Belgium	OVERVIEW EBA challenges the score assigned by ECHA to disodium tetraborates as regards to the volumes under the scope of authorisation. ARGUMENTS Boron is one of seven essential micronutrients required by plants for normal	**A.1.2. Prioritisation: Volume** **A.1.3. Prioritisation: Wide-dispersiveness of uses:** 1. Scope of the assessment of wide-dispersiveness of uses

		and productive growth and accordingly is incorporated in the EU Fertiliser Regulation. The use of boron in fertilizers accounts for over 8% of the diboron trioxide, boric acid and disodium tetraborates entering the EU market. Acknowledging the essentiality of boron for agriculture, the authorisation would have to be granted for agriculture and would not achieve the aim of authorisation. It would become a "tax system". As reported in the registration dossiers, the total volume placed on the market of disodium tetraborates in 2012 by EBA member companies was 203,260 metric tonnes, which represented 100% of the volume placed on the market in Europe. The disodium tetraborates volume that are in uses falling outside the scope of authorisation, as an intermediate, in articles, covered by other legislation or in mixtures below the concentration limit is 90% (~183,000 metric tonnes) It is our understanding that the essential use of disodium tetraborates as a micronutrient shall not fall under the scope of authorisation. Consequently, another 17,767metric tonnes (9%) will fall outside the scope of authorisation. Therefore, Out of a total volume of 203,260 metric tonnes, the remaining volume assessed to be in scope of authorisation is 2,579 metric tonnes (1%). The volume score for disodium tetraborates should thus be reduced from 15 (very high volume 10,000 – 100,000 T) to 12 (high volume 1,000 – 10,000 T). The total sore for disodium tetraborates would then be 25 instead of 28. CONCLUSION The score assigned by ECHA to disodium tetraborates needs to be revised according to the information provided here-above and the prioritisation needs to be re-evaluated in light of the new score.	**A.2.3: As a high fraction of the volume of the substance seems to be used in uses that are out of the scope of Authorisation, the substance should not be prioritised** **A.2.5: Disputing the volume score, claiming various uses of the substance as being outside the scope of authorisation, e.g. the essential use of boric acid as micronutrient** **C.1.3. Aspects not justifying an exemption from authorisation** **C.2. Responses to exemption requests referring to other legislation**
2516 2014/10/28	Individual, United Kingdom	Exemption should be considered for it's use as a cleanser and water treatment. The excellent pH buffering property and stain removal along with it's inherent inhibition of certain organisms e.g. bacteria and fungi make this a multi functional compound.	**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
2517 2014/10/29	Company, Switzerland	Melting agent to perform pyrometallurgical separation of metals.	Thank you for the information
2522 2014/10/31	European Borates Association (EBA), Industry or trade association, Belgium	2522_EBA comments - ECHA PC - 6th priority list (final).pdf	Please see references to responses in section I
2527 2014/11/05	Company, Germany	Subjecting disodium tetraborate, anhydrous to the authorisation requirement might endanger the treatment of severe and life-threatening immune diseases. Further details on the concerned use and the socio-economic effects were subject to a statement in the Call for information on the possible socio-economic consequences of the authorisation requirement. Possible exemptions for usage of small quantities (< 1 tonne/year) or the supply chain of exempted uses (Article 56/6) / exempted products (medical devices; Article 60/2) should be taken into account to prevent disproportionate negative effects.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban **C.2. Responses to exemption requests referring to other legislation** **C.3.6: Claim that substances used in the manufacture of medical devices should be exempt from authorisation**
2531 2014/11/10	Individual, Germany	2531_ECHA attachments.zip *Confidential attachment removed*	Please see references to responses in section I
2538 2014/11/14	Company, Germany	-	Please see references to responses in section I
2549 2014/11/18	ANASTA/ANIMA, Industry or trade association, Italy	According to our knowledge, for soft soldering, brazing and braze welding no substances alternative to 'the listed borates' are available for formulating de oxidizing mixtures. Following is a list* of the most relevant industrial sectors where soft soldering, brazing and braze welding processes, and associated use of deoxidizing mixtures, are not technologically	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

		replaceable. *List of the most relevant industrial sectors ☐ Chilling, heating and air conditioning ☐ Gas networks and transportation ☐ Goggles ☐ Hard steel tools ☐ House appliances ☐ Cooking tools ☐ Electro mechanics (transformers, motors, …) ☐ Plumbing ☐ Machinery for cosmetic industry ☐ Drilling and offshore ☐ Solar panels ☐ Automotive ☐ Railway industry ☐ Valves Taps Fittings Industry	corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives **C.1.1. General principles for exemptions under Art. 58(2)** **C.1.2. Generic exemptions** **C.1.3. Aspects not justifying an exemption from authorisation**
2576 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 and fixers It is present in the processing chemicals as sold below its specific concentration limit, and at much lower levels in the "working strength" solutions actually used in photographic 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.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks **A.2.8: Claim that formulation of mixtures where the final concentration of the substance is below the specific concentration limit for classification should fall under the generic exemption of such mixtures.** **C.1.3. Aspects not justifying an exemption from authorisation**
2595 2014/11/24	Company, Germany	2595_Comment_K+S_KALI_GmbH_boron2.doc *Confidential attachment removed*	Please see references to responses in section I

2609 2014/11/24	PROBELTE S.A., Company, Spain	The use as plant fertilizer-nutrient.	Please see references to responses in section I
2632 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. 2632_Frit Consortium - borates intermediate in frits.pdf	Please see references to responses in section I
2652 2014/11/25	Company, Germany	Uses within articles, where borates are encapsulated in the finished product matrix and there is no intended release of the substance during product use, should be exempted.	**C.3.2: Claim that encapsulated uses without release should be exempt from authorisation** Please also see references to responses in section I
2659 2014/11/25	Company, United Kingdom	Disodium tetraborate, anhydrous is used as a flux in our specialist casting process. It is an essential component in the process although it does not end up in the finished part. Our process is already very well controlled by UK regulations such as CoSHH (Control of substances hazardous to health) IPPC (Integrated pollution prevention and Control) and their EU equivalents. Within our business we carry out rigorous occupational health checks as per the regulations and have never recorded any adverse effects on our workers. If well regulated industrial uses of Disodium tetraborate, anhydrous such as our casting process are not exempted then manufacture of our products will be exported outside the EU with the loss of hundreds of jobs.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 7. Burden for industry and potential competitive disadvantage **A.2.13: Claim that risks for workers are controlled by other legislation** **A.2.21: Boron is a critical raw material**
2662 2014/11/26	Individual, France	The major uses of the borate substances in the EU are outside the scope of authorisation, either as intermediates or as mixtures below the specific concentration limit (SCL), or covered by other legislation. Nearly 79% of diboron trioxide, the boric acid and disodium tetraborates used in Europe is outside	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives **A.2.3: As a high fraction of the volume of the substance**

		the scope of authorisation, as these substances are mainly used in: ☐ the manufacture of glass and frits or for the synthesis of new substances: in these uses, the substances qualify as an intermediate since they are completely consumed and transformed into another substance. In the new substance formed, boron is part of the chemical structure and thus, these uses fall outside the scope of authorisation. ☐ mixtures below the specific concentration limits ☐ covered by other sector- specific legislation (e.g. biocides), again, falling outside the scope of authorisation. 3. Boron is irreplaceable in certain uses a. Bioessentiality Boron is an essential micronutrient for normal, productive plant growth and is one of seven essential micronutrients for plants according to the EU Fertiliser Regulation. The use of boron in fertilizers accounts for about 13.7% of the diboron trioxide, boric acid and disodium tetraborates entering the EU market. Acknowledging the essentiality of boron for agriculture, the authorisation would have to be granted for agriculture and would not achieve the aim of authorisation. It would become a "tax system". b. Essential for nuclear safety The use of boric acid in nuclear power plants is essential for safety reasons. The natural boron isotope, 10B, is required and cannot be substituted. Therefore the authorisation would have to be granted and would not achieve the aim of authorisation. Use : formulation of metal working fluids (mixtures) should be exempt as adequate Risk Management Measures have already been implemented. Measurement of airborne concentration have provided evidence that the risk is adequate controlled. Use: formulation of metal working fluids (mixtures) should be exempt, as adequate Risk Management Measures have already been implemented.	**seems to be used in uses that are out of the scope of Authorisation, the substance should not be prioritised** **A.2.16: Risks should be managed using risk management measures like PPE, LEV, exposure tracking, training** **A.2.21: Boron is a critical raw material C.2. Responses to exemption requests referring to other legislation** **C.3.5: Claim that products not containing the substance in the final product should be exempt from authorisation**

		Measurement of airborne concentration have provided evidence that the risk is adequately controlled. Use in Metal working fluids (concentrates and emulsions) as risk are adequately controlled. As the main exposure route in these uses is dermal and boric acid and sodium borates are not absorbed through the skin, the critical concentration to provoke reprotoxic effects (LOAEL) in the human body will not be achieved by skin contact.	
2665 2014/11/26	Individual, Poland	We strongly suggest that the use of boron, one of critical element in fertilizer industry should be excluded from the scope of authorization as it has no alternatives to secure both, high yields and quality of agricultural products. There is known evidence that in case of boron deficiency there is no other element (product) substance that could replace boron, as it plays important role in all metabolic processes during growing period. Boron is irreplaceable as a micronutrient a. for plants Boron is one of the 7 essential micronutrients for plants (according to the EU Fertiliser Regulation) which are implemented as a set for fertilizers. Each of them has a definite impact on the plant and on the operation of the other components of fertilizer. Excluding one of them causes the fertilizer product to cease to be not full-fledged. The use of boron in fertilizers accounts for about 13.7% of the diboron trioxide, boric acid and disodium tetraborates entering the EU market. Boron is necessary for all plants, aiding in the transfer of sugars and nutrients from leaves to fruit, and increasing pollination and seed development. Boron also improves winter hardiness of plants, enhances root growth and root nodule development for fixing nitrogen, provides better water use efficiency and drought tolerance. The use of boron as a fertilizer has a great impact on harvest of all plants and there is no possibility to replace it by any other micronutrients and opposite. The most sensitive plants for deficiency of boron are corn, sugar beet and rape. Most of soils worldwide show boron deficiency and the influence of boron	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives **A.2.20: Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **C.2. Responses to exemption requests referring to other legislation**

		shortage for plants is very significant. For sugar beets, for example, the deficit of this micronutrient can cause the decrease of yields of roots of even 50% (Artyszak A.,Fragm.Agron.31(3) 2014, 7-18). Also the sugar yield is diminished significantly, because one of the important functions of boron is sugar translocation into the plants. Boron increases the rate of transport of sugars (which are produced by photosynthesis in mature plant leaves) to actively growing regions. Without an adequate amount of boron, the beet roots are not fully of standard value. Taking into consideration the acreage of sugar beets in Poland (about 190 000 ha in 2014) and European Union (1463 000 ha), the yield decrease will have significant influence of economy, especially in agriculture. Other plants heavily impacted by boron deficiency are corn and rapeseed, with the acreage in the world of 170 mln ha (939 mln mt) for corn and 30 mln ha (67 mln mt) for rapeseed, respectively. The shortage of boron causes incomplete pollination, grain formation and precludes proper creation of corn cobs. It is said that corn requires about 20 g of B for 1 mt of corn. Taking into consideration current yield of corn, the total use of boron is: - 18789 mt worldwide (the yield 939 mln mt) - 1330 mt in EU (the yield 66.5 mln mt) - 79 mt in Poland (the yield 3.9 mln mt) For oilseed rape, boron deficiency shows diminished growth, the formation of empty seats in the roots and basis of blades, small lateral root growth and poor tying of the pods after flowering are the effects of boron deficiency, which in turn has a negative impact on the yield of oilseed rape. In young plants a reddish coloration of leaves and petioles appear. If boron deficiency is not removed, the plant does not grow and is creeping close to the ground. In general, the rapeseed requires about 350-450 g B/ha. That gives the consumption of boron, respectively: - 10500 mt worldwide (the acreage 30 mln ha) - 2275 mt in EU (the acreage 6.5 mln ha) - 294 mt in Poland (the acreage 840 000 ha) b. for humans	

		Boron is much more than just another mineral in human nutrition. It affects a broad range of life processes involving macrominerals, energy substrates such as glucose and triglycerides, amino acids and proteins, free radicals, bone mineralization, prostate health, mental function, estrogen metabolism and numerous body systems. Boron is a mineral that is critical to our health. One of the first recognized roles of boron in human nutrition was its contribution to promoting and maintaining good bone mineralization. In areas around the world where boron intake is 1 mg or less per day, the incidence of arthritis ranges from 20% to 70%. In areas where boron intake is usually 3-10 mg per day, the incidence of arthritis is 0-10%. Boron has also demonstrated an ability to protect against bone loss in the presence of a vitamin D deficiency. It has been demonstrated that the combination of Boron, vitamin D, calcium and magnesium in adequate amounts act synergistically to maintain good bone mineralization. It has been observed that dietary boron has a similar effect as supplementation with estrogen in humans. Boron is also necessary for the formation of specific steroid hormones. It is a trace mineral required to convert estrogen and vitamin D to their most active forms. Studies have shown that boron provides protection against osteoporosis and reproduces many of the positive effects of estrogen therapy in postmenopausal women. Boron and its compounds could protect against prostate cancer by inhibiting the activity of many serine protease enzymes, including prostate-specific antigen (PSA). Another very important boron function in human organisms is its impact on the cognitive function. Studies have shown that low boron diet can cause decrease of manual dexterity, hand-to-eye coordination, attention, perception, and short- and long-term memory. Inadequate boron intake can also contribute to a lack of energy, ability to stay focused on tasks and mental alertness. Although there is no recommended dietary allowance for boron, evidence places the optimal daily boron intake at 2-3 mg or more. Another thing which should be strongly considered is the influence on the availability of food and nutrient content of agricultural crops. More than two billion people in the world are undernourished, 800 million are starving. Every action which results in diminishing food availability should be very carefully considered and broadly consulted, especially with WHO and IFPRI. Shenggen Fan, the general director of IFPRI says that 800 million people in the world go hungry because there is not enough food. It is about the quantity of calories	

		delivered. Two billion people are affected by chronic hunger, because their diet is too low in nutrients. The effects of this hidden malnutrition are equally lethal, as the effects of hunger. The difference is that malnourished man dies slower. Many programs, like for example HarvestPlus, are conducted, just to eliminate the problem of insufficient microelement nutrition. Bill Gates, the main sponsor of HarvestPlus program, says: "Two billion people in the developing world suffer from diets lacking essential vitamins and minerals. Foods rich in vitamins and minerals are essential for a healthy diet. When diets do not contain sufficient amounts of vitamin A, folic acid, iodine, iron, and zinc, the consequences include significantly lower birth weight, a decrease in cognitive development, and increased susceptibility to other diseases." 	
2670 2014/11/26	Individual, Italy	USES: Metallurgy of non-ferrous metals (e.g. brass, copper, lead, zinc, aluminium) IMPORTANCE/EFFECT: B2O3 is the active ingredient, inside the fluxes for treatments of copper alloys, for dissolving the metallic oxides. Copper oxides, for example, are converted in copper metaborates, when they come in contact with B2O3, and are dissolved away in the pickle on the surface after soldering. Fluxes based on borax or boric acid, which melts at copper alloy melting temperatures, provide a fluid slag cover. Borax melts at approximately 740°C (1365°F). In addition, such glassy fluxes are especially effective when used with zinc-containing alloys, preventing zinc flaring and reducing subsequent zinc loss by 3 to 10%. Even if for processing Aluminium alloys it has been possible to find alternative products, for Copper alloys the use of Borax is again, at the moment, not replaceable. WAY OF PREPARATION: Many soldering fluxes, for Copper alloys in particular, have borax (anydrous, pentahydrate or decahydrate) as main component together with other components, like alkaline chlorides and alkaline/alkaline-earth carbonates salts. These products in powder, are mixed together in an fully closed apparatuses system. WAY OF UTILISATION: The bags of fluxes containing borax are used, without opening the bags: the bag is wholly thrown inside the bath of alloy and, in this way, it is avoided any contact of workers with the material. REASONS FOR EXEMPTED THESE USES BY AUTHORISATION: As above	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 **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**

		reported, for Copper and Copper alloys treatments, fluxes Borax based are not replaceable with other products. In addition the preparation of mixtures and their uses in foundry don't represent a risk neither for workers nor for the environmental.	
2671 2014/11/26	UNIFA, Industry or trade association, France	Fertilizers must be exempted because BORON is essential. 2671_Commentaires UNIFA_Novembre 2014_EN_VF.pdf	**C.2. Responses to exemption requests referring to other legislation**
2684 2014/11/26	Company, Portugal	The formulations of Metal Working Fluids (mixtures), should be exempted, since the risk management measures have already been implemented. The measure of airborne concentration have provided evidence that the risk is adequately controlled. The risks in using Metal Working Fluids (concentrates and emulsions)are adequately controlled. As the main exposure route in these uses is dermal and boric acid and sodium borates are not absorbed through the skin, the critical concentration to cause reprotoxic effects (LOAEL) in the human body will not be achieved by skin contact.	**A.2.15: Claim that exposure data shows low/no risks** **C.1.1. General principles for exemptions under Art. 58(2)** **C.1.2. Generic exemptions** **C.1.3. Aspects not justifying an exemption from authorisation**
2688 2014/11/26	CooperVision, Company, United States	CooperVision anticipates that the use of disodium tetraborate in the final medical device will be exempted from Authorisation in accordance with Article 56, as the concentration of the substance in the final product will be below the levels at which the substance is considered safe for use. CooperVision requests an exemption from Authorisation for use in quality control, validation and biocompatibility testing. Such uses are carried out under controlled conditions within the scope of the medical devices directive and in accordance with adopted, internationally recognised, industry standards such as ISO 10993. Article 3(23) of REACH, defines scientific research and development as any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume of less than 1 tonne per year. The use of the substance in biocompatibility and validation activities of the medical device meets this definition and thereby should fall within the exemption laid down in article 56(3) of REACH. In addition, formulation of mixtures to be used as such	**C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation** **C.3.1: Claim that solutions below the specific concentration limit should be exempt from authorisation**

		should also fall within the scope of this exemption. CooperVision requests an exemption for the use of disodium tetraborate in the formulation of buffering solutions for the production of contact lenses. The function of the substance contained in a buffer solution is to provide a medium allowing the lenses to be maintained in a sterile environment during storage prior to use. This packaging environment is critical to the correct and safe functioning of the device. The buffer solution allows for the fulfilment of the requirements under the medical devices directive that the devices are packaged and delivered and fit for purpose. It is acknowledged that medical devices directive provides a framework that aims to ensure that the benefits of using medical devices outweigh any risk, whilst guaranteeing the free movement of such devices within the internal market. Imposing Authorisation on the use of disodium tetraborate in the manufacture of medical devices acts to contravene this objective at least in part. CooperVision requests that an exemption from Authorisation is granted for the use of the substance in buffer solution used for packaging and storage of soft contact lenses on the basis that the provisions of the exemptions of Article 60(2) should also include the incorporation of a substance during the manufacturing process where the final product falls within the scope of the medical devices directive.	
2689 2014/11/26	Comité Européen de la Tréfilerie (CET), Industry or trade association, United Kingdom	The use of borates as a coating carrier for lubricants should be exempted given that: - The total volume used for this application within Europe is quite low (in the range of 1,000 ton/year) compared to the total volume of borax used (100,000 to 1,000,000 ton borax/year), - Exposure is limited to the workplace and adequate exposure reduction measure restrict exposure even further. Authorisation will not lead to supplementary exposure reduction. We believe that alternative risk management options, such as exposure limit values, would have a more positive effect on further limiting exposure rather than the authorization of the substance. - Substitution is a challenge due to the high number of different product requirements and processes. Different substitutes have to be found with a	**A.1.5. Aspects not considered in ECHA's prioritisation:** 1. Potential other regulatory actions 5. Availability of suitable alternatives **C.1.2. Generic exemptions**

		higher global cost, including the cost of the substance, further investments needed in supplementary installations, loss of production flexibility, etc. 	
2696 2014/11/27	Outokumpu Stainless ltd., Company, United Kingdom	Steel making slag stabiliser 2696_Outokumpu input to EC Socioeconomic consultation on Borax 20141121.docx	Please see references to responses in section I
2697 2014/11/27	European Special Glass Association and European Domestic Glass Association, Industry or trade association, Belgium	Borosilicate glass Justification is developed in the attached document. 2697_FINAL EDG-ESGA - Use of borates as intermediates in the manufacture of borosilicate glass.docx	Please see references to responses in section I
2701 2014/11/27	Company, Sweden	Disodium tetraborate anhydrous (often referred to as Borax) is used by our company as a slag stabiliser. Based on exposure facts and socioeconomic impacts our organization proposes to • Remove Disodium tetraborate, anhydrous from final proposal or • Exempt Disodium tetraborate, anhydrous use as slag stabiliser from authorization more, see attachment 2701_Outokumpu input to EC Socioeconomic consultation on Borax 20141121.docx	Please see references to responses in section I
2706 2014/11/27	Vesuvius Group, Company, United Kingdom	Mixing/blending and transfer operations intended to manufacture mixtures where the sodium tetraborate is below the specific concentration limit and/or articles should be exempt from authorisation where the manufacturer can demonstrate adequate risk management measures are in place. *Confidential attachment removed*	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks **C.2. Responses to exemption requests referring to other legislation** **C.3.1: Claim that solutions below the specific concentration limit should be exempt from authorisation**

2713 2014/11/27	Company, Germany	Using disodium tetraborate, anhydrous in nuclear electric power plants is vital to preserve cooling chains and therefore to ensure nuclear safety. disodium tetraborate, anhydrous is used in boiling water nuclear reactors; no other chemical compound has the same characteristics required to replace disodium tetraborate, anhydrous for this use as expected when placing it in Annex XIV. The use of disodium tetraborate, anhydrous in German nuclear power plants takes place within strictly closed systems inside buildings with monitored building sumps, mostly inside the controlled area as defined by EU Directive 2013/59/EURATOM. Due to its function as preservative the amount of disodium tetraborate, anhydrous handled in nuclear power plants is very small. Therefore the usage of disodium tetraborate, anhydrous in nuclear power plants does not constitute any danger for the environment. The only process with a potential exposition of staff is the production of the solution by the plant´s chemistry department. disodium tetraborate, anhydrous is classified as toxic for reproduction Category 1B according to EU Regulation 790/2009 (belongs since then to the CMR substances) and therefore requires a safety data sheet according to Regulation 1907/2006 also defining it´s content and the personnel safety measures when dealing with this substance. The safety data sheets are used for establishing operator´s guidelines for handling chemicals following a mandatory risk assessment in hazardous working environments. This process is required by German labor protection law implementing the EU Council Directive 89/391/EEC. So the protection of health is ensured for our workers Consequently the uses of disodium tetraborate, anhydrous on nuclear sites are governed by EU regulation adequately controlling the relevant risks. Consequently, if the above arguments for the re-evaluation of disodium tetraborate, anhydrous as member of the candidate list is not followed it is suggested to exempt nuclear uses from authorization, as EU legislation (and subsequent German law) is applied to control the risks of the uses of disodium tetraborate, anhydrous in nuclear power plants. The criteria for an exemption for nuclear industry mentioned in article 58 (2) of EU Regulation 1907/2006 are fulfilled:	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives **A.2.13: Claim that risks for workers are controlled by other legislation** **C.2. Responses to exemption requests referring to other legislation**

		"Uses or categories of uses may be exempted from the authorization requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled." *Confidential attachment removed*	
2721 2014/11/27	Wieland-Werke AG, Company, Germany	Use to be exempted: Metallurgy. The use of disodium tetraborate 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 disodium tetraborate 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. 2721_Comments to 6th priority list of substances for inclusion in Annex XIV _ Wieland-Werke.pdf	Please also see references to responses in section I **C.2. Responses to exemption requests referring to other legislation** **C.3.5: Claim that products not containing the substance in the final product should be exempt from authorisation**
2730 2014/11/27	Company, Germany	The element B is an essential micronutrient to plants which is not substitutable, the use of Disodium tetraborate for the formulation of fertilizers should be exempted from the authorization scope. 2730_COMPO.pdf	**C.1.1. General principles for exemptions under Art. 58(2)** **C.1.2. Generic exemptions** **C.1.3. Aspects not justifying an exemption from authorisation** **C.2. Responses to exemption requests referring to other legislation**
2743 2014/11/27	RWE Power AG, Company, Germany	Using disodium tetraborate, anhydrous in nuclear electric power plants is vital to preserve cooling chains and therefore to ensure nuclear safety. disodium tetraborate, anhydrous is used in boiling water nuclear reactors; no other chemical compound has the same characteristics required to replace disodium tetraborate, anhydrous for this use as expected when placing it in Annex XIV.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives

		The use of disodium tetraborate, anhydrous in German nuclear power plants takes place within strictly closed systems inside buildings with monitored building sumps, mostly inside the controlled area as defined by EU Directive 2013/59/EURATOM. Due to its function as preservative the amount of disodium tetraborate, anhydrous handled in nuclear power plants is very small. Therefore the usage of disodium tetraborate, anhydrous in nuclear power plants does not constitute any danger for the environment. The only process with a potential exposition of staff is the production of the solution by the plant´s chemistry department. disodium tetraborate, anhydrous is classified as toxic for reproduction Category 1B according to EU Regulation 790/2009 (belongs since then to the CMR substances) and therefore requires a safety data sheet according to Regulation 1907/2006 also defining it´s content and the personnel safety measures when dealing with this substance. The safety data sheets are used for establishing operator´s guidelines for handling chemicals following a mandatory risk assessment in hazardous working environments. This process is required by German labor protection law implementing the EU Council Directive 89/391/EEC. So the protection of health is ensured for our workers Consequently the uses of disodium tetraborate, anhydrous on nuclear sites are governed by EU regulation adequately controlling the relevant risks. Consequently, if the above arguments for the re-evaluation of disodium tetraborate, anhydrous as member of the candidate list is not followed it is suggested to exempt nuclear uses from authorization, as EU legislation (and subsequent German law) is applied to control the risks of the uses of disodium tetraborate, anhydrous in nuclear power plants. The criteria for an exemption for nuclear industry mentioned in article 58 (2) of EU Regulation 1907/2006 are fulfilled: "Uses or categories of uses may be exempted from the authorization requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled." 2743_2-2_ECHA_consultation_disodium tetraborate anhydrous	**A.2.13: Claim that risks for workers are controlled by other legislation** **C.2. Responses to exemption requests referring to other legislation**

		paper_final.docx	
2748 2014/11/28	Poland, Member State	Major uses of disodium tetraborate, anhydrous in the EU are outside the scope of authorization: ☐ disodium tetraborate, anhydrous is mainly used in the manufacturing of glass and frits (in these uses the boric acid is qualifies as intermediate since is completely consumed and transformed into another substance - glass and frits) ☐ disodium tetraborate, anhydrous (and other borates) is used in mixtures below specific concentration limits ☐ disodium tetraborate, anhydrous 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 in fertilizers and the use of borates in nuclear plants should be exempted from authorization.	**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** **C.1.3. Aspects not justifying an exemption from authorisation** **C.2. Responses to exemption requests referring to other legislation**
2751 2014/11/28	BOCI, CFHM, UFBJOP et Comité Francéclat, Industry or trade association, France	2751_Sample of testimonials.pdf	Please see references to responses in section I
2756 2014/11/28	Company, Germany	The substance is used e.g. to formulate a buffer for SRD. The application is a routine analytical use in a laboratory within the scope of scientific R&D. The risk for the environment and consumers is very low. Usually the volumes and the concentration of the substance are low. The disposal of the substance is also controlled. The use of disodium tetraborate as analytical reagent is exempted from authorisation (Art. 56 (3), scientific R&D). Therefore, necessary upstream processes like packaging/refilling and formulation of the pure substance into the ready to sell analytical reagent should be exempted.	**C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation**

2772 2014/11/28	WKÖ, Other contributor, Austria	See PDF attached. 2772_su_85_WKÖ Borate.pdf	Please see references to responses in section I
2776 2014/11/28	Aurubis AG, Company, Germany	See details in the attachment (section V). *Confidential attachment removed*	Please see references to responses in section I
2790 2014/11/28	Industry or trade association, Belgium	Please see attachement 2790_FEFCO comments on uses that should be expemt from the 6th ECHA priority list for authorization_to ECHA.pdf	Please see references to responses in section I
2807 2014/11/28	Norway, Member State	The Norwegian CA does not support that any exemptions from the authorisation requirement should be proposed.	Thank you for your support
2808 2014/11/28	Eurima, Industry or trade association, Belgium	Borosilicate glasses are used in the manufacture of glass wool insulation. Boron is a major structural component of the glass used for this purpose. The products are manufactured using thin strands of molten glass which are extruded into fibres with small diameter on which a binder is applied, collected to form a continuous mat before the binder is cured in an oven. The vitreous silicate fibres produced are compliant with Note Q of annex VI of the Regulation (EC) n° 1272/2008 on the classification, labelling and packaging of substances and mixtures, (CLP) under the index number 650-016-00-2. They are also registered under the Regulation (EC) n° 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) under the EC number; 926-099-9 and the definition:- Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxides (Na2O+K2O+CaO+MgO+BaO) content greater than 18% by weight and fulfilling one of the Nota Q conditions. In addition to traditional glass raw materials Sand (SiO2), Soda (Na2O) and Lime (CaO), additional raw materials are added to the glass batch. The glass wool industry typically uses Sodium Tetraborate Pentahydrate (Na2 2B2O3 5H2O); CAS number 12179-04-3 as a source of Boron which is major structural component of the glass (A glass former).	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**

		The simplified formula for Borosilicate glass is:- A SiO_2 [sand] + b $Na_2B_4O_7$ [borax] + c Na_2CO_3 [soda] + d Al_2O_3 [alumina] + …… → x Si(m) B(n) Na (o) Al (p) …… O(s) [glass] + y CO_2 + …..↑ During the melting process the Pentahydrate is converted into the oxide and chemically fixed in the glass network, either by its own improved bonding to the glass network or by the surrounding SiO_2 network. The final amount of the oxide in the glass is typically around 5%. Under normal conditions of use, the solid glass wool fibres do not allow any release of boron oxide. Thus glass wool insulation products do not contain any borate and do not represent any risk to users. Consequently Eurima members are not required to identify borates as a hazard in their product labelling or Safety Data Sheets. Boron oxide confers a number of important properties to the glass, it reduces the melting temperature and therefore energy consumption, it is also beneficial in aiding advantageous properties such as viscosity, surface tension and prevention of crystallisation. In addition it impacts post production product properties such as thermal conductivity, hydrolytic resistance, bio-solubility and the flexibility of the fibres. Raw materials that are used in the manufacture of glass meet the definition of transported isolated intermediates as they are produced elsewhere and transformed at the glass "manufacturers" production plants. The glass mineral wool industry requires that all boron containing raw materials subject to registration requirements are fully registered and therefore there is no requirement to demonstrated strictly controlled conditions. Borates used in the manufacture of glass wool are therefore exempt from authorisation. 2808_Final answer.zip	**C.2. Responses to exemption requests referring to other legislation** **C.3.5: Claim that products not containing the substance in the final product should be exempt from authorisation**
2836 2014/11/28	Intermag Sp. z .o.o., Company, Poland	2836_boron consulatation.pdf	Please see references to responses in section I
2851 2014/11/28	Agoria, Industry or trade association,	The use of borates as a coating carrier for lubricants should be exempted given that: - The total volume used for this application within Europe is quite low (in the	**A.1.5. Aspects not considered in ECHA's prioritisation:** 1. Potential other regulatory

	Belgium	range of 1,000 ton/year) compared to the total volume of borax used (100,000 to 1,000,000 ton borax/year), - Exposure is limited to the workplace and adequate exposure reduction measure restrict exposure even further. Authorisation will not lead to supplementary exposure reduction. We believe that alternative risk management options, such as exposure limit values, would have a more positive effect on further limiting exposure rather than the authorization of the substance. - Substitution is a challenge due to the high number of different product requirements and processes. Different substitutes have to be found with a higher global cost, including the cost of the substance, further investments needed in supplementary installations, loss of production flexibility, etc. *Confidential attachment removed*	actions **C.1.3. Aspects not justifying an exemption from authorisation**
2852 2014/11/28	ACEA, Industry or trade association, Belgium	2852_20141128_Proposal for annex XIV recommendation on Borates Final.pdf	Please see references to responses in section I
2857 2014/11/28	Company, France	The formulation of mixtures containing Disodium tetraborate below the Specific Concentration Limit should not be subjected to authorization because their use is exempted.	**C.2. Responses to exemption requests referring to other legislation** **C.3.1: Claim that solutions below the specific concentration limit should be exempt from authorisation**
2867 2014/11/28	European Borates Association, Industry or trade association, Belgium	2867_EBA comments - ECHA PC - 6th priority list - glass-frits.pdf	Please see references to responses in section I
2877 2014/11/28	Japan Business Council in Europe (JBCE), Industry or trade association,	Certified Reference Material and Reference Material. See an attached file for the reason. 2877_JBCE response for REACH authorization_RM.pdf	Please see references to responses in section I

	Belgium		
2880 2014/11/28	Company, France		Please see references to responses in section I
		2880_EBA comments - 6th priority list (final).pdf	
2884 2014/11/28	Company, Sweden	We use Disodium tetraborate for radiation protection/attenuation. Disodium tetraborate is essential for nuclear safety which requires the boron isotopes. The cross section of the Boron is many times greater for neutron capture than other elements. This is also the reason why nuclear plants use Borate mixtures as an emergency protection to stop a potential non-controlled reactor activity. Currently, there is no viable substitute for Boric acid that is available with the same properties as Boron when it comes to attenuation – neutron capture. If ECHA decides not to exempt this essential use of Disodium tetraborate and recommends the "Authorisation" route as the preferred risk management option, then we strongly believe that this would negate the current safety measures afforded by the use of Disodium tetraborate. It would further compromise human safety and result in highly technical challenges which cannot be overcome given the current technologies available to the nuclear industry. Disodium tetraborate is used for neutron capture as part of the shielding for radiation protection in our particular application. We recommends that the use of Disodium tetraborate for radiation shielding, is excluded from the usage limitations in Annex XIV. There are currently no known technically equivalent substitutes for this use.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives **A.2.21: Boron is a critical raw material** **B.2.4: Investment cycles should be taken into account** **C.2. Responses to exemption requests referring to other legislation** **C.3.6: Claim that uses in healthcare sector in small quantities should be exempt from authorisation**
2911 2014/11/30	Company, France	Although formulations are above SCL that at the moment that the mixes of substances are prepared in the glue kitchens the borate level below SCL and reaction is taken place to provide for starch crosslinked by boron and eventually borates converted to metaborate which is not a substance of very high concern. In gluing applications the borates are intermediates that are converted to non SVHC substances as borated starch and metaborate. For uses in corrugated board it is required that reaction of alkalizing agents with borates to allow crosslinking of starch to provide for the proper functional properties for gluing the tips.	**A.1.2. Prioritisation: Volume** **A.1.3. Prioritisation: Wide-dispersiveness of uses:** 1. Scope of the assessment of wide-dispersiveness of uses **A.2.4: Claim of use as intermediate:**

		Following the approach set out in paragraph 2.4 in the draft background document from ECHA, the total score = IP+V+ WDU should equal 18 instead of 28. 2911_Attach IV ECHA.docx *Confidential attachment removed*	**- 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** See also **C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation**
2924 2014/11/30	Company, Belgium	 *Confidential attachment removed*	Please see references to responses in section I
2928 2014/11/30	Association of European Airlines, Industry or trade association, Belgium	Some uses of boron compounds are covered by BPR regulation (EU) 528/2012.	**C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation**
2952 2014/12/01	Company, Ireland	We support the rationale behind the REACH provisions on authorisation, i.e., to make sure that risks from the use of substances of very high concern are properly controlled, in view of a progressive substitution of these substances with suitable safer alternatives. When properly implemented, these provisions will certainly stimulate innovation in the EU. However, the REACH text also emphasises that substances of very high concern should be substituted with suitable "safer" alternative substances or technologies (Recital 74), and "where these are economically and technically viable" (Article 55).	**A.2.13: Claim that risks for workers are controlled by other legislation** **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**

		When substitution of certain uses is not feasible, or unlikely to happen in the next foreseeable future, REACH authorisation is unlikely to stimulate innovation; it may rather stimulate innovation in regions outside of the EU, as non-EU manufacturers exporting to the EU may not be subject to REACH authorisation rules. We emphasise that the risks from substances of very high concern may vary depending on the specific uses of those substances. We believe that the current requirements applying to the use of disodium tetraborate in the manufacturing process of contact lenses qualifying as medical devices are sufficient to properly control such risks. In particular, we highlight that the use of disodium tetraborate in the manufacturing process of contact lenses, such as in the hydration solution of contact lenses: - Does not pose any risk for workers because it is subject to stringent internal quality control requirements, as well as to EU and national requirements, such as the EU Directive 98/24/EC on risks related to chemical agents at work; and the related Irish Code of Practice under the Safety, Health and Welfare at Work (Chemicals Agents) Regulations 2001 (S.I. No. 619 of 2001), which includes requirements on occupational exposure limit values (OELV). - It is subject to stringent EU and national environmental regulatory requirements, such as the EU Directive 2010/75/EU, on industrial emissions (integrated pollution prevention and control); and the relevant national requirements, such as the Irish Industrial Emissions Licensing system, granted by the Irish Environmental Protection Agency. - It is subject to the essential requirements of the medical device directive 93/42/EEC, which impose to pay special attention and to "reduce to a minimum the risks" posed by substances which are carcinogenic, mutagenic and toxic to reproduction (CMR). While these requirements focus on substances which may "leak" from the device, they play a crucial role in the entire manufacturing process of devices such as contact lenses, where the use of CMR substances is subject to the most severe controls.	**C.2. Responses to exemption requests referring to other legislation**

		In view of the above, we strongly encourage the European Commission to consider the introduction of a specific exemption from the REACH authorisation requirements for the use of disodium tetraborate in all the relevant steps of the manufacturing process of contact lenses falling in the scope of Directive 93/42/EEC. *Confidential attachment removed*	
2954 2014/12/01	ASD, Industry or trade association, Bulgaria	2954_ASD answer to ECHA consultation_General Conclusions for all Boron and lead compounds_281114.pdf	Please see references to responses in section I
2961 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
2965 2014/12/01	CEA, Company, France	2965_PC-ECHA-boric_acid-comment_CEA_nov2014.pdf	Please see references to responses in section I
2968 2014/12/01	Company, Germany	2968_Comments ECHA 01.12.14.pdf	Please see references to responses in section I
2969 2014/12/01	Company, Germany	2969_Comments ECHA 01.12.14.pdf	Please see references to responses in section I
2972 2014/12/01	Outokumpu, Company, Finland	Outokumpu is a European stainless steel company with a global presence, operating in more than 40 countries, head office in Finland and employing more than 12,500 people. The largest stainless steel mills are located at its Tornio site (Finland), in Sweden, Germany, the UK and USA. Disodium Tetraborate Anhydrous in used at all Outokumpu´s steel melt shops in above mentioned countries, as well as globally in many other countries by our competitors. Disodium tetraborate anhydrous (often referred to as product name Borax) is used at all our steel melt shops for the production of aggregate material from slag and to avoid serious dusting problems at the production sites and neighbourhood areas. The slag treatment plants including important metal recovery processes are planned and based on solid disodium tetraborate treated slag. Safe production process	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

		▪ Outokumpu uses about 2000 tonnes of disodium tetraborate per annum for production of about 800 kilo-tonnes of aggregates. ▪ Disodium tetraborate is added to the raw material (slag: EINECS 932-476-9, steelmaking, elec. Furnace from stainless/high alloy steel production) which is considered a substance within the meaning of REACH and used in producing aggregate material. ▪ Risk management measures in place (IED Directive, BAT/Bref), very low exposure, and well below national OEL. ▪ No disodium tetraborate in final product Compliant with EU legislations and objectives Environmental benefits and part of a circular economy ▪ Slag is a by-product/waste of the stainless steel production process. The addition of disodium tetraborate to slag not only enables the production of aggregate material but also reduces the dust emissions to air or the environment ensuring high air quality standards and exceeding air quality limits mandated by the EU and national air pollution legislation. ▪ The aggregate is used as an alternative aggregate for earth construction purposes as a replacement of natural stone, done in accordance with EN standard 13242 or 13043. The market in which our aggregates are used, is based on a low cost product for local usage where the product competes with natural stone and demolition products. This practice is fully in line with the European Union's Waste Framework Directive 2008/98/EC, which demands producers to move up the waste hierarchy and to prevent waste generation. The production of aggregates conforms with the objectives set in the EU Strategy on resource efficiency, the life cycle approach and the Circular Economy. No workers exposure ▪ There is no exposure of workers handling disodium tetraborate in the process. In our operations standard operating procedures are defined in order to secure that work is conducted under safe conditions. Workplace exposure measurements performed indicate that Boron OELs are not exceeded. The actual measured exposure levels have varied between less than 0.1 to 3 % of the OEL's applied in most EU Member States. Assuming worst case scenario, that 100 % of the measures Boron is in the form of disodium tetraborate, would still mean that also disodium tetraborate levels are clearly well below national OEL. ▪ Risk reduction measures vary slightly from factory to factory. They involve	actions 2. Aim & proportionality of authorisation system - Authorisation is not a ban 6. Socio-economic benefits of continued use **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** **A.2.20: Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry** **C.2. Responses to exemption requests referring to other legislation** **C.3.5: Claim that products not containing the substance in the final product should be exempt from authorisation**

		adding disodium tetraborate only underneath local exhaust ventilation (LEV). The LEV is designed to provide suitable levels of extraction to prevent exposure to employees. Other measures include handling only sealed bags and automated feeding into the process at our melt shops. No disodium tetraborate in final product and significant reduction of waste from production of stainless steel ▪ There is no disodium tetraborate in the end-product. It should be noted that disodium tetraborate or any other boron mineral phases are not present in the final product (Ref 1,2). The constitutive elements are to be found as part of the crystalline structure of the aggregate, but the molecule of disodium tetraborate is no longer present (Ref 3). The Na2B4O7 is thermally reduced to remove the oxygen; the boron is complexed in the material matrix to provide material stability and the sodium is dissolved into the aggregate. The above information shows that there is neither worker exposure nor a health or environmental risk associated with the use of disodium tetraborate in the slag stabilizer application for production of aggregates. Moreover, as already explained, the addition of disodium tetraborate has a beneficial environmental and health impact as it eliminates dust emissions to the air enabling us to meet or stay clearly below set limit values of health based occupational and ambient air. Regulatory options: Disodium tetraborate, anhydrous as used by Outokumpu in production of aggregates should be exempted from authorisation according to EU REACH regulation. The substance is not contained in the end-product and there is no consumer exposure. Since our use is an end-use of the product, taking place in controlled IED (Industrial Emissions Directive) facilities we suggest binding OELs at EU level as the most appropriate measure. This approach would be fully compatible with the main aim of REACH as stated in Recital 1: "ensure a high level of protection of human health and the environment as well as the free movement of substances". It has to be underlined that the text regarding the exemption of specific uses in REACH and the existing ECHA guidance documents are not sufficiently clear. If it is interpreted to mean that our type of use could not be exempted we would consider this a serious unintended consequence which deserves to be included in the reviews the Commission is currently carrying out on authorisation before	

		a decision regarding the inclusion in Annex XIV is taken. We do not see either that authorisation in our case would speed up substitution of disodium tetraborate which is another objective of REACH. The work on the substitution of disodium tetraborate started before the inclusion of the substance on the ECHA candidate list and this will continue for a number of reasons, but notably also because it is a policy of Outokumpu as well as that of other market actors to replace SVHCs with less hazardous substances. On the contrary, we believe that the inclusion of disodium tetraborate in Annex XIV of REACH would probably delay substitution on the basis that our focus and resources and that of many other actors will then be devoted on achieving authorisation which after all in the current circumstances complies with a sound business practice (securing the use of a substance critical for production of aggregates, reducing waste, etc.). The cost efficiency and R&D related to modifying molten steel and slag for better final properties in steel and slag products is a key driver for substitution. E.g. Outokumpu melt shops have studied the item together with universities and research institutes, slag treatment contractors and slag users for over a decade. In view of all the above authorisation would in no way improve safety and health of workers nor reduce the negative impact on the environment. On the contrary, it would raise uncertainties which would reduce competitiveness of a key industry in the EU. Authorisation would be counter-productive to European Commission President Jean-Claude Juncker's number one priority: "Getting Europe growing again and getting people back to work" and his statement that "we need to bring industry's weight in the EU's GDP back to 20% by 2020, from less than 16% today." We also believe that the inclusion of disodium tetraborate to the authorization list would not comply with Juncker's priority on better regulation: "Jobs, growth and investment will only return to Europe if we create the right regulatory environment and promote a climate of entrepreneurship and job creation. We must not stifle innovation and competitiveness with too prescriptive and too detailed regulations". References: 1. D. Geysen, S. Huang, P. Lhoëst, J. Van Dyck, Y. Pontikes, D. Durinck, T.	

		Jones, B. Blanpain, E. Nagels, S. Arnout , A. Cotton, "Boron in stainless steel slag", 6th European Slag Conference Proceedings, 20th-22nd October 2010, Madrid, 235-249. 2. A. Seki, Y. Aso, M. Okubo, F. Sudo and K. Ishizaka, "Development of dusting prevention stabilizer for stainless steel slags". Kawasaki Steel Giho, 18 (1) 20-24, (1986). 3. D. Durinck, S. Arnout, G. Mertens, E. Boydens, P. T. Jones, J. Elsen, B. Blanpain and P. Wollants, "Borate distribution in stabilized stainless-steel slag". J. Am. Ceram. Soc., 91(2) 548-554 (2008). 4. European Chemicals Agency (ECHA), preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV, 21 August 2014, http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf 5. Juncker, J-C, Political Guidelines for the next European Commission, Opening Statement in the European Parliament Plenary Session, A New Start for Europe: My Agenda for Jobs, Growth, Fairness and Democratic Change, http://ec.europa.eu/priorities/docs/pg_en.pdf#page=5	
		2972_Illustration of effect of Disodium Tetraborate addition.pdf	
2974 2014/12/01	GIFAS, Industry or trade association, France		Please see references to responses in section I
		2974_20010_ECHA_Annex XIV_Boron_substances.pdf	
2985 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	**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**

		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.	**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**
2992 2014/12/01	Company, Netherlands	Some uses of boron compounds are covered by BPR regulation (EU) 528/2012.	**C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation**
3014 2014/12/01	Cerame-Unie - the European Ceramics Industry Association, Industry or trade association, Belgium	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 boron carbide, boronitride, titanium boride, zirconium boride and calcium boride.	**A.2.4: Claim of use as intermediate:** **- in manufacture of boron glass** **- in manufacture of frits** **- manufacture of starch glues** **- production of fluoroboric acid (CAS 16872-11-0** **- in manufacture of boron carbide, boron nitride, titanium boride, zirconium boride and calcium boride** **C.1.2. Generic exemptions**
3021	LightingEurope,	Raw materials, used in the manufacture of glass meet the definition of	**A.1.5. Aspects not considered**

2014/12/01	Industry or trade association, Belgium	intermediates as much as they are transformed into a new substance, namely glass. They are transported isolated intermediates, since they are produced elsewhere and transformed at the sites of LightingEurope member companies. Disodium tetraborate is used to manufacture the glass article, they are not present in the final article anymore as glass is a non-crystalline or virtuous inorganic macromolecular structure, which does not contain the chemical components of the different raw materials. The main function of boron in a borosilicate glass is to increase the mechanical and chemical resistance and thermal shock resistance of the glass – so some of the lamp types where mechanical resistance and thermal stock resistance is essential cannot be manufactured without borosilicate glass components (CAS number is 65997-17-3) Under REACH glass is classified as a UVCB substance (substance of unknown or variable composition, complex reaction products or biological materials - CAS number is 65997-17-3). It is exempted from the registration requirement under REACH under certain conditions laid down in Annex V (11) REACH. Today, the substance is an essential ingredient and there is no alternative known on the market with the same performance levels. We therefore request an exemption from authorization for this use. 3021_LE_consultation_Disodium tetraborate_anhydrous_20141201_final.pdf	**in ECHA's prioritisation:** 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** **C.1.1: General principles for exemptions under Art. 58(2)** **C.1.2: Generic exemptions**
3023 2014/12/01	LightingEurope, Industry or trade association, Belgium	Disodium tetraborate is used as a raw material and is an intermediate in the production of boron containing glass. E.g.: - BORATE GLASS PRODUCTION FOR LAMP APPLICATIONS - BORATE- AND BOROSILICATE GLASS FOR MANY SPECIAL APPLICATIONS Addition of boronoxide (from disodiumtetraborate) enables the reduction of the alkaline or earth alkaline contents of the glass. This results in improved chemical durability, lower electrical conductivity, higher mechanical strength, higher thermal shock resistance and thermally resistant glasses. Disodium tetraborate, anhydrous is an essential and irreplaceable ingredient in the manufacture of borate, borosilicate glass and (ceramic) frit glass Today, the substance is an essential ingredient and there is no alternative known on the market with the same performance levels.	Please see response to comment #3021 in this section (LightingEurope comment)

		Under REACH glass is classified as a UVCB substance (substance of unknown or variable composition, complex reaction products or biological materials - CAS number is 65997-17-3). It is exempted from the registration requirement under REACH under certain conditions laid down in Annex V (11) REACH.	
		3023_LE_consultation_Disodium tetraborate_anhydrous_20141201_final.pdf	