25.05.2010

COMMENTS AND RESPONSE TO COMMENTS ON ANNEX XV SVHC : PROPOSAL AND JUSTIFICATION

Substance name: **Boric acid**
CAS number: **233-139-2 (234-343-4)**
EC number: **10043-35-3 (11113-50-1)**

Reason of the submission of the Annex XV: CMR

Disclaimer: The European Chemicals Agency is not responsible for the content of this document. The Response to Comments table has been prepared by the competent authority of the Member State preparing the proposal for identification of a Substance of Very High Concern. The comments were received during the public consultation of the Annex XV dossier

General comments

Date	Submitted by (name, Organisation/MSCA)	Comment	Response
20100318	On behalf of an organisation, Industry or trade association, Germany	We reject the ban boric acid in general, because in our application it is used in an almost closed system of cuvette tests.	The identification of Boric acid (BA) as SVHC is not a ban of boric acid. An application for authorization can be submitted once BA has been added to REACH Annex XIV.
20100322	Individual, Germany	Regarding the 1st ATP for the CLP regulation (Annex II), a mixture containing boric acid with more than 5.5% BA has to be labelled as Repr. 1B; H360FD. That means, there is no need to label a mixture with a concentration below 5.5%. This bound has no relation to the limit of 0.1% mentioned in Art. 33 of the Regulation No. 1907/2006 for articles. If there would be an entry of boric acid in the candidates list, there should be a corresponding limit in the candidate list. Otherwise we cause unnecessary panic under the user of mixtures/articles with less than 5.5% boric acid! For this reason, boric acid is a pontential candidate for annex XVII.	Classification and labelling of Boric acid is required at and above its specific concentration limit. We recognize the discrepancy between this and the limit of 0.1% mentioned in REACH Art. 33.
20100324	AffiliatedWithOrganisation, BEKUTEC GmbH, Company, Germany	Boric acid is used for Nickel Bath, we have no alternate acid for using.	The question of alternatives needs to be addressed when an application for authorisation becomes necessary.
20100326	On behalf of an organisation, vanBaerle AG , Company,	Bringing Substances like Boric Acid on the SVHC list is completly overreacting considering the poor relevance of the data.	BA meets as well the criteria according to REACH article 57c as

	Switzerland		those of article 58.
20100331	On behalf of an organisation, Ti group automotive system Company, Belgium	Boric acid is a major additive in our process of nickel electrolytic deposit. The boron acid is a buffering compound. It helps buffer the bath pH of 4 in the cathode film. Without this compound, the proton reduction, which relatively increases with current density and acidity of the bath, leads to a rise in pH in the cathode film and to the formation of nickel hydroxide. The minimum concentration of our bath is about 50g/l. We work with a bath volume of $25m^3$. The annual consumption is about 6000kg.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the

			sweeping of dry dusts has to be avoided.
20100407	On behalf of an organisation, Industry or trade association, Belgium	080707 BORATES FINAL.pdf	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council

			Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100409	On behalf of an organisation, European Borates Association, Industry or trade association, Belgium	EBA Comments Hazard assess Annex XV April 10 final.pdf European Borates Association (EBA) members are deeply concerned over the proposal to identify disodium tetraborates and boric acid as candidates for authorisation. We do not believe that adding these substances to the candidate list is appropriate. Central to our position is the notion that disodium tetraborates and boric acid are relatively benign substances whose classification as reproductive toxicants was (and continues to be) controversial and contested. This is a point that should be taken into account at this point of the process as it appears from ECHA's consultation notice that this consultation specifically focuses on hazard properties. With a view to safeguarding public health, the environment and good governance, it is EBA's view that of all substances meeting the Art 57 criteria, boric acid and disodium tetraborates are of lower concern. The system for putting substances on the candidate list should be subject to a more critical qualitative selection procedure than the approach that is currently used. The dossiers contain many factual errors, are incomplete and confusing in many sections and lack consistency throughout. EBA feels strongly that these deficiencies should be addressed and corrected before they are presented for consideration by the Member States Committee and later on by ECHA. The EBA has elaborated the below list of arguments to support the position that disodium tetraborates and boric acid should not be added to the candidate list for potential future authorisation: 1. Boron is one of seven micronutrients essential to plant nutrition and so healthy diets associated with fruits and vegetables will contain relatively high levels of boron. 2. Borates have been used safely for generations and people's greatest exposure to borates is through a healthy diet. Recent research has demonstrated several benefits associated with boron exposure in humans including bone health, cell membrane function, psychomotor skills and cognitive processes, control of inflammatory disease, enzyme regulation, energy metabolism, and potential anticarcinogenic properties. A more detailed discussion of this research is presented in the comments on the Annex (hazard section).	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned nor discussed. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation. As reprotoxic substance cat. 1B boric acid meets the criteria of REACH Art. 57c.

		3. Boric acid and disodium tetraborates are relatively benign, which is a fact that was recognised when the Member States experts decided on a high concentration limit and high safety threshold as part of the decision to classify these substances. EFSA (2004) was asked by the European Parliament to provide an opinion on boron in its review of vitamins and minerals under Article 4 of the Food Supplements Directive (2002/46/EC). EFSA stated that boron might have a beneficial effect on bone calcification and maintenance and derived a tolerable upper intake level (UL) of 10 mg boron/day for adults. Based on this opinion, boron was added to Annex I (and boric acid and sodium borate were added to Annex II) in November 2009. This followed consideration of the reproductive toxicology of boric acid and the publication in September 2009 of the 1st ATP of the CLP regulation classifying these substances as 1B reproductive toxicants. The approval by EFSA of boron as a food supplement, even after publication of the 1st ATP of the CLP regulation, provides further support that including boric acid and disodium tetraborates on the candidate list is not warranted. 4. The classification decision itself was the result of a controversial, extremely lengthy and unsatisfactory decision-making process. It was a decision that was opposed by seven EU Member States (Poland, UK, Italy, Ireland, Belgium, Slovenia, Latvia), which specifically and uniquely signed a declaration that stated that they were in favour of a less rigorous classification category for boric acid and disodium tetraborates. In fact a majority of Member States experts had recommended earlier (in the context of the 29th ATP to the Dangerous Substances Directive) that boric acid and disodium tetraborates should be classified as a Category 3 under the previous Directive (note: when Member States eventually voted for a Category 2, this was done on the basis of the same evidence and arguments). Numerous European user industries have written to the European Commission to argue that borates have been used for centuries and have never raised safety issues for its workers. At different times in the process, European Commission officials and departments themselves were divided on the appropriate level of classification for borates. And finally, as part of the WTO TBT process, several non-EU countries (including Turkey, Argentina, Chile, Canada, the U.S., China and Malaysia) expressed concern over the Category 2 classification of boric acid and disodium tetraborates and some stated that this was more trade disruptive than necessary. 5. The main source of disagreement over the appropriate level of classification of boric acid and disodium tetraborates is related to the way effects found in animal studies were extrapolated to humans. Industry acknowledges that there is a reproductive effect from borates in animals that have been force-fed large quantities	

		of boric acid or disodium tetraborates on a daily basis for a long period of time. However, industry has always argued that the Member States and the European Commission have not demonstrated that the classified borate substances have intrinsic properties which give rise to a risk of reproductive toxicity in humans during normal handling and use, as required by law (Annex VI of the Dangerous Substances Directive). 6. Moreover, multiple existing studies on humans have found no reproductive effects. Recital (2) of the 30th ATP which added certain borates to the Dangerous Substances Directive as a Category 2 toxicant and which was inserted by the European Commission, states that "special attention should be paid to further results of epidemiological studies on the Borates concerned by this Directive including the ongoing study conducted in China.". This study among workers in a borates mine has now been completed and peer-reviewed and confirms that there is no reproductive effect in men, which indicates even at very high exposures the effect in humans is different than the effect on laboratory animals. In the light of this Recital and since the Chinese study has not yet been evaluated by ECHA or Member States experts, adding boric acid and disodium tetraborates to the candidate list now simply does not make sense. 7. The Commission's decision to classify certain borates (including boric acid or disodium tetraborates) is subject to two court cases that are currently before the European Court of Justice and the General Court. An annulment of classification would remove the basis for the inclusion of borates under REACH authorisation as well as the legal basis for including them in the authorisation process. In the light of this uncertainty, it is not appropriate to include boric acid or disodium tetraborates on the candidate list. 8. Including disodium tetraborates and boric acid at this point does not make sense as producers and importers are developing a REACH registration dossier, which will be submitted by the December 2010 deadline. The current Annex XV dossiers are based on fragmented and incomplete information largely based on modelling data from the transition dossiers of both substances. The transition dossiers concluded however that "There is a need for better information on occupational exposure for producing/importing processing sites, downstream user and consumer applications to adequately characterize the risks to workers and consumers from boron exposure via boric acid and sodium tetraborates". Industry is following-up on these recommendations. The REACH registration dossiers will contain the necessary information to identify whether there are risks for workers and consumers requiring	

		further measures. 9. Boric acid and disodium tetraborates are already subject to strict regulation under a range of downstream EU legislation, intended to protect workers and consumers which is another argument against adding disodium tetraborates and boric acid to the candidate list for authorisation. This legislation includes: 1. Eco-Label Award Scheme Regulation (1980/2000/EC) 2. Directive on the safety of toys (2009/48/EC) 3. Regulation on Cosmetic Products (RECAST) (1223/2009) 4. Food Supplements Directive; 5. Medicinal Products Directive 6. Waste Framework Directive (2006/12/EC) 7. Detergents Regulation (648/2004/EC) 8. Regulation on the export and import of dangerous chemicals (689/2008) 9. Biocidal Products Directive (98/8/EC) 10. Water Framework Directive (2000/60/EC) 11. Directive on integrated pollution prevention and control (2008/1/EC) 12. ADR and RID Framework Directive (Transport of Dangerous Goods) (2000/61/EC) 13. Chemical Agents Directive (2007/30/EC) 14. Pregnant and Breastfeeding Workers Directive (92/85/EEC) 15. Young Workers Directive (94/33/EC) 16. Signs at Work Directive (92/58/EEC) 17. Personal Work Equipment Directive (2007/30/EC) 10. Similarly, consumer protection from exposure to boric acid and disodium tetraborates will be addressed through Annex XVII-restrictions of CMR substances for consumer use. At the direction of the Commission RPA (2008) reviewed the uses and risks associated with borates for consumers not currently regulated by some of the legislation noted above, and concluded that risks associated with these other uses are unlikely to be of serious concern. 11. Adding disodium tetraborates and boric acid to the candidate list would have immediate negative consequences without generating public health benefits. Producers of these substances would have the obligation to communicate this listing to customers and (if requested) consumers and this involves an increase in cost and may have economic consequences, particularly with respect to the viability of any possible future applications. It is our understanding that ECHA, the Commission and	Limitations of the RPA report have been discussed in the consumer exposure part of the annex XV dossier.

		the EU Member States are considering a more elaborate and balanced system for prioritising substances on the candidate list for authorisation. It is the view of the EBA that the system for putting substances on the candidate list should also be subject to a more qualitative selection procedure than the approach that is currently used.	
20100412	On behalf of an organisation, CARL BECHEM GMBH, Company, Germany	Carl-Bechem-Statement-public-consultation-boric-acid-2010.doc 2 pages	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present the current classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation. BA clearly fulfils the criteria for SVHC substances as set out in REACH Art. 57c: substances meeting the criteria for classification as toxic for reproduction category 1A odr 1B in accordance with Regulation (EC) 1272/2008. We are also aware of the discrepancy between the specific exposure limit and the limit of 0.1 % in Art. 33 of the REACH regulation. Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric

			acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100413	On behalf of an organisation, Fuchs Lubrifiant France, Company, France	We use boric acid and borates in metal working application and the advantages of such substances are : - Anticorrosion performances, to get the same performances we will be oblige to use	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the

		more amide or amine sopas which are hazard potential for human health and environment. - Bacteriostatic properties: this provide to use less biocide which are R 43. Without Boric acid or borates we will be oblige to increase post treatment (manupilation of high hazard potential for human health and environment) so an increase of dermatosis for the workers. The fact taht we will face a lot of bacteria growth, the workers will be expose to high amount of endotoxine which are the main cause of pneumony deseases. - Lifetime of emulsion tank. We have a lot of centralised system with tank volume of 50 to 400m3. Boric acid and borates increase lifetime of the emulsion. The dumping frequency is arround 3 to 5 yaers, without the bacteriostatic effect the dumping will every 6 or 12 months. So the environemental consquences will of increase of waste treatment by using chemical agents.	exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100413	On behalf of an organisation, AVEBE U.A., Company,	As starch producer, we are deeply concerned over the proposal to identify disodium	Prior to the preparation of the Annex

	Netherlands	tetraborates and boric acid as candidates for authorisation. Please consider next arguments for our belief that the SVHC identification is not appropriate: Borate substances are key ingredients in starch formulation used in the paper and board industry for many decades. They provide circumstances to manufacture widely used paper and board products as corrugated board and cardboard tubes in an energy efficient way using natural polymers from renewable sources. Placing borates substances on the candidate list will push the industry towards less sustainable manufacturing methods without being beneficial for public health. Using borates in paper and board applications are unlikely to be of serious concern (study RPA 2008). Borate substances have been used safely for generations. The classification of borates as toxic for reproduction has been considered as not globally recognised (trade disruptive), controversial and incomplete, especially in view of pending studies on human exposure. A recent finished Chinese study on mine workers confirms that there is no reproductive effect in men. Moreover borates are essential minerals for plants and are naturally present in human environment and diet in relatively high levels. From the current Annex XV dossier it can be concluded that the exposure form these natural/environmental sources well exceeds the reasonable worst case exposure from industrial scenarios. Regulating borate substances via the REACH authorisation process is deemed to be unnecessary or not compatible with current inclusions (with restrictions) on positive lists of a range of downstream legislation: e.g. Food contact materials (2002/72/EC, Dutch VGB II.1.2.2.h, German BfR XXXVI and XXXVI/2), Human food (2002/46/EC, (EC)1333/2008, Water framework directive (2006/12/EC, European standard EN1406) and many more. The selection of borate substances for the candidate list at this moment is not appropriate: the classification is still contested, the results of epidemiological studies are not yet included and the REACH registration dossier is under construction.	XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.

			Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present the current classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation.
20100413	AffiliatedWithOrganisation, Institute of Metal Finishing, Industry or trade association, United Kingdom	Boric acid has been listed as a SVHC. The MSDS states that it is an irritant to eyes and skin and may cause reproductive effects. Boric acid is used to maintain pH because it is a 'relatively' weak acid. In the plating industry, amongst other things, it is used in nickel plating baths to maintain pH. At the present moment in time there is no other substance identified as a suitable replacement. This would require some research to ensure that any alternative compound maintains the pH without otherwise affecting the plating qualities and condition of the nickel baths. This would also apply to other applications of boric acid in surface finishing.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of

			approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100413	AffiliatedWithOrganisation, Industry or trade association, International NGO, Belgium	svhcreaction DE.doc CONGRATULATIONS! THE SAFEST EXISTING PESTICIDES IN THE SVHC LIST BEFORE THE OTHER LESS SAFE !!! ANOTHER NATURAL OCCURRING ELEMENT IN THE BLACK LIST, ECHA THINK THAT EARTH IS NOT SUITABLE FOR HUMAN LIFE !!! A NATURAL MEDICINE FOR SKIN AND EYES IN THE BLACK LIST!!	Boric acid was proposed as SVHC based on its classification as toxic to reproduction, its wide use in consumer products, and its high production volume. Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. However, we are aware that boric acid will be registered by the end of this year and further information may become available.

20100414	AffiliatedWithOrganisation, UEIL, Industry or trade association, Belgium	UEIL will make a formal documented submission but as an Officer but with 25 specific experience in the preparation of metalworking fluids containing boric acid I have high levels of personal experience. I am not affiliated today with any Company or commercial enterprise using products of this type	Your comment has been taken note of.
20100414	On behalf of an organisation, UEIL, Industry or trade association, Belgium	EBA comments Annex XV 100104 final.pdf Independent Union of the European Lubricants Industry, UEIL, is the pre-eminent Trade Association in Europe representing the interests of companies involved in the Lubricant Industry. With Members in nineteen European Countries and a unique collective experience of Lubricants and the Lubricants Market, UEIL is the strongest Representative Body for Independent producers of lubricants in Europe. www.ueil.org	See response to EBA comments
20100416	On behalf of an organisation, Verband Schmierstoff Industrie e.V., Industry or trade association, Germany	EBA comments Annex XV 100104 final.pdf The annex xv dossier submitted by German authorities contains a number of errors. We refer to the EBA document (attached) for details. Based on that dossier, inclusion of boric acid on the candidate list does not seem appropriate.	See response to EBA comments
20100416	On behalf of an organisation, RWE Power AG, Company, Germany	We are concerned that an Annex XV dossier was filed on Boric Acid to identify the substance as potential "Substance of Very High Concern (svhc)". According to our understanding the substance classification as Category 2 reprotoxic is not justified. Moreover, we understand that the substance is allowed as a dietary food supplement. Boron is one of a few essential trace elements in human diet and so people's main exposure to borated compounds is through a healthy diet, based on fruits and vegetables.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present the current classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation.
20100416	AffiliatedWithOrganisation, Industry or trade association, Company, Germany	Boron containing metal working fluids are used worldwide since many years. They have a lot of advantages and there is no disadvantage known in practical use,	Prior to the preparation of the Annex XV dossier, the BAuA made a brief

		concerning the health of the workers. A restriction of boron in Europe will only cause a shifting abroad for all worldwide operating companies.	investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.

20100416	BehalfOfAnOrganisation, Fuchs Europe Schmierstoffe GmbH, Company, Germany	Evaluation and Filing of the Annex XV dossier should be postponed until the registration dossier of Boric Acid have been received and reviewed. the Dossier will provide a lot of useful data. There are new epidemiolgocial studies ongoing in china and in Turkey. Review, evaluation and filing of Annex XV dossier shall be postponed until the information of those studies is available.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present the current classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation.
20100417	BehalfOfAnOrganisation, European Trade Union Confederation, Trade Union, Belgium	ETUC supports the identification of Boric acid as a SVHC.	Thank you.
20100417	BehalfOfAnOrganisation, Industry or trade association, Company, United Kingdom	Boric acid is used in the formulation of electrolytes for aluminium electrolytic capacitors. The electrolyte is a conductive liquid used to impregnate the structure of the anode foil and papers and forms the contact on one side of the dielectric (aluminium oxide) and is effectively the real cathode of the device.It is our recommendation consideration be given in light of the fact there is no specific alternatives available and risk of exposure is very minimal. Addition of Boric Acid as a SVHC and possible authorization would present a significant economic hardship to our European operation.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates

			indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100418	BehalfOfAnOrganisation, WWF European Policy Office, International NGO, Belgium	WWF supports the inclusion of this substance in the candidate list according to REACH article 57 c).	Thank you.
20100419	Individual, Germany	1. The dossier is not complete and not accurate. It contains the summary of examinations to Boric Acid and Borates. There is no finally concluding statement that both substances have identical effects and identical solubility's. 2. The results are not finally discussed by the technical commission of EU. 8. Annex XV Dossiers can only put to a fundamental basis after checking the registration dossier and should submit by valid Guidelines afterwards.	The dossier summarizes the information available at the time when the SVHC dossier was prepared. BA clearly meets as well the criteria according to REACH article 57c as the high tonnage according to article 58.
20100419	MSCA, Norway	The Norwegian CA supports that the following substances: Trichloroethylene: CAS number: 79-01-6 Boric acid: CAS number: 10043-35-3/11113-50-1	Thank you.

		Disodium tetraborate anhydrous: Cas number: 1330-43-4 and 12179-04-3 and 1303-96-4 Tetraboron disodium heptaoxide hydrate: CAS number: 12267-73-1 Sodium chromate: CAS number: 775-11-3 Potassium chromate: CAS number: 7789-00-6 Ammonium dichromate: CAS number: 7789-09-5 Potassium dichromate: CAS number: 7778-50-9 should be identified as substances of very high concern and included in the "Candidate List" of substances of very high concern for authorisation. This is in accordance with REACH Article 57 (a, b and c), since the substances are classified as either toxic for reproduction category 2, carcinogenic category 2 or mutagenic category 2 according to Directive 67/548/EEC and Repr. 1B, Carc 1B or Muta 1B according to Regulation (EC) No 1272/2008 and the COM Regulation (EC) No 790/2009 (1st ATP to CLP).	
20100419	BehalfOfAnOrganisation, BMS Micro-Nutrients NV, Company, Belgium	Comments regarding the different lists.doc Unclear and confusing classification of boron substances in the different circulating (proposed) European lists.	Boric acid specified by CAS-No.'s 233-139-2 and 234-343-4 are classified according to directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 % and were found to be present in consumer products. These substances were relevant for this dossier.
20100419	AffiliatedWithOrganisation, Industry or trade association, National Authority, Austria	We support grouping in the authorisation process in the case of borates and boric acid. There is an increase of use of borates and their derivatives as additives in lubricants. These uses often lead to airborne exposure within the metalworking industry. There most of the workers are not specially trained in handling hazardous substances. We claim excluding this use from a possible authorisation because there are a lot of borate-free alternatives. Organic esters of boric acid are quiet often in equilibrium between the alcohols and boric acid.	Thank you.
20100419	BehalfOfAnOrganisation, Industry or trade association, Company, United Kingdom	Boric acid and Sodium Borates have been safely used in many consumer and professional products for decades and no evidence exists to date which supports the	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009

		classification as a Category 2 reproductive toxicant for humans. Only animal studies involving forced feeding of quite high doses have revealed reprotoxic effect , these doses would be considered substance abuse if applied to humans. There are legal challenges underway in Europe which it is hoped may overturn and annul the false classification as a Category 2 reproductive toxicant, it is important that the outcome of this European challenge is taken into account before any further consideration under Reach. As formulators of lubricants we have utilised Boric acid and salts of this substance for several decades. Its properties of corrosion protection and contribution to buffering of fluids such as metalworking fluids and brake fluids make it a highly valued and technically very difficult to replace material. We believe that if this process of substance of high concern classification goes ahead it will lead to the use of less robust fluids having reduced sump life and greater frequency of disposal. The effects in Europe will be an inevitable increased burden of cost for no benefit in terms of environmental and safety of humans and will further increase the risks of transfer of Industrial processes outside of Europe.	(1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low

			dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100419	Individual, France	Dans un process de brasage laiton dans les raccords hydrauliques (brasure étanche), nous utilisons une pâte flux recuite à base d'acide borique.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was

			derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100419	BehalfOfAnOrganisation, Industry or trade association, Company, Switzerland	EBA comments Annex XV 100104 final.pdf Based upon the findings of your studies and other given information so far we are deeply concerned about boric acid being named on the SVHC candidate list. We confirm and agree on the statement by EBA (European Borate Association) that we have also added as annex to this comment.	See response to EBA comments
20100419	BehalfOfAnOrganisation, Alpha Fry Limited, Company, United Kingdom	As a major manufacturer of water treatment chemicals for hot water systems, we have had many years of experience of developing, manufacturing and handling Boric acid based products. Our manufacturing sites handle 150+ tonnes of Boric acid annually, and have been in operation for over 20 years. In that time we have not experienced health concerns either from our staff or our customer base (domestic and commercial). We have concerns over the validity of the read across toxicological data derived from animal testing and would challenge the conclusions that like for like heath concerns can be contributed to humans from animal testing. Boric acid is used in many facets of food, cosmetic and common industrial application, we would have expected to have seen a large number of historical health effects over the years if boric acid was contributing to the ill health of the community.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as

			cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100419	Industry or trade association, Company, Portugal	We are a UE member state user of boric acid. As a formulator, we are industrial downstream user. Our formulations (metalworking fluids) are used by industrial and professional users only. Boric Acid Benefits: -Important micronutrient in nutrition and food production; -Hazards are well-known and risks are adequately controlled; -Stable buffer capacity, thus robust against microbial attacks; -Good availability; -Good price performance ratio; -Used without problems for many decades in the metalworking fluid industry.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the

			case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100420	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my employees. Why instead of helping the industry to compete with Asian countries, who are operating without any rules, you introduce more difficulty in working with new rules absurd? In this way, you contribute to close the European industry.	Your comment has been taken note of.
20100420	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the worrking conditions of my employees, my life.	Your comment has been taken note of.
20100420	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the	Your comment has been taken note

		relevant consequences, will change for the worse my job, the working conditions of my employees, my life.	of.
20100420	Industry or trade association, Japan	Dear Mr. Dancet, Re: Proposals to identify Boric Acid as Substance of Very High Concern (SVHC) On behalf of one of our clients, a non-EU manufacturer of food contact materials containing Boric Acid and exporting them to the EU, we are writing to submit comments against the proposal to identify boric acid as a Substance of Very High Concern (SVHC) (on the candidate list established under the REACH Regulation 1907/2006). By way of background, we note that Member States Competent Authorities or the European Chemicals Agency (ECHA), on request of the European Commission, may prepare an Annex XV dossier for the identification of an SVHC. For boric acid, the Annex XV dossier has been submitted by Germany and Slovenia. For a chemical substance to qualify as SVHC, it must meet one or more of the requirements laid down in Article 57 of Regulation 1907/2006 (REACH). These requirements are: (a) substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC; (b) substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC; (c) substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC; (d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of REACH; (e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of REACH; and (f) substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59. 1. SVHC prioritisation among hazardous substances A teleological interpretation of the REACH Regulation provides guidance as to how to prioritise the SVHC identification among substances that are all classified as “hazardous”. Specifically, the identification of a substance as SVHC is in fact instrumental to the inclusion of that substance in a Annex XIV (Article 59(1) of	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. Boric acid clearly meets the criteria according to REACH article 57c, which is sufficient for an SVHC proposal (it is not required for one substance to meet all criteria of art. 57). Therefore, the SVHC proposal of Boric Acid is justified. By the time of dossier preparation the available information on uses in consumer products was reviewed and used for the dossier. We are aware that CMR substances as well as substances with high production volumes will be registered by the end of this year and further information may become available. The use in food contact materials within the scope of Regulation 1935/2004 is exempted from the provisions of Article 56 (1) and (2) of the REACH Regulation (EC) 1907/2006.

		REACH). Annex XIV of REACH deals with substances that are subject to authorisation, i.e., which cannot be placed on the market unless they are authorised (or unless they are exempted from the authorisation). Therefore, an SVHC is a substance which will be considered for inclusion in Annex XIV of REACH. With regard to the Annex XIV inclusion, REACH provides (at Article 58(3)) that priority should be given to substances with PBT/vPvB properties, or wide dispersive use or in high volumes. As a result, an argument can be made that in the SVHC identification process, precedence should be given to those substances which are more likely to be included in Annex XIV, i.e. to substances with PBT/vPvB properties, or wide dispersive use, or high volumes. In any event, the SVHC identification should not be based on a random selection exercise and this for two reasons: (i) first, a random selection exercise would frustrate the purpose of the SVHC identification process which is, indeed, to establish a list of substances being capable of being included in Annex XIV of REACH. This could result in qualifying as SVHC a number of substances which will not, or only late, be included in Annex XIV of REACH; and (ii) second, the SVHC identification will undoubtedly stigmatise those "identified" substances, which would be seen as potential Annex XIV substances, i.e., as being so hazardous to be prohibited from being placed on the EU market, except under a specific authorisation. 2. Reasons justifying the SVHC identification in Annex XV We note that the proposal to identify boric acid as an SVHC is based on the fact that boric acid meets only one of the Article 57 REACH criteria, i.e. that it can be classified as R60-61, toxic for reproduction. Importantly, however, this is only valid if boric acid is present in concentrations higher than 5.5% by weight, which is a significantly high threshold if compared to the concentration limits set for other R60-61 substances in Directive 67/548/EEC and in Regulation (EC) 1272/2008. Further, a more careful reading of the Annex XV dossier concerning boric acid reveals that, while consumer use with boric acid weight concentration lower than 5.5% is rather common, use of boric acid in concentration higher than 5.5% is limited to "soldering products, film developer and raw material for pharmaceuticals" (page 10 of the Annex XV dossier). In addition, the Annex XV dossier informs that the main uses of boric acid are out of the scope of the REACH authorisation provisions. For example, the main use of boric acid is indicated to be in biocides, which are exempted from REACH authorisation provisions pursuant to Article 56(4)(b) of REACH. Some of the other minor uses listed at page 10 of Annex XV, such as the use in veterinary medicines or in food additives are also exempted pursuant to, respectively, Article 2(5)(a) and (b) of	

		REACH. Furthermore, Annex XV refers (at page 15) to "Consumer Products under Sectoral Regulation" including therein boric acid uses in cosmetics and food contact materials, which are expressly exempted (pursuant to Article 56(5) (a) and (b) of REACH) from the Annex XIV provisions, hence also from the SVHC identification process. As a consequence, the identification of boric acid as an SVHC, at least when used in concentrations lower than 5.5% and when used in biocides, veterinary medicines, food and food additives, cosmetics and food contact materials, does not achieve the purpose sought by such identification, i.e., selection of substances for subsequent prohibition unless an authorisation is obtained. We further argue that the remaining uses of boric acid – i.e., in concentrations above 5.5% by weight and for uses other than those exempted from the provisions on authorisation under REACH – can still justify the need of an SVHC identification, in particular due to the health related risks to humans. Here again, however, the Annex XV dossier does not appear to provide clear-cut information. At page 11 and following, the Annex XV dossier deals with "Information from the Transitional Dossier and the RPA report" on consumer exposure. This section of the Annex XV dossier makes it clear that: "[a] risk characterisation assessment for boron exposure via consumer products was not derived due to the lack of information on other consumer uses"; that "minimal data are available on consumer exposure" and that "a need for further information was concluded" since "the RPA report was not available at the time of submission of this dossier" (page 10). As regards the dermal absorption of boric acid, the Annex XV dossier provides that the "Committee for Risk Assessment the European Chemicals Agency (RAC) is currently discussing an opinion on the use of boric acid and boron compounds in photographic products for consumers, which will also cover dermal absorption of borates. Therefore, the following consumer exposure calculations might need a revision after the publication of the RAC opinion". In conclusion, it appears that the SVHC identification of boric acid is not based on the risks related to human exposure to such substance, rather on toxicological studies describing the substance's characteristics. Further, while these studies are not definitive, they also determine a concentration threshold limit for boric acid which is, in practice, very rarely met and they consider boric acid uses which are exempted from the provisions of the REACH Regulation on authorisation. We further conclude from the above that the SVHC identification of boric acid will have no, or little discernible benefit for consumers, in particular if compared to the many other substances with hazardous properties, while it will certainly stigmatise boric acid. Based on the foregoing, and on the understanding that the SVHC identification	

		process is not a random exercise and that it follows certain rules as described above, we therefore submit that boric acid should not be identified as a SVHC, or at a minimum that its identification should be accompanied by a note indicating the it does not concern boric acid when used in food contact materials. We thank you for your attention to this matter and look forward to hearing from you. Yours sincerely, Kazumi Yuki SCAS Europe S.A./N.V.	
20100420	Industry or trade association Company, Germany	We are Industry or trade association, a EU member state user metal-working fluids containing compounds of boric acid and a member of the VKIS, the association of the German user of metalworking fluids. We are an industrial downstream user.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were

			regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100420	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my employees, my life.	Your comment has been taken note of.
20100420	Individual, Italy	The use of Boric Acid is essential in my buisiness in electroplating, The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my employees, my life.	Your comment has been taken note of.
20100420	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my employees, my life.	Your comment has been taken note of.
20100420	ZINCATURA MAL, Company, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my employees, my life.	Your comment has been taken note of.
20100420	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my employees, my life	Your comment has been taken note of.
20100420	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my employees, my life	Your comment has been taken note of.
20100420	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my employees, my life	Your comment has been taken note of.
20100420	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the	

		relevant consequences, will change for the worse my job, the working conditions of my employees, my life.	Your comment has been taken note of.
20100420	Industry or trade association, Belgium	General Comment We wish to comment on the whole basis of the Annex XV dossier submitted by Germany, rather than highlighting any specific aspect. We highlight the following two points: • We consider the proposal to be premature, given that the reclassification of these boron compounds is still not complete, and inappropriate because the dossier provides no additional justification for the identification of the compounds as SVHC, besides their reclassification as CMR Category 2. • The use made of these compounds in the European Corrugated Board Industry is as a minor but technically important additive for which no alternative currently exists. It is used a levels far below the specific concentration limits in the reclassification and there is a long history of safe use of the compounds in the industry.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation. The question of alternatives should be discussed in case authorization for the production processes, uses or applications becomes necessary.
20100420	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my employees, my life.	Your comment has been taken note of.
20100420	AffiliatedWithOrganisation, A.I.F.M., Regional or local authority, Italy	"L'INSERIMENTO DELL'ACIDO BORICO NELLA LISTA SVHC E LE CONSEGUENZE DI QUESTO FATTO CAMBIERANNO IN PEGGIO IL MIO LAVORO, LE CONDIZIONI DI LAVORO DEI MIEI DIPENDENTI , LA MIA VITA"	Your comment has been taken note of.
20100420	Individual, Italy	This will change in worse my life and conditions of my employes	Your comment has been taken note of.
20100420	Zeller+Gmelin GmbH & Co. KG, Company, Germany	In 2011 REACH dossiers are reviewed. Annex XV dossiers should not be filed, until the complete submitted information and test studies included in the REACH registration dossier are evaluated.	We are aware that CMR substances as well as substances with high production volumes will be registered by the end of this year and

			further information may become available.
20100420	Individual, France	Le classement de l'acide borique à l'annexe XIV de REACH, risquant de conduire à terme à sa suppression du marché fait courir un risque fort, voire même stratégique sur la production d'électricité d'origine nucléaire car l'acide borique est un composant qui est utilisé comme neutrophage dans les centrales nucléaires PWR. Un pourcentage important de l'électricité produite en Europe provient de centrales nucléaires de ce type. Il n'apparait vraiment pas envisageable d'envisager sa disparition, car il n'est pas possible d'utiliser un autre produit qui présente les mêmes caractéristiques que l'acide borique.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of

			exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100420	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my employees, my life.	Your comment has been taken note of.
20100420	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my employees, my life.	Your comment has been taken note of.
20100420	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my employees, my life.	Your comment has been taken note of.
20100420	MSCA, Belgium	We agree on the general conclusion for the identification of the substance as a SVHC, as boric acid will be listed in annex VI of Regulation (EC) No 1272/2008 as toxic to reproduction category 2 (part 3, table 3.2). We have some minor comments (most of them, editorial comments) on the annex XV dossier: p.3: editorial comment: the substance does not meet the criteria for classification as carcinogen, but it does support the criteria for classification as toxic to reproduction in accordance with Article 57 (c) of REACH. p.9: editorial comments: Classification information is provided in section 3 (and not in section 2) p.23: editorial comment: Key repeat dose studies on boric acid are summarized in table 4 (not in table 3). p.24: editorial comment: 3rd§, 4th line … 4480 mg boric acid (mg boron)/kg bw/day… Shouldn't it be 4480 mg boric acid/kg bw/day? p.26: editorial comment: In the table, for the reference NTP, 1987, in the column "Dose levels", between brackets, the first and second equivalent are in mg boric acid /kg bw/day (and not boron) in males and mg boric acid/kg bw/day (and not boron) in females. In the latest dose levels mentioned, "in females" is missing. Furthermore, is it 392 mg boron/kg bw/day (in table) or 292 mg boron/kg bw/day (in the text, p.24)? (392 seems to be the correct value, as to go from boric acid to boron, you have to divide by 5.719). Furthermore, for the same study, the value of 47 is incorrect in the table and in the text (p.24) (should be around 29.6).	The annex XV report was amended.

		p.27: editorial comment: Key fertility studies are summarized in table 5 (not in table 4), Key developmental studies in table 6 (not in table 5). p.28: In Fail et al., 1991 (NTP, 1990), the different NOAEL and LOAEL are: F0-females NOAEL=1000ppm (or 26.6 mg boron/kg bw/day) F0-males LOAEL=1000ppm F1 LOAEL=1000ppm F2 LOAEL=1000ppm However, in the table on page 30, this dose (26.6 mg/kg bw/day) is stated as a NO(A)EL for all the generations. p.28: editorial comment: effects on fertility: Fail et al.(1989): if male deer mice were fed a diet to which boric acid was added (resulting in doses of 108.1 mg boron/kg bw/day and 216.2 mg boron/kg bw/day), how can it be concluded that complete infertility was observed in male deer mice exposed to 38.5 boron/kg bw/day and no decrease in fertility observed in deer mice that consumed 19.3 mg boron/kg bw/day. We suspect the values of 108.1 and 216.2 mg to be boric acid instead of boron. p.30: editorial comment: In the table, for Weir and Fisher, 1972, in the column Doses, the unit "ppm" is missing. For the doses used by Fail et al., 1991 (NTP, 1990) we should read 111.3 and 220.9 (and not 111,3 and 220,9) p.33: editorial comment: in the table, for Price et al., 1996a, the doses are not specified for the 2 groups (phase 1 and phase 2).	
20100420	Individual, Italy	"L'INSERIMENTO DELL'ACIDO BORICO NELLA LISTA SVHC E LE CONSEGUENZE DI QUESTO FATTO CAMBIERANNO IN PEGGIO IL MIO LAVORO, LE CONDIZIONI DI LAVORO DEI MIEI DIPENDENTI, LA MIA VITA"	Your comment has been taken note of.
20100420	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my employees, my life.	Your comment has been taken note of.
20100420	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my employees, my life.	Your comment has been taken note of.
20100420	Silvaprodukt, Company, Slovenia	Human health hazard assessment	
20100420	SILVAPRODUKT D.O.O., Company, Slovenia	Silvaprodukt d.o.o. Dolenjska cesta 42, 1000 Ljubljana	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric

		European Chemicals Agency Urad Republike Slovenije za kemikalije Ajdovščina 4 1000 Ljubljana Response to the Proposals to identify Substances of Very High Concern: Annex XV reports for commenting by Interested Parties – BORIC ACID The decision of the European Chemicals Agency to identify Boric acid as Substance of very high concern surprised us. Our company Silvaprodukt has long tradition of producing wood preservatives. We are producing wood preservatives for more than 60 years. Products, based on (containing) boric acid are in our market for almost 50 years. They are extensively used in the industrial scale and "do it yourself" program. Despite of the fact that boric acid is used for decades, there was no report on the any kind of the CMR issues nor by the employees in our company, nor by the our consumers, nor by the users. Boron is present in small amounts in nature everywhere. It is located in the soil, water, plants and animals. The average concentration of boron in soil is between 3 mg/kg and 10 mg/kg of soil (Adams, 1964). Sea water on average contains 4,5 mg/kg of B (Jenkins, 1980) and drinking water between 0,05 mg/L and 0,3 mg/L. Concentrations can be higher, depending on the location, mostly (Yazbeck et al., 2005). For example, boron concentration in drinking water, in the sounding of boron mines in Turkey, is between 21 mg/L to 29 mg/L (Sayli et al., 1998). Boron is also used as an additive or in can preservative in food products. Estimates of daily intakes vary. They depend on local eating habits and the use of preservatives in food. The average daily intake of boron per person in the US is according to Murray (1995) at least 1,5 mg of B/day/person. Rainer (1993) estimated, that the average daily intake is even higher (up to 3 mg of B/day/person), and can reach up to 10 mg of B/day/person. While Roper (1992) indicates even higher quantities of boron compounds, each day we consume between 10 and 25 mg of B/day/person. The most famous dish which preserved with boric acid is caviar. Only the use of boric acid allows the transport of caviar Boron may enter the human body through the skin and respiratory tract. Inhalation of air, which contains 4,1 mg/m3 of boron, causes irritation of the nose, throat or eyes. Boron irritate the eyes, but only when workers are exposed to boron over longer	acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.

		period (Roper, 1992). Maximum working concentration of boron oxide and borax in the air is 10 mg/m3. On the other hand, studies of borates in practice showed, that the introduction of the borates to the inhalator tract does not reflected in any detectable chronic effect; additionally dermal contact did not cause any irritation or inflammation of the skin also (Culver and Shen, 1994). Boron toxicity studies on mammals (mice, rats and dogs) showed that it affects the male sex organs (reproductive toxicity). This was shown especially in tests where the animals have consumed large quantities of boric acid for shorter or longer period of time (Roper, 1992). Similar studies of influence of boric acid on the pregnant mice, rats and rabbits showed a lesser effect on the cub development (Fail, 1998). On the other hand, Weir and Fisher (1972) report that 8,8 mg boron/kg/ day, which was added to the dogs food for two years, did not affect their reproduction. Adverse effect of boron on reproductive was found in rats chronically exposed to significantly higher concentrations (58,5 mg boron/kg/day). So person of 75 kg, should consume daily 4 m3 of impregnated wood to achieve this intake. The survey data on influence of boron on reproductive toxicity of humans are too poor to be able to confirm or discard the boron reproductive toxicity toward humans. There are also no available data to confirm teratogenicity properties of boron compounds. In a survey based study carried out on 542 men employed in the manufacture of borax (boron mining and processing), which were more than five years daily exposed to the high concentrations of boron (at least 23,2 mg borax/m3, 0,48 boric acid mg/kg body weight/day), noted that there were no statistically significant effects on their reproductive properties. Fertility of the men was in the average reported for the US (Whorton, 1994). Similar conclusions were reported by Sayli and colleagues (1998), who conclude that high concentrations of boron in drinking water (21 mg/L to 29 mg/L) does not affect fertility and reproduction of population in this region in Turkey. Boron compounds are not accumulated in the human body. Research mobility of boron in the human body have shown that 50 % of the consumed boron is excreted by the urine within 21 hours. The remaining amount is excreted in 95 hours after ingestion of the boron (Rainer, 1993). However, it should be considered, that boric acid based wood preservatives used for treatment of wood are stable. They are used for impregnation of construction that is not in contact with people. This construction is covered by insulation, façade… Boric acid does not evaporate from wood. It is stabilized in wood. Furthermore, impregnation of wood is rather hard physical work. It is not suitable for pregnant women in general. Therefore, in our 60 year old history, we have never met pregnant women working on the impregnation plant.	

		However, it should be considered, that treatment of wood with wood preservatives based on boric acid is taking place in closed system in impregnation tank. The surface of impregnated wood is rather dry at the end of impregnation procedure. So users are not in direct contact with boric acid aqueous solution, but in with boric acid fixed in wood. So there are other type of interaction then described in this study. Furthermore, it should be considered, that boric acid treated wood is generally treated with surface coatings that limit contact of boric acid with wood. Furthermore it should be considered, that boric acid remained in wood and does not evaporate from wood during wood service life. Therefore we believe, that the authorities will consider, that the boric acid in not chemical of high concern, at least in the applications related to wood preservation, and can be used for industrial applications. References: 1. Adams, R., 1964: Boron, Metalloboron Compounds and Borates . N.Y. 2. Culver, B., Shen, P., 1994: A study of absorption of boron in workers engaged in the production of borax. Environmental Health Perspect, 102 (7), 122. 3. ECETOC, 1995: Technical report No. 63. Reproductive and General Toxicology of some Inorganic Borates and Risk Assessment for Human Beings. European Centre for Ecotoxicology and Toxicology of Chemicals, Brussels. 4. Fail, P. A., 1998: General, reproductive, developmental and endocrine toxicity of boronated compounds. Reproductive Toxicology, 12, 1-18. 5. Jenkins, D., 1980: U.S. Environmental Protection Agency Report. 6. Lloyd, J. D., 1998: Borates and their biological applications. International Research Group for Wood Preservation. IRG/WP 30178, 26. 7. Moore, J., 1997: An assessment of boric acid and borax using the IEHR evaluative process for assessing human developmental and reproductive toxicity of agents. Reproductive Toxicology, 11, 123-160. 8. Murray, F., 1995: A human Health Risk Assessment of Boron (Boric Acid and Borax) in Drinking Water. Reg. Toxicol. and Pharmacol., 22, 221-230. 9. Rainer, M. J., 1993: Borates as wood preservatives - an environmental, health and safety perspective. International Research Group on Wood Preservation. RG/WP 50001-03, 17 str. 10. Roper, W. L., 1992: Toxicological profile for boron. Agency for Toxic Substances and Disease Registry U.S. Public Health Service, 110 str. 11. Sayli, B. S., Tuccar E., Elhan, A.H., 1998: An assessment of fertility in boron-exposed Turkish subpopulation. Reproductive Toxicology, 12, 297-304. 12. Weir, R., Fisher, R., 1972: Toxicology and Applied Pharmacology. 23, 351-364.	

		13. Whorton, M., 1994: Reproductive effect of inorganic borates on male employees: birth rate assessment. Environmental Health prospect, 7, 29-32. 14. Yazbeck, C., Kloppmann, W., Cottier, R., Shauquillo, J., Debotte, G., Huel, G. 2005 Health impact evalution of boron in drinking water: a geographical risk assessment in Northern France. Environmental Geochemistry and Health, 27, 419-427. Director Dušan Radoš Ljubljana, 19.4.2010 SLOVENIJA	
20100420	Industry or trade association Company, United Kingdom	ECHA Reference Document 1.docx ECHA Reference Document 2.pdf ECHA Reference Document 3.pdf ECHA Reference Document 4.pdf ECHA Reference Document 5.pdf ECHA Reference Document 6.pdf ECHA Reference Document 7.pdf ECHA Reference Document 8.pdf ECHA Reference Document 9.pdf ECHA Reference Document 10.pdf While we cannot dispute the obvious link between exposure to high concentrations of boric acid and reproduction damage, the levels of exposure given to laboratory animals are massively above any exposure that could occur during industrial handling of this product under good industrial practice. Our site measurements for our use show a safety margin of a factor of >100 between operator exposure and stated NO(A)EL . Therefore although we sympathise with the principle of classification as a reprotoxic substance we do not feel any restriction on its use in industrial fire protection coatings is necessary to protect human health and safety. While there is undoubtedly a hazard associated with this material the risk in our industry is trivial. We therefore request authorisation for the continued use of boric acid within the industrial coatings industry and its Industrial and Professional customer base.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of

			ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100420	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my employees, my life.	Your comment has been taken note of.
20100420	The Association of Contact Lens Manufacturers Ltd, Industry or trade association, United Kingdom	Borates and Boric Acid is a naturally occurring chemical used widely such as in detergents, cleaners, personal care products, agriculture, it is even available as a food supplement. The toxicity of Boric Acid (oral rat LD50: 2660 mg/kg) is only slightly higher than Sodium Chloride (kitchen salt) (oral rat LD50: 3000 mg/kg). There is currently no evidence of harm to humans regarding reproductive toxicity. Borates and Boric Acid are used in a range of medical devices, controlled by sectoral legislation (Medical Devices Directive 93/42/EEC), such as contact lens buffered solutions, contact lens care products and eye drops. These products are used in the eye, so the exposure to diluted borates is limited to the topical route of delivery. There are currently no acceptable substitutes available. The Medical Devices Directive requires manufacturers to do a risk assessment, whereby the benefit of the device has to outweigh the risk associated with the device and its components.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned.
20100420	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my employees, my life.	Your comment has been taken note of.
20100420	Chambre Syndicale Nationale de l'Industrie des Lubrifiants, Industry or trade association, France	EBA comments Annex XV 100104 final.pdf We are the CSNIL, the EU Member State Trade Association representing France' lubricants Industry and are the member organisation for our country within UEIL, the European Lubricants Industry Organisation.	See response to EBA comments

20100420	UNITI, Industry or trade association, Germany	EBA comments Annex XV 100104 final.pdf In Germany UNITI is the sole professional representation for small and medium-sized companies producing and dealing with fuel, heating fuel and lubricants. With about 3000 member companies and over 60.000 employees UNITI is a strong German association. As REACH dossiers are reviewed in 2011, until this time Annex XV Dossiers should not be filed	See response to EBA comments We are aware that CMR substances as well as substances with high production volumes will be registered by the end of this year and further information may become available.
20100421	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my employees, my life.	Your comment has been taken note of.
20100421	Rhenus Lub GmbH & Co KG, Company, Germany	EBA comments Annex XV 100104 final.pdf We are Rhenus Lub GmbH & Co KG a EU member state user of boric acid. We are a member of the German Lubricant Industry (VSI). We formulate metalworking fluids and therefore we are an industrial down stream user. Our metal working fluids are used by industrial and professional users only.	See response to EBA comments
20100421	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my employees, my life.	Your comment has been taken note of.
20100421	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life	Your comment has been taken note of.
20100421	Proviron Industries, Company, Belgium	boric acid comments19042010 .doc April 19,2010 Proviron Industries nv Comments on the German/Slovenia Annex XV dossier on Boric Acid dated February 2010. German/Slovenia have submitted an Annex XV SVHC dossier on boric acid for the identification of boric acid as toxic for reproduction category 2 according to Article 57(c) REACH. Boric acid is manufactured or imported in the EU for various uses including as an	Thank you for the information. “Brake fluids” have been reported to the Swedish product register as a use category for boric acid in 2008.

		intermediate. All uses of boric acid are described in the Annex XV dossier (including uses related to brake fluids). Since boric acid is an intermediate in the production of brake fluids, as defined in REACH, Title VII REACH and its Article 57(c) cannot apply to the use of boric acid in brake fluids as described in the Annex XV dossier. Consequently, it is our opinion that the Annex XV dossier can not be used for the purpose of identification of boric acid as toxic for reproduction category 2 as far as it relates to the use in brake fluids. Accordingly, the Annex XV dossier submitted by German/Slovenia lacks legal basis, where it suggests that brake fluids contain free boric acid. This is not the case since boric acid is chemical bounded to the glycol-ether back bone. In general is has to be stated that the wording “brake fluids” is not correct or is confusing in this context. Most brake fluids on the market today are glycol-ether based borate esters, but mineral oils and silicone based fluids are also available, but have no relation to boric acid.	
20100421	Individual, Italy	"The identification of boric acid as SVHC and the relevant consequences will seriously complicate my job, worse my employees work condition, and my life".	Your comment has been taken note of.
20100421	Individual, Italy	Boric Acid is an important substance used for nickel and zinc electroplating. The alternatives for zinc is to use Ammonium salt, what creates several problems for the water depuration in the depuration plant. For nichel plating there are not alternatives to the usage. So the inclusion of Boric Acid in the list will create several problems for all the galvanic industries.	Your comment has been taken note of.
20100421	Individual, Italy	"The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life".	Your comment has been taken note of.
20100421	Česká společnost pro povrchové úpravy, Industry or trade association, Czech Republic	we do not agree to enclosing boric acid to cadidate list SVHC	
20100421	Individual, Italy	"The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life".	Your comment has been taken note of.
20100421	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job and the working conditions of my employees.	Your comment has been taken note of.

20100421	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my employees, my life.	Your comment has been taken note of.
20100421	EDF, Company, France	English version : Using boric acid in nuclear electric power plants is vital to managing nuclear reaction and ensuring plant safety. Boric acid is used in all of the world's water nuclear power plants; no other chemical compound has the same characteristics needed to replace boric acid for this use (see "information on alternatives" section). In France, the use of boric acid in nuclear power plants is controlled by both radiochemical specifications and legal limits for discharge established by the French nuclear safety Authority. This administrative independent body set up by law no. 2006-686 of 13 June 2006 pertaining to the transparency and safety of nuclear activities and is in charge of monitoring civil nuclear activities in France. Boric acid is used in nuclear power plants because natural boron is approximately 20% isotope boron-10, which gives it neutron-absorbing capabilities. Used in the primary circuit pressure boundary, in direct connection with the nuclear reactor, the isotope boron-10 found in boric acid helps control fuel fission reactions by adjusting reactivity according to the fuel burn up between the beginning and end of the cycle. Boric acid is purchased in powder form. It is used in the primary circuit pressure boundary at a concentration of less than 5.5%, as well as in an auxiliary system important to nuclear safety at a concentration of 12%. The effluents produced by reactors in operation are treated by filtration, demineralization, and evaporation before discharge to reduce the activities and substances released into the receiving environment. Evaporation allows to produce clean distillates and to concentrate substances. EDF's French nuclear power plants (58 production units located in 19 different sites) consume 300 tons of boric acid annually; i.e. an average of 5 to 6 tons per reactor, which represents 0.5% of European consumption (source EBA 2008). Comments also available in pdf format in attachment Version française : L'usage de l'acide borique dans les centrales nucléaires de production d'électricité est indispensable pour permettre la maîtrise de la réaction nucléaire et assurer la sûreté des installations. L'acide borique est utilisé dans toutes les centrales nucléaires	Alternatives or substitution will have to be discussed in case application for an authorization for the production processes, uses or applications becomes necessary. Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of

		à eau du monde ; aucun autre composé chimique ne présente les caractéristiques nécessaires pour remplacer l'acide borique dans cet usage (Cf. § « information on alternatives »). En France, l'utilisation de l'acide borique dans les centrales nucléaires est contrôlée à la fois par les spécifications radiochimiques et par les limites réglementaires de rejets, toutes deux définies par l'Autorité de sûreté nucléaire ; Autorité administrative indépendante créée par la loi n° 2006-686 du 13 juin 2006 relative à la transparence et à la sécurité en matière nucléaire, chargée de contrôler les activités nucléaires civiles en France. Dans une centrale nucléaire, l'acide borique est utilisé pour ses propriétés d'absorbant neutronique que lui confère l'isotope 10 du bore présent à hauteur de 20% dans l'acide borique à l'état naturel. Utilisé principalement dans le circuit primaire principal, en liaison directe avec le réacteur nucléaire, l'isotope 10 du bore présent dans l'acide borique permet de contrôler les réactions de fission du combustible, en ajustant la réactivité en fonction de l'épuisement du combustible entre le début et la fin du cycle. L'acide borique est acheté sous forme pulvérulente. Il est utilisé dans le circuit primaire principal à une concentration inférieure à 5.5% ainsi que dans un circuit auxiliaire important pour la sûreté nucléaire à une concentration de 12%. Les effluents produits par le fonctionnement des réacteurs sont traités avant rejet pour réduire les activités et substances rejetées dans le milieu récepteur, par filtration, déminéralisation et évaporation. L'évaporation permet de recueillir des distillats propres et de concentrer les substances. La consommation annuelle d'acide borique des centrales nucléaires françaises d'EDF (58 unités de production réparties sur 19 sites) est de l'ordre de 300 tonnes par an, soit en moyenne 5 à 6 tonnes par réacteur ; ceci représente 0.5% de la consommation européenne (source EBA 2008). Ces commentaires sont également disponibles au format pdf dans la pièce jointe	ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100421	Verband der Deutschen Feuerfest-Industrie e. V., Industry or trade association, Germany	Boric acid comments.pdf The German Refractory association was really astonished about the Annex XV Dossier for identification Boric acid as Substance of very high concern. Boric acid is well regulated in different EU legislations. There are more than fifteen EU legislations, which mention Boric acid. There are also national legislations, which mention Boric acid. Putting Boric acid on the Candidate List for authorisation is considered an over-regulation and not necessary. The workplace exposure limit for Boric acid in Germany is 0,5 mg/m3. Based on	Boric acid clearly meets the criteria according to REACH article 57c, which is sufficient for an SVHC proposal. Therefore, the SVHC proposal of Boric Acid is justified.

		monitoring data it could be demonstrated that it is no problem to meet the exposure limit. Boric acid has been used safely for a long time in the Refractory-Industry there are a lot of other substances, which are not regulated by several legislations. Therefore, the limited resources of the Member states would better be used to put other substances on the candidate list for authorization before Boric acid should be treated. The Annex XV-Dossier for Boric acid does not contain the complete available information. There are further studies, which are not mentioned, e. g. the Chinese worker study. On page eleven the author writes: "The RPA report was not available at the time.........Therefore, minimal data are available on consumer exposure." The Reach registration dossier will close this data gaps. Therefore the Member states should wait for their decision until the Reach registration dossier is submitted before December 2010. Our industry will provide worker and environmental exposure data for the Reach registration dossier. Boric acid is very important as binder for special shaped and unshaped refractory products. The German refractory industry is looking for alternative substances, however it will not possible to replace Boric acid completely. Not using Boric acid it would have enormous consequences for the environment. Due to the shorter life time of refractory materials without Boric acid, customers would have to replace more frequently the refractory products, with the consequence of a lot more raw materials are required (in a time of limited available resources). This means a higher environmental pollution by transport, a higher energy consumption for the calcination of raw materials and baking of the refractory products, a higher CO2-production detrimental to the targets to Europe´s in its Climate Change Programme (ECCP), more waste and last but not least supports the transfer of workplaces to counties outside of European Countries. Refractory products with Boric acid are used in the Steel-, Glass-, Cement- and Aluminium-Industry. The authorisation of Boric acid also would therefore have severe consequences to those industries. Conclusions There are no reasons to place Boric acid on the candidate list at this point of time. A	The RPA report was not finalised at the time when the transitional dossier was finalised, but it has been evaluated for the annex XV dossier. We are aware that CMR substances as well as substances with high production volumes will be registered by the end of this year and further information may become available.

		decision for further regulatory actions could take place at the earliest after the registration of Boric acid. The German Refractory Association requests that the Annex XV dossier is withdrawn.	
2010421	Euromcontact, Industry or trade association, Belgium	Borates and Boric Acid is a naturally occurring chemical used widely such as in detergents, cleaners, personal care products, agriculture, it is even available as a food supplement. The toxicity of Boric Acid (oral rat LD50: 2660 mg/kg) is only slightly higher than Sodium Chloride (kitchen salt) (oral rat LD50: 3000 mg/kg). There is currently no evidence of harm to humans regarding reproductive toxicity. Borates and Boric Acid are used in a range of medical devices, controlled by sectoral legislation (Medical Devices Directive 93/42/EEC), such as contact lens buffered solutions, contact lens care products and eye drops. These products are used in the eye, so the exposure to diluted borates is limited to the topical route of delivery. There are currently no acceptable substitutes available. The Medical Devices Directive requires manufacturers to do a risk assessment, whereby the benefit of the device has to outweigh the risk associated with the device and its components.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned.
20100421	Industry or trade association, Company, United Kingdom	Information attached is confidential	Boric acid was proposed as SVHC based on its classification as toxic to reproduction, its use in consumer products, and its high production volume. However, we are aware that boric acid will be registered by the end of this year and further information may become available.
20100421	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life	Your comment has been taken note of.
20100421	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life	Your comment has been taken note of.
20100421	MSCA, United Kingdom	Limited information is presented in the dossier compared with the information available in the transition dossier. The SVHC dossier does not adequately reflect the conclusions reached in the transition dossier.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress). Therfore, only brief information on toxicity was given in the dossier.

20100421	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life	Your comment has been taken note of.
20100421	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life	Your comment has been taken note of.
20100421	VGB PowerTech e.V., Industry or trade association, Germany	Boric acid is used in pressurized water reactors for reactivity control in nuclear power plants, whereby the boron-10 isotope is a neutron-absorber. Boric acid is used in form of natural boric acid, which contains about 20 At% boron-10 and in combination with enriched boric acid with a boron-10 content of about 98 At%. Boric acid is also used in pressurized water reactors in severe emergency situations as neutron absorbing agent to stop the chain reaction immediately. In boiling water reactors it is also used with Disodiumtetraborate in poisoning basins. These basins contain the poisoning solution to shut down the reactor immediately in case of damage.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3

			(inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100421	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my employees, my life.	Your comment has been taken note of.
20100421	MSCA, Netherlands	NL supports the proposal to include boric acid in the candidate list of substances of very high concern.	Thank you.
20100421	Industry or trade association, Company, Spain	We are a downstream user of a Member State. Boric acid/borates have good buffer and antirust properties allowing metalworking fluids used in highly polluted media to last longer (almost double) and use less chemicals (antirust, biocides) in their formulations thus reducing waste generation. Then, we are of the opinion that any decision on them should be postponed till REACH dossiers are finished.	We are aware that CMR substances as well as substances with high production volumes will be registered by the end of this year and further information may become available.
20100421	FUCHS Lubrificanti S.p.A., Company, Italy	p.14 - The percentage of boric acid is often less then 5% in these concentrates and emulsions in service are generally between 5 and 10%; this means that boric acid in emulsions in use is below 0.5%. Several studies showed that usually metalworking fluids mist in working area is about 1 mg/m3; consequently boric acid concentration in oil mist is less that 0.01 mg/m3, a very low value (in Germany a health risk exposure limit was fixed at 2.6 mg/m3).	The specific concentration limit for classification of boric acid is 5.5 %.
20100421	AIFM, Industry or trade association, Italy	Boric acid is essential in electroplating process as: Buffer of pH of¬ nickel plating baths Boric acid is a week acid, it enables the buffering of pH of the nickel plating bath that during the process of electrolysis fluctuates and increases. As a rule the concentration of boric acid is in the range between 35 and 50 g/l. As far as alternatives are concerned, at present there is no substance that can replace it giving the same effectiveness and quality of production. Major implications are: • Without boric acid it is impossible to assure good quality indexes. • The use of strong acids to control the pH needs frequent additions. Sulphuric acid with concentration between 33 and 66% enhances as time goes by the instability of	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to

		pH due to the electroplating process. As a matter of fact the process will be no longer under control with dramatic increase of low quality products and waste. • The buffering effect of boric acid can not actually be replaced even by careful additions of sulphuric or hydrochloric acid that give to the nickel coating the burn effect. It enables the substitution of hexavalent chromium¬ bath Boric acid is an essential component of the saline matrix used in the most recent, low concentration bath of trivalent chromium (< 7g/l) that increasingly substitutes the electroplating process based on hexavalent chromium both in chromium and in acid zinc plating.	overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100421	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life	Your comment has been taken note of.
20100421	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life	Your comment has been taken note of.
20100421	UKLA Metalworking Fluid Product Stewardship Group, Industry or trade association, United Kingdom	EBA comments Annex XV 100104 final.pdf The United Kingdom Lubricants Association Ltd (UKLA) is the EU Member State Trade Association representing the United Kingdom lubricants industry. This	See response to EBA comments

		submission is made by the Metalworking Fluid Product Stewardship Group of UKLA.	
20100421	Industry or trade association, Company, Germany	Confidential comment submitted	Boric acid was proposed as SVHC based on its classification as toxic to reproduction, its wide use in consumer products, and its high production volume. We are aware that boric acid will be registered by the end of this year and further information may become available.
20100421	Eye-Care Industries European Economic Interest Grouping, Industry or trade association, United Kingdom	Boric acid and borates - response from Eye-Care Industries - REACH.pdf Boric acid and borates are naturally occurring chemicals used widely (such as in detergents, cleaners, personal care products, agriculture) and the compounds are also available in food supplements. The acute toxicity of boric acid is comparable to that of sodium chloride (oral rat LD50 2660 mg/kg compared to oral rat LD50 3000 mg/kg). Based on the concentrations of boric acid typically used in ophthalmic pharmaceutical preparations, the dose of boric acid from ocular administration results in safety margins of greater than 600 times the no observed adverse effect level of 125 mg/kg/day reported in animal maternal and developmental reproduction studies. There is currently no evidence of harm to humans regarding reproductive toxicity. Boric acid and borates are used in a number of ophthalmic pharmaceutical products, controlled by sectoral legislation (Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use as amended). These products are used in the eye, so the exposure to diluted borates is limited to the topical route of delivery. There are currently no acceptable substitutes available. All pharmaceutical products are subject to assessment and authorisation and oversight by relevant EU national competent authorities or the European Medicines Agency.	Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its high production volume. So far, boric acid meets as well the criteria according to REACH article 57c as those of article 58. Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. Medicinal products are not subject to Title VII of the REACH regulation.
2010421	Industry or trade association, Company, Switzerland	The FibreCem Group is a manufacturer of high quality fibrecement products and based in Switzerland, with production facilities in Austria, Germany and Slovenia.	Prior to the preparation of the Annex

		We are using polyvinylalcohol fibres for the production of our goods. These fibres are imported from Japan and China. In the fibre production boric acid is used as a process additive in an amount of 0.1 to 0.5 % based on the weight of the PVA resin. We have learned that ECHA has proposed to identify boric acid (CAS 10043-35-3, 11113-50-1) as a Substance Of Very High Concern. Stated below you can find some arguments against listing boric acid as a substance of very high concern. "Firstly, boric acid has a quite extensive use in medicine: it is used in inhalatory capsules (in other words: deliberate inhalation, on purpose), eye drops (collyria) and a series of dermatologic ointments and solutions. So far, neither pharmaceutical companies nor doctors have felt that there would be sufficient reasons to stop this. Secondly, as far as I can imagine any exposure resulting from skin contact with PVA fibres (or even inhalation) by FC production workers (and a fortiori downstream FC article users) can only be several orders of magnitude lower than those resulting from medical applications. Thirdly, boric acid is not classified as confirmed, suspected or possible carcinogenic by either IARC, the German MAK Commission, the British HSE, the US NTP and ACGIH. or any other relevant agency that I screened in this regard. Fourth, I have a strong impression that very high numbers of substances are getting classified as "very high concern" and I would expect later (more reasonable) revisions on the notification system. We do not understand the background of the proposal by ECHA to list boric acid as a substance of very high concern and believe the risk to human health linked to the presence of such small amounts of boric acid in PVA fibers for the manufacture of fiber-cement materials is negligible. Would you kindly take into account those elements in the course of the evaluation of this proposal.	XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.

20100421	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life	Your comment has been taken note of.
20100421	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life	Your comment has been taken note of.
20100421	Industry or trade association, Company, Luxembourg	EBA comments Annex XV 100104 final.pdf 1. Industry or trade association hereby submits comments in exercise of its procedural rights granted by Article 59(4) REACH. 2. Under CLP Regulation, the test of normal handing and use has been replaced and built upon by the "weight of evidence" approach whereby all the available information bearing on the determination of hazard is considered together (see point 1.1.1.3 of Annex I to the CLP Regulation). This legislative change does not undermine the relevance of the argument on normal handling and use because exposure remains a key criteria in the Annex XV dossier. 3. Industry or trade association refers to the REACH guidance on the preparation of an Annex XV dossier (http://guidance.echa.europa.eu/docs/guidance_document/svhc_en.pdf) which states at page 17 that the first source of information for the Annex XV dossier should be the full study reports in the REACH registration dossier and that secondary sources should not generally be used as the basis for the proposal unless there is a high confidence in the robustness of the approach used to review the data for the secondary source. 4. Please also see attached pdf file.	See response to EBA comments
20100421	Cimcool Industrial Products B.V., Company, Netherlands	EBA comments Annex XV 100104 final.pdf We are Cimcool Industrial Products B.V. www.cimcool.net , a Dutch manufacturer of Metalworking fluids, and as such EU member state user of boric acid and a member of the VSN, the association of the Dutch lubricant industry. VSN, http://www.smeerolievereniging.nl, is member of Independent Union of the European Lubricants Industry, UEIL, which is the pre-eminent Trade Association in Europe representing the interests of companies involved in the Lubricant Industry. With Members in nineteen European Countries and a unique collective experience of Lubricants and the Lubricants Market, UEIL is the strongest Representative Body for Independent producers of lubricants in Europe. www.UEIL.org	See response to EBA comments

20100421	Cimcool Europe B.V., Company, Netherlands	EBA comments Annex XV 100104 final.pdf We are Cimcool Europe B.V., the sales office of Cimcool Industrial Products B.V. www.cimcool.net . Cimcool Industrial Products B.V. is a Dutch manufacturer of Metalworking fluids, and as such EU member state user of boric acid and a member of the VSN, the association of the Dutch lubricant industry. VSN, http://www.smeerolievereniging.nl, is member of Independent Union of the European Lubricants Industry, UEIL, which is the pre-eminent Trade Association in Europe representing the interests of companies involved in the Lubricant Industry. With Members in nineteen European Countries and a unique collective experience of Lubricants and the Lubricants Market, UEIL is the strongest Representative Body for Independent producers of lubricants in Europe. www.UEIL.org	See response to EBA comments
20100421	Cimcool Europe B.V.-Italian branch, Company, Italy	EBA comments Annex XV 100104 final.pdf We are Cimcool Europe B.V.-Italian branch, the Italian branch of Cimcool Europe B.V. www.cimcool.net . Cimcool Europe B.V. is the sales office of Cimcool Industrial Products B.V. Cimcool Industrial Products B.V. is a Dutch manufacturer of Metalworking fluids, and as such EU member state user of boric acid and a member of the VSN, the association of the Dutch lubricant industry. VSN, http://www.smeerolievereniging.nl, is member of Independent Union of the European Lubricants Industry, UEIL, which is the pre-eminent Trade Association in Europe representing the interests of companies involved in the Lubricant Industry. With Members in nineteen European Countries and a unique collective experience of Lubricants and the Lubricants Market, UEIL is the strongest Representative Body for Independent producers of lubricants in Europe. www.UEIL.org	See response to EBA comments
2010421	Cimcool Polska Sp. z o.o., Company, Poland	EBA comments Annex XV 100104 final.pdf We are Cimcool Polska Sp. z o.o., the Polish branch of Cimcool Europe B.V. www.cimcool.net . Cimcool Europe B.V. is the sales office of Cimcool Industrial Products B.V. Cimcool Industrial Products B.V. is a Dutch manufacturer of Metalworking fluids, and as such EU member state user of boric acid and a member of the VSN, the association of the Dutch lubricant industry. VSN, http://www.smeerolievereniging.nl, is member of Independent Union of the European Lubricants Industry, UEIL, which is the pre-eminent Trade Association in Europe representing the interests of companies involved in the Lubricant Industry. With Members in nineteen European Countries and a unique collective experience of Lubricants and the Lubricants Market, UEIL is the strongest Representative Body for Independent producers of lubricants in Europe. www.UEIL.org	See response to EBA comments
2010421	Cimcool Europe B.V.-Swedish branch, Company, Sweden	EBA comments Annex XV 100104 final.pdf	See response to EBA comments

		We are Cimcool Europe B.V.-Swedish branch, the Swedish branch of Cimcool Europe B.V. www.cimcool.net . Cimcool Europe B.V. is the sales office of Cimcool Industrial Products B.V. Cimcool Industrial Products B.V. is a Dutch manufacturer of Metalworking fluids, and as such EU member state user of boric acid and a member of the VSN, the association of the Dutch lubricant industry. VSN, http://www.smeerolievereniging.nl, is member of Independent Union of the European Lubricants Industry, UEIL, which is the pre-eminent Trade Association in Europe representing the interests of companies involved in the Lubricant Industry. With Members in nineteen European Countries and a unique collective experience of Lubricants and the Lubricants Market, UEIL is the strongest Representative Body for Independent producers of lubricants in Europe. www.UEIL.org	
2010421	Cimcool Europe B.V.- Czech Branch, Company, Czech Republic	EBA comments Annex XV 100104 final.pdf We are Cimcool Europe B.V.- Czech Branch, the Czech branch of Cimcool Europe B.V. www.cimcool.net . Cimcool Europe B.V. is the sales office of Cimcool Industrial Products B.V. Cimcool Industrial Products B.V. is a Dutch manufacturer of Metalworking fluids, and as such EU member state user of boric acid and a member of the VSN, the association of the Dutch lubricant industry. VSN, http://www.smeerolievereniging.nl, is member of Independent Union of the European Lubricants Industry, UEIL, which is the pre-eminent Trade Association in Europe representing the interests of companies involved in the Lubricant Industry. With Members in nineteen European Countries and a unique collective experience of Lubricants and the Lubricants Market, UEIL is the strongest Representative Body for Independent producers of lubricants in Europe. www.UEIL.org	See response to EBA comments
2010421	Cimcool Europe B.V.- Slovak Branch, Company, Slovakia	EBA comments Annex XV 100104 final.pdf We are Cimcool Europe B.V.- Slovak Branch, the Slovak branch of Cimcool Europe B.V. www.cimcool.net . Cimcool Europe B.V. is the sales office of Cimcool Industrial Products B.V. Cimcool Industrial Products B.V. is a Dutch manufacturer of Metalworking fluids, and as such EU member state user of boric acid and a member of the VSN, the association of the Dutch lubricant industry. VSN, http://www.smeerolievereniging.nl, is member of Independent Union of the European Lubricants Industry, UEIL, which is the pre-eminent Trade Association in Europe representing the interests of companies involved in the Lubricant Industry. With Members in nineteen European Countries and a unique collective experience of Lubricants and the Lubricants Market, UEIL is the strongest Representative Body for Independent producers of lubricants in Europe. www.UEIL.org	See response to EBA comments
2010421	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the	Your comment has been taken note of.

		relevant consequences, will change for the worse my job, the working conditions of my employees, my life.	
2010421	EURIMA, Industry or trade association, Belgium	Boron in Glass Wool Insulation GTS Final.pdf Article Risk assessment Boron in glass wool insulation Environ Sci Pollut Res 2009 A.A. Jensen.pdf Members of EURIMA, European Association of mineral wool insulation manufacturers (glass wool, stone wool and slag wool), have the interests of their consumers, employees and the environment at the very top of their agenda and any request for substitution of borates within the manufacturing process because of legal requirements or media pressure knowing that risk assessment show insignificant risk level, would not be economically or technically desirable. EURIMA members are in particular concerned over the proposal by Denmark with regard to annex XV and the possible addition of this substance onto the candidate list, for the following reasons: 1. Recent studies commissioned by EURIMA have shown that borates used in the manufacture of the glass are in fact chemically bonded within the glass structure and therefore not available in the chemical forms which are to be regulated - Note (1). Risk assessment has also shown that un-intentional dissolution of borates from the glass structure in abnormal circumstances does not pose any health risk - Note (2). 2. Borates have been used within the glass wool industry as part of its manufacturing process for many years and there is no evidence which indicates that this has negatively impacted either the health of employees or the environment surrounding the manufacturing facilities. 3. EURIMA members are currently working closely with the borates industry to prepare accurate exposure scenarios using actual exposure and emission information for our manufacturing processes, it is of concern to us that the current Annex XV dossiers were submitted while industry is working to provide this information for the substance REACH dossier, the likely consequence of which is that the annex XV dossiers will be based on incomplete information without the benefit of the more detailed information which is being provided. 4. There is no available substitution possible to produce glass wool insulation products. Notes: (1) - Boron in Glass Wool Insulation; Glass Technology Services; January 2007. (2) - Risk assessment of Boron in Glass Wool Insulation – A.A. Jensen; January 2007	Thank you for the information. The study by Jensen et al 2007 has been used for consumer exposure assessment during do it yourself work in the annex XV dossier.
2010421	Cimcool Europe B.V.-UK branch, Company, United	EBA comments Annex XV 100104 final.pdf	See response to EBA comments

	Kingdom	We are Cimcool Europe B.V.-UK branch, the UK branch of Cimcool Europe B.V. www.cimcool.net . Cimcool Europe B.V.-UK branch is member of the United Kingdom Lubricants Association, UKLA, www.ukla.org.uk. The United Kingdom Lubricants Association is the UK's lubricant industry lead trade association. It represents 103 companies who produce the majority of the UK's £2 billion, 800,000+ tonne output. Members include multi-national major oil companies, independently owned lubricant manufacturers / marketers and the sector's raw material suppliers. Its activities are currently being widened to encompass distributors and stockists, end-users, academics & individuals; in fact everyone involved in lubricants, beginning to end. UKLA is member of Independent Union of the European Lubricants Industry, UEIL, which is the pre-eminent Trade Association in Europe representing the interests of companies involved in the Lubricant Industry. With Members in nineteen European Countries and a unique collective experience of Lubricants and the Lubricants Market, UEIL is the strongest Representative Body for Independent producers of lubricants in Europe. www.UEIL.org	
2010421	Cimcool Europe B.V.- France branch, Company, France	EBA comments Annex XV 100104 final.pdf We are Cimcool Europe B.V.- France branch, the French branch office of Cimcool Europe B.V. www.cimcool.net . Cimcool Europe B.V.- France branch is member of the CSNIL, the French Lubricants Association, http://www.csnil.com/ CSNIL is member of Independent Union of the European Lubricants Industry, UEIL, which is the pre-eminent Trade Association in Europe representing the interests of companies involved in the Lubricant Industry. With Members in nineteen European Countries and a unique collective experience of Lubricants and the Lubricants Market, UEIL is the strongest Representative Body for Independent producers of lubricants in Europe. www.UEIL.org	See response to EBA comments
2010421	Federchimica, Industry or trade association, Italy	We are Federchimica (the Italian Federation of the chemical industry). At the present time 1300 companies, with a total of 100.000 employees, are part of Federchimica. They are grouped into 16 Associations. Some of that are in the field of paints, ceramics, metalworking fluids, abrasives, fertilizers specifically interested in the acid boric. Federchimica is a member of Confindustria (General Confederation of the Italian Industry) and CEFIC (European Chemical Industry Council).	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at

		Our position is based on two aspects: 1. the notion that boric acid is relatively benign substance which classification as reproductive toxicants was (and continues to be) controversial and contested. 2. The Annex XV Dossier for boric acid shall not be filed until REACH Dossiers are reviewed in 2011. The following are our general comments: 1. The boric acid classification decision was the result of a controversial, extremely lengthy and unsatisfactory decision-making process. It was a decision that was opposed by seven EU Member States (Poland, UK, Italy, Ireland, Belgium, Slovenia, Latvia), which specifically and uniquely signed a declaration that stated that they were in favour of a less rigorous classification category for boric acid and disodium tetraborates. In fact a majority of Member States experts had recommended earlier (in the context of the 29th ATP to the Dangerous Substances Directive) that boric acid and disodium tetraborates should be classified as a Category 3 under the previous Directive (note: when Member States eventually voted for a Category 2, this was done on the basis of the same evidence and arguments). At different times in the process, European Commission officials and departments themselves were divided on the appropriate level of classification for borates. And finally, as part of the WTO TBT process, several non-EU countries (including Turkey, Argentina, Chile, Canada, the U.S., China and Malaysia) expressed concern over the Category 2 classification of boric acid and disodium tetraborates and some stated that this was more trade disruptive than necessary. 2. The main source of disagreement over the appropriate level of classification of boric acid and disodium tetraborates is related to the way effects found in animal studies were extrapolated to humans. Industry acknowledges that there is a reproductive effect from borates in animals that have been force-fed large quantities of boric acid or disodium tetraborates on a daily basis for a long period of time. However, industry has always argued that the Member States and the European Commission have not demonstrated that the classified borate substances have intrinsic properties which give rise to a risk of reproductive toxicity in humans during normal handling and use, as required by law (Annex VI of the Dangerous Substances Directive). Moreover, multiple existing studies on humans have found no reproductive effects. Recital (2) of the 30th ATP which added certain borates to the Dangerous Substances Directive as a Category 2 toxicant and which was inserted by the European Commission, states that “special attention should be paid to further results of epidemiological studies on the Borates concerned by this Directive	present, the current classification will not be questioned nor discussed. . We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation. We are also aware that boric acid will be registered by the end of this year and further information may become available.

		including the ongoing study conducted in China". This study among workers in a borates mine has now been completed and peer-reviewed and confirms that there is no reproductive effect in men, which indicates even at very high exposures the effect in humans is different than the effect on laboratory animals. In the light of this Recital and since the Chinese study has not yet been evaluated by ECHA or Member States experts, adding boric acid and disodium tetraborates to the candidate list now simply does not make sense. 3. The Commission's decision to classify certain borates (including boric acid or disodium tetraborates) is subject to two court cases that are currently before the European Court of Justice and the General Court (C - 15/10; T539/08). Both court cases ask for an annulment of classification so to remove the basis for the inclusion of borates under REACH ¬authorisation as well as the legal basis for including them in the authorisation process. 4. Producers and importers of boric acid are working on a REACH registration dossier which will provide new scientific data and should be used as a mechanism to determine the risks and hazards of this substance. Including disodium tetraborates and boric acid at this point does not make sense as producers and importers are developing a REACH registration dossier, which will be submitted by the December 2010 deadline. The current Annex XV dossiers are based on fragmented and incomplete information largely based on modelling data from the transition dossiers of both substances. The transition dossiers concluded however that "There is a need for better information on occupational exposure for producing/importing processing sites, downstream user and consumer applications to adequately characterize the risks to workers and consumers from boron exposure via boric acid and sodium tetraborates The REACH registration dossiers will contain the necessary information to identify whether there are risks for workers and consumers requiring further measures. 5. Consumer protection from exposure to boric acid and disodium tetraborates will be however addressed through Annex XVII-restrictions of CMR substances for consumer use. At the direction of the Commission RPA (2008) reviewed the uses and risks associated with borates for consumers not currently regulated by some of the legislation, and concluded that risks associated with these other uses are unlikely to be of serious concern. 6. Adding disodium tetraborates and boric acid to the candidate list would have immediate negative consequences without generating public health benefits. Producers of these substances would have the obligation to communicate this listing	

		to customers and (if requested) consumers and this involves an increase in cost and may have economic consequences, particularly with respect to the viability of any possible future applications. 7. The free acid is found native in certain volcanic districts such as Tuscany, the Lipari Islands, issuing mixed with steam from fissures in the ground; it is also found as a constituent of many minerals (borax, boracite, boronatrocaicite and colemanite). No evidence for free acid and borate to raise safety issues for local population 8. Boric acid, is a “ancient acid” : it was first prepared by Wilhelm Homberg (1652-1715) from borax, by the action of mineral acids, and was given the name sal sedativum Hombergi ("sedative salt of Homberg"). However borates, including boric acid, have been used since the time of the Greeks for cleaning, preserving food, and other activities. 9. Based on mammalian median lethal dose (LD50) rating of 2,660 mg/kg body mass, boric acid is poisonous if taken internally or inhaled in large quantities. However, it is generally considered to be not much more toxic than table salt. The Thirteenth Edition of the Merck Index indicates that the LD50 of boric acid is 5.14 g/kg for oral dosages given to rats, and that 5 to 20 g/kg has produced death in adult humans. The LD50 of sodium chloride is reported to be 3.75 g/kg in rats according to the Merck Index. 10. Borates have been used safely for generations and people’s greatest exposure to borates is through a healthy diet. Recent research has demonstrated several benefits associated with boron exposure in humans including bone health, cell membrane function, psychomotor skills and cognitive processes, control of inflammatory disease, enzyme regulation, energy metabolism, and potential anticarcinogenic properties.	
20100421	Cimcool Europe B.V.-German branch, Company, Germany	EBA comments Annex XV 100104 final.pdf We are Cimcool Europe B.V.-German branch, the German sales office of Cimcool Europe B.V. www.cimcool.net . Cimcool Europe B.V.-German branch is member of the VSI, the German Lubricants Association, www.vsi-schmierstoffe.de	See response to EBA comments
20100421	UNIFA, Industry or trade association, France	UNIFA Comments on Bore proposed for Authorisation_Vf.pdf I. Boron in plants	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier

		Boron is an essential micronutrient required for crop nutrition Micronutrients are essential for the normal growth and health of plants. When soil supply is inadequate, defects in development arise and this can lead to poor growth and premature death of plants. The micronutrient requirement by crops for normal growth and high yield is small compared to that of the macronutrients. Nevertheless, each of the micronutrients, boron (B), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo), cobalt (Co) and zinc (Zn), meet the requirements for essentiality in plants and, despite the small amounts needed by crops to complete their life cycles, deficiencies of one or more of these elements frequently occur in agriculture, horticulture and forestry. There is no substitution to this nutrient. Plant uptake of this nutrient is mostly in the form of boric acid H3BO3 or borate anion B(OH)4-. Plant B requirements are well documented and critical B concentrations have been determined for a range of species for the diagnosis of B deficiency. When needed this nutrient must be available to farmers and allow for an accurate application. Boron is applied as straight fertilizers or added in a small quantity to NPK fertilizers or in liquid specialties for foliar or soil application. The burden of an authorization process will severely limit the number of products on the market and the availability of this nutrient for farmers. Functions in plants Boron is required in the stabilisation of cell walls by forming the borate-rhamnogalacturonan II (RG-II, a complex pectic polysaccharide structurally located in the primary cell wall) cross-link (Matoh, 1997; O'Neill et al., 2004). This primary function is reflected in the cessation of growth of young leaves and roots in response to B deficiency in plants (Dell and Huang, 1997). Boron also forms cross-links with glycoproteins in cell membranes and may regulate physical properties such as membrane fluidity. This may have implications in plant tolerance of high irradiance (Huang et al., 2002) and low temperature stresses (Huang et al., 2005). Although proposed B functions in the metabolism of phenols and lignin (Cakmak and Römheld, 1997) may be secondary effects (Cara et al., 2002), B deficiency can influence lumber quality. Boron is essential for normal development of reproductive tissues and deficiency results in low grain set or poor seed quality (Dell et al., 2002). Also, B deficiency may trigger the early synthesis of ethylene, leading to the rapid deterioration of fruit quality. In brief, the main functions of boron relate to cell wall strength and development, cell division, fruit and seed development, flower production, pollen tube elongation and germination, sugar transport, and hormone development.	nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.

		Boron deficiency Boron deficiency symptoms in plants have been described in numerous studies (Bell, 1997). In plants subject to mild B deficiency, leaves appear dark green and leathery with downward cupping and small size. When B deficiency becomes severe, dieback of the shoot tip occurs. Plant symptoms can be greatly influenced by other stress factors, such as high light intensity and low temperature. In reproductive parts, B deficiency causes abortion of flower buds and/or flowers (e.g. sterile ears in wheat), abnormally shaped fruits (e.g. avocado and citrus) and malformed seeds (e.g. hollow heart in peanut). Boron deficiencies are found mainly in acid, sandy soils in regions of high rainfall, and those with low soil organic matter and soils with a high pH or high calcium content. Borate, negatively charged ions, are mobile in soil when not adsorbed on organic matter or metal oxides or hydroxides (Al,Fe) and can be leached from the root zone. Boron deficiencies are more pronounced during drought periods when root uptake activity is restricted. Boron deficiency corrections Given its tendency to be absorbed by the organic matter and soil iron and aluminium hydroxides in the soil and susceptibility to leaching of the free B fraction, annual or more frequent applications of boron are required in most situations. Boric acid (17.5% boron), sodium tetraborate decahydrate (or borax) (11.3% boron) or sodium octaborate tetrahydrate (20.9% boron) can be applied to soils to correct boron deficiency. Typical applications are about 1.1 kg/hectare or 1.0 lb/acre of actual boron expressed as B. These products can be dissolved in water and sprayed for soil or foliar application. Small quantities of boron (B) are needed for healthy crops when soils are affected by boron deficiency. Due a large array of fertilizers types it is possible to achieve uniform application in the field using sprayer or spreader farm equipment. Commonly less than 1kg of boron (B) is applied per ha (0.1 g per square meter) on sensitive species (sunflower, sugar beet, apple tree, clover and alfalfa…). From the elements above, it is clearly demonstrated that boron cannot be substituted. II. Human health Borates have been used safely for generations and people exposed to borates are healthy. EFSA stated that boron is suitable for use in foods in 2004 (Question number EFSA-	

		Q-2003-017). Besides, the characteristics of fertilizers containing of boron are defined by the regulation CE N°2003/2003 of 13 October 2003 (Annex I, section E).	
20100421	Bausch & Lomb, Inc, Medical Device and Pharmaceutical manufacturer, United States	Borates and Boric Acid is a naturally occurring chemical that has wide use in products such as in detergents, cleaners, personal care products, agriculture, and food supplement. The toxicity of Boric Acid (oral rat LD50: 2660 mg/kg) is only slightly higher than Sodium Chloride (kitchen salt) (oral rat LD50: 3000 mg/kg). There is currently no evidence of harm to humans regarding reproductive toxicity. Borates and Boric Acid are used in a range of medical devices, controlled by sectoral legislation (Medical Devices Directive 93/42/EEC), such as contact lens buffered solutions, contact lens care products and eye drops. These products are used in the eye and the exposure to diluted borates is limited to the topical route of delivery. There are currently no acceptable substitutes available and these substances have been used in these ophthalmic products for several decades with no reported adverse effects. Medical Device products are subject to the oversight of National regulatory bodies and in Europe, the Medical Devices Directive requires manufacturers perform and maintain risk assessments to evaluate the benefit of the device against the risks that may be associated with the device and its components. These risk assessments are continually reviewed to assure that the information and data available are appropriate for the continued use of the subject products.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned.
20100421	AFILUB, Industry or trade association, Spain	EBA comments Annex XV 100104 final.pdf We are AFILUB, lubricants association of independent manufacturersrepresenting 16 companies in Spain. Our organizationis also is member of UEIL.	See response to EBA comments
20100421	Federchimica-Gail, Industry or trade association, Italy	EBA comments Annex XV 100104 final.pdf We are Gruppo aziende industriali della lubrificazione (Gail), the EU Member State Trade Association within Federchimica, representing the Italian lubricants Industry and are the member organisation for our country within UEIL, the European Lubricants Industry Organisation.	See response to EBA comments
20100421	INKABOR S.A.C., Company, Peru	-There is a considerable opposition to Borates industry. -If the Borates are included within SVHC list, the result will be that a relatively benign substance that has been used safely for generations will be subject to authorization and substitution, ahead of the ones that are much more dangerous. -These developments will affect many businesses in Europe.	Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its high production volume. So far, boric acid meets the criteria of

		-The RPA report does not contain sufficient information, additional consumer exposure information and data will be required if those uses are to be supported by the REACH registration dossier; minimal data are available on consumer exposure -Waiting for REACH registration dossier which will provide new scientific data and should be used as a mechanism to determine the risks and hazards appear to be the best option for end users; Inkabor is providing worker and environmental exposure data for REACH dossier, too. -The process of prioritization of substances for authorization is driven by a number of Member States without having a legal remit to do this and is done on the basis of very rough criteria (which are not in REACH, so again no legal basis) that do not do justice to all the complexities involved. -Boric acid is already subject to strict regulation under a range of downstream EU legislation, intended to protect workers and consumers which is another argument against adding boric acid to the candidate list for authorization: 1.Waste Framework Directive (2006/12/EC) 2.Detergents Regulation (648/2004/EC) 3.Regulation on the export and import of dangerous chemicals (689/2008) 4.Biocidal Products Directive (98/8/EC) 5.Water Framework Directive (2000/60/EC) 6.Directive on integrated pollution prevention and control (2008/1/EC) 7.Chemical Agents Directive (2007/30/EC) 8.Pregnant and Breastfeeding Workers Directive (92/85/EEC) 9.Young Workers Directive (94/33/EC) 10.Signs at Work Directive (92/58/EEC) 11.Personal Work Equipment Directive (2007/30/EC)	REACH articles 57c and 58. Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. However, we are aware that boric acid will be registered by the end of this year and further information may become available.
20100421	Industry or trade association, Company, Germany	ACS Boric acid.pdf Reag Ph Eur Borsäure.pdf p. 10 General remarks: The laboratory uses should be exempted from the authorisation because they are performed under controlled conditions and there is a negligible exposure to consumers and the environment. The analytical standards are manufactured and used by industrial and professional personnel, which are well trained. The waste stage of the substance is controlled also. Detailed information: The substance is a component of analytical standards for calibration of measuring	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as

		instruments. It is also an ingredient of reagents and test kits for routine analysis. These applications are conducted by industrial and professional users in laboratory only. Moreover, the concentration of the substance in these applications, and thus the substance volumes, are low. Therefore, the exposure for the environment and for consumers is very low. Additionally, the substance is described in standard references like e.g. Reag. Ph. Eur and ACS or ISO and DIN or referenced in NIST or PTB. Applications described in these references should also be exempted from authorisation. Boric acid is mentioned as reagent in NIST, PTB, ISO, Reag. Ph. Eur. and ACS.	cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100421	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life".	Your comment has been taken note of.
20100421	Individual, Germany	The German Annex XV dossier lists the multifold daily intake of boron compounds for human beings and also lists information on animal tests which were conducted some time ago. Question: Mostly the dosis used in the animal experiments was way above any realistic intake of boron compounds by human beings other than by force or accident or abuse. Innumerous other natural substances would have to be categorized as toxic for all sorts of aspects if such dosis as used in the animal experiments were the foundation for such classifications.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1^{st} adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification

		In the animal experiments up to 94 mg B/kg bw/day were force fed to rats. For a human being weighing 60 kg this would amount to 5658 mg per day. Boric acid has served as a highly effective protection for the human environment by protecting wood and wood related structures over decades. Now an ambigoues decision by the EU Commission with several member states voting against the decision) leads to an abolishment of a highly successful substance - I ask for revision fo the decisions by the EU Commission regarding the conclusions drawn from rat and mice experiments which have used unrealistic and irresponsibly high dosis of boron compounds which do not in any way correspond with real life situations any where in Europe.	will not be questioned.
20100421	Individual, Italy	the identification of boric acid as SVHC and relevant consequences will change for the worse my job, the work conditions of my employees, my life	Your comment has been taken note of.
20100421	Industry or trade association, Company, Albania	EBA comments Annex XV 100104 final.pdf A number of our companies are EU member state users of boric acid and a member of the UEIL (the association of the European lubricant industry) and the ELGI (the European Lubricting Greases Institute)	See response to EBA comments
20100421	CPIV, Industry or trade association, Belgium	Statement on Exposure to Borates and REACH.pdf For other comments as to glass, please see EBA Position Paper on borates.	See response to EBA comment. Alternatives should be discussed in case application for authorisation becomes necessary.
20100421	EDMA, Industry or trade association, Belgium	EDMA_Comments_Borates_Final.pdf In vitro Diagnostic medical devices (IVDs) fulfil a medical purpose. They do not come into contact with patients. IVDs containing borates are used only by professionally trained staff in professional clinical or laboratory settings. Requirements for management and mitigation of health risks to patients or users of IVD products are addressed within the requirements of Directive 98/79/EC. IVDs are not made available to the general public and the potential for the general public to be directly exposed to borates in IVDs is minimal. With respect to professional users of IVDs, the concentration of borates in IVDs is below the concentration criteria of the first ATP. The risk of exposure by professional users is negligible, thanks to the design of IVDs and standard professional practices or occupational health and safety guidelines. Inclusion of borates in the Candidate List is not timely. In addition, the authorisation	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as

		procedure under REACH is not adequate to address the concerns that are identified in Annex XV dossiers. Should authorities confirm the inclusion of borates in the Candidate List of Substances of Very High Concern, and later on in Annex XIV, an exemption for uses of borates in IVDs should be granted.	cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100421	Individual, Italy	"The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life".	Your comment has been taken note of.
20100421	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life.	Your comment has been taken note of.
20100421	Industry or trade association, Company, Germany	We are a EU member state user of boric acid and a member of the VSI, the association of the German lubricant industry. As a formulator, we are industrial downstream user. Our formulations (metalworking fluids - MWF) are used by industrial and professional users only. We use boric acid in about 50 different products which represent about 40% of our turnover.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in

			the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100421	Bundesverband Glasindustrie e.V., Industry or trade association, Germany	EBA comments Annex XV 100104 final.pdf CPIV Statement on Exposure to Borates and REACH.pdf VBG Borauswertung_Glas.pdf	See response to EBA comments

20100421	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life	Your comment has been taken note of.
20100421	Eucomed, Industry or trade association, Belgium	Borates and Boric Acid is a naturally occurring chemical used widely such as in detergents, cleaners, personal care products, agriculture, it is even available as a food supplement. The toxicity of Boric Acid (oral rat LD50: 2660 mg/kg) is only slightly higher than Sodium Chloride (kitchen salt) (oral rat LD50: 3000 mg/kg). There is currently no evidence of harm to humans regarding reproductive toxicity. Borates and Boric Acid are used in a range of medical devices, controlled by sectoral legislation (Medical Device Directive 93/42/EEC), such as contact lens buffered solutions, contact lens care products and eye drops. These products are used in the eye, so the exposure to diluted borates is limited to the topical route of delivery. There are currently no acceptable substitutes available. The Medical Device Directive requires manufacturers to do a risk assessment, whereby the benefit of the device has to outweigh the risk associated with the device and its components.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned.
20100421	Industry or trade association, Belgium	The starch industry delivers mixes of borates and starch for use on the part of the cardboard/paper industry. No chemical reaction takes place in the mix that, as it is not an intermediate, does not need to be authorised under REACH. However, as user of borates, the AAF considers it important to provide the information they hold.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of

			approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100421	BP International Ltd, Company, United Kingdom	BP is a globally operating company with strong position on industrial lubricant. BP produces industrial lubricants in various European countries for the European market. We are a member of different industrial association including UKLA (UK industrial association) and the VSI (German industrial association). As a formulator of metalworking fluids, we are an industrial downstream user of boric acid and borax (disodium tetraborate). Our final products are used by industrial users only.	Comment on use
20100421	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life	Your comment has been taken note of.
20100421	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life.	Your comment has been taken note of.
20100421	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life.	Your comment has been taken note of.
20100421	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life.	Your comment has been taken note of.
20100421	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life.	Your comment has been taken note of.

20100421	Individual, Italy	Boric acid is at the moment irreplaceable in electrolytic nickel plating. Despite our experience and knowledge we don't understand the reason why boric acid should be included in this list because it isn't so dangerous. The identification of boric acid as SVHC will cause dramatic consequences to various galvanic processes in which the boric acid is currently used as at the moment there isn't an opportunità for replacement.	Boric acid was proposed as SVHC based on its classification as toxic to reproduction, its wide use in consumer products, and its high production volume. Your comment has been taken note of.
20100421	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life.	Your comment has been taken note of.
20100421	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life.	Your comment has been taken note of.
20100421	ESK Ceramics GmbH & Co. KG, Company, Greece	Comments on Annex XV Dossier Boric Acid ESK Ceramics GmbH & Co. KG, a high volume downstream user of boric acid, is deeply concerned over the proposal to identify boric acid as potential substance for the REACH authorisation process. We believe that adding this substance to the SVHC candidate list is not appropriate. Boric acid is a relatively benign substance whose classification as toxic regarding reproduction is still controversially discussed. It appears from ECHA's consulta-tion notice that this consultation specifically focuses on hazard properties. It is ESKs view that of all substances meeting the Art 57 criteria, boric acid (and disodium tetraborates) are of lower concern. The system currently used for putting substances on the candidate list should be subject to a more critical qualitative selection procedure. Including boric acid in the SVHC candidate list in advance of submission of the registration dossier (deadline December 2010) does not make sense. The current Annex XV dossier is based on incomplete information based on data from the transition dossier. The transition dossier concluded however that "There is a need for better information on occu-pational exposure for producing/importing processing sites, downstream user and con-sumer applications to adequately characterize the risks to workers and consumers from boron exposure via boric acid and sodium tetraborates". The REACH registration dossier will contain the information to identify whether there are risks for workers and consumers requiring further measures. ESK Ceramics GmbH & Co. KG is a high volume manufacturer of boron carbide, boron nitride, titanium boride, zirconium boride and calcium hexaboride. Boric acid	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation. Boric acid was proposed as SVHC based on its classification as toxic to reproduction, its wide use in consumer products, and its high production volume. However, we are aware that boric acid will be registered by the end of this year and further information may become available. Prior to the preparation of the Annex

		is used as an intermediate in the production of these substances. The total annual tonnage of boric acid consumed in these chemical synthesis routes adds up to several thousand metric tons. The only relevant processes for high volume technical scale production of above named substances are carbothermal reduction of boric acid in electric arc furnaces (boron car-bide B4C), simultaneous carbothermal reduction of metal oxides and reaction with boric acid (titanium boride TiB2, zirconium boride ZrB2 and calcium boride CaB6), and simultaneous carbothermal reduction and nitridation of boric acid by a carbon and nitrogen bearing source (boron nitride BN). The use of boric acid as raw material in these processing routes is safe, the occupational and environmental risks are adequately controlled by processing under strictly controlled conditions (occasional infrequent exposure strictly controlled by personal and technical risk management measures). Personal monitoring of nuisance particulates shows that the risk management measures are effective to comply with an OEL of 0.5mg/m3 (Boron). No adverse health effects have been observed and/or reported with workers exposed to inhalable boric acid dust since 70 years of production of boron carbide, 45 years of production of boron nitride and 35 years of production of borides. This is a statement of ESKs company medical officer. A costly authorisation process would have a major impact on competitiveness for powders and articles on the world market compared to non EU manufacturers. Boron Carbide is besides diamond and cubic boron nitride the hardest substance hitherto known. The worldwide annual tonnage adds up to appr. 4000 metric tons corresponding to a sales value of appr. 100.000.000 EURO. There is no substance available so far to substitute boron carbide in the following main high volume applications due its unique combination of properties: — Due to its high hardness and low specific weight it is the most widely used material for protective body and vehicle armor systems. — Due to its high hardness and wear resistance loose boron carbide grains are readily used for the grinding and lapping of hard metals and ceramics. — Due to its high neutron absorbing efficiency, boron carbide is used both in powdered and solid form as shield and control component in nuclear reactors. — Due to its high hardness it is the most widely used material for sand blasting nozzles.	XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.

		— Due to its unique reaction with ferrous metals it is used as boronizing agent — Due to its unique reaction with carbon bonded refractories applied in metallurgy it is used as antioxidant improving service life. — Due to its excellent wear resistance it is used to improve service life of electrodes in the harsh environment during welding. Besides the use in evaporation boats boron nitride is used as refractory material, as starting material for the synthesis of cubic boron nitride, as release agent in metallurgy and manufacturing of glass, as lubricating agent, as filler in polymers to enhance thermal conductivity and antifriction, and as additive in cosmetics to improve tactile feeling and spreadability. The annual worldwide tonnage adds up to appr. 2500 metric tons corre-sponding to a market value of 100.000.000 EURO. Hitherto there is no substance available to substitute for boron nitride in above named applications. Titanium diboride as well as boron nitride are the main substances contained in evaporation boats which are used in the aluminium coating process of all kinds of plastic films. No other material is hitherto known to fulfil the requirements of good wetting by liquid alu-minium, high refractoriness and metal-like electric conductivity. It is additionally used as refractory material in aluminum smelters due to its high refractoriness, corrosion resistance to cryolite and excellent electric conductivity. Future development of aluminium smelting concentrates on reduction in energy consumption and carbon dioxide emission where the use of titanium boride will assist in providing step changes. Zirconium diboride is mainly used as antioxidant in carbon bonded refractory materials applied in metallurgy improving service life. There is no substitute available hitherto. Calcium hexaboride is used as antioxidant in carbon bonded refractory materials applied in metallurgy improving service life, as deoxidant of copper melts and as boronizing agent for wear protection of ferrous metals. There is no substitute available hitherto. Ceradyne Inc., the parent US company of ESK Ceramics GmbH & Co. KG, manufactures B10 isotope enriched boric acid and exports annual tonnages in the 1-100t/a range to Europe. This substance is used in nuclear reactors as neutron poison. The use of Isotope enriched boric acid in nuclear applications is safe, as the substance	

		is used under strictly controlled conditions. Personal and technical risk management meas-ures exclude exposure of workers during infrequent (every few years) refilling of the cooling circuits. There is no substitute for boric acid in this application, because its effect is based on high water solubility and the high neutron absorbing efficiency of the boron atom. No adverse health effects have been reported for workers involved in the refilling step.	
20100421	Industry or trade association, Company, United Kingdom	In many years of experience with Boric Acid use to manufacture Zinc Borate, there have have been no concerns and Boric Acid has been used safely. It would not be possible to manufacture Zinc Borate without Sodium Borate or Boric Acid.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3

			(inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100421	Industry or trade association, Company, Ireland	The timing for submission of Annex XV dossiers for borates conflicts with the currently on-going preparation of the REACH registration dossier, to be submitted by the December 2010 deadline. The current Annex XV dossiers are based on fragmented information largely based on modeling data from the transition dossiers of these substances. The transition dossiers concluded that “There is a need for better information on occupational exposure for producing/importing processing sites, downstream user and consumer applications to adequately characterize the risks to workers and consumers from boron exposure via boric acid and sodium tetraborates”. Industry is following-up on these recommendations. The REACH registration dossiers will contain the necessary information to identify whether there are risks for workers and consumers requiring further measures. Including borates in the Candidate List in the absence of this information is premature at this stage. In addition the Commission’s decision to classify certain borates (including boric acid or disodium tetraborates) is subject to two court cases that are currently before the European Court of Justice and the General Court. An annulment of classification would remove the basis for the inclusion of borates under REACH authorisation as well as the legal basis for including them in the authorisation process. In the light of this uncertainty, it is not appropriate at this stage to include boric acid or disodium tetraborates on the Candidate List. Borates and Boric Acid are used in a range of medical devices, controlled by sectoral legislation (Medical Device Directive 93/42/EEC), such as contact lens products and eye drops. These products are used in the eye, so the exposure to diluted borates is limited to the topical route of delivery. There are currently no acceptable substitutes available. Contact lens products meet the regulatory requirements of a Class IIa medical device in the EU as defined by Council Directive 93/42/EEC concerning medical devices. The Directive ensures the design and manufacture of medical devices is subject to essential requirements concerning protection of the health and safety of patients and users of these devices. Risks to patients or users of medical devices due to the	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. Boric acid was proposed as SVHC based on its classification as toxic to reproduction, its wide use in consumer products, and its high production volume. However, we are aware that boric acid will be registered by the end of this year and further information may become available. Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the

		presence of any substance contained within these products are addressed by this Directive. Therefore additional regulation of the use of chemicals in medical devices under REACH is not warranted as stated in Article 60(2) of the Regulation itself: “The Commission shall not consider the risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices or Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.”	EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100421	Jones Fiber Products, Inc, Company, United States	Binder1.pdf Boric Acid is used extensively to make cotton based non-woven products fire resistant. If Europe uses such data as has been proposed by Germany to invalidate the use of Boric acid as being safe, not only will there have been a terrible misinterpretation of the data there will also be significant finacial impact all around the world felt by the manufacturing community that uses Boric Acid in so many applications. This will ultimately effect the consumers which will directly impact economies in all regions of the world. We are submitting data that proves that Boric	Thank you. The submitted study by Murray is cited in the annex XV dossier.

		Acid is very safe to the consumer. The LDL of Boric Acid is very similar to common table salt, do you consider table salt to be a substance of very high concern?	
20100421	Rohm and Haas Company, Company, United States	The addition of boric acid to the SVHC list will have adverse economic impact in Europe. Boric acid is a substance our company uses to produce a number of important intermediates and products. These products are valuable to our company and in particular valuable to our company in Europe. They are also exported from Europe to many other countries. As an example, boric acid is used as a raw material intermediate in the production of sodium borohydride (SBH). Currently, SBH producers in Europe are the primary source for SBH in Europe. There are also significant sales of SBH that is manufactured in Europe and exported to other parts of the world. If boric acid is Authorized, SBH manufacturers outside the EU, primarily in China, are likely to fill the EU demand for SBH. Numerous jobs within the EU would be forfeited.	Socioeconomic aspects may be discussed in case an application for authorization becomes necessary. Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not

			regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100421	Cerame-Unie, Industry or trade association, Belgium	Cerame-Unie position on boric acid and disodium tetraborates.pdf Cerame-Unie believes that any proposal to add boric acid and disodium tetraborates to the candidate list is pre-mature and requires further investigation. • The industry is currently preparing its registration dossier (for December 2010) and the information available in this dossier should be taken into account in the assessment by ECHA and the Member States. • In addition, when certain borates were added as toxicant Cat. 2 to the Dangerous Substances Directive (at the 30th ATP) a recital was added stating explicitly that "special attention should be paid to further results of epidemiological studies on the Borates concerned by this Directive including the study conducted in China". We therefore strongly suggest that any further steps in the process are carried out taking due account of the Chinese study that is now available. The current Annex XV dossiers are therefore to be regarded as outdated. • Cerame-Unie also questions the current arbitrary approach to propose Annex XV dossiers as a wide number of substances which are of higher concern are not yet proposed. With only a handful of substance on the candidate list, the 'emotional' damage through the supply chain is considerable. In conclusion, based on (i) the pre-mature timing to submit these dossiers, (ii) the well-regulated and safe use of boric acid and disodium tetraborates and (iii) the non-substitutable and essential uses of these substances, Cerame-Unie requests that the Annex XV dossiers on boric acid and disodium tetraborates are withdrawn and these substances are not placed on the REACH candidate list.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. However, we are aware that boric acid will be registered by the end of this year and further information may become available.
20100422	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job. At the best of my information I dont find any reason for considering boric acid really dangerous for the health. The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life".	Your comment has been taken note of.

20100422	Industry or trade association, Company, United Kingdom	Boric acid has 2 principal uses within this industry or trade association, both utilise borons ability to capture neutrons and control criticality • Boric acid is added to all BE fuel storage ponds to avoid a criticality incident and as such minimum boron levels are defined within each Station Safety Cases. The levels (both high and low) are strictly controlled by BE processes and the limits and monitoring requirements are all defined within BE's internal technical governance documents (BEOM 010). All Stations are regularly assessed against these standards. Whilst boron levels are relatively constant within the fuel storage ponds, tops ups (with boric acid) are required as boron levels will gradually decrease as the fuel (and some pond water) is transferred to fuel transport flasks and ultimately for re-processing. There is no alternative to boric acid and without it continued operation of all our nuclear fleet will not be possible. • Boron (as boric acid) is dosed in the primary circuit of a PWR and is fundamental to its operation in controlling reactivity. Boron concentration is added or removed during a operating cycle to control reactivity changes as the fuel is used up. In this way power levels can be maintained, and hence more easily controlled. There is no alternative and if boric acid was unavailable then the Power Station would shut down. In short, if boric acid was unavailable it would shutdown the entire BE nuclear fleet within days of supplies being exhausted.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be

			avoided.
20100422	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life.	Your comment has been taken note of.
20100422	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life.	Your comment has been taken note of.
20100422	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life.	Your comment has been taken note of.
20100422	Individual, Italy	The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life.	Your comment has been taken note of.
20100422	StonCor Europe, Company, Belgium	EBA comments Annex XV (00059414).PDF Memo to ECHA on behalf of StonCor re boric acid (00059408).PDF Annex XV dossier, Conclusions, Sections 2 and 3 on page 7, Section and Sections 1, 2, 3 and 4 of the Information on Use, Exposure, Alternatives and Risk	See response to EBA comments Boric acid was proposed as SVHC based on its classification as toxic to reproduction, its wide use in consumer products, and its high production volume. However, we are aware that boric acid will be registered by the end of this year and further information may become available. Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially

			when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100422	Alcon Laboratories, Inc, Company, United States	Borates and Boric Acid is a naturally occurring chemical used widely such as in detergents, cleaners, personal care products, agriculture, it is even available as a food supplement. The toxicity of Boric Acid (oral rat LD50: 2660 mg/kg) is only slightly higher than Sodium Chloride (kitchen salt) (oral rat LD50: 3000 mg/kg). There is currently no evidence of harm to humans regarding reproductive toxicity. Borates and Boric Acid are used in a range of medical devices, controlled by sectoral legislation (Medical Devices Directive 93/42/EEC), such as contact lens buffered solutions, contact lens care products and eye drops. These products are used on the eye to achieve a mildly-buffered solution in which other ingredients are dissolved, so the exposure to diluted borates is limited to the topical route of delivery. There are currently no acceptable substitutes available. The Medical Devices Directive requires manufacturers to do a risk assessment, whereby the benefit of the device has to outweigh the risk associated with the device and its components.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned.

20100422	VÖZ, Industry or trade association, Austria	X-ray fluoescence is a common tool in the Austrian and European cement industry for analyzing the chemical composition of construction products. In order to perform measurements on powders like raw materials for clinker production, on clinker or cements, the powders have to be formed into powder pellets. For this forming boric acid is used as an ingredient to facilitate the forming process. Boric acid has the advantage of not interfering with the x-ray measurements. If the use of boric acid will become illegal, an organic wax would have to used as a substitute. As organic compounds are interfering with the x-rays, x-ray measurements of the carbon content will be impossible , therefore.The use of x-ray fluorescence measurements would be restricted by using this substitue of boric acid.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the

			sweeping of dry dusts has to be avoided.
20100422	Bausch & Lomb Inc, Company, United States	Borates and Boric Acid are naturally occurring compounds used in many applications such as detergents, cleaners, personal care products, agriculture, it is even available as a food supplement. The toxicity of Boric Acid (oral rat LD50: 2660 mg/kg) is only slightly higher than Sodium Chloride (kitchen salt) (oral rat LD50: 3000 mg/kg). There is currently no evidence of harm to humans regarding reproductive toxicity	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned.
20100422	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job, the working conditions of my colleagues, my life, because this can also mean loose my job	Your comment has been taken note of.
20100422	Council of Europe, Directorate for the Quality of Medicines and HealthCare, European governmental organisation, France	Article 56(3) of the Regulation (EC) No 1907/2006 corr applies. Some reagents and raw materials of high concern should remain on the market for the convention on the elaboration of the European Pharmacopoeia (European Treaty Series 50) and the protocol to the elaboration of the European Pharmacopoeia, which are necessary for the implementation of the Directive 2001/82/EC on the community code relating to veterinary medicinal products and Directive 2001/83/EC on the community code relating to medicinal products for human use.	This identificationof Boric acid (BA) as SVHC is not a ban of boric acid. An application for authorization can be submitted once BA was added to REACH Annex XIV. Medicinal and veterinary medicinal products are not subject to Title VII of the REACH. Regulation. Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as

			cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100422	Industry or trade association, Company, Germany	We have Boric acid since about 30 years in the production. It is a very important product for our processes. There are no indication with any healthy or toxical problems.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %.
20100422	Industry or trade association, Company, United Kingdom	Boric acid used in a formulated gel which is applied directly to wounds to assist in hydration. Theoretical % w/w 0.5% boric acid Used in this application in excess of 18 years, no adverse events linked to the	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1^{st} adaptation of regulation 1272/2008 to the technical progress)

		presence of boric acid known, reported or recorded during this time.	with a specific concentration limit for boric acid in preparations of 5.5 %. Medicinal products are not subject to Title VII of the REACH regulation.
20100422	Individual, Italy	The introduction of boric acid in the list of substances identified as SVHC and the relevant consequences, will change for the worse my job. I don't see a specific risk for me and my employees after the normal protection devices	Your comment has been taken note of.
20100422	Individual, Germany	Letter_Bolt_ECHA.pdf p. 35 (Human data, last sentence) [and p.36, last sentence“: "Thus, the epidemiological studies in humans are insufficient to demonstrate the absence of an adverse effect on fertility" - The current Dossier dates February 2010. Since that, new data have appeared in the literature (Robbins WA et al., Chronic boron exposure and human semen parameters. Reproductive Toxicology 29: 184-190, 2010) on this specific subject. Moreover, the extensive summary of the studies in Chinese boron workers (Scialli AR et al. An overview of male reproductive studies of boron with an emphasis on studies of highly exposed Chinese Workers. Reproductive Toxicology 29: 10-24, 2010) has been published in the meantime. Taking these publications together, the new data on the Chinese cohort, which are specifically directed towards the point of epidemiological studies on fertility that is made in the Annex XV dossier, require a re-assessment of the aforementioned statement/conclusion of the Dossier. I refer to the uploaded attachment.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation.
20100422	Wirtschaftskammer Österreich, Chamber, Austria	su_133_öffentliche Konsultation ECHA BorVerbindungen.pdf Angefügt ist ein Dokument, mit Gründen, warum die WKÖ eine Aufnahme folgender Stoffe in die Kandidatenliste nach Art. 59 Abs. 1 als nicht statthaft ansieht: - Borsäure (EC 233-139-2 und 234-343-4) - Dinatriumtetraborat, wasserfrei (EC 215-540-4) - Tetrabordinatriumheptaoxid, hydrat (EC 235-541-3)	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are, however, aware of the pending

			decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation.
20100422	Industry or trade association, Belgium	As a downstream using sector for boric acid and disodium tetraborates ("tetraborates" in this document), A.I.S.E. is concerned that listing these substances as Substances of Very High Concern is inappropriate. Not only is it premature, but it will likely generate undue and misleading concern among further users, e.g. retailers, consumers and professional users of detergents cleaning products, and create unnecessary burden on companies (e.g. reformulation requests). The use of boric acid and tetraborates at low concentration in certain detergents and maintenance products – and in other uses – has been shown to be safe. Submitting these substances to the REACH Authorisation process is disproportionate. Safe use of boric acid and borates can be managed adequately via chemicals safety assessments and related exposure scenarios. Furthermore, communication of hazardous properties of boric acid and tetraborates is ensured by the provisions laid down in the CLP Regulation (EC) No 1272/2008. Note: boric acid and tetraborates in solution give rise to the same chemical species: boric acid and the borate ion (in equilibrium depending on pH). Therefore, our comments address both Annex XV dossiers. The impact of SVHC listing on downstream users, our concerns on the timing, comments on the uses of the substance reported in the Annex XV Dossier and on the toxicological justification, data on consumer exposure, and specific comments on the content of the Dossier are provided in the attached document.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1^{st} adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation. Boric acid was proposed as SVHC based on its classification as toxic to reproduction, its wide use in consumer products, and its high production volume. However, we are aware that boric acid will be registered by the end of this year and further information may become available.
20100422	Industry or trade association, Company, United Kingdom	Confidential comment submitted	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1^{st} adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned.

			We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation. We are also aware that boric acid will be registered by the end of this year and further information may become available.
20100422	CETS, Industry or trade association, Belgium	The electroplating branch is good controlled (by legislative and by ourselves). Our products extend the lifetime of the treated products substantial. We encourage the function of the surfaces to enable the use of cheep available basic material for industry products, i.e. - Hardness - Lubrication - Tribology - Brilliance - Electric conductivity - Shielding - Corrosion protection Electroplated surfaces are completely recyclable and avoid the consumption of large amount of resources and the production of carbon dioxide.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of

			ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100422	Industry or trade association, Company, Germany	Biotest.xls We are Industry or trade association, a EU member state user of boric acid and a member of the VSI, the association of the German lubricant industry. As a formulator, we are industrial downstream user. Our formulations (metalworking fluids) are used by industrial and professional users only	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic

			burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100422	Pemco International, Company, Netherlands	On the importance of borates in the enameling process Pemco International, Division Brugge, Pathoekeweg 116, B-8000 Brugge An enamel (frit) is a vitreous solidified compound with an entirely inorganic, mainly oxidic composition. According to EN1900, an enamel is a substance resulting from the melting or sintering of inorganic constituents and designed to form a surface layer, which is fused or capable of being fused in one or more coats at a firing temperature which is higher than 500°C. Mostly, the substrates are steel, cast iron or aluminium. Enamel coatings offer an indispensable corrosion protection. Additionally, they offer a great functional value because of their chemical resistance, surface smoothness, scratch resistance, hygiene, cleanability, … As for each coating technology, the enameling process comprises different important facets: the fabrication of the main constituents, their application on the substrate and the properties of the coating itself. In each of these areas, borate species play an important role. Frits or enamel coatings are made of (milled) enamel flakes as major constituent.	Thank you for the information. A clarification has been added to the consumer exposure part of the annex XV dossier. Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations.

		The production of enamel flakes is almost always done by specialized companies and consists of melting a recipe of raw materials to obtain a well-defined oxidic composition, which determines the final chemical and physical properties of the enamel coating. The oxides are generally classified either as network formers (most commonly SiO2) or as network deformers (most commonly alkali or earth alkali). The network formers are the major building blocks and are responsible for the general properties (such as durability) of the enamel coating, whereas the network deformers are responsible for a larger (and more appropriate) thermal expansion coefficient and for a lower (and more appropriate) viscosity at firing temperatures. At the same time, they are responsible for a partial destruction of the positive effects of SiO2, such as chemical durability, as they "de-form" the network. Therefore, a careful equilibrium between network formers and deformers is of primordial importance. Exactly at this point boron oxide plays a necessary balancing role, lowering the viscosity at high temperatures while maintaining a moderate thermal expansion coefficient and good chemical resistance (compared to alkali). Moreover boron oxide has a strong influence on lowering the surface tension of a glassy surface. Therefore, almost all enamels are borosilicates having mainly SiO2 and B2O3 as network builders. The B2O3 in viscous melt and later in the matrix usually stems from borate species, such as borax or boric acid as raw materials. These raw materials offer the advantage of introducing only B2O3 (and Na2O for borax). During the melting process itself, typically at 1200°C, these raw materials also fulfill an important role. By melting at moderate temperatures (<800°C), they can wet other components, so facilitating the chemical dissolution of high melting components such as quartz, which has a melting temperature much higher than the typical fusion temperature of 1200°C. From the moment the boric acid or borax raw materials are melted into an enamel matrix, all their typical properties disappear and a new substance is created with other properties. In order to realise the enamel coating itself, the milled flakes have to be applied on a substrate. This can be done using powder technology or via wet application, such as spraying, dipping, electrophoresis … Today, wet application still remains the most used technique. In order to keep the enamel particles in solution, a colloid clay suspension is used. Conclusion :	Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.

		The use of Boric Acid and Borax is essential in the melting process of frits (enamels). Attempts to produce enamels without boric compounds have been unsuccessful in the past. At this moment we do not have alternatives to replace boric compounds in the production in borosilicates enamels. Once melted in an enamel matrix all the properties of the borates compounds are disappeared. The fact that frits are included in Point 11 of Annex 5 of the Reach Regulation demonstrates the low concern that this type of material should have from the safety point of view.	
20100422	Fuchs Austria Schmiermittel GmbH, Company, Austria	We are Fuchs Austria Schmiermittel GmbH 100% Fuchs subsidiary, an EU member state user of boric acid and a member of the VSI, the association of the German lubricant industry. As a formulator, we are industrial downstream user. Our formulations (metalworking fluids) are used by industrial and professional users only.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were

			regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100422	Fuchs Oil Hungaria Ltd., Company, Hungary	We use bor containing metal working fluids for general metal cutting operations. We enjoy excellent corrosion protection properties of bor, while we haven't experienced any health issues in the past 3,5 years. So far we haven't seen any reliable alternative of bor, where alternative substance's long term health effects are not clear.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of

			ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100422	MSCA, Austria	The Austrian CA supports the inclusion into the candidate list on the basis of the submitted dossier.	Thank you.
20100422	Individual, Germany	Good afternoon, I am manager of our companiy's plating shops which are located in diffrent countries in europe, our daily bussines include the use of boric acid which is essential for our process and the resulting quality of our products. For the electro plating indutry is boric acid a very improtant intrigent for a plenty of applications for example nickel plating, acid zinc plating and various other electrolytes also in the enviromental friendly trivalent chrome plating electrolytes is boric acid the prefferabled buffer in all state of the art process' without boric acid it would be impossible to work with these electrolytes for some cases there may be some alternatives but they can not give the same properties as electrolytes which include boric acid can, this means for the most applications it will be impossible to replace it. When we consider how much of the products which we daily use can not be produced anymore because of some strict regulations, to where this will lead I don't know. Furthermore we should not forget that in some european countries boric acid is still used as an food additive and on the bags which we use is written food grade that is confussing me. For sure I agree that there is a risk by the use of boric acid especially in private use or in some industrial usages either but in the plating industry working people which handle every day a plenty of chemicals from non toxic to highest toxic and the people are trained to work with such chemicals and know how to handle them in a save way (Safety glasses, dust masks ....) so even they are not really exposed to the boric acid it is just a matter of how to. Another improtant fact is that we use boric acid in the process but we don't have	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low

		boric acid on the plated products! I just can repeat that without boric acid the european industry will loose a lot of products, and Asia will be happy to receive the orders. I am a friend of enviromental and human protection but we have to consider is that what we are doing sensfull or is it may be just moving a problem to another place, as I said there are no other possible chemicals which can be used for this applications if we will prohibit the use of them the parts will be plated in asia so are you sure that they can avoid a emmiting to the enviroment on the same level as we could do this in europe with our possiblities? Beside this with such regulations europe will hurt his industrie that much that I have to addmit I am scared about my future, I am 27 years old what will be in 10 years will I have work to pay my bills? I don't know! But I know that I will be still alive even if I handle every day boric acid!!! kind regards J. Bleisinger	dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided. Socioeconomic aspects should be discussed in case an application for authorisation becomes necessary.
20100422	UITS, Industry or trade association, France	USE OF BORIC ACID IN SURFACE FINISHING.pdf page 17: alternatives	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations.

			Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100422	Chemservice S.A. / REACH Zinc-Borate Consortium, Industry or trade association, Luxembourg	EFSA opinion on BA and STB as food add 80.pdf EFSA PUB Statement of AFC on BA and ST as nutrient sources of boron.pdf Boric Acid is used as raw material for Zinc-Borate production and has been safely used for decades. There is no evidence of reprotoxic effects in workers. Therefore, we are concerned that an Annex XV dossier was filed on Boric Acid to identify the substance as potential "Substance of Very High Concern". The substance classification as Category 2 reprotoxic is not a clear cut and there were already controversial discussions during the Member States Technical Meetings on Classification & Labelling. According to the attachments “Boron” is allowed as a dietary food supplement - which contradicts the current identification as potential SVHC.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation.
2010422	Independent Lubricant	EBA comments Annex XV 100104 final.pdf	See response to EBA comments

	Manufacturers Association, Industry or trade association, United States	The Independent Lubricant Manufacturers Association (ILMA) wishes to comment on the nomination of several inorganic borates and boric acid on the Substances of Very High Concern (SVHC) List. The Independent Lubricant Manufacturers Association (ILMA) was established in 1948 in order to meet the needs of its members by providing advocacy, networking, and a collaborative effort to succeed in today's business world. The trade association is the principal voice for the industry before Congress, federal regulatory agencies and other industry groups. ILMA promotes integrity and quality in lubricant manufacturing and marketing. Manufacturing Members are independent lubricant companies that produce over 25% of all lubricants and 80% or more of the metalworking fluids and other specialty industrial lubricants sold in North America.	
2010422	Industry or trade association, Belgium	210410_boric_acid_stakeholder_final.doc	Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its high production volume. However, we are aware that boric acid will be registered by the end of this year and further information may become available. Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned.
2010422	FEPA, Industry or trade association, France	We have been informed that there is an intention to include boric acid into the list of substances of very high concern (SVHC). Some companies of the European abrasive industry are currently investigating whether their products might contain traces of boric acid. As you may know the measurement process is complex and time consuming for potential amounts in a matrix. If necessary we will inform you as soon as measurement data of the contracted laboratory will be available.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne

		Our toxicological and chemical experts have checked the published annex XV dossier on boric acid and indicated concern about the findings and conclusions, in particular as there are obvious gaps in the causal chain and a complete REACH dossier with further information will be provided by the manufacturers by the end of this year. From the side of the abrasive industry we have never received any indication that potentially existing boric acid in abrasive products caused any health problems or adverse effects. On the other hand, information obligations that would result from inclusion of boric acid into the SVHC list would cause huge administrative efforts. If the ongoing measurements really show contents of boric acid above 0.1% and boric acid is considered a SVHC then a huge number of commercial users of coated abrasives might need to be informed. As we are talking of more than 10 million clients of the European abrasive industry costs certainly would exceed €20 million . Against the background that there are serious uncertainties (deficits and gaps of the existing annex XV dossier, upcoming additional information from the registration dossier) the decision to include boric acid into the list of SVHC should be postponed to avoid potentially unjustified efforts for the European industry that would unnecessarily affect its international competitiveness. If you need any further information please let us know and we will be happy to support you with further details.	concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
2010422	Industry or trade association Company, Netherlands	page 1 - 4, propriatary	See response to EBA comments. Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier

			nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
2010422	Certigaz, Company, France	It is important to maintain a level of 5.5% for the applications of welding or brazing. There is no substitute and the activity would be dead.	Alternatives should be discussed in case application for authorisation becomes necessary.

2010422	Eurocolour, Industry or trade association, Belgium	frits-borates-final version.pdf COMMENTS ON ANNEX XV DOSSIERS GENERAL COMMENTS Eurocolour is the European umbrella organization for pigments, dyes and fillers producers. Ceramic frits are also covered by Eurocolour. For the purpose of REACH registration a frit consortium has been founded in Castellon, Spain. The Frit Consortium had access to the comments provided by the European Borates Association (EBA) regarding the inclusion of Boric Acid and Disodium tetraborates in Annex XV as SVHC substances. We feel that inappropriate priority is being given to inclusion of disodium tetraborates and boric acid in the Annex XV inclusion proposals. In particular, our sector evaluations of the circumstances of use of these key substances in frit applications, leads us to the conclusion that risks are well controlled at all life-cycle stages, and the applications are non-dispersive. SPECIFIC FRIT SECTOR COMMENTS Definition of frits and frits sector According to their classification as a differentiated substance under CAS No. 65997-18-4 or EINECS No. 266-047-6, frits are defined as a mixture of inorganic chemical substances obtained from the fast cooling of a melted complex combination of materials by which the chemicals become insoluble vitreous compounds appearing in the form of scales or granules. Thus, ceramic frits are amorphous vitreous materials comprising mainly chemical oxides, which are the most important glass formers of technical and industrial interest in the production of glazes to be used for example in ceramic tiles. The frits sector is concentrated mainly in Spain and in other countries like Italy, Belgium, Germany, UK, Poland and Czech Republic. The Frit Consortium was constituted on June 4th, 2009, with headquarters in Castellon, Spain, and currently groups 32 companies, all of them are aware of the need to combine progress and economic development with technological innovation, employment creation and the protection of safety and environment, directing their lines of action towards the basis of the Lisbon strategy of the European Union and to a framework of sustainable development. The frits sector has done a considerable effort in R&D in order to achieve new products and quality improvement, without forgetting compliance with relevant	Thank you for the information. A clarification has been added to the consumer exposure part of the annex XV dossier for boric acid.

		environmental legislation such as the REACH regulation, IPPC, trade emissions, and so on. Manufacturing process of frits The manufacture of frits is covered by the IPPC Directive (2008/1/EC) and is technically explained in the BREF-Document on Best Available Techniques in the Glass Manufacturing Industry. Frits are manufactured using melting furnaces with a production capacity under 30 tons/day. The process is normally operated continuously (water or air cooled furnaces) but also discontinuous operation exists, i.e. in batches in rotary water cooled furnaces. In the manufacture of frits, the starting materials are formulated and melted at 1350 to 1550 °C ensuring the vitreous matrix . As a second step the material is cooled suddenly and, thus, turned into a solid material fragmented into insoluble compounds (fritting process). Figure shows the frits production process. Figure 1: Manufacturing of frits A key issue that needs to be considered is the fact that during the production process, the boric acid or borate compound is chemically transformed from these substances into a complex solid solution which is a vitreous matrix containing boron. Therefore in these applications, the substances are essentially “Intermediates” as defined by the REACH regulation. In addition, in these circumstances the transformed forms of boron are matrixed and have low bioavailability / leaching characteristics. Frits are used mainly to prepare glazes or enamels, which are then used to provide a glassy surface for protective and/or decorative purposes to a wide variety of articles. In many cases this surface is the only part of the article which is visible, and therefore it constitutes a critical part of the article. During the preparation of these articles (e.g. ceramic tiles, dinnerware, electronic devices), different processes such as firing take place, where the glaze or enamel becomes tightly fixed to a support, with the following consequences: • Formation of a compact, strong and resistant structure; • Reaction and immobilization of the inorganic raw materials into complex compounds (silicates) characterized by a high chemical inertia. Use of boron in frits The importance of the frits sector related to the uses of borates is well known, as is indicated in the Danish proposal of inclusion of Disodium tetraborate anhydrous in Annex XV of REACH. Table 4 of the mentioned document describes that glass and ceramics amount to 65% of the relative uses of borates in industry. Moreover, this	

		document specifies that the demand for borates in the frits and ceramic sector has increased in the past years, and that the expected tendency is a 2-4% increase per year over the next five years. Besides, the "Assessment of the Risk to Consumers from Borates and the Impact of Potential Restrictions on their Marketing and Use" prepared by the European Commission specifically states that "one of the largest uses of borates in Europe is in frits and glazes for ceramics. Borates are included in frits formulations because of their low fusion temperature and their flux properties, with the scope to control fusion properties. Boric oxide, which is a generator of vitreous matrix, contributes decisively to form the vitreous structure, lower viscosity, and therefore strengths the matrix and reduces possibility of migration of elements . Boric oxide may be introduced in a glaze as decahydrate borax, anhydrous borax or boric acid. During the process, boric oxide acts as a solvent and promotes chemical action between other constituents of the batch. It has the ability to dissolve other metal oxides and is thus an invaluable constituent of ground-coat enamels. Its solvent action on the surface layer promotes enamel adherence and the formation of an interfacial layer contributing to the bond between other components and the enamel. Attempts which have been made to produce satisfactory ground-coat enamels containing no boric oxide have all been unsuccessful, since such enamels are always very prone to copperheading effects. Boric oxide exerts a very pronounced effect on the expansion of enamel glasses and replacement of alkali by boric oxide reduces expansion to a considerable extent. The presence of boric oxide is usually associated with low viscosity and a rapid setting rate, and the good surface gloss of enamels with high boric oxide contents is quite characteristic. Exposure and toxic effects of frits Different studies exist that show the inertness and lack of toxic effects of several frits, many of them containing boron in their composition . In addition, it is well known within the frit manufacturing industry that exposure to boron is negligible from a workplace exposure perspective. Available measured data reported by representative companies within the frit sector show that concentrations rank between 0.01-0.06 mgB/m3 (expressed as equivalent of boron) the TLV for boron being 2 mg/m3, which shows that the exposure to this element during frit production is absolutely negligible . This data is significant when compared to the typical values for inhalation of borates given in the Danish proposal of inclusion of Disodium tetraborate anhydrous in	

		Annex XV of REACH. Table 7 of this document indicates that, for the group where ceramic frits are included, typical inhalation exposure (expressed as equivalent of boron for disodium tetraborate anhydrous) is 0.75 mg/m3. The measured values available within the frits industries are 12.5 times lower than this value, even in the worst case (0.06 mgB/m3). Boron is usually not measured in atmospheric emissions since it is well known that the amount of boron released is minimum. It also needs to be considered that all the companies manufacturing frits include appropriate filters in exhaust systems in order to minimize releases of boron and any other materials . The highest exposure to elements like boron during the life cycle of frits should be expected during the handling of raw materials, and maybe during the milling operations right after the frit has been produced. However, the data described previously shows that exposure to workers or the environment during these steps is minimum (if not completely inexistent). In subsequent steps of the uses of frits, as described during the previous sections, the nature of the glazing process generates an even tighter structure which binds the glaze to final articles, which should in any case reduce even more any possible exposure to the elements contained in frits. It is important to underline that the "Assessment of the Risk to Consumers from Borates and the Impact of Potential Restrictions on their Marketing and Use" prepared by the European Commission, specifically states in its Table 4.5 that: "Frits and glazes used in ceramics are very unlikely to result in exposure to borates for consumers"; moreover, the following paragraph can be read at the same document (page 35-36): "Borates are also used in glazes and enamels (with borate concentrations of up to 25%) for ceramics and other materials as well as being used within ceramic tiles. As for glass, such uses result in the borates being chemically bound into the product. Although the resultant degree of exposure of consumers to boron containing compounds will be minimal, it could be argued that direct exposure to the borates (as defined for this study) will be zero - since they have been chemically transformed in the glass/glaze/enamel/ceramic production process34. Indeed, even the ingestion or inhalation of glass particles (from glass fibre dust for example) will not result in the release of borates from the glass". Furthermore, it has to be stressed that any consumer exposure will be to transformed boron in a matrix, and not to the Annex XV proposed substances themselves.	

		CONCLUSION The use of Boric Acid and other borates as raw materials in the frit manufacturing industry is totally safe. Boric Acid and Borates are an essential and irreplaceable ingredient in the manufacture of ceramic frits Taking into account all the information describe previously, and the fact that frits are including in Point 11 of Annex V of the Reach Regulation demonstrate the low concern that this type of material should have from the point of view of safety. Furthermore, as stated in Page 33 of the Annex XV dossier for Disodium tetraborate, anhydrous and Tetraboron disodium heptaoxide, hydrate, “there are no alternatives for use of borates in the production of ceramic frits as well as in glaze and enamel. By the industry, the borates used for producing the ceramic frits may be regarded as isolated intermediates as the ceramic frits are considered as a substance. Thus, the borates are intermediates in the production of frits.”. Following their demonstrated compromise with safety and the environment, companies involved in frit manufacturing dedicate many economic resources to R&D in order to find alternative ways for manufacturing of frits. As mentioned in the Danish proposal of inclusion of Disodium tetraborate anhydrous in Annex XV of REACH, currently it is not possible, due to technical reasons, to replace the use of borates in the manufacturing of frits. For these reasons, it is clear that the use of these raw materials in the production of frit should never be included in any kind of authorization process. Anyhow, we consider unnecessary to include boric acid and other borates in Annex XV given the large amount of information provided by EBA and others, being totally injustified include reference to authorization for the use in ceramic frits, which could cause an unnecessary impact on Manufacturers, Importers, Suppliers and Users in the EU	

		COMMENTS ON ANNEX XV DOSSIERS GENERAL COMMENTS Eurocolour is the European umbrella organization for pigments, dyes and fillers producers. Ceramic frits are also covered by Eurocolour. For the purpose of REACH registration a frit consortium has been founded in Castellon, Spain. The Frit Consortium had access to the comments provided by the European Borates Association (EBA) regarding the inclusion of Boric Acid and Disodium tetraborates in Annex XV as SVHC substances. We feel that inappropriate priority is being given to inclusion of disodium tetraborates and boric acid in the Annex XV inclusion proposals. In particular, our sector evaluations of the circumstances of use of these key substances in frit applications, leads us to the conclusion that risks are well controlled at all life-cycle stages, and the applications are non-dispersive. SPECIFIC FRIT SECTOR COMMENTS Definition of frits and frits sector According to their classification as a differentiated substance under CAS No. 65997-18-4 or EINECS No. 266-047-6, frits are defined as a mixture of inorganic chemical substances obtained from the fast cooling of a melted complex combination of materials by which the chemicals become insoluble vitreous compounds appearing in the form of scales or granules. Thus, ceramic frits are amorphous vitreous materials comprising mainly chemical oxides, which are the most important glass formers of technical and industrial interest in the production of glazes to be used for example in ceramic tiles. The frits sector is concentrated mainly in Spain and in other countries like Italy, Belgium, Germany, UK, Poland and Czech Republic. The Frit Consortium was constituted on June 4th, 2009, with headquarters in Castellon, Spain, and currently groups 32 companies, all of them are aware of the need to combine progress and economic development with technological innovation, employment creation and the protection of safety and environment, directing their lines of action towards the basis of the Lisbon strategy of the European Union and to a framework of sustainable development. The frits sector has done a considerable effort in R&D in order to achieve new products and quality improvement, without forgetting compliance with relevant environmental legislation such as the REACH regulation, IPPC, trade emissions, and so on.	

		Manufacturing process of frits The manufacture of frits is covered by the IPPC Directive (2008/1/EC) and is technically explained in the BREF-Document on Best Available Techniques in the Glass Manufacturing Industry. Frits are manufactured using melting furnaces with a production capacity under 30 tons/day. The process is normally operated continuously (water or air cooled furnaces) but also discontinuous operation exists, i.e. in batches in rotary water cooled furnaces. In the manufacture of frits, the starting materials are formulated and melted at 1350 to 1550 °C ensuring the vitreous matrix . As a second step the material is cooled suddenly and, thus, turned into a solid material fragmented into insoluble compounds (fritting process). Figure shows the frits production process. Figure 1: Manufacturing of frits A key issue that needs to be considered is the fact that during the production process, the boric acid or borate compound is chemically transformed from these substances into a complex solid solution which is a vitreous matrix containing boron. Therefore in these applications, the substances are essentially "Intermediates" as defined by the REACH regulation. In addition, in these circumstances the transformed forms of boron are matrixed and have low bioavailability / leaching characteristics. Frits are used mainly to prepare glazes or enamels, which are then used to provide a glassy surface for protective and/or decorative purposes to a wide variety of articles. In many cases this surface is the only part of the article which is visible, and therefore it constitutes a critical part of the article. During the preparation of these articles (e.g. ceramic tiles, dinnerware, electronic devices), different processes such as firing take place, where the glaze or enamel becomes tightly fixed to a support, with the following consequences: • Formation of a compact, strong and resistant structure; • Reaction and immobilization of the inorganic raw materials into complex compounds (silicates) characterized by a high chemical inertia. Use of boron in frits The importance of the frits sector related to the uses of borates is well known, as is indicated in the Danish proposal of inclusion of Disodium tetraborate anhydrous in Annex XV of REACH. Table 4 of the mentioned document describes that glass and ceramics amount to 65% of the relative uses of borates in industry. Moreover, this document specifies that the demand for borates in the frits and ceramic sector has increased in the past years, and that the expected tendency is a 2-4% increase per year	

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20100422	Verband Deutscher Schleifmittelwerke e.V., Industry or trade association, Germany	VDS-Statement_22-4-10.pdf	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in

			the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided. Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress)

			with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. However, we are aware that boric acid will be registered by the end of this year and further information may become available.
20100422	Industry or trade association, Company, United Kingdom	Our company manufactures and distributes In Vitro Diagnostics (IVD) products in the European Union. These products are tests performed on biological samples (derived from the human body) to provide information to assist in clinical decision making. There is no direct physical contact between a patient and these medical devices. Furthermore, our products are not of the self-testing type, i.e. they are used in professional laboratory settings, by professionally trained staff, and are not placed on the market for use by the general public (e.g. a glucose meter or a pregnancy test). All In Vitro Diagnostic (IVD) products meet the regulatory requirements in the EU as defined by the IVD Directive (Directive 98/79/EC). The essential requirements of the IVD Directive aim to ensure that conforming IVD products do not compromise the health and safety of patients and users. Requirements for management and mitigation of health risks to patients or users of IVD products due to the presence of any substance contained within these products are addressed within the requirements of this Directive. Additional regulation of the use of chemicals in in vitro diagnostic products under REACH is also not warranted as stated in Article 60(2) of the REACH Regulation itself: The Commission shall not consider the risks to human health arising from the use of a substance in a medical device regulated by • Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, • Council Directive 93/42/EEC of 14 June 1993 concerning medical Devices, or • Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.	We are aware that boric acid will be registered by the end of this year and further information may become available.

		As mentioned above, IVD products are designed to be used in a clinical laboratory setting by professionally trained staff for the benefit of human health. Therefore, there is no risk of unwitting exposure to members of the general public to materials used in these products. Risk to the professionally trained users of these products is mitigated by the use of standard precautions as well as protective clothing and processes as specified by local regulations, standard professional practices and occupational health and safety guidelines. The products themselves are designed in such a way as to minimize contact by the trained professional users under standard conditions of use. Lastly, including disodium tetraborates and boric acid at this point does not make sense as producers and importers are developing a REACH registration dossier, which will be submitted by the December 2010 deadline. The current Annex XV dossiers are based on fragmented and incomplete information largely based on modeling data from the transition dossiers of both substances. The transition dossiers concluded however that "There is a need for better information on occupational exposure for producing/importing processing sites, downstream user and consumer applications to adequately characterize the risks to workers and consumers from boron exposure via boric acid and sodium tetraborates". Industry is following-up on these recommendations. The REACH registration dossiers will contain the necessary information to identify whether there are risks for workers and consumers requiring further measures. Including borates in the Candidate List in the absence of this information is therefore premature at this stage.	
20100422	Industry or trade association, Company, Belgium	As downstream user, we are not able to justify or not the Boric Acid as candidate for authorisation. We are just highly surprised by this proposal, becose this substance has up to now always been considered as weakly hazardous.	Boric acid was proposed as SVHC based on its classification as toxic to reproduction cat. 1B, its wide use in consumer products, and its high production volume.
20100422	GIFAS, Industry or trade association, France	20012_100419_Echa.pdf Please refer to attachment.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at

			workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100422	Ceramicolor - National Association of Ceramic Glaze, Inorganic Pigments and Metal Oxides, Industry or trade association, Italy	frits-borates-Ceramicolor.pdf	Thank you for the information. A clarification has been added to the consumer exposure part of the annex XV dossier for boric acid.
20100422	Federchimica, Industry or trade association, Italy	I sent comments yesterday and I received this reference number: 19e53438-c0f5-498a-b1e9-31c1a3db372e, now I report again the same comments with an	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009

		integration of the point 11. We are Federchimica (the Italian Federation of the chemical industry). At the present time 1300 companies, with a total of 100.000 employees, are part of Federchimica. They are grouped into 16 Associations. Some of that are in the field of paints, ceramics, metalworking fluids, abrasives, fertilizers specifically interested in the acid boric. Federchimica is a member of Confindustria (General Confederation of the Italian Industry) and CEFIC (European Chemical Industry Council). Our position is based on two aspects: 1. the notion that boric acid is relatively benign substance which classification as reproductive toxicants was (and continues to be) controversial and contested. 2. The Annex XV Dossier for boric acid shall not be filed until REACH Dossiers are reviewed in 2011. The following are general comments: 1. The boric acid classification decision was the result of a controversial, extremely lengthy and unsatisfactory decision-making process. It was a decision that was opposed by seven EU Member States (Poland, UK, Italy, Ireland, Belgium, Slovenia, Latvia), which specifically and uniquely signed a declaration that stated that they were in favour of a less rigorous classification category for boric acid and disodium tetraborates. In fact a majority of Member States experts had recommended earlier (in the context of the 29th ATP to the Dangerous Substances Directive) that boric acid and disodium tetraborates should be classified as a Category 3 under the previous Directive (note: when Member States eventually voted for a Category 2, this was done on the basis of the same evidence and arguments). At different times in the process, European Commission officials and departments themselves were divided on the appropriate level of classification for borates. And finally, as part of the WTO TBT process, several non-EU countries (including Turkey, Argentina, Chile, Canada, the U.S., China and Malaysia) expressed concern over the Category 2 classification of boric acid and disodium tetraborates and some stated that this was more trade disruptive than necessary. 2. The main source of disagreement over the appropriate level of classification of boric acid and disodium tetraborates is related to the way effects found in animal studies were extrapolated to humans. Industry acknowledges that there is a reproductive effect from borates in animals that have been force-fed large quantities	(1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation.

		of boric acid or disodium tetraborates on a daily basis for a long period of time. However, industry has always argued that the Member States and the European Commission have not demonstrated that the classified borate substances have intrinsic properties which give rise to a risk of reproductive toxicity in humans during normal handling and use, as required by law (Annex VI of the Dangerous Substances Directive). Moreover, multiple existing studies on humans have found no reproductive effects. Recital (2) of the 30th ATP which added certain borates to the Dangerous Substances Directive as a Category 2 toxicant and which was inserted by the European Commission, states that "special attention should be paid to further results of epidemiological studies on the Borates concerned by this Directive including the ongoing study conducted in China". This study among workers in a borates mine has now been completed and peer-reviewed and confirms that there is no reproductive effect in men, which indicates even at very high exposures the effect in humans is different than the effect on laboratory animals. In the light of this Recital and since the Chinese study has not yet been evaluated by ECHA or Member States experts, adding boric acid and disodium tetraborates to the candidate list now simply does not make sense. 3. The Commission's decision to classify certain borates (including boric acid or disodium tetraborates) is subject to two court cases that are currently before the European Court of Justice and the General Court (C - 15/10; T539/08). Both court cases ask for an annulment of classification so to remove the basis for the inclusion of borates under REACH ¬authorisation as well as the legal basis for including them in the authorisation process. 4. Producers and importers of boric acid are working on a REACH registration dossier which will provide new scientific data and should be used as a mechanism to determine the risks and hazards of this substance. Including disodium tetraborates and boric acid at this point does not make sense as producers and importers are developing a REACH registration dossier, which will be submitted by the December 2010 deadline. The current Annex XV dossiers are based on fragmented and incomplete information largely based on modelling data from the transition dossiers of both substances. The transition dossiers concluded however that "There is a need for better information on occupational exposure for producing/importing processing sites, downstream user and consumer applications to adequately characterize the risks to workers and consumers from boron exposure via boric acid and sodium tetraborates The REACH registration dossiers will contain the necessary information to identify whether there are risks for workers and consumers requiring further measures.	

		5. Consumer protection from exposure to boric acid and disodium tetraborates will be however addressed through Annex XVII-restrictions of CMR substances for consumer use. At the direction of the Commission RPA (2008) reviewed the uses and risks associated with borates for consumers not currently regulated by some of the legislation, and concluded that risks associated with these other uses are unlikely to be of serious concern. 6. Adding disodium tetraborates and boric acid to the candidate list would have immediate negative consequences without generating public health benefits. Producers of these substances would have the obligation to communicate this listing to customers and (if requested) consumers and this involves an increase in cost and may have economic consequences, particularly with respect to the viability of any possible future applications. 7. The free acid is found native in certain volcanic districts such as Tuscany, the Lipari Islands, issuing mixed with steam from fissures in the ground; it is also found as a constituent of many minerals (borax, boracite, boronatrocaicite and colemanite). No evidence for free acid and borate to raise safety issues for local population 8. Boric acid, is a “ancient acid” : it was first prepared by Wilhelm Homberg (1652-1715) from borax, by the action of mineral acids, and was given the name sal sedativum Hombergi ("sedative salt of Homberg"). However borates, including boric acid, have been used since the time of the Greeks for cleaning, preserving food, and other activities. 9. Based on mammalian median lethal dose (LD50) rating of 2,660 mg/kg body mass, boric acid is poisonous if taken internally or inhaled in large quantities. However, it is generally considered to be not much more toxic than table salt. The Thirteenth Edition of the Merck Index indicates that the LD50 of boric acid is 5.14 g/kg for oral dosages given to rats, and that 5 to 20 g/kg has produced death in adult humans. The LD50 of sodium chloride is reported to be 3.75 g/kg in rats according to the Merck Index. 10. Borates have been used safely for generations and people’s greatest exposure to borates is through a healthy diet. Recent research has demonstrated several benefits associated with boron exposure in humans including bone health, cell membrane function, psychomotor skills and cognitive processes, control of inflammatory disease, enzyme regulation, energy metabolism, and potential anticarcinogenic properties.	

		11. Don't forget boron is one of the seven micronutrients essential to plant nutrition and so healthy diets associated with fruits and vegetables will contain relatively high levels of boron. Again in the plant metabolism boron plays an important role in the other nutrients absorption.	
20100422	Industry or trade association, Company, United Kingdom	We are Lubrizol Limited, an EU member state user of boric acid and member of the UK Lubricants Association.	
20100422	Industry or trade association, Company, France	We are using Boric acid only in grease and specially in vacuum grease. The pourcentage is less than 0,5 % for one and less of 1 % for the 2 others.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %.
20100422	Industry or trade association, Germany	Substances introduced in Candidate list are normally substances of Very High Concern well known for years. Boric Acid is not yet classified as dangerous by EU regulation. Date of new classification will is December 2010 with an exemption of marking fixed 5.5%. Acid Boric is used in brazing industry and no adverse fertility or developmental effects have been observed. Current regulation, as defined in 1st ATP of CLP or 30th ATP of 67/548/EEC should be respected when Boric Acid is used in preparation (e.g. welding consumable). Boric acid should not be placed on the "Candidate List".	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned.
20100422	Industry or trade association, Company, France	Page 1 - General comments We are making this submission because boric acid has important properties. Substitute products with the same properties are not known. The biological activity deeply depends on the chemical effect of the preparation, not on the individual ingredients. Reprotoxic tests have been performed and effects were found only at high doses in animals by oral route where many chemical products would also present strong toxic effects. The results are not transposable to humans, where there is no evidence of harm. Boron and boric acid are able to combine with other substances/ingredients which then have different hazardous properties. The objective of REACH is to prove how products can be used safely, on their own and in	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned.

		preparations. Eye/skin washing solutions and contact lens buffered solutions which are medical devices can contain boric acid or borates well below the accepted threshold safety level. Boric acid can exhibit microcidal properties and healing properties. We propose to pay attention to this use of boric acid in medical devices and include the previously published concentration limits in Annex XV as an exemption and consider that the dermal route is free of absorption and should also be exempted.	
20100422	Industry or trade association Company, United Kingdom	Borates With regard to the proposal for Annex XV Candidate List status for borates, we believe that this is not justified for the following reasons: 1. The proposal has been made on the basis that borates are classified as Category 1B. In the meeting where this classification was agreed, 6 of the 13 Member States present disagreed with this classification and supported either Category 2 or 3. More and better data are now available than were considered in this decision. 2. A Chinese epistudy on the exposure of a large number of Chinese workers to large doses of borates for an extended period has now been published and the conclusion is of no classification. 3. Further, a US study of the same dataset, also now published, reaches the same conclusion. 4. Also, since a comprehensive, high-quality Dossier for REACH purposes will be submitted to ECHA in the next few months, consideration of this as well as the epistudy would improve the reliability of a judgement on Candidate List status. 5. With regard to use, borates have been used safely by the metallurgical industry for many years. 6. We have used borates since the 1980s. We changed from the previously used substances on the basis of a reduction of risk to the environment and a reduction in costs, with borates being the best of the alternatives investigated. We herewith submit research reports from this time in support of this. Background to our use of borates:	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation. We are also aware, that boric acid will be registered by the end of this year and further information may become available. Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the

		In more detail, we are a major European producer of lead and lead alloys, widely used in applications such as batteries for cars, aircraft, stand-by power and motive power, sheathing for international submarine ultra-high voltage electricity links and connectors to off-shore wind farms, and many other applications essential to the European and Global economy. We import crude lead into Europe and refine it to remove impurities, resulting in lead of a purity greater than 99.99%. One of the impurities that is removed from the lead during processing is silver, which is as valuable financially as the lead from which it is removed. The refinery was built in 1931, using technology that was of its time. Over the intervening decades, plant and methods have been updated regularly as improvements became available, so that we are today one of the best refineries in the world. To remove silver from lead, zinc is added, which combines with the silver, and is then separated from the bulk of the lead. The zinc is then removed from the silver, allowing the zinc to be re-used and the silver to be further refined. Until the early 1980s, zinc was removed from the silver by boiling it off in vessels known as Retorts. This resulted in the loss of 20% of the zinc per pass, and posed some risks to the environment and to human health. The company commissioned research into improving the process. This was followed up by in-house research and development which resulted in replacement of the original retort process with a new one which gave considerable improvements. Part of the new process involved a step called liquation, where silver became further concentrated in a zinc- and silver-rich layer. To minimise oxidation of zinc and aid the removal of oxides from the molten metal, a fluxing agent was required. Many alternatives were shown not to be viable and mixed chlorides were chosen. This flux worked, but it was soluble, necessitating a water-based post-treatment to recover heavy metals and allow disposal. This added cost and posed some environmental risks. Further work in the late 1980s resulted in the replacement of the chloride flux with borates. This allowed removal of the costly and environmentally risky water-based	EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.

		step. This is the process used up to the present. Borates (currently in the form of borax) are a now a vital reagent used in our core business in the removal of silver from our feedstock If we had to use an alternative, there would be an increase in environmental impact, a substantial cost penalty to our business, and no benefit in risk reduction to Human Health. Our site operates under an IPPC licence and complies with stringent discharge limits to air and to water. We also operate under the Control of Lead at Work Act. Emissions from our processes are tightly controlled. We have an ongoing culture of continual improvement to ensure that we remain well ahead of national and international targets for heath, safety and the environment. The spent flux is sent to a world-class metallurgical company in Europe for recovery of residual silver and is processed and disposed of under strictly controlled conditions, compliant with all regulations. Because this use of borates is intimately linked with significant levels of lead compounds for which strict control measures are implemented, borates will also be strictly controlled as a consequence. In summary, use of borates in our process results in a net benefit in health and environmental impacts over the alternatives and we feel that we can fully justify their ongoing use for the foreseeable future. Justification for continued use of borates is further supported by our submission of relevant research work from the 1980s referred to earlier. We request that ECHA consider our views and our evidence in their consideration of the status of borates.	
20100422	European Oilfield Speciality Chemicals Association, Industry or trade association, United Kingdom	Submission re borates to ECHA final.pdf EOSCA wishes to emphasize that boric acid and boron salts are naturally present in vast amounts in seawater, rocks and soil. There is no evidence to indicate that these substances have any potential, to harm aquatic organisms or to accumulate in the food chain. Indeed boron is cited as a mineral essential to human and animal health and is an important contributor for algae and plant growth.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1^{st} adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification

			will not be questioned.
20100422	Industry or trade association, Company, United States	Confidential comment submitted	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the

			sweeping of dry dusts has to be avoided.
20100422	Frit Manufacturers and Importers, A.E.I.E., Industry or trade association, Spain	Frit Consortium- Comments of borates Annex XV.pdf p.1	Thank you for the information. A clarification has been added to the consumer exposure part of the annex XV dossier for boric acid.
20100422	ANFFECC, Industry or trade association, Spain	We support all the comments sent by the Frits Manufacturers and Importers A.E.I.E.	Thank you for the information. A clarification has been added to the consumer exposure part of the annex XV dossier for boric acid.
20100422	AIMPR, Industry or trade association, Spain	We support all the comments sent by the Frits Manufacturers and Importers A.E.I.E.	Thank you for the information. A clarification has been added to the consumer exposure part of the annex XV dossier for boric acid.
20100422	Individual, Italy	COMMENT RECEIVEID 25 TIMES: The identification of boric acid as SVHC and the relevant consequences will change for the worse my job, the work conditions of my employees, my life.	Your comment has been taken note of.

Specific comments on the justification

Date	Submitted by (name, Organisation/MSCA)	Comment	Response
20100318	On behalf of an organisation, Industry or trade association, Germany	Because of the closed system, the user can hardly get in touch with the hazardous boric acid.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as

			well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100409	On behalf of an organisation, European Borates Association, Industry or trade association, Belgium	EBA Comments Hazard assess Annex XV April 10 final.pdf Summary (p. 3) EBA notes that on page 3 of the Annex XV dossier on boric acid in the following paragraph: “Therefore, this classification of the substance in Commission Regulation (EC) No 790/2009 shows that the substance meets the criteria for classification as carcinogen in accordance with Article 57 (c) of REACH.” The term “carcinogen” should be replaced by “reproductive toxicant”. 3. Classification and Labelling (p. 7) It should be noted that Recital (2) of the Commission directive 2008/58/EC (30th ATP) which added certain borates including boric acid to the Dangerous Substances Directive as a	 Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are, however, aware of the pending decision of the European

		Category 2 toxicant, states that "special attention should be paid to further results of epidemiological studies on the Borates concerned by this Directive including the ongoing study conducted in China.". This study among workers in a borates mine has now been completed and peer-reviewed and confirms that there is no reproductive effect in men, which indicates even at very high exposures the effect in humans is different than the effect on laboratory animals.	General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation.
20100413	On behalf of an organisation, Fuchs Lubrifiant France, Company, France	Environmental hazard assessment	
20100413	AffiliatedWithOrganisation, Institute of Metal Finishing, Industry or trade association, United Kingdom	The controls on nickel plating baths are already very strict because of the health effects of nickel. The boric acid component is minor in comparison. Any potential health effect will be under control due to the controls relating to the nickel.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to

			be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100413	AffiliatedWithOrganisation, Industry or trade association International NGO, Belgium	svhcreaction DE.doc PLATING SHOPS EMPLOYEES WILL USE STRONG ACID EVERY MINUTE INSTEAD OF A WEAK ACID EVERY 6 WEEKS!!! A NEW BEST AVAILABLE TECHNIQUE KILLED BY THE BUREAUCRACY: TRIVALENT CHROMIUM PROCESS IS BASED ON BORIC ACID , BACK AGAIN TO HEXAVALENT CHROMIUM PROCESS???	Boric acid was proposed as SVHC based on its classification as toxic to reproduction, its wide use in consumer products, and its high production volume. Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. However, we are aware that boric acid will be registered by the end of this year and further information may become available.
20100414	AffiliatedWithOrganisation, UEIL, Industry or trade association, Belgium	The overwhelming body of evidence produced by Trade Associations such as the European Borates Association based on occupational studies in situations such as boric acid mines etc shows that the supposed reproductive toxicity effects observed in animals cannot be translated to humans. The fundamental lack of a vomit response in laboratory animals skews the results achieved on the basis that human beings would be phhysically incapable of taking on board the levels of boric acid associated with any quantifiable negative effects	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current

			classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation.
20100414	On behalf of an organisation, UEIL, Industry or trade association, Belgium	EBA comments Annex XV 100104 final.pdf In our opinion Annex XV Dossiers should not be filed until REACH Dossiers are reviewed in 2011. We support the arguments given by the European Boric acid Association (EBA).	See response to EBA comments
20100416	On behalf of an organisation, Verband Schmierstoff Industrie e.V., Industry or trade association, Germany	EBA comments Annex XV 100104 final.pdf In our opinion Annex XV Dossiers should not be filed until REACH Dossiers are reviewed in 2011. We support the arguments given by the European Boric acid Association (EBA).	See response to EBA comments
20100416	On behalf of an organisation, RWE Power AG, Company, Germany	The declaration Boron and it's compounds as a svhc should depend on the New science reports, such as the data from the Chinese boron-mining-worker-study. Furthermore no hazard exposure to staff of nuclear power plants and related industry has been reported in the past. The use of boric acid in our industry is proven to be absolutely safe and permitted by authorities.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned.
20100416	BehalfOfAnOrganisation, Fuchs Europe Schmierstoffe GmbH, Company, Germany	p 3 the conclusion on classification of Boric Acid as carcinogen is not correct. boric acid is classified as toxic for reproduction. p 14: 1.1.3.8 other products:The main application for boric acid in lubricant industry is in metal working fluids, which are not sold to the general public. Therefore Consumer use can be excluded. The concentration in lubricating oils is very low. Additionally the oils are used in closed systems. Those applications are exempt from authorisation according to Article 56(6)(b) p 23: repeated dose toxicity: oral last paragraph - calculation of the dose of boric acid and boron is not correct.	Thank you for the information.

		p 27: effects on fertility: Doses used in this study are similar to doses used in Repeated Dose Toxicity study: oral, in which all animals died at the highest dose. It seems that the Fertility effects occur in a dose range of the LD50. The correctness and credibility of this Annex XV dossier is insufficient. Boron is a benign element and an important micronutrient in nutrition and food production. It's hazard are well-known and associated risks (if any) can be adequately controlled. Therefore it seems to be disproportionate to classify it as SVHC and make it subject to authorisation.	
20100417	BehalfOfAnOrganisation, European Trade Union Confederation, Trade Union, Belgium	Boric acid is included in the Trade Union Priority List for REACH Authorisation (see http://www.etuc.org/a/6023)	Thank you for the information.
20100419	Individual, Germany	3. Fundamental facts are missing in the dossier to a) physical and chemical properties b) concentrations of Boric Acid in soil and sediment c) studies of intake at humans and animals d) new studies (China Workers Study) are not considered 4. Examinations of reproduction toxic did not follow the demands of standard (RL 67/548/EWG) at the time of examination. The demand is minimum 20 individuals per group, used are maximum 18 individuals.	Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its high production volume. Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned.
20100419	BehalfOfAnOrganisation, BMS Micro-Nutrients NV, Company, Belgium	Comments regarding the different lists.doc Dear Sir Madam Checking the lists of boric acid and borates tabulated in the ECHA "Press Release-8 March 2010" (SVHC-proposal), Regulation EC 790/2009 and the Biocide Directive 2009/96/EC, concerns about borates and boric acid are clearly expressed implying special handling precautions, specific labelling and possible exposure dangers for the final user . Many other boron compounds are appearing on the REACH "Pre-registered lists" having potentially the same chemical behaviour but apparently without any restrictions (condensed boric acid, sodium, potassium and ammonium	Boric acid was proposed as SVHC based on its classification as toxic to reproduction, its wide use in consumer products, and its high production volume to meet the criteria of REACH articles 57 and 58.

		salts). For manufacturers and transform industry (formulators) this situation poses problems concerning handling, packing and final labelling. Can it be considered that substances not appearing on the lists are not restricted to the same rules as those appearing on the restrictive lists. The selection criteria for the lists are absolutely not clear. Also the ESIS tabulation gives in many cases no further information. Joined are 3 lists of boron substances. 1. Press Release + Regulation EC 790/2009 2. Several of the Pre-registered substances not appearing on the restrictive lists (acid precursors, sodium salts) 3. Potassium, ammonium, magnesium forms Sincerely Yours Drs.Sci Camerlynck Rudi BMS Micro-Nutrients NV Rijksweg 32 B 2880 Bornem Belgium	
20100419	AffiliatedWithOrganisation, Industry or trade association National Authority, Austria	Here respective to the legal status of classification and labelling of borates and boric acid scientific literature provides clear evidence for the borates and boric acid to be toxic to reproduction.	Thank you.
20100419	BehalfOfAnOrganisation, Industry or trade association, Company, United Kingdom	Boric Acid and Disodium Tetraborates are already subject to strict regulation under a range of downstream uses and under EU regulation sensible labelling limits have been applied which recognise the relatively benign nature of these substances. There is adequate control of exposure and risk , adding Boric acid to the candidate list would lead to no public health benefits. As regards specific items in the proposal document there are several things which are in error such as terms such as carcinogen , where it should state reproductive toxicant. The dossier contains substance names which are mixed up, is quoting tonnage data which is unclear and calculated exposure values which need to be replaced by actual monitoring data.	Boric acid was proposed as SVHC based on its classification as toxic to reproduction, its wide use in consumer products, and its high production volume. The dossier was prepared using the information available by then.
20100419	Individual, France	Le brasage laiton devant s'effectuer dans la plage 890-930°C, nous devons utiliser une pâte flux qui reste efficace dans ces températures-là d'une part et qui tiennent à la flamme (notre process n'est pas au four mais à base de caroussel de brasage et de torches). Sans ce produit, notre production ne peut fonctionner.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid.

			Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100419	BehalfOfAnOrganisation, Industry or trade association, Company, Switzerland	EBA comments Annex XV 100104 final.pdf This industry or trade association finds the evaluation by ECHA was done inaccurate & untimely, given the fact that the respective REACH dossier is still under process. The classification as reproductive toxicant is still controversial and	See response to EBA comments

		there are manifold studies on human beings (not only on rats) that show clear evidence that there is no higher risk of a reproductive toxicant in boric acid for people that are living in such areas with higher contents in their evnironment as well to workers (this study in China) in boron mining.	
20100419	Industry or trade association, Company, Portugal	In our opinion Annex XV dossiers should not be filled until Reach Dossiers are reviewed in 2011. We support the arguments given by the European Boric Acid Association (EBA). Boric acid and disodium tetraborates are relatively benign, which is a fact that was recognized when the Member States experts decided on a high concentration limit and high safety threshold as part of the decision to classify these substances. Page 3: ...the substance (i.e. boric acid) meet the criteria for classification as carcinogen in accordance with Article 57 c of REACH. This is not correct – boric acid meets the criteria for classification as toxic for reproduction not as carcinogen Page 14: 1.1.3.8 Other products: The main application for boric acid in lubricant industry is in metal working fluids, which are not sold to the general public. Therefore Consumer use can be excluded. The concentration in lubricating oils is very low. Additionally the oils are used in closed systems. Those applications are exempt from authorization according to Article 56 (6) (b) Page 23: Annex I: Repeated Dose toxicity: oral last paragraph – calculation for the dose of Boric Acid and Boron is not correct in comparison to second paragraph on page 24. Page 27: Effects on fertility: Doses used in this study are similar to doses used in Repeated Dose Toxicity study: oral, in which all animals died at the highest dose. It seems that the Fertility effects occur in a dose range of the LD50.	See response to EBA comments We are aware that boric acid will be registered by the end of this year and further information may become available. Thank you for the information.
20100420	Individual, Italy	Why instead of helping the industry to compete with Asian countries, who are operating without any rules, you introduce more difficulty in working with new rules absurd? In this way, you contribute to close the European industry.	Your comment has been taken note of.
20100420	Industry or trade association, Company, Germany	In our opinion Annex XV Dossiers should not be filed until REACH Dossiers are reviewed in 2011. We support the arguments given by the European Boric acid Association (EBA).	See response to EBA comments
20100420	Industry or trade association, Belgium	Specific Comments The following specific issues are raised in relation to the proposal to identify	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to

		specific compounds of boron as SVHC: 1. The reclassification of boric acids and borates is being challenged in the courts. Without wishing to comment on the cases, we suggest that it would be preferable to wait until these cases are concluded before starting the authorisation procedure. 2. Related to these court cases, there is continuing international concern, specifically from the World Trade Organization, over the reclassification of boric acid and borates as toxic for reproduction, (Repr.1B, H360FD). We suggest that classifying them as SVHC would lead to a reopening of the issue, which we consider would be both unwelcome and unfortunate. 3. Even if points (1) and (2) are not accepted, we suggest that initiating the authorisation procedure should at the very least wait for the completion of the REACH registration documentation, which is due before December 2010. 4. The underlying case is that high concentration limits have been set in the classification and there is a long history of safe use of the substances across a wide range of applications. We believe that this is a very good justification for not starting the authorisation process. 5. It is noted that boric acid and borax are included with restrictions on the positive lists in relation to materials and articles in contact with food, for instance Directive 2002/72/EC as modified. They are additionally classified as food additives under Regulation (EC) No 1333/2008 as amended and they also have a role as food supplements. The question has to be asked if this classification is compatible with the substances being identified as SVHC. 6. Finally we would ask if there are specific areas of use of the compounds which give particular cause for concern? If this is the case we could suggest that these might be better handled through the "restrictions route", that is the use of Annex XVII of the REACH Regulation. This might be seen as a more effective route to targeting applications of concern without affecting those where there are no significant health or environmental concerns.	the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are, however, aware of the ongoing activities regarding worker studies, the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation. We are also aware that boric acid will be registered by the end of this year and further information may become available.
20100420	AffiliatedWithOrganisation, A.I.F.M., Regional or local authority, Italy	"L'INSERIMENTO DELL'ACIDO BORICO NELLA LISTA SVHC E LE CONSEGUENZE DI QUESTO FATTO CAMBIERANNO IN PEGGIO IL MIO LAVORO, LE CONDIZIONI DI LAVORO DEI MIEI DIPENDENTI , LA MIA VITA"	Your comment has been taken note of.
20100420	Individual, Italy	All plating shops that use nichel watts plating will close	The comment is appreciated.
20100420	Zeller+Gmelin GmbH & Co. KG, Company, Germany	As a member of UNITI, the sole professional German representation for small and medium sized companies producing and dealing with fuel, heating fuel and lubricants, we fully support the arguments of UNITI (see comment of UNITI). In general we also support the EUROPEAN BORATES ASSOCIATION	See response to EBA comments

		COMMENTS ON ANNEX XV DOSSIERS.	
20100420	Industry or trade association, Company, United Kingdom	ECHA Reference Document 1.docx ECHA Reference Document 2.pdf ECHA Reference Document 3.pdf ECHA Reference Document 4.pdf ECHA Reference Document 5.pdf ECHA Reference Document 6.pdf ECHA Reference Document 7.pdf ECHA Reference Document 8.pdf ECHA Reference Document 9.pdf ECHA Reference Document 10.pdf A human with a body weight of 60kg would not typically work as either an industrial paint maker or an industrial high performance coating applicator. A more realistic average body weight is closer to 80kg. This would give a NO(A)EL daily intake of 1,360 mg/day. • Average breathing rate 15 / min • Average breath volume 0.5L / breath • $1m^3$ of air contains 2.3mg of dust (measured on-site) • $1m^3$ of air equals 2000 breaths • 133 minutes to consume $1m^3$ of air • Inhale $4m^3$ in a shift • Inhale 9.2mg of dust per day • Theoretical boric acid concentration in dust < 75% • This equates to < 7mg Boric Acid per day • For an 80Kg worker – NO(A)EL=1360mg/day • Industrial Exposure < 7mg/day • =0.5% of NO(A)EL Boric acid is used in epoxy materials which require that skin protection is given a high priority, therefore both workers and professional site applicators of this	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.

		industry or trade association wear gloves, which will result in lower dermal exposure. The use of these products is restricted to professional contractors, who have to be approved to install the material due to the safety critical nature of the products end use. The general public are therefore not at risk. Once the material has cured up, the boric acid is encapsulated within an epoxy resin matrix. There is no release of the boric acid as a consequence of the encapsulation. Therefore there is no dermal, inhalation or ingestion exposure risk to individuals who may come into contact with articles protected with epoxy intumescent coatings containing boric acid.	
20100420	The Association of Contact Lens Manufacturers Ltd, Industry or trade association, United Kingdom	Classification and labeling Annex XV does not offer the specific safe concentration limits for boric acid and disodium tetraborate for human exposure. Therefore, it is assumed that only 0.1% w/w is the concentration below which substances would be considered exempted from the authorization per Directive 1999/45/EC. However, Annex XV does refer to the RPA report (2008) which offers the specific limit based on No Observable Adverse Effect Level (NOAEL) values obtained in animal studies (also included in Annex XV) and additional safety factor thus providing a scientifically justified acceptable human exposure level also commonly used in risk evaluations. In addition, the 30th Adaptation to Technical Progress (ATP) of Council Directive 67/548/EEC (paragraph 2.32) provides the following borate classification: “In the course of discussions it was clear that the available evidence justifies the establishment of a specific concentration limits for borates, higher than the generic concentration limit for substances toxic for reproduction of 0.1%. The TC C&L (Technical Committee on Classification and Labeling) experts therefore decided that a concentration limit of 5.5 percent for boric acid is appropriate, based on the level at which no adverse effects is seen for the substance. The other borate compounds have been given a specific concentration limit based on their boric acid content”. Concentration limits of 5.5% and 4.5% for boric acid and disodium tetraborate, respectively were identified in Commission Directive 2008/58. Thus, we propose to be more specific and include the previously published concentration limits into Annex XV as exemption condition.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation.
20100420	Chambre Syndicale Nationale de l'Industrie des Lubrifiants, Industry or trade association, France	EBA comments Annex XV 100104 final.pdf From our point of view, Annex XV Dossiers should not be filed until REACH Dossiers are reviewed in 2011. We support the arguments given by the European Boric acid Association (EBA).	See response to EBA comments

20100420	UNITI, Industry or trade association, Germany	EBA comments Annex XV 100104 final.pdf Generally, we fully the support the arguments of the European Boric Acid association (EBA). As the German member representation in UEIL we also agree to the UEIL position.	See response to EBA comments
20100421	Rhenus Lub GmbH & Co KG, Company, Germany	EBA comments Annex XV 100104 final.pdf We support the arguments given by the European Boric Association (EBA). In our opinion the Annex VX Dossier should not be filed until the REACH Dossiers are reviewed in 2011.	See response to EBA comments
20100421	Proviron Industries, Company, Belgium	boric acid comments19042010 .doc Proviron Industries nv A. INTRODUCTION 1 In February 2010, German/Slovenia submitted a dossier under Article 59(3) and Annex XV REACH for the substance boric acid. The dossier proposes to identify boric acid as a toxic for reproduction cat 2 substance according to Article 57(c) REACH. 2 The dossier was posted on the website of the European Chemicals Agency ("ECHA") On March 2010 and the deadline for submitting comments is 22 April 2010. 3 This position paper presents the comments of Proviron Industries nv on the Annex XV SVHC dossier for boric acid drafted and submitted to ECHA by the German/Slovenia under Article 59(3) REACH (hereinafter the "dossier"). B. COMMENTS ON THE ANNEX XV SVHC DOSSIER 1 Under section 1 (information on exposure), the dossier states the following in	Thank you for the information. "Brake fluids" have been reported to the Swedish product register as a use

		respect to the uses of boric acid in the European Union :“use categories communicated to the Swedish Product Register for boric acid in 2008(cas Nr 10043-35-3 and 11113-50-1, KEMI 2009 include:(….) Brake fluids”. 2 The crucial point is that the use of boric acid related to brake fluids, falls under the definition of intermediates under REACH. 3 The wording in the dossier suggests that boric acid is present in brake fluids. However, this use of boric acid clearly meet the definition of on-site and transported intermediates as defined under REACH, as explained below. 4 Article 3(15) REACH defines intermediate as “a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance . On-site isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an) other substance(s) from that intermediate take place on the same site, operated by one or more legal entities; Transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites.” Proviron Industries nv C. AS AN INTERMEDIATE, BORIC ACID RELATED TO BRAKE FLUIDS CANNOT BE COVERED BY TITLE VII AND THE IDENTIFICATION PROCEDURES PROVIDED THEREIN (INCLUDING IN ARTICLE 57) ARE NOT APPLICABLE IN THIS CASE. 1 According to Article 2(8) REACH, on-site isolated intermediates and transported isolated intermediates are exempt from Title VII REACH. This means that, because it is always used as an on-site or transported intermediate in the production of brake fluids, boric acid related to brake fluid cannot be subject to any identification or other procedure laid down in Title VII, including listing in the candidate list or in	category for boric acid.

		Annex XIV to REACH. 2 As a result, the categorisation of boric acid -as far as it relates to brake fluids- as a SVHC therefore lacks support in a legal provision. D. CONCLUSION 1 The Annex XV SVHC dossier on boric acid submitted by the German/Slovenia in February 2010 covers, the use of boric acid related to brake fluids This use clearly meets the definition of an on-site or transported isolated intermediate (as defined in Article 3(15) REACH). All such uses of the substance boric acid are exempt from title VII REACH according to Article 2(8)(b) REACH. 2 Consequently, the dossier cannot be used for the purposes of the procedures laid down in Title VII, as far as it relates to the use of boric acid in brake fluids. 3 Accordingly, the Annex XV dossier submitted by the German/Slovenia lacks legal basis, as far as its relates to the use of boric acid in brake fluids, and the reference to the use of brake fluid must be withdrawn from the dossier. * * * Proviron Industries nv A. INTRODUCTION 1 In February 2010, German/Slovenia submitted a dossier under Article 59(3) and Annex XV REACH for the substance boric acid. The dossier proposes to identify boric acid as a toxic for reproduction cat 2 substance according to Article 57(c) REACH. 2 The dossier was posted on the website of the European Chemicals Agency (“ECHA”) On March 2010 and the deadline for submitting comments is 22 April 2010.	

		3 This position paper presents the comments of Proviron Industries nv on the Annex XV SVHC dossier for boric acid drafted and submitted to ECHA by the German/Slovenia under Article 59(3) REACH (hereinafter the "dossier"). B. COMMENTS ON THE ANNEX XV SVHC DOSSIER 1 Under section 1 (information on exposure), the dossier states the following in respect to the uses of boric acid in the European Union :"use categories communicated to the Swedish Product Register for boric acid in 2008(cas Nr 10043-35-3 and 11113-50-1, KEMI 2009 include:(….) Brake fluids". 2 The crucial point is that the use of boric acid related to brake fluids, falls under the definition of intermediates under REACH. 3 The wording in the dossier suggests that boric acid is present in brake fluids. However, this use of boric acid clearly meet the definition of on-site and transported intermediates as defined under REACH, as explained below. 4 Article 3(15) REACH defines intermediate as "a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance . On-site isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an) other substance(s) from that intermediate take place on the same site, operated by one or more legal entities; Transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites." Proviron Industries nv	

		C. AS AN INTERMEDIATE, BORIC ACID RELATED TO BRAKE FLUIDS CANNOT BE COVERED BY TITLE VII AND THE IDENTIFICATION PROCEDURES PROVIDED THEREIN (INCLUDING IN ARTICLE 57) ARE NOT APPLICABLE IN THIS CASE. 1 According to Article 2(8) REACH, on-site isolated intermediates and transported isolated intermediates are exempt from Title VII REACH. This means that, because it is always used as an on-site or transported intermediate in the production of brake fluids, boric acid related to brake fluid cannot be subject to any identification or other procedure laid down in Title VII, including listing in the candidate list or in Annex XIV to REACH. 2 As a result, the categorisation of boric acid -as far as it relates to brake fluids- as a SVHC therefore lacks support in a legal provision. D. CONCLUSION 1 The Annex XV SVHC dossier on boric acid submitted by the German/Slovenia in February 2010 covers, the use of boric acid related to brake fluids This use clearly meets the definition of an on-site or transported isolated intermediate (as defined in Article 3(15) REACH). All such uses of the substance boric acid are exempt from title VII REACH according to Article 2(8)(b) REACH. 2 Consequently, the dossier cannot be used for the purposes of the procedures laid down in Title VII, as far as it relates to the use of boric acid in brake fluids. 3 Accordingly, the Annex XV dossier submitted by the German/Slovenia lacks legal basis, as far as its relates to the use of boric acid in brake fluids, and the reference to the use of brake fluid must be withdrawn from the dossier. * * *	
2010421	Euromcontact, Industry or trade association, Belgium	Classification and labeling Annex XV does not offer the specific safe concentration limits for boric acid and disodium tetraborate for human exposure. Therefore, it is assumed that only 0.1%	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to

		w/w is the concentration below which substances would be considered exempted from the authorization per Directive 1999/45/EC. However, Annex XV does refer to the RPA report (2008) which offers the specific limit based on No Observable Adverse Effect Level (NOAEL) values obtained in animal studies (also included in Annex XV) and additional safety factor thus providing a scientifically justified acceptable human exposure level also commonly used in risk evaluations. In addition, the 30th Adaptation to Technical Progress (ATP) of Council Directive 67/548/EEC (paragraph 2.32) provides the following borate classification: "In the course of discussions it was clear that the available evidence justifies the establishment of a specific concentration limits for borates, higher than the generic concentration limit for substances toxic for reproduction of 0.1%. The TC C&L (Technical Committee on Classification and Labeling) experts therefore decided that a concentration limit of 5.5 percent for boric acid is appropriate, based on the level at which no adverse effects is seen for the substance. The other borate compounds have been given a specific concentration limit based on their boric acid content". Concentration limits of 5.5% and 4.5% for boric acid and disodium tetraborate, respectively were identified in Commission Directive 2008/58. Thus, we propose to be more specific and include the previously published concentration limits into Annex XV as exemption condition.	the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation.
20100421	Industry or trade association, Company, United Kingdom	Borates Objection ECHA.pdf Please see attached confidential information	Boric acid was proposed as SVHC based on its classification as toxic to reproduction, its use in consumer products, and its high production volume. However, we are aware that boric acid will be registered by the end of this year and further information may become available.
20100421	MSCA, United Kingdom	The substance is classified as toxic to reproduction, cat 2 and hence the criteria for an SVHC are met.	Thank you.
20100421	VGB PowerTech e.V., Industry or trade association, Germany	Without using boric acid it is impossible to produce electricity with light water reactors. There is no substitute available.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was

			estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100421	FUCHS Lubrificanti S.p.A., Company, Italy	p.14 - The percentage of boric acid is often less then 5% in these concentrates and emulsions in service are generally between 5 and 10%; this means that boric acid in emulsions in use is below 0.5%. Several studies showed that usually metalworking fluids mist in working area is about 1 mg/m3; consequently boric acid concentration in oil mist is less that 0.01 mg/m3, a very low value (in Germany a health risk exposure limit was fixed at 2.6 mg/m3).	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was

			estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100421	AIFM, Industry or trade association, Italy	It enables the substitution of hexavalent chromium bath	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model

			which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided. Socioeconomic aspects and substitution may be addressed when an application for authorization becomes necessary.
20100421	UKLA Metalworking Fluid Product Stewardship Group, Industry or trade association, United Kingdom	EBA comments Annex XV 100104 final.pdf We support the arguments given by the European Borates Association (EBA) and in our opinion Annex XV Dossiers should not be filed until the REACH Dossiers are reviewed in 2011.	See response to EBA comments

20100421	Industry or trade association, Company, Germany	Confidential comment submitted	Boric acid was proposed as SVHC based on its classification as toxic to reproduction, its use in consumer products, and its high production volume. However, we are aware that boric acid will be registered by the end of this year and further information may become available.
20100421	Eye-Care Industries European Economic Interest Grouping, Industry or trade association, United Kingdom	Boric acid and borates - response from Eye-Care Industries - REACH.pdf Classification and labelling Annex XV does not offer the specific safe concentration limits for boric acid and disodium tetraborate for human exposure. Therefore, it is assumed that only 0.1% w/w is the concentration below which substances would be considered exempted from the authorization per Directive 1999/45/EC. However, Annex XV does refer to the RPA report (2008)* which offers the specific limit based on No Observable Adverse Effect Level (NOAEL) values obtained in animal studies (also included in Annex XV) and additional safety factor thus providing a scientifically justified acceptable human exposure level also commonly used in risk evaluations. In addition, the 30th Adaptation to Technical Progress (ATP) of Council Directive 67/548/EEC (paragraph 2.32) † provides the following borate classification: 'In the course of discussions it was clear that the available evidence justifies the establishment of a specific concentration limits for borates, higher than the generic concentration limit for substances toxic for reproduction of 0.1%. The TC C&L (Technical Committee on Classification and Labelling) experts therefore decided that a concentration limit of 5.5 percent for boric acid is appropriate, based on the level at which no adverse effects is seen for the substance. The other borate compounds have been given a specific concentration limit based on their boric acid content'. * Risk & Policy Analysts Limited (RPA), 2008: Assessment of the risk to consumers from borates and the impact of potential restrictions on their marketing and Use. Final report – November 2008, prepared for European commission, DG Enterprise and Industry. † Commission Directive 2008/58/EC. 21 August 2008. Amending, for the purpose	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation.

		of its adaptation to technical progress, for the 30th time, Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Concentration limits of 5.5% and 4.5% for boric acid and disodium tetraborate, respectively, were identified in Commission Directive 2008/58. It is proposed that the text be more specific and include the previously published concentration limits into Annex XV as an exemption condition.	
20100421	Industry or trade association, Company, Luxembourg	EBA comments Annex XV 100104 final.pdf 1. Classification of this substance (category “2” under DSD; thus, category ”1B” under CLP regulation) is subject to legal challenge in case T-539/08, which argues that “seven Member States in the Technical Progress Committee were opposed to the category 2 classification, preferring a category 3 classification". Their votes would have been sufficient to block the proposal. The category 2 classification was only adopted due to the bundling of the proposed classifications into one package. 2. Please also see attached pdf file especially for the human health hazard assessment.	See response to EBA comments Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation.
20100421	MSCA, France	Another IUPAC name of boric acid is trihydroxiboron.	The comment is appreciated.
20100421	Cimcool Industrial Products B.V., Company, Netherlands	EBA comments Annex XV 100104 final.pdf In our opinion Annex XV Dossiers should not be filed until REACH Dossiers are reviewed in 2011. We support the arguments given by the European Borates Association (EBA).	See response to EBA comments
20100421	Cimcool Europe B.V., Company, Netherlands	EBA comments Annex XV 100104 final.pdf	See response to EBA comments

		In our opinion Annex XV Dossiers should not be filed until REACH Dossiers are reviewed in 2011. We support the arguments given by the European Borates Association (EBA).	
20100421	Cimcool Europe B.V.-Italian branch, Company, Italy	EBA comments Annex XV 100104 final.pdf In our opinion Annex XV Dossiers should not be filed until REACH Dossiers are reviewed in 2011. We support the arguments given by the European Borates Association (EBA).	See response to EBA comments
2010421	Cimcool Polska Sp. z o.o., Company, Poland	EBA comments Annex XV 100104 final.pdf In our opinion Annex XV Dossiers should not be filed until REACH Dossiers are reviewed in 2011. We support the arguments given by the European Borates Association (EBA).	See response to EBA comments
2010421	Cimcool Europe B.V.-Swedish branch, Company, Sweden	EBA comments Annex XV 100104 final.pdf In our opinion Annex XV Dossiers should not be filed until REACH Dossiers are reviewed in 2011. We support the arguments given by the European Borates Association (EBA).	See response to EBA comments
2010421	Cimcool Europe B.V.- Czech Branch, Company, Czech Republic	EBA comments Annex XV 100104 final.pdf In our opinion Annex XV Dossiers should not be filed until REACH Dossiers are reviewed in 2011. We support the arguments given by the European Borates Association (EBA).	See response to EBA comments
2010421	Cimcool Europe B.V.- Slovak Branch, Company, Slovakia	EBA comments Annex XV 100104 final.pdf In our opinion Annex XV Dossiers should not be filed until REACH Dossiers are reviewed in 2011. We support the arguments given by the European Borates Association (EBA).	See response to EBA comments
2010421	EURIMA, Industry or trade association, Belgium	Boron in Glass Wool Insulation GTS Final.pdf Article Risk assessment Boron in glass wool insulation Environ Sci Pollut Res 2009 A.A. Jensen.pdf Page 23 – section 2.1.2; Borates are used in the manufacture of glass wool insulation and impart a number of important and valuable properties to the finished product. In addition to the properties described in paragraph 2 of this section, Boron is beneficial in aiding the following important properties both in the production process and post production:- • Viscosity, • Liquidus temperature.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships

		• Surface tension. • Thermal conductivity, • Hydrolytic resistance. • Bio-solubility. While borates are used as a raw material for glass production, they are modified during the melting process and chemically bonded within the vitreous glass structure, they are not available for release during normal use of the products and do not represent any risk to users of glass mineral wool insulation products. Page 33 – section 3.1, while the industry acknowledges the existence of Boron free glass fibres for reinforcement purposes. But there is no boron free glass wool insulation manufacture available. The technology to produce reinforcement glass fibres is quite different of that to produce glass wool.	(EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided. The cited document is not the annex XV dossier for boric acid.

2010421	Cimcool Europe B.V.-UK branch, Company, United Kingdom	EBA comments Annex XV 100104 final.pdf In our opinion Annex XV Dossiers should not be filed until REACH Dossiers are reviewed in 2011. We support the arguments given by the European Borates Association (EBA).	See response to EBA comments
2010421	Cimcool Europe B.V.- France branch, Company, France	EBA comments Annex XV 100104 final.pdf In our opinion Annex XV Dossiers should not be filed until REACH Dossiers are reviewed in 2011. We support the arguments given by the European Borates Association (EBA).	See response to EBA comments
2010421	Federchimica, Industry or trade association, Italy	3. Classification and Labelling (p. 7) It should be noted that Recital (2) of the Commission directive 2008/58/EC (30th ATP) which added certain borates including boric acid to the Dangerous Substances Directive as a Category 2 toxicant, states that "special attention should be paid to further results of epidemiological studies on the Borates concerned by this Directive including the ongoing study conducted in China.". This study among workers in a borates mine has now been completed and peer-reviewed and confirms that there is no reproductive effect in men, which indicates even at very high exposures the effect in humans is different than the effect on laboratory animals.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation.
20100421	Cimcool Europe B.V.-German branch, Company, Germany	EBA comments Annex XV 100104 final.pdf In our opinion Annex XV Dossiers should not be filed until REACH Dossiers are reviewed in 2011.	See response to EBA comments

		We support the arguments given by the European Borates Association (EBA). In our opinion Annex XV Dossiers should not be filed until REACH Dossiers are reviewed in 2011. We support the arguments given by the European Borates Association (EBA).	
20100421	Bausch & Lomb, Inc, Medical Device and Pharmaceutical manufacturer, United States	Classification and labeling Annex XV does not describe a specific safe concentration limit for boric acid and disodium tetraborate for human exposure. Therefore, it is assumed that only 0.1% w/w is the concentration below which substances would be considered exempted from the authorization per Directive 1999/45/EC. Annex XV does refer to the RPA report (2008) which offers the specific limit based on No Observable Adverse Effect Level (NOAEL) values obtained in animal studies (also included in Annex XV) and additional safety factor thus providing a scientifically justified acceptable human exposure level also commonly used in risk evaluations. In addition, the 30th Adaptation to Technical Progress (ATP) of Council Directive 67/548/EEC (paragraph 2.32) provides the following borate classification: "In the course of discussions it was clear that the available evidence justifies the establishment of a specific concentration limits for borates, higher than the generic concentration limit for substances toxic for reproduction of 0.1%. The TC C&L (Technical Committee on Classification and Labeling) experts therefore decided that a concentration limit of 5.5 percent for boric acid is appropriate, based on the level at which no adverse effects is seen for the substance. The other borate compounds have been given a specific concentration limit based on their boric acid content". Concentration limits of 5.5% and 4.5% for boric acid and disodium tetraborate, respectively were identified in Commission Directive 2008/58. Thus, we propose to be more specific and include the previously published concentration limits into Annex XV as exemption condition.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation.
20100421	AFILUB, Industry or trade association, Spain	EBA comments Annex XV 100104 final.pdf In our opinion Annex XV should not be filed until REACH dossiers are reviewed in 2011. We support the arguments given by the European Boric acid association (EBA).	See response to EBA comments
20100421	MSCA, Ireland	The Irish Competent Authority agrees with the identification of boric acid as a substance meeting the criteria set out in Article 57 of REACH.	Thank you.
20100421	Federchimica-Gail, Industry or trade association, Italy	EBA comments Annex XV 100104 final.pdf In our opinion Annex XV Dossiers should not be filed until REACH Dossiers are reviewed in 2011. We support the arguments given by the European Boric acid Association (EBA).	See response to EBA comments

20100421	INKABOR S.A.C., Company, Peru	Inkabor notes that on page 3 of the Annex XV dossier on boric acid in the following paragraph: “Therefore, this classification of the substance in Commission Regulation (EC) No 790/2009 shows that the substance meets the criteria for classification as carcinogen in accordance with Article 57 (c) of REACH.” The term “carcinogen” should be replaced by “reproductive toxicant”	Thank you. The wording was amended.
20100421	Individual, Germany	How do you explain the absence of any significant data from the various studies which have been conducted involving human beings? Is there any study available which proves the toxicity level stated by the EU Commission last year? Is there any evidence that such levels (e.g. 13.7 mg B/kg/ bw/day would be or ever were consumed by a human being? The conclusion that these data could be transferred to a situation for human beings cannot be accepted. I challenge that assumption and I ask for evidence that this may be the case other than by criminal force or by abuse as an attempt to commit suicide.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation.
20100421	Industry or trade association, Company, Albania	EBA comments Annex XV 100104 final.pdf In our opinion Annex XV Dossiers should not be filed until REACH Dossiers are reviewed in 2011. We support the arguments given by the European Boric acid Association (EBA).	See response to EBA comments
20100421	CPIV, Industry or trade association, Belgium	Statement on Exposure to Borates and REACH.pdf Please see attached document.	See response to EBA comment. Alternatives should be discussed in case an application for authorisation becomes necessary.
20100421	Industry or trade association, Company, Germany	In our opinion Annex XV Dossiers should not be filed until REACH Dossiers are reviewed in 2011. We support the arguments given by the European Boric acid Association (EBA).	See response to EBA comments
20100421	Bundesverband Glasindustrie e.V., Industry or trade association, Germany	EBA comments Annex XV 100104 final.pdf CPIV Statement on Exposure to Borates and REACH.pdf	See response to EBA comment. Alternatives should be discussed in case an application for authorisation

		VBG Borauswertung_Glas.pdf	becomes necessary.
20100421	Eucomed, Industry or trade association, Belgium	Annex XV does not offer the specific safe concentration limits for boric acid and disodium tetraborate for human exposure. Therefore, it is assumed that only 0.1% w/w is the concentration below which substances would be considered exempted from the authorization per Directive 1999/45/EC. However, Annex XV does refer to the RPA report (2008) which offers the specific limit based on No Observable Adverse Effect Level (NOAEL) values obtained in animal studies (also included in Annex XV) and additional safety factor thus providing a scientifically justified acceptable human exposure level also commonly used in risk evaluations. In addition, the 30th Adaptation to Technical Progress (ATP) of Council Directive 67/548/EEC (paragraph 2.32) provides the following borate classification: "In the course of discussions it was clear that the available evidence justifies the establishment of a specific concentration limits for borates, higher than the generic concentration limit for substances toxic for reproduction of 0.1%. The TC C&L (Technical Committee on Classification and Labelling) experts therefore decided that a concentration limit of 5.5 percent for boric acid is appropriate, based on the level at which no adverse effects is seen for the substance. The other borate compounds have been given a specific concentration limit based on their boric acid content". Concentration limits of 5.5% and 4.5% for boric acid and disodium tetraborate, respectively were identified in Commission Directive 2008/58. Thus, we propose to be more specific and include the previously published concentration limits into Annex XV as exemption condition.	Authorisation applies to all uses of a substance regardless of specific concentration limits. 0.1% w/w is the limit for the requirements according to Art. 33 of REACH.
20100421	Industry or trade association, Belgium	It is understood that the classification as SVHC follows from the substance at stake being classified as CMR. Also, we understand this classification is being challenged, but we do not directly hold necessary information to comment on this specific point. Please read this in conjunction with next section	Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its high production volume. So far, boric acid meets as well the criteria according to REACH article 57c as those of article 58.
20100421	BP International Ltd, Company, United Kingdom	BP supports the arguments of ILMA, UKLA and the European Boric acid Association (EBA). In our opinion Annex XV Dossiers should not be filed until the REACH Dossiers are reviewed in 2011.	See response to EBA comments
20100421	Industry or trade association, Company, United Kingdom	p.7 Classification and labelling More consideration should be given to the Chinese epidemological studies where	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st

		there has been no reproductive effect on male mine workers.	adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned.
20100421	Industry or trade association, Company, Ireland	Classification and labeling The Annex XV proposal does not offer the specific safe concentration limits for boric acid and disodium tetraborate for human exposure. Therefore, it is assumed that only 0.1% w/w is the concentration below which substances would be considered exempted from the authorisation per Directive 1999/45/EC. However, Annex XV does refer to the RPA report (2008) which offers the specific limit based on No Observable Adverse Effect Level (NOAEL) values obtained in animal studies (also included in Annex XV) and additional safety factor thus providing a scientifically justified acceptable human exposure level also commonly used in risk evaluations. In addition, the 30th Adaptation to Technical Progress (ATP) of Council Directive 67/548/EEC (paragraph 2.32) provides the following borate classification: “In the course of discussions it was clear that the available evidence justifies the establishment of a specific concentration limits for borates, higher than the generic concentration limit for substances toxic for reproduction of 0.1%. The TC C&L (Technical Committee on Classification and Labeling) experts therefore decided that a concentration limit of 5.5 percent for boric acid is appropriate, based on the level at which no adverse effects is seen for the substance. The other borate compounds have been given a specific concentration limit based on their boric acid content”. Concentration limits of 5.5% and 4.5% for boric acid and disodium tetraborate, respectively were identified in Commission Directive 2008/58. It is proposed that ECHA be more specific and include the previously published concentration limits into any Annex XV as exemption condition.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We recognise the discrepancy between the specific concentration limit and the limi t0.1 % mentioned in REACH Art. 33.
20100420	Jones Fiber Products, Inc, Company, United States	Binder1.pdf Pages 6,7,8 and 9 of Dr Jay Murray's report.	Dr. Murray`s report has been cited in the annex XV dossier.
20100422	Industry or trade association, Company, United Kingdom	We have only just been made aware of the proposal to classify this chemical as a SVHC. Given the limited time to prepare a detailed response, the comments above are our initial views and we can provide additional information as required.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave

			measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100422	StonCor Europe, Company, Belgium	EBA comments Annex XV (00059414).PDF Memo to ECHA on behalf of StonCor re boric acid (00059408).PDF Please see appended documents.	See response to EBA comments
20100422	Alcon Laboratories, Inc, Company, United States	Classification and labeling	Boric acid has been classified as toxic to reproduction category 1B with

		Annex XV does not offer the specific safe concentration limits for boric acid and disodium tetraborate for human exposure. Therefore, it is assumed that only 0.1% w/w is the concentration below which substances would be considered exempted from the authorization per Directive 1999/45/EC. However, Annex XV does refer to the RPA report (2008) which offers the specific limit based on No Observable Adverse Effect Level (NOAEL) values obtained in animal studies (also included in Annex XV) and additional safety factor thus providing a scientifically justified acceptable human exposure level also commonly used in risk evaluations. In addition, the 30th Adaptation to Technical Progress (ATP) of Council Directive 67/548/EEC (paragraph 2.32) provides the following borate classification: "In the course of discussions it was clear that the available evidence justifies the establishment of a specific concentration limits for borates, higher than the generic concentration limit for substances toxic for reproduction of 0.1%. The TC C&L (Technical Committee on Classification and Labeling) experts therefore decided that a concentration limit of 5.5 percent for boric acid is appropriate, based on the level at which no adverse effects is seen for the substance. The other borate compounds have been given a specific concentration limit based on their boric acid content". Concentration limits of 5.5% and 4.5% for boric acid and disodium tetraborate, respectively were identified in Commission Directive 2008/58. Thus, we propose to be more specific and include the previously published concentration limits into Annex XV as exemption condition.	directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We recognize the discrepancy between this and the limit of 0.1% mentioned in REACH Art. 33. This may be subject to the revision of REACH.
20100422	Bausch & Lomb Inc, Company, United States	Classification and labeling Annex XV does not offer the specific safe concentration limits for boric acid and disodium tetraborate for human exposure. Therefore, it is assumed that only 0.1% w/w is the concentration below which substances would be considered exempted from the authorization per Directive 1999/45/EC. However, Annex XV does refer to the RPA report (2008) which offers the specific limit based on No Observable Adverse Effect Level (NOAEL) values obtained in animal studies (also included in Annex XV) and additional safety factor thus providing a scientifically justified acceptable human exposure level also commonly used in risk evaluations. In addition, the 30th Adaptation to Technical Progress (ATP) of Council Directive 67/548/EEC (paragraph 2.32) provides the following borate classification: "In the course of discussions it was clear that the available evidence justifies the establishment of a specific concentration limits for borates, higher than the generic concentration limit for substances toxic for reproduction of 0.1%. The TC C&L (Technical Committee on Classification and Labeling) experts therefore decided that a concentration limit of 5.5 percent for boric acid is appropriate, based on the level at which no adverse effects is seen for the substance. The other borate	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We recognize the discrepancy between this and the limit of 0.1% mentioned in REACH Art. 33. This may be subject to the revision of REACH.

		compounds have been given a specific concentration limit based on their boric acid content". Concentration limits of 5.5% and 4.5% for boric acid and disodium tetraborate, respectively were identified in Commission Directive 2008/58. Thus, we propose to be more specific and include the previously published concentration limits into Annex XV as exemption condition.	
20100422	Council of Europe, Directorate for the Quality of Medicines and HealthCare, European governmental organisation, France	Boric acid is used in a wide range of test solutions, mainly for buffers in the quality control of materials used for medicinal products. Although the European Pharmacopoeia use falls under article 56(3) and the European Pharmacopoeia is continuously seeking for alternatives to substances of very high concern, this substance should remain available on the market to enable the quality control of raw materials used in medicinal products.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction

			of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100422	Industry or trade association, Company, United Kingdom	Use of boric acid in medical devices supported by industry representative body, Eucomed.	The comment is appreciated.
20100422	Individual, Germany	Letter_Bolt_ECHA.pdf Summary, pages 35/36: The now available quantitative data on human exposure (see my "General Comments") are by far not adequately considered in the Dossier. For details, I refer to the uploaded attachment.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation. We are also aware that boric acid will be registered by the end of this year and further information may become available.
20100422	Individual, Denmark	Human data AND Summary and discussion of reproductive toxicity, p 35 There are sound reasons to be concerned about the reproductive toxicity of boron based upon the extensive and consistent animal experimental data that is summarized in the annex to the proposal. Unfortunately human data on this issue are limited. Few studies on fertility rates in various populations are not providing reliable information on reproductive toxicity in humans as fertiliy rates are a very crude and insensitive indicator of fecundity. There is, however, one Chinese study of semen quality in workers with well characterized exposure data that clearly indicate that human males are not more sensitive to the testicular toxicity of Boron than dogs, rabbits, mice and rats. It is correct that 'epidemiological studies in	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid

		humans are insufficient to demonstrate the absence of an adverse effect of inorganic borates on fertility' (as stated in BORIC ACID ANNEX XV DOSSIER FOR THE IDENTIFICATION AS SVHC, p 36), but epidemiological studies almost never exclude a health risk. Although results of one epidemiological study should not be overstated, the findings of the comprehensive Chinese study (for a review se Scialli et al. Reprod Toxicol. 2010 Jan;29(1):10-24) clearly show that the expected effects on semen charateristics are not seen at exposure levels that are high in comparison with other human exposure scenarios. This important information is not appropriately accounted for in the justification for labeling boron as a compound of very high concern. In short, knowledge is sufficient to indicate that reproductive effects at exposure levels that are relevant for humans are unlikely. This is supported by findings in a recent publication concluding 'No significant correlations were found between blood or urine boron and adverse semen parameters. Exposures did not reach those causing adverse effects published in animal toxicology work but exceeded those previously published for boron occupational groups' (Robbins WA et al.Reprod Toxicol. 2010 Apr;29(2):184-90). There are sound reasons to be concerned about the reproductive toxicity of boron based upon the extensive and consistent animal experimental data that is summarized in the annex to the proposal. Unfortunately human data on this issue are limited. Few studies on fertility rates in various populations are not providing reliable information on reproductive toxicity in humans as fertiliy rates is a very crude and insensitive indicator of fecundity. There is, however, one Chinese study of semen quality in workers with well characterized exposure data that clearly indicate that human males are not more sensitive to the testicular toxicity of Boron than dogs, rabbits, mice and rats. It is correct that 'epidemiological studies in humans are insufficient to demonstrate the absence of an adverse effect of inorganic borates on fertility' (as stated in BORIC ACID ANNEX XV DOSSIER FOR THE IDENTIFICATION AS SVHC, p 36), but epidemiological studies almost never exclude a health risk. Although results of one epidemiological study should not be overstated, the findings of the comprehensive Chinese study (for a review se Scialli et al. Reprod Toxicol. 2010 Jan;29(1):10-24) clearly show that the expected effects on semen charateristics are not seen at exposure levels that are high in comparison with other human exposure scenarios. This important information is not appropriately accounted for in the justification for labeling boron as a compound of very high concern. In short, knowledge is sufficient to indicate that reproductive effects at exposure levels that are relevant for humans are unlikely. This is supported by findings in a recent publication concluding 'No significant correlations were found between blood or urine boron and adverse semen parameters. Exposures	and the Commission proposal to include boric acid in Annex XVII of the REACH regulation. We are also aware that boric acid will be registered by the end of this year and further information may become available.

		did not reach those causing adverse effects published in animal toxicology work but exceeded those previously published for boron occupational groups' (Robbins WA et al.Reprod Toxicol. 2010 Apr;29(2):184-90).	
20100422	Industry or trade association, Belgium	See attachment	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation. Boric acid was proposed as SVHC based on its classification as toxic to reproduction, its wide use in consumer products, and its high production volume. However, we are aware that boric acid will be registered by the end of this year and further information may become available. Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as

			well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100422	Industry or trade association, Company, Germany	Biotest.xls In our opinion Annex XV Dossiers should not be filed until REACH Dossiers are reviewed in 2011. We support the arguments given by the European Boric acid Association (EBA)	See response to EBA comments
20100422	Fuchs Austria Schmiermittel GmbH, Company, Austria	Very good buffer capacity, thus much more robust against microbial attacks than any other products No acquisition problems Good price performance ratio In use without problems in the industry for many years No alternatives were found, despite intensive research All alternative formulations are, due to reduced buffer capacity, much less robust	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was

		against bacterial attacks leading to increased usage of biocides, which from a health, safety and environment perspective is undesirable. The lifetime of alternative formulations is significantly lower, resulting in a more frequent change and will have a higher consumption of resources and thus is poorer from a sustainability standpoint. Lastly, the alternative formulations that use higher biocide levels are coupled with increased disposal rates and these higher waste levels will cause increased pressures on the environment	estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100422	MSCA, Austria	Based on its classification as toxic for reproduction category 2 boric acid clearly fulfils the criteria according to article 57(c) of REACH.	Thank you
20100422	UITS, Industry or trade association, France	USE OF BORIC ACID IN SURFACE FINISHING.pdf Borid acid is used in many industrial sectors. Boric acid is used in surface treatment preparation and can't be remplace by another substance.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air.

			Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100422	Chemservice S.A. / REACH Zinc-Borate Consortium, Industry or trade association, Luxembourg	EFSA opinion on BA and STB as food add 80.pdf EFSA PUB Statement of AFC on BA and ST as nutrient sources of boron.pdf A decision on SVHC status should not be taken based on the available information and is pre-mature. Boric Acid is a Tier 1 Substance under REACH and more relevant information, including sophisticated hazard, exposure and risk assessments (CSR) will be provided in 2010. This should clarify contradicting interpretations of	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current

		the available information. Any decisions should be science based and not politically motivated.	classification will not be questioned. We are aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation.
2010422	Independent Lubricant Manufacturers Association, Industry or trade association, United States	EBA comments Annex XV 100104 final.pdf In our opinion Annex XV Dossiers should not be filed until REACH Dossiers are reviewed in 2011. We support the arguments given by the European Boric acid Association (EBA).	See response to EBA comments
2010422	Industry or trade association, Company, Netherlands	Page 1 - 4, contains technical and economic confidential information	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden.

			Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided. See response to EBA comments
20100422	Industry or trade association, Company, United Kingdom	The Annex XV Dossiers for boric acid and sodium tetraborate reference the classification of these chemicals according to the thirty first ATP to Regulation 67/548/EEC (the EU Dangerous Substance Directive). The concentration limits for boric acid and sodium tetraborate are 5.5 w/w % and 4.5 w/w %, respectively. Therefore, uses of these chemicals below these limits should NOT be considered dangerous. A general SVHC limit of 0.1w/w % threshold does not apply in these cases.	We recognize the discrepancy between the specific concentration limit and the limit of 0.1% mentioned in REACH Art. 33.
20100422	MSCA, Sweden	We agree that Boric acid, being classified as Toxic to reproduction Cat 2, meets the criteria according to Article 57 (a) in REACH and is thus eligible for identification as a substance of very high concern.	Thank you.
20100422	Federchimica, Industry or trade association, Italy	3. Classification and Labelling (p. 7) It should be noted that Recital (2) of the Commission directive 2008/58/EC (30th ATP) which added certain borates including boric acid to the Dangerous Substances Directive as a Category 2 toxicant, states that "special attention should be paid to further results of epidemiological studies on the Borates concerned by this Directive including the ongoing study conducted in China.". This study among workers in a borates mine has now been completed and peer-reviewed and confirms that there is no reproductive effect in men, which indicates even at very high exposures the effect in humans is different than the effect on laboratory animals.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned.
20100422	Industry or trade association, Company, United Kingdom	We support the arguments given by the European Borates Association(EBA) and it	See response to EBA comments

		is our opinion Annex XV Dossiers should not be filed until REACh Dossiers are reviewed in 2011	
20100422	Industry or trade association, Company, France	We use them in lot of different products but after delivery, the customer can't be exposed to them.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the

			sweeping of dry dusts has to be avoided.
20100422	Industry or trade association, Company, France	Page 2 - Specific comments on the justification Classification and labelling: The objective of REACH is for producers and importers of substances to prove how their substances can be produced and used safely. The exposure scenarios are a key communication tool. Considering any solutions containing some boric acid without taking into account the other constituents makes no sense as the properties of the preparation are different than that of the individual constituents in particular for preparations used for antisepsis and healing. The studies which indicate reprotoxic effects of boric acid, indicate effects only at very high doses to animals (1), are not transposable to humans (2) nor can be extrapolated to solutions (preparations) containing boric acid. In Annex XV, no reference is made to the safe concentration limits for boric acid or the comparative reprotoxic effect in humans. At a lower concentration (3), a NOAEL dose was demonstrated. This should be added to the Annex XV. It seems unreasonable to propose such substance as a candidate for authorisation based on reprotoxic effect observed at high doses in animals only and only by oral route. If the concentration of boric acid in a solution is higher than 0.1 %, this needs to be communicated to downstream users (Directive 1999/45/EC). Under this concentration the substances would be considered as exempted. This is probably discriminatory for many products because of the high specific concentration limit for boric acid (5, 5%) identified in Commission Directive 2008/58 and because the properties of the preparation do not necessarily depend on the properties of the individual constituents, as it is the case for products of ocular washing solutions or cutaneous healing products. These preparations have an effect which is the synergy of the ingredients and conferring other specific properties. The cosmetics directive asks that for a concentration superior to 3 % of boric acid, the responsible persons indicate this during the launching on the market of a cosmetic product. The specific concentration limit of 5.5% for boric acid is about 20 times higher than the default concentration limit of 0,3%, applied to most of the other reproductive toxicants (CLP 1272 2008 CE). Does such substance really belong on the candidate list of substances for potential authorisation? We would like to emphasize that under reasonable foreseeable circumstances, boric acid is not dangerous by different routes of exposure, especially not by the dermal	

		route (4, 5, 6), the route where many cosmetics and drugs are applied. The absorption through the skin is very weak, an indicator that the toxicity cannot not be high. This confirms that boric acid is not the substance of greatest concern and that attention should be focused on other, more potentially dangerous chemicals than this one. Classifying boric acid as a SVHC would be in contradiction to the objectives of REACH which requires every company to investigate and to communicate, through the exposure scenarios, how its substances (e.g. boric acid) can be produced and used safely. Through REACH, a lot of knowledge will be gathered on chemicals and their effects on humans and the environment. REACH is in its infancy, and one should first await the registration dossiers so that decisions can be taken on the best available information. Bibliography: 1. Price CJ, Marr MC, Myers CB, Seely JC, Heindel JJ, Schwetz BA, The developmental toxicity of boric acid in rabbits, Fundamental and Applied Toxicology 1996 (34) 176-187 2. Scialli AR, Bonde JP, Brüske-Holfeld I, Dwight Culver B, Li Y, Sullivan FM, An overview of male reproductive studies of boron with an emphasis on studies of highly exposed Chinese workers, Reproductive Toxicology 2010 (29) 10-24 3. Price CJ, Strong PL, Marr MC, Myers CB, Murray FJ, Developmental toxicity NOAEL and postnatal recovery in rats fed boric acid during gestation, Fundamental and applied toxicology, 1996 (32) 179-196 4. Wester RC, Hui X, Maibach HI, Bell K, Schell MJ, In vitro percutaneous absorption of boron as boric acid, borax and disodium octaborate tetrahydrate in human skin: a summary, Biol Trace Elem Res, 1998, 66(1-3), 111-120 5. Wester RC, Hartway T, Maibach HI, Schell MJ, In vivo percutaneous absorption of boron as boric acid, borax and disodium octaborate tetrahydrate in human skin: a summary, Biol Trace Elem Res, 1998, 66 (1-3), 101-109 6. Wester, Hui, Hartway T, Maibach HI, Bell K, Schell MJ, In vivo percutaneous absorption of boron as boric acid, borax and disodium octaborate tetrahydrate in human compared to In vitro absorption in human skin from infinite and finite doses, Toxicol Sci, 1998, 45 (1), 42-51.	
20100422	Industry or trade association, Company, United Kingdom	1. The proposal has been made on the basis that borates are classified as Category 1B. In the meeting where this classification was agreed, 6 of the 13 Member States	

		present disagreed with this classification and supported either Category 2 or 3. More and better data are now available than were considered in this decision. 2. A Chinese epistudy on the exposure of a large number of Chinese workers to large doses of borates for an extended period has now been published and the conclusion is of no classification. 3. Further, a US study of the same dataset, also now published, reaches the same conclusion. 4. Also, since a comprehensive, high-quality Dossier for REACH purposes will be submitted to ECHA in the next few months, consideration of this as well as the epistudy would improve the reliability of a judgement on Candidate List status.	
20100422	Frit Manufacturers and Importers, A.E.I.E., Industry or trade association, Spain	Frit Consortium- Comments of borates Annex XV.pdf p.1-3	
20100422	ANFFECC, Industry or trade association, Spain	We support all the comments sent by the Frits Manufacturers and Importers A.E.I.E.	
20100422	AIMPR, Industry or trade association, Spain	We support all the comments sent by the Frits Manufacturers and Importers A.E.I.E.	
20100422	Individual, Sweden	Boric acid is used for catching neutrons used to absorb or switch off the nuclear chain reaction in nuclear reactors. The substance is thus very important.	

INFORMATION ON USE, EXPOSURE, ALTERNATIVE AND RISKS ON ANNEX XV SVHC

Substance name: **Boric acid**
CAS number: **233-139-2 (234-343-4)**
EC number: **10043-35-3 (11113-50-1)**

Reason of the submission of the Annex XV: CMR

Disclaimer: The Response to Comments table has been prepared by the competent authority of the Member State preparing the proposal for identification of a Substance of Very High Concern. The comments were received during the public consultation of the Annex XV dossier. The table does not contain any confidential information provided.

Specific comments on use, exposure, alternatives and risks

Date	Submitted by (name, Organisation/MSCA)	Comment	Response
20100318	On behalf of an organisation, Industry or trade association, Germany	Boric acid is used for water analytical testing In comparison to the standard method for the water testing, the volume of Boric acid in cuvette tests is very small.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the

			transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100331	On behalf of an organisation, Ti group automotive system Company, Belgium	Boric acid is a major additive in our process of nickel electrolytic deposit. The boron acid is a buffering compound. It helps buffer the bath pH of 4 in the cathode film. Without this compound, the proton reduction, which relatively increases with current density and acidity of the bath, leads to a rise in pH in the cathode film and to the formation of nickel hydroxide. The minimum concentration of our baht is about 50g/l. We work with a bath volume of 25m³. The annual consumption is about 6000kg. Today, we have no other buffer substance ready to use, giving the same result.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the

			transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100406	Affiliated with an organisation, DALIC, Company, France	NiD+Axle Euro GB.pdf SLAT NICKEL D+ GB.pdf SNCF.AX.FR.pdf Spoornet07FR.pdf TR1-011.doc Pages 10 to 17. Boric acid is used in sulphamate nickel plating baths and is today an essential constituent without known equivalent. According to published scientific evaluations, boric acid acts on tensile internal stress in the nickel deposit plated from a sulphamate bath and on the risk of hydrogen embrittlement of the substrate. The first are not modified by boric acid concentrations from 26 to 49 g/L and the second is reduced by using high concentrations of this acid. High ductile nickel deposits without cracks can be obtained with such sulphamate bath containing boric acid using the localised brush repair process. It gives a very good protection against corrosion on steel or aluminium even after several heat treatments between -80 and 200°C and is very efficient against fretting. Another advantage is the possibility to plate high thickness (up to 1 mm) and to restaure deep damages like holes, scratches.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the

		Application in railway: in Europe, 3.000.000 Kms run per month by DALIC coated axles (time needed for qualification: around 10 years!) Applications in aeronautics: slat repair... Applications in nuclear industry for non-porous coatings.	transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100409	On behalf of an organisation, European Borates Association, Industry or trade association, Belgium	EBA Comments Hazard assess Annex XV April 10 final.pdf Overall, EBA would like to comment that • The information on tonnage, import and export is missing in this dossier. • The substance naming is not accurate. • The use of boric acid in consumer uses will be restricted through Annex XVII, it does not seem relevant to include the consumer exposure estimates in this dossier.. • The exposure estimations that are included in the dossier are incomplete and several of the realistic worst case (RWC) assumptions are not realistic. Examples of this are: o The maximum reported value of borates in mineral water is used as the exposure scenario even though the drinking water limit is 4 times lower. o The potential exposure from supplements was determined from a 16 year old personal communication from the United States reporting on body builder's use of supplements. The daily intake being proposed would be considered abusive. 1.1.3.3 Toys (p. 13, 1st paragraph) On page 13, 1st paragraph, no source has been quoted regarding the concentration of up to 8% in silly putty. It would be useful for stakeholders to know where this reference comes from. Furthermore, the RWC scenario assumes accidental	Boric acid concentrations of up to 5.5% may lead to considerable consumer exposure in special cases. It was not the intention to give a complete picture of consumer exposure, as there are data gaps on product contents and use patterns, but to report the existing knowledge. 1.1.3.3 Toys (p. 13, 1st paragraph)

		swallowing of the entire package (17g), however, assuming that this happens daily is not realistic to serve as a reference point. According the RIVM factsheet reasonable worst case conditions include an ingestion frequency of 1/week and ingestion of 1g of product each time. Using these conditions, the weekly ingestion rate is 0,23 mgB/kgBW/week. Further, use of boric acid in toys is expected to be restricted according to directive 2009/48/EC on the safety of toys, due to its classification as Reprotoxic 1 B by Commission Regulation (EC) No 790/2009. Last, on page 13, 3rd paragraph, EBA considers that the data should be corrected: the RWC exposure of 0.025 mg boric acid corresponds to 0,0044 mg B/kg BW/day and not 0,036 mg B/kg BW/day as stated. 1.1.3.5 Cellulose Insulation (p. 14) On page 14, line 6: "…with respirable particle concentrations of 2,75 mg/m3…" should be "…with inhalable particle concentrations of 2,75 mg/m3…" according to the reference (BTU, 2000). In addition, exposure estimates for disodium tetraborate are included, which is not relevant for this dossier. 1.1.3.6 Glass Wool Insulation (p. 14) The substance boric acid is an intermediate to manufacture the substance glass. Therefore it is no longer present in the final product. The boron present in ceramics and glass-ware is physically/chemically bound into the product, therefore in these cases, the potential for the consumers to be directly exposed to the borates present is minimal (RPA 2008). 1.1.4.2 Food contact material (p. 15) The substance boric acid is an intermediate to manufacture the substances glass and ceramic frits. Therefore it is no longer present in the final products. The boron present in ceramics and glass-ware is physically/chemically bound into the product, therefore in these cases, the potential for the consumers to be directly exposed to the borates present is minimal (RPA 2008). 1.1.4.4 Mineral water (p. 16) Maximum exposures are calculated using the maximum value reported in mineral water. This value of 4,35 mgB/L exceeds however the EU drinking water limit of 1 mg B/L. A realistic worst case scenario should rather assume concentrations equivalent to the	The concentration of 8% in silly putty was cited from BfR 2005. It was derived from two unpublished analysis reports which were communicated to the Federal Institute for Risk Assessment by two different federal control laboratories in the year 2004. The first sample was prepared by alkaline ashing, the second was boiled up with water. Analyses were done by potentiometric titration in both cases. Results were 7 – 8% in the first sample and 8.5% in the second. Ingestion of 17g is declared as accidental in the annx XV dossier. According to ECHA-Guidance for CSR/CSR R15, use frequencies of less than one per day are beyond the skope of tier 1 calculations and should only be used if justified data are provided. But the use frequency of 52/year in the RIVM factsheet has a value of 4 for data quality, "…,parameter value doubtful as default value". Therefore it is not used in this calculation. Boric acid concentrations below the concentration limit of 5.5% are not expected to be restricted according to directive 2009/48/EC on the safety of toys. They might still lead to considerable exposures in the case of

		drinking water limit. This approach was also followed by ECHA (2008). 1.1.4.5 Food supplements (p. 16) It is stated that "Food supplements for bodybuilders may possibly lead to maximum boron intakes of up to 30 mg/day (0.5 mg/kg bw/day) for a 60 kg person, BfR 2006a". The original source of this statement (Loscutoff S. Personal Communication (Memorandum)) cannot be verified nor is it a peer-reviewed or official publication. Therefore this value is not credible nor relevant. Further, consumption amounts of this nature as supplements would clearly be considered serious abuse by deliberate ingestion of extreme amounts and therefore is not relevant for this assessment.	slimy toys. Thank you, the value will be corrected. 1.1.3.5 Cellulose Insulation (p. 14) Thank you, the wording will be corrected. The inclusion shows that boron exposure from one preparation or article may result from two boron compounds. 1.1.3.6 Glass Wool Insulation (p. 14) Thank you, a clarification has been added to the dossier. 1.1.4.2 Food contact material (p. 15) Thank you for the information. A clarification has been added to the dossier. 1.1.4.4 Mineral water (p. 16) The EU drinking water directive does not regulate mineral waters. 1.1.4.5 Food supplements (p. 16) The source was also used by EFSA 2004, but nevertheless the wording will be revised.

20100413	On behalf of an organisation, Fuchs Lubrifiant France, Company, France	Alternative will oblige us to monitore emulsion with a level of bacteria so to increase human hazard with endotoxine	Your comment is appreciated.
20100413	AffiliatedWithOrganisation, Institute of Metal Finishing, Industry or trade association, United Kingdom	Boric acid is also used to maintain a balanced pH in other products. For example Optrex eye drops which can be purchased over the counter at any chemist or pharmacist. Admittedly the quantity of boric acid to which one is exposed when using eyedrops is considerably lower than when adding powder to a nickel plating bath. In my role as an Environmental, Health and Safety advisor I am aware that the plating technicians are routinely subject to health surveillance due to the nickel salts and chromic acid salts used within the plating shop. I am also aware that there are no issues with exposure to nickel and chrome. It can therefore be extrapolated that there are no issues with exposure to boric acid either.	Medicinal products are not subject to Title VII of the REACH regulation.
20100413	AffiliatedWithOrganisation, Industry or trade association, Belgium	svhcreaction DE.doc THE BEST SUBSTANCE USED IN PLATING SHOPS IS BORIC ACID, ISN'T POSSIBLE TO MAKE PLATING WITHOUT IT. PLEASE SEE THE ATTACHMENT AND IF YOU ARE ABLE ANSWER TO IT.	Boric acid was proposed as SVHC based on its classification as toxic to reproduction, its wide use in consumer products, and its high production volume. Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. However, we are aware that boric acid will be registered by the end of this year and further information may become available.

20100414	AffiliatedWithOrganisation, UEIL, Industry or trade association, Belgium	The concern given the entirely trouble free use of boric acid in metalworking fluids since the mid 1970's is that such fluids will continue by necessity to be used and fluid formulators will be forced to resort to other chemistries. These will be less well documented, will lack the field experience and therefore practical occupational references and in many cases will revert to formulation chemistries relying upon far more pervasive ingredients such as biocides. Having enjoyed the performance benefits of boric acid based fluids biocide levels needed to achieve the same performance life will need to be excessive. The alternative is an high level of increase applied cost to metalworking fluid users at a time when Europe's industrial manufacturing economy is staggering in the wake of a recession and facing even greater competitive threat from India and China	Your comment is appreciated. Socioeconomic aspects should also be discussed in case an application oforauthorisation becomes necessary.
20100414	On behalf of an organisation, UEIL, Industry or trade association, Belgium	EBA comments Annex XV 100104 final.pdf Exposure to boric acid during metalworking fluid (MWF) manufacturing: We have some data for manufacturing sites, were boric acid is filled into mixing vessels and some of the cutting fluid manufacturers have already workplace measurement in place to reduce the exposure to boric acid to a minimum. Furthermore, there is a workplace threshold for boron in place (in Germany). All data show, that nowhere the threshold limit is exceeded Exposure to boric acid in use as metalworking fluid. The official UK method for determining metalworking fluid mist is based on a tracer such as sodium or boron: http://www.hse.gov.uk/pubns/mdhs/pdfs/mdhs95-2.pdf The UK Guidance value metal working fluid end users for mist is 1 mg/m3; assuming a worse case scenario of a 10% MWF containing 10% boric acid, than the maximum exposure would give the extremely low 0,01 mg/m3 boric acid. In Germany, since March 2007 a health risk based exposure limit of 2,6 mg/m3 boric acid is in place (“gesundheitsbasierter AGW”, published in the TRGS 900), corresponding to 0,5 mg/m3 Boron (lead component). According to the definition of an AGW, acute or long term hazard can be excluded if the exposure limit is not exceeded. Furthermore, there is a remark (“Y”), that there is no expected risk for fertility/harm to the unborn child (R60/61) if the limit is not exceeded. Initial measurements of the Berufsgenossenschaft showed that the limit was never exceeded.	See response to EBA comments

		Link to the TRGS 900: http://www.baua.de/cae/servlet/contentblob/666762/publicationFile/55576/TRGS-900.pdf Data generated by the BG Metall and the Verband Schmierstoffindustrie (VSI) in Germany showed, that the concentration of free boric acid in metalworking fluid concentrates is by far below 5 %. Measurements performed by 11B NMR spectroscopy showed an average concentration of 2% in the metalworking fluid concentrate, leading to a maximum of 0,1% in the emulsion used by the end user (metalworking fluids are a mixture of 4-5% concentrate in water). Apart from health and safety aspects, there are a number of other issues to look for Boric Acid Benefits: • stable buffer capacity, thus robust against microbial attacks. • good availability • good price performance ratio • used without problems for many decades in the metalworking fluid industry. Are there alternatives? • Although industry investigated alternatives for many years, no alternatives were found • All alternative formulations are, due to reduced buffer capacity, much less robust against bacterial attacks leading to increased usage of biocides, which from a health, safety and environment perspective is undesirable. • The lifetime of alternative formulations is significantly lower, resulting in a more frequent change and will have a higher consumption of resources and thus is poorer from a sustainability standpoint. • Lastly, the alternative formulations that use higher biocide levels are coupled with increased disposal rates and these higher waste levels will cause increased pressures on the environment. The European metalworking fluid manufacturers support the Product Stewardship principle to supply products that can be manufactured, transported and used safely. We work with suppliers, customers and regulatory authorities to reduce the health and environmental impact of metalworking fluids. We believe the use of boric acid / borates is safe within our industry. The below give links to documents that demonstrates our work.	

		Safe handling of metalworking fluids: http://www.hse.gov.uk/metalworking/video/ Comment of the Berufsgenossenschaft (Accident Prevention & Insurance Association, Germany) on boric acid containing metalworking fluids: "The MWF product containing derivatives of boric acid shows a good stability to colonisation with mycobacteria already in the non-preserved state (formulation without biocides) and thus also the best effect of the biocides tested", cited from: http://www.bg-metall.de/praevention/gesundheitsschutz/biologische-gefaehrdungen/kuehlschmierstoffe/mykobakterien.html UKLA boric acid position paper: http://ueil.org/health_environment/documents/ukla-boric-oct09.pdf BG boric acid information sheet http://www.vsi-schmierstoffe.de/fileadmin/template/VSI-Verwaltung/Texte/030_MFS_E2009-04_Boric_Acid.pdf Concluding, we feel that the use of boric acid is safe. Including Boric acid and disodium tetraborates on the list of SVHC will force end-users to move to boron free metalworking fluids. This will result in higher biocide usage (with their related health issues) and higher consumption of resources. Including boric acid and disodium tetraborates on the list of SVHC will have an opposite effect compared to REACH's targets	
20100415	On behalf of an organisation, VALDEPHARM, Company, France	Boric Acid (10043-45-3) is used in 29 monographs of European Pharmacopeia and 50 monographs of US Pharmacopeia. It is used for example in urea proportioning according to European Pharmacopeia. The maximum quantity used each year at Valdepharm is 100g. There is no substitute available to Pharmaceutical Industry. Methods of controls are defined by Pharmacopoeias. This substance is used in limited quantities, in labs where technicians handle it with all necessary precautions in strictly controlled conditions.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE:

			typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided. Medicinal products are not subject to Title VII of the REACH regulation.
20100416	On behalf of an organisation, Verband Schmierstoff Industrie e.V., Industry or trade association, Germany	EBA comments Annex XV 100104 final.pdf Since March 2007 a health risk based exposure limit of 2,6 mg/m3 boric acid is in place in Germany (“gesundheitsbasierter AGW”, published in the TRGS 900), corresponding to 0,5 mg/m3 Boron (lead component). According to the definition of an AGW, acute or long term hazard can be excluded if the exposure limit is not exceeded. Furthermore, there is a remark (“Y”), that there is no expected risk for fertility/harm to the unborn child (R60/61) if the limit is not exceeded. Initial measurements of the Berufsgenossenschaft showed that the limit was never exceeded. Data generated by the BG Metall and the Verband Schmierstoffindustrie (VSI) in	See response to EBA comments

		Germany showed, that the concentration of free boric acid in metalworking fluid concentrates is by far below 10%. Measurements performed by 11B NMR spectroscopy showed an average concentration of 2% in the metalworking fluid concentrate, leading to a maximum of 0,1% in the emulsion used by the end user (metalworking fluids are a mixture of 4-5% concentrate in water). All known replacements of boric acid containing additives in metalworking fluids lead to reduced product lifetime, strongly increased waste volume, increased use of biocides (thus higher risk for workers). To our knowledge, not a single case of health hazard was documented for the use and production of boric acid containing metalworking fluids world wide.	
20100416	On behalf of an organisation, RWE Power AG, Company, Germany	Boric acid is used in general in nuclear power plants as a neutron absorbing agent, mainly in the primary cooling systems and the fuel storage pond. For this application in nuclear power plants, no alternatives exist. Due to the applied strictly controlled conditions and safeguards of radiation protection and the therefore provided technical systems in NPP, i. e. such as a leak tight containment, no release to the environment can occur. During conditioning of the cooling system with boric acid strict occupational health & safety measures are applied. Therefore no risk remains for the use of boric acid in this application.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to

			be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100416	AffiliatedWithOrganisation, Industry or trade association, Company, Germany	I have worked for many years in metal working industry and our company has a lot of boron free metal working fluids in use and even a lot of boron containing metal working fluids. Both due to technical reasons. In every case the boron free metal working fluids need more intensive testing and larger amounts of additives to keep the systems in stable conditions. Additives are biocides and anticorrosives (alkalines and amines). Risk for skin irritations is increased in comparison to boron free metal working fluids. So the expected reduced health hazards for the few people working with the high concentrated boron compounds is payed with increased skin hazards for thousands of workers working with the diluted metal working fluids!	Boric acid was proposed as SVHC based on its classification as toxic to reproduction cat. 1B, its wide use in consumer products, and its high production volume.
20100416	BehalfOfAnOrganisation, Fuchs Europe Schmierstoffe GmbH, Company, Germany	Boric acid has been used safely in metal working fluids decades. In general, metal working fluids are used in industrial and professional settings, where adequate Risk management measures can be implemented and controlled. Metal working fluids are not sold to the general public therefore the wide dispersive use is questionable. Emissions to the environment are extremely low, because in general MWF are collected separately, treated and disposed off by certified contractors. boric acid helps to enhance the stability and lifetime of aqueous emusions by approximately factor 2. Consequently it helps to decrease the consumption of energy and chemicals, e.g. biocides. additionally it helps to reduce the amount of waste water and waste significantly. Therefore the use fo Boric acid is beneficial for the protection of the environment. exposure monitoring data in our plants show, that the use is safe. We have made this data available to the lead registrant for boric acid to include it in his CSA and CSR. In Germany, the use of CMR substances in category 1 and/or 2requires maximum risk management measures to minimize exposure of workers to the lowest achievable level to make the use safe. We believe that those measures are sufficient to adequately control the risk. Therefore we do not see a good reason how auhtorisation should further improve the situation.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present the current classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation.

20100417	BehalfOfAnOrganisation, Industry or trade association, Company, United Kingdom	The electrolyte is essentially composed of an organic solvent to which is added an acid and base in order to provide the solution with conductivity. Other additives are also used to absorb gas, inhibit corrosion and boost the voltage capability. The electrolyte must meet a range of requirements including high conductivity, neutral or slightly acidic pH, suitable voltage capability, wide temperature range with good high temperature stability, ability to form aluminium oxide, compatibility with other capacitor materials, low viscosity, low flammability, low toxicity and low cost. These demanding requirements place significant restrictions on the chemicals that can be used and result in new electrolytes taking several years to develop. Boric acid is widely used within the industry, and has been for many decades, as it satisfies the specific requirements of electrolytes for aluminium electrolytic capacitors. This industry or trade association electrolytes rely heavily on the use of boric acid in order to achieve the required performance at a competitive cost. Boric acid is a key component in many of the electrolytes and is used in concentrations ranging from 1% to 30% by weight. There are no direct substitutes for boric acid, any change of acid would require a complete re-formulation of the electrolyte followed by and extensive evaluation and qualification test program and ultimately customer approval for the new variant. Development timescales would realistically be in the order of several years and there is no guarantee that we can replicate the properties of boric acid based electrolytes by the use of alternative acids, which in all probability will be more expensive. The quantity of electrolyte used per capacitor is in the range of less than 10 grams for a small device to around 500 grams for the largest devices. Risk of exposure to boric acid is extremely unlikely. Under normal circumstances there is no possibility of exposure to the electrolyte as the capacitors are sealed. In the event of a device failure, or case rupture due to physical damage, there is a possibility of a few drops of electrolyte being expelled from the capacitor, however since capacitors are normally mounted inside equipment the chance of exposure is very remote. Furthermore the amount of boric acid within the electrolyte is a maximum of 30%. Exposure to the electrolyte will not lead directly to exposure to boric acid as it is dissolved and reacted with other components of the electrolyte.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.

20100419	Individual, Germany	5. Boron is an essential mineral for plants and organism. 6. Boric Acid is badly changeable for processing of steel. Other usable substances can be more toxic. 7. Boric Acid allows more energy efficient and powerful processing at safe usage (TRGS 900 in Germany) than other substances.	Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its high production volume.
20100419	AffiliatedWithOrganisation, Industry or trade association, National Authority, Austria	Pursuant to Art. 60 (8) we claim that every use of boric acid has to fulfil requirements (e.g in the use of glass production). In the past boric acid was used as bacteriostatic in eye wash solutions (e.g 2% concentration). It should be mentioned that this use obsolete and overcome since many years. Due to toxicological reasons and available substitutes	Your comment is appreciated. To apply art. 60 (8) an authorisation must have been granted first.
20100419	BehalfOfAnOrganisation, Industry or trade association, Company, United Kingdom	Multiple existing studies on Humans have been undertaken especially for Miners of Borax who have the highest exposure to the substance and it is vitally important that the Chinese studies which show no evidence of reprotoxic effects in Men is taken into account before any further incorrect decisions are made about this substance. Boric acid has many beneficial technical properties , especially its buffering capacity and excellent corrosion inhibiting effects. Its safe use in many Medicinal and Industrial and consumer products has been established for decades. Over classification of a substance is wrong and leads to an overburden of control and in this case we believe strongly that it is wrong to consider adding Boric acid and Sodium Borate to the candidates list as the underlying data is flawed in our opinion.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned.
20100419	Individual, France	Nous utilisons ce produit depuis 8 ans. les différents essais de produits essayés à l'époque (pâte à l'eau en général) ainsi que les différents produits de substitutions essayés à ce jour n'ont pas permis de trouver un autre produit efficace.	
20100419	BehalfOfAnOrganisation, Industry or trade association, Company, United Switzerland	EBA comments Annex XV 100104 final.pdf Our company is using borate products only as a cross-linker between water and galactomannan masses (made of guar gum). The included boric acid and disodium tetraborate (borax) are not "free" in this mass as they exist only as boron ions. Also it is fact that this cross linker needed for our mass has to be pH neutral and from its properties we only have these 2 substances that can work with our formulations. Other possibilities such as chitin proved to be non-working so we highly depend on the allowance to use these borate without such a SVHC classification. This would certainly stop our business and be a major threat for the future of our company. Industry or trade association is always trying to limit these ingredients (borate are currently in percentages of 0.1 - 0.4% in our products and we are always trying to limit them as much as possible). Still due to the nature of galactomannan compounds	See response to EBA comments

		there are certain limits where the content of borate cannot be lowered any further.	
20100419	BehalfOfAnOrganisation, Alpha Fry Limited, Company, United Kingdom	The most common inhibitors in wet recirculating heating systems of this category are borates and phosphates. Boric acid is commonly used as corrosion inhibitors and buffers in these types of system that are found in most domestic dwellings in Europe. In these systems corrosion is a major concern and can lead to damages due to the effects of slow build up of corrosion products. This can manifest itself in blockages of pumps and valves, reduced circulation, reduced efficiency of heat exchangers and boiler noise. Phosphates have ecological consequences when released into the environment and therefore their use is discouraged. Boric acid provides the best solution in terms of performance, cost and low toxicity. Various tests have shown that the efficiency of a domestic heating system can be reduced by a third due to build up of corrosion products. Boric acid provides a very good and cost effective solution to inhibit corrosion in these systems. For the past three years our R&D departments have been endeavouring to replace boric acid in our range of products, without success, projects have failed on two accounts – efficiency and stability, we have been unable to find alternative substances that give the same level of benefits of hot water system protection and maintenance of boiler performance, efficiency and power output. Where possible replacements have been found, compatibility and stability of the system have necessitate withdrawal from the market.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be

			avoided. Alternatives or substitution should be discussed in case an application for authorisation becomes necessary.
20100419	Industry or trade association, Company, Portugal	Exposure to boric acid during metalworking fluid manufacturing: We had made some air measurements in working place when the worker is adding the boric acid to the mixing vessel. The results showed that the values where under the quantification limit, who lets us conclude that there is no risk to workers health. Nevertheless we have some practical procedure that reduces the exposure to boric acid to a minimum. Boric acid is delivery in plastics bags (25 kg each) inside a big bag. Each plastic bag is filled directly to the mixing vessel, where the metalworking fluid is manufactured. Workers handling boric acid (about 15 minutes /4 bags, normally) wear protective equipment completed and discharged. There is local exhaust ventilation, and the empty bags and the discharged equipment are putted on special vessel to be eliminated by an official company. Exposure to boric acid in use as metalworking fluid: Data generated by the BG Metall and the Verband Schmierstoffindustrie (VSI) in Germany showed, that the concentration of free boric acid in metalworking fluid concentrates is by far below 10%. Measurements performed by 11B NMR spectroscopy showed an average concentration of 2% in the metalworking fluid concentrate, leading to a maximum of 0,1% in the emulsion used by the end user (metalworking fluids are a mixture of 4-5% concentrate in water). The official UK method for determining metalworking fluid mist is based on a tracer. This could be: sodium or boron. See the link below for details: http://www.hse.gov.uk/pubns/mdhs/pdfs/mdhs95-2.pdf The UK Guidance value metal working fluid end users for mist is 1 mg/m3; assuming a worse case scenario of a 10% MWF containing 10% boric acid, than the maximum exposure would give the extremely low 0,01 mg/m3 boric acid. Alternatives: Boric Acid is difficult to substitute, because it functions in many different aspects: -Emulsions show high stability with long lifetime; this results in less use of hazardous chemicals; -Boric acid functions as pH-Buffer, the pH-Stability is very high – this results in higher stability and less use of chemicals;	Alternatives or substitution should be discussed in case an application for authorisation becomes necessary.

		-Boric acid functions as excellent corrosion prevention – this also results in less use of chemicals; -Use of Boric acid results in low foam formation, therefore less use of de-foaming agents is required; -Boric Acid shows weak bacteriostatic properties, these results in less use of biocides with high hazard potential for human health and environment; -Water-miscible Metal Working Fluids are used in industrial or professional applications, where adequate risk management measures (e.g. local exhaust ventilation, closed processes, personal protective equipment) have been applied. Emissions to the Environment are extremely low, because metal working fluids in general are hazardous waste, which have to be collected and treated separately before disposal; -Use of Boric acid results in higher stability of the product, less use of chemicals, lower amount of waste, which needs to be disposed off. Additionally the exposure of workers to hazardous chemicals is also reduced.	
20100419	ASSOGALVANICA, Industry or trade association, Italy	1 Boric acid is essential in electroplating process as buffer of pH of nickel plating baths. Boric acid is a week acid, it enables the buffering of pH of the nickel plating bath that during the process of electrolysis fluctuates and increases. As a rule the concentration of boric acid is in the range between 35 and 50 g/l. As far as alternatives are concerned, at present there is no substance that can replace it giving the same effectiveness and quality of production. Major implications are: - Without boric acid it is impossible to assure good quality indexes. - The use of strong acids to control the pH needs frequent additions. Sulphuric acid with concentration between 33 and 66% enhances as time goes by the instability of pH due to the electroplating process. As a matter of fact the process will be no longer under control with dramatic increase of low quality products and waste. - The buffering effect of boric acid can not actually be replaced even by careful additions of sulphuric or hydrochloric acid that give to the nickel coating the burn effect. 2 Boric acid is essential in electroplating process because it enables the substitution of hexavalent chromium bath. Boric acid is an essential component of the saline matrix used in the most recent, low concentration bath of trivalent chromium (< 7g/l) that increasingly substitutes the electroplating process based on hexavalent chromium both in chromium and in acid	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low

		zinc plating.	dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100420	Industry or trade association, Japan	Dear Mr. Dancet, Re: Proposals to identify Boric Acid as Substance of Very High Concern (SVHC) On behalf of one of our clients, a non-EU manufacturer of food contact materials containing Boric Acid and exporting them to the EU, we are writing to submit comments against the proposal to identify boric acid as a Substance of Very High Concern (SVHC) (on the candidate list established under the REACH Regulation 1907/2006). By way of background, we note that Member States Competent Authorities or the European Chemicals Agency (ECHA), on request of the European Commission, may prepare an Annex XV dossier for the identification of an SVHC. For boric acid, the Annex XV dossier has been submitted by Germany and Slovenia. For a chemical substance to qualify as SVHC, it must meet one or more of the requirements laid down in Article 57 of Regulation 1907/2006 (REACH). These requirements are: (a) substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC; (b) substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC; (c) substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC; (d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of REACH; (e) substances which are very persistent and very bioaccumulative in accordance with	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. Boric acid clearly meets the criteria according to REACH article 57c, which is sufficient for an SVHC proposal (it is not required for one substance to meet all criteria of art. 57). Therefore, the SVHC proposal of Boric Acid is justified. By the time of dossier preparation the available information of uses in consumer products was reviewed and used for the dossier. We are aware that CMR substances as well as

		the criteria set out in Annex XIII of REACH; and (f) substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59. 1. SVHC prioritisation among hazardous substances A teleological interpretation of the REACH Regulation provides guidance as to how to prioritise the SVHC identification among substances that are all classified as “hazardous”. Specifically, the identification of a substance as SVHC is in fact instrumental to the inclusion of that substance in a Annex XIV (Article 59(1) of REACH). Annex XIV of REACH deals with substances that are subject to authorisation, i.e., which cannot be placed on the market unless they are authorised (or unless they are exempted from the authorisation). Therefore, an SVHC is a substance which will be considered for inclusion in Annex XIV of REACH. With regard to the Annex XIV inclusion, REACH provides (at Article 58(3)) that priority should be given to substances with PBT/vPvB properties, or wide dispersive use or in high volumes. As a result, an argument can be made that in the SVHC identification process, precedence should be given to those substances which are more likely to be included in Annex XIV, i.e. to substances with PBT/vPvB properties, or wide dispersive use, or high volumes. In any event, the SVHC identification should not be based on a random selection exercise and this for two reasons: (i) first, a random selection exercise would frustrate the purpose of the SVHC identification process which is, indeed, to establish a list of substances being capable of being included in Annex XIV of REACH. This could result in qualifying as SVHC a number of substances which will not, or only late, be included in Annex XIV of REACH; and (ii) second, the SVHC identification will undoubtedly stigmatise those “identified” substances, which would be seen as potential Annex XIV substances, i.e., as being so hazardous to be prohibited from being placed on the EU market, except under a specific authorisation. 2. Reasons justifying the SVHC identification in Annex XV We note that the proposal to identify boric acid as an SVHC is based on the fact that boric acid meets only one of the Article 57 REACH criteria, i.e. that it can be classified as R60-61, toxic for reproduction. Importantly, however, this is only valid if boric acid is present in concentrations higher than 5.5% by weight, which is a significantly high threshold if compared to the concentration limits set for other R60-	substances with high production volumes will be registered by the end of this year and further information may become available. We recognize the discrepancy between the specific concentration limit of boric acid and the limit of 0.1% mentioned in REACH Art. 33.

		61 substances in Directive 67/548/EEC and in Regulation (EC) 1272/2008. Further, a more careful reading of the Annex XV dossier concerning boric acid reveals that, while consumer use with boric acid weight concentration lower than 5.5% is rather common, use of boric acid in concentration higher than 5.5% is limited to “soldering products, film developer and raw material for pharmaceuticals” (page 10 of the Annex XV dossier). In addition, the Annex XV dossier informs that the main uses of boric acid are out of the scope of the REACH authorisation provisions. For example, the main use of boric acid is indicated to be in biocides, which are exempted from REACH authorisation provisions pursuant to Article 56(4)(b) of REACH. Some of the other minor uses listed at page 10 of Annex XV, such as the use in veterinary medicines or in food additives are also exempted pursuant to, respectively, Article 2(5)(a) and (b) of REACH. Furthermore, Annex XV refers (at page 15) to “Consumer Products under Sectoral Regulation” including therein boric acid uses in cosmetics and food contact materials, which are expressly exempted (pursuant to Article 56(5) (a) and (b) of REACH) from the Annex XIV provisions, hence also from the SVHC identification process. As a consequence, the identification of boric acid as an SVHC, at least when used in concentrations lower than 5.5% and when used in biocides, veterinary medicines, food and food additives, cosmetics and food contact materials, does not achieve the purpose sought by such identification, i.e., selection of substances for subsequent prohibition unless an authorisation is obtained. We further argue that the remaining uses of boric acid – i.e., in concentrations above 5.5% by weight and for uses other than those exempted from the provisions on authorisation under REACH – can still justify the need of an SVHC identification, in particular due to the health related risks to humans. Here again, however, the Annex XV dossier does not appear to provide clear-cut information. At page 11 and following, the Annex XV dossier deals with “Information from the Transitional Dossier and the RPA report” on consumer exposure. This section of the Annex XV dossier makes it clear that: “[a] risk characterisation assessment for boron exposure via consumer products was not derived due to the lack of information on other consumer uses”; that “minimal data are available on consumer exposure” and that “a need for further information was concluded” since “the RPA report was not available at the time of submission of this dossier” (page 10). As regards the dermal absorption of boric acid, the Annex XV dossier provides that the “Committee for Risk Assessment the European Chemicals Agency (RAC) is currently discussing an opinion on the use of boric acid and boron compounds in photographic products for consumers, which will also cover dermal absorption of borates. Therefore, the following consumer exposure calculations might need a	

		revision after the publication of the RAC opinion”. In conclusion, it appears that the SVHC identification of boric acid is not based on the risks related to human exposure to such substance, rather on toxicological studies describing the substance’s characteristics. Further, while these studies are not definitive, they also determine a concentration threshold limit for boric acid which is, in practice, very rarely met and they consider boric acid uses which are exempted from the provisions of the REACH Regulation on authorisation. We further conclude from the above that the SVHC identification of boric acid will have no, or little discernible benefit for consumers, in particular if compared to the many other substances with hazardous properties, while it will certainly stigmatise boric acid. Based on the foregoing, and on the understanding that the SVHC identification process is not a random exercise and that it follows certain rules as described above, we therefore submit that boric acid should not be identified as a SVHC, or at a minimum that its identification should be accompanied by a note indicating the it does not concern boric acid when used in food contact materials. We thank you for your attention to this matter and look forward to hearing from you. Yours sincerely, Kazumi Yuki SCAS Europe S.A./N.V.	
20100420	Industry or trade association, Company, Germany	The compounds of boric acid used in metalworking fluids have a good influence on the lifetime of the fluids in the machines. If boric acid will be prohibited we will be forced to use an increasing amount of biocides to get an acceptable lifetime of the metalworking fluids. In our opinion the influence of biocides on human health is much worse than of the boric acid compounds.	Your comment is appreciated. Alternatives will have to be discussed in case an application for authorisation becomes necessary.
20100420	Industry or trade association, Company, Germany	Irrespective of the question whether boric acid really meets the criteria of article 57 of the REACH regulation, we would like to point out that the use of boric acid in the semiconductors industry should be exempted from authorization requirements according to REACH. Boric acid and sodium and potassium salts of boric acid are components of developers used in the electronic industry during the photolithography process. Typical concentration of boric acid in this kind of developers is approx. 5%. The components of the developer are not part of the final article. Developers for the photolithography process in the electronic industry are typically	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the

		used in a clean room environment where no or little potential exists for human exposure. Any transfer sampling or maintenance is performed via engineering and administrative controls. The use in the semiconductors industry can be described with following use descriptors: Sector of use: Main SU3 - Industrial Uses Sub: SU16 - Manufacturing of computer, electronic and optical product, electrical equipment Process Categories: PROC1 - Substances are used in closed process, no likelihood of exposure Article Category: N/A - substances are processing aids and do not end up in the final product Due to the limited risk related to the use of boric acid and sodium and potassium salts of boric acids as components of developers used in the electronic industry during the photolithography process, it seems to be appropriate to exclude this use according article 58, No. 2 of REACH regulation from authorization requirements if the substance should be added to Annex XIV of REACH regulation.	case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided. Exemptions, alternatives and socioeconomic aspects will have to be discussed in case an application for authorisation becomes necessary.
20100420	Industry or trade association, Company, United Kingdom	Boric acid is used as a key ingredient within fire protection paints. It is used within epoxy resin based fire protection coatings which are applied to structural steelwork, pipes and vessels on amongst others offshore oil and gas platforms, Liquid Natural Gas facilities and onshore petrochemical refineries. These “Intumescent” coatings afford protection to these structures during fires by reacting to create an insulative layer which protects the substrate from heating above its critical failure temperature.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available

		This retardation of substrate heating lengthens the time to structural failure and so allows for personnel evacuation and escape and also provides a longer time for active fire-fighting. In the oil and gas market there are two predominant fire scenarios. These are pool-fire and jet-fire. Both are fuelled by hydrocarbons which provide a more intense fire than normal fire conditions. The pool-fire scenario is effectively a standing fire due to ignition of non-contained fuel. A jet-fire scenario occurs where the fuel, under pressure, for example within a pipeline, escapes at high velocity through a rupture in the pipe and then ignites. This creates a high velocity, highly erosive flame. Fire protection coatings to resist jet-fires therefore have to show not only insulative characteristics but also resistance to the erosive effects of the jet-flame. Boric acid is unique in that it can impart within the fire protection coating both insulative and erosion resistant characteristics. In the initial phases of a fire at relatively low temperature below 200ºC it dehydrates, eliminating water as vapour which assists in the formation of a foam-like insulative layer. Above 300ºC it melts and hardens to provide glass-like properties which reinforce the insulative layer and provides resistance to erosive nature of the jet-flame. Boric acid plays a key role in providing jet-fire resistance to fire protection coatings and so plays a major part in preservation of life in these high risk fire situations These fire protection coatings containing boric acid are applied as highly viscous liquids with low risk of inhalation. They are applied only by trained, professional applicators using appropriate risk management measures.	gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100420	Industry or trade association, Belgium	Up to date there are not alternatives subsances known or in use (on the market) to substitute borax in starch applications.	Your comment is appreciated. Alternatives should be discussed in case an application for authorisation becomes necessary.

20100420	AffiliatedWithOrganisation, A.I.F.M., Regional or local authority, Italy	"L'INSERIMENTO DELL'ACIDO BORICO NELLA LISTA SVHC E LE CONSEGUENZE DI QUESTO FATTO CAMBIERANNO IN PEGGIO IL MIO LAVORO, LE CONDIZIONI DI LAVORO DEI MIEI DIPENDENTI , LA MIA VITA"	Your comment has been taken note of.
20100420	Industry or trade association, Company, Germany	Boric Acid – Input for ECHA Confidential comment submitted	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and

			would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided. Your comment is appreciated. Alternatives will have to be discussed in case an application for authorisation becomes necessary.
20100420	Industry or trade association Company, Germany	General Comment: Commercial calcined alumina powders are generally produced with alumina coming from Bayer process (aluminum hydrate or smelter grade alumina SGA). They are available in a wide range of purity and crystal size. Crystal sizes ranges from about 0,2 to over 20 microns in size to fit a variety of ceramic, refractory and abrasive applications. For products with a crystal size above 2 microns, beside others boron compounds are used as "mineralizers" to accelerate the crystal growth during production process. Therefore energy consumption can be reduced significantly. (Compare with page 3 in document) Specific comments on the justification: Beside boron compounds there are some other additives known as "mineralizers" like halides and chlorides, with the known environmental issues. No mineralizing additives were found in a study of 1993 that were not already known. (Compare tables annexed in document). It was not possible to calcine starting material to the same crystal size and crystal shape as with mineralizers based on boron. No chemical way could be figured out which showed promising results and as conclusion it was stated that a combination of starting material, mineralizers and operating conditions might lead to further improvements. Also more actual patents do not figure out alternatives: Patent number Published in EP19920113913 2000	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and

		DE000010297611T5 2002 EP 1854762 2003 EP1854762 2007 Specific comments on use, exposure: All alumina producers use boron compounds for mineralization for over 60 years. Nevertheless the functionality of the "mineralizers" is not well known, as chemical reactions are quite complex. During that time no impact on health of an employee was reported. The filters for exhaust gases are state of the art, to prevent boron containing dust exiting the production system. The prescriptive limits for the workplace boron compounds are used have been checked by an external engineering company and are below the allowed limits.	cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided. Your comment is appreciated. Alternatives will have to be discussed in case an application for authorisation becomes necessary.
20100420	Zeller+Gmelin GmbH & Co. KG, Company, Germany	Zeller+Gmelin GmbH & Co. KG is a manufacturer (formulation) of metalworking fluids containing boric acid. Exposure during formulation of lubricants: We have already workplace measurements in place to reduce the exposure to boric acid to a minimum. All data show, that nowhere the threshold limit is exceeded. Boric acid is delivered in plastic bags ("BigBags") and filled directly via a funnel into the mixing vessel, where the metalworking fluid is manufactured. The vessel is equipped with an exhaustion. Small bags with boric acid are opened in a special device (with exhaustion) which also folds the empty bags avoiding any dust. Workers handling boric acid (about 0,5h/shift) always wear FFP3 dust masks. Therefore exposure to human and environment during manufacturing can be excluded. According to the German regulation TRGS 900 a health risk based threshold exposure limit of 2,6 mg/m3 boric acid is required. This is equivalent to 0,5 mg/m3 boron as the lead component. Referring to the definition of these thresholds acute or long term hazard can be excluded if the exposure limit is not exceeded. Furthermore, there is a remark ("Y"), that there is no expected risk for fertility/harm to the unborn child (R60/61) if the limit is not exceeded. Test data from measurements at plants of Zeller+Gmelin indicate that the limits are never exceeded. As a result it can be said that the use of boric acid for manufacturing lubricants is safe.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5

		Exposure during application of metalworking fluids: Data generated by the BG Metall and the Verband Schmierstoffindustrie (VSI) in Germany showed, that the concentration of free boric acid in metalworking fluid concentrates is by far below 5 %, typically 1-3 %, leading to a concentration of about 0,1% in the emulsion used by the end user (metalworking fluids are a mixture of ca. 5% concentrate in water). The German guidance value metalworking fluid for end users for mist is 10 mg/m3. Assuming a worst case scenario of 10% concentrate in the metalworking fluid containing 10 % boric acid, the maximum exposure would give the very low value of 0,1 mg/m3 boric acid. So the threshold limit of boric acid (2.6 mg/m3) can be met very easily. The benefits of using boric acid in metalworking fluids are: - stable buffer capacity, thus robust against microbial attacks - good availability and good price performance ratio - used without problems for many decades in the metalworking fluid industry Alternatives: Taking into account performance, sustainability and cost considerations equivalent replacements are not available. Potential alternatives have a shorter lifetime, are less stable to bacterial degradation and need a higher biocide level. So all in all they would be disadvantageous for health and environment. Concluding we are convinced that the use of boric acid in metalworking fluids is safe. Boron free metalworking fluids are no alternative, because of their low performance resulting in higher biocide usage (harmful to human health!)and higher consumption of resources. Hence including boric acid on the SVHC list is counterproductive. This would reduce the level of protection.	mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100420	Redco NV, Company, Belgium	boric acid.doc see attachment	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be

			questioned. We are, however, aware of the ongoing activities regarding worker studies, the pending decision of the European General Court regarding boric acid and the commission proposal to include boric acid in Annex XVII of the REACH regulation. Medicinal products are not subject toTitle VII REACH regulation.
20100420	MSCA, Belgium	p.12: editorial comment: The third scenario addresses the occasional misuse of automatic dishwashing liquids for hand dishwashing (and not misuse of liquid laundry detergent for dish washing).	Thank you. The wording has been corrected.
20100420	Industry or trade association, Company, United Kingdom	ECHA Reference Document 1.docx ECHA Reference Document 2.pdf ECHA Reference Document 3.pdf ECHA Reference Document 4.pdf ECHA Reference Document 5.pdf ECHA Reference Document 6.pdf ECHA Reference Document 7.pdf ECHA Reference Document 8.pdf ECHA Reference Document 9.pdf ECHA Reference Document 10.pdf Boric Acid - ECHA Submission Specific Comments on Use, Exposure, Alternatives and Risks Use Industry or trade association are engaged in the R&D, testing and manufacture of	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low

		epoxy based fire proofing formulations for use in Oil, Gas and Chemicals installations worldwide. These coatings are then sold to companies who manufacture rigs / platforms and appropriate application contractors globally. Boric acid is a key raw material component of these coating systems. Intumescent coatings are coatings where a series of active ingredients are present within a durable resin matrix. The active ingredients are present, so that in a fire situation they will react and form an insulating layer. The insulating layer will protect the steel substrate from the effects of the fire, and stop the steel from softening to a point where collapse becomes a possibility. The resin binder is chosen to protect the active ingredients in a non-fire situation, so that they are not leached out into the environment. Thick film epoxy Intumescent coatings have become the preferred route of providing fireproofing for Oil Gas and Chemicals installations since the recommendations of the Cullen Report into the Piper Alpha disaster. Lord Justice Cullen published his report in 1990, investigating what had failed on the Piper Alpha platform after a serious incident in July 1988, where 167 of 228 men on board lost their lives. Cullen made several recommendations, including the following: 1) Introduction of the Safety Case regulations, where an analysis of the risks of each platform and facility was carried out looking at Explosion risks, Quantity of Cargo available (fire load), type of fire (pool fire or high pressure Jet fire) 2) Explosion proofing of facilities so that fire proofing would not be destroyed in the case of an explosion (as was the case on Piper Alpha, and also on the World Trade Centre over 10 years later) 3) Fire proofing specifications to be improved, so that personnel on platforms should be able to survive incidents without needing outside help. The typical case here is that one of the main fireproofing bulkheads on Piper Alpha's accommodation block failed due to explosion damage, and the bulk of the fatalities were individuals trapped in the accommodation block. These recommendations saw a significant improvement in safety on these platforms, and they are still in use today. The main Classification societies (Lloyds Register, Det Norsk Veritas and Bureau Veritas) are used by the oil majors to ensure that any new build or refurbishment is carried out to the necessary standards laid down in the safety case regulations, regardless of where in the world the platform is being constructed and/or operated. It is common practice today for a platform to be built in the Middle East (Abu Dhabi / Kuwait / Doha) or Far East (Korea / China / Malaysia) for shipping	dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided. Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its high production volume. However, we are aware that boric acid will be registered by the end of this year and further information may become available. Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned.

		to its intended site (Nigeria / Brazil / Iran etc) Since Piper Alpha and the Cullen report, Epoxy Intumescent coatings have been seen as the main choice of fireproofing product because of :- • Excellent explosion resistance performance (undamaged at 4 Bar overpressure) • Up to 120 mins fire resistance in pool fire and Jet fire for structural steel • Up to 120 mins fire resistance for Divisions (Bulkhead and Deckhead) • Exposure durability that can withstand the harsh operating conditions in Offshore Environments with no loss of fire resistance performance The global market size is €100 million pa at present and forecast to increase markedly between now and 2014. The cost of entry for a new product is over €500K. Therefore the market has very few players. Two – including ourselves – carry out all activities (R&D and manufacture) within the EU. Both of these players are SME's, and each has only one site. A third company (the biggest in the market place) carries out R&D and manufacture in the EU, but is a global player and could manufacture outside the EU. Two others have R&D facilities in the USA, and can manufacture in the USA or other worldwide sites. Recently, a large EU manufacturer has indicated a preference to join this market place. They have set up a new R&D /manufacture facility outside the EU (in Dubai, UAE). Exposure Industry or trade association Staff Exposure Industry or trade association has used a third party occupational hygienist to measure exposure of our operators to various workplace chemicals at different stages of our operations. Measured exposure for the operation of loading a 5000 Litre vessel from 25Kg bags of various powders gave a total inhalable dust exposure of 2.3mg/m³ as an 8 hour time weighted average (see Reference Document 2). This is well below the 10mg/m³ exposure limit for total inhalable dust. Approximately 70% of the powders added were boric acid by weight. The control methods in place are: 1) LEV system at entrance to vessel and over the bin for the emptied bag.	

		2) Operator wearing FFP2 dust mask 3) Operator wearing thin nitrile rubber gloves (surgical style) 4) Operator wearing cotton drill one piece overalls and safety boots 5) Room has good natural ventilation As stated earlier in the document, the product is used to provide fire protection for steelwork in a jet or hydrocarbon fire situation. Obviously as part of our development of this product and ongoing testing of the material we have to simulate these conditions and therefore have a series of furnaces which test samples are put through various fire tests to demonstrate the performance of the product. Again Industry or trade association have used a third party occupational hygienist to monitor personal exposure during the fire testing, sample clean down after burning and stack emissions. Exposure* Reference Document Furnace Operator in control room No exposure 3 Cleaning down of sections after burn 6.4 mg/m³ 3 Background levels in furnace room during burn 0.7 – 3.2 mg/m³ 3 Stack emission 0.09 mg/m³ 4 *All the above readings are of total inhalable dust not boron. The furnace operator sits in a positive pressure control room to monitor the burn and to control the furnace temperatures so that the heating process follows the theoretical heating curve as required. The background monitoring samples were taken above the furnace and are a measure of the fugitive emissions which escape from the furnace during the burn. The cleaning down of the steel test sections involves the chipping off with a scraper the intumescent char which is developed during the fire test and the sweeping up of the residue and its placement in an 1100Litre four wheeled bin. The operator wears a FFP3 dust mask but there is not at present any LEV provision. The operator then wears the same clothing as discussed above. The furnace is coupled to a complex extraction system where the hot flue gases are treated with sodium bi carbonate and activated charcoal before being cooled and passed through a reverse jet bag filter. The measurement recorded is from the stack after the flue gases have been treated and filtered. Industry or trade association do not have any current data on the exposure to operators during the spray application of this product. This is due to our standard application set up providing excellent control. The arrangements are as follows:-	

		Operator wears – air fed mask with air supplied from an external clean source, gloves, overalls and boots Full spray booth with capture velocity in the range 0.5-1m/s We firmly believe that the spray application when carried our as described above poses negligible risk of exposure to an operator. Non- Industry or trade association Exposure The finished product is applied by licensed applicators and not available to the general public. The locations where these products are used are on and off shore petrochemical installations so again, the general public will not be in contact with the finished product. Professional, licensed industrial applicators will have full Control of Substances Hazardous to Health assessments in place based on the material safety data sheet supplied by Industry or trade association or one of the other manufacturers of this type of coating. This allows the development of safe systems of work to minimise the exposure of the applicators and of other persons who could potentially be exposed through their work. Applicators have a dedicated work area segregated from other trades to allow safe application of the material by spray and trowel. The segregation distances prevent overspray affecting other workers. Applicators wear one piece full body coveralls, chemical resistant gloves, air-fed respirator and safety boots for spray application. For trowel application a respirator would not be worn. As the boric acid is fully encapsulated within the epoxy resin paint film trowel application would not give rise to any inhalation risk. With the use of air fed respirators during spray application there would be no significant inhalation exposure. In all cases, chemical resistant gloves would be worn so minimising any limited risk of skin exposure. Alternatives Work has been done to look to eliminate boric acid from Epoxy Intumescent coatings for Oil / Gas and Chemical Installations. Industry or trade association did file a patent looking to replace boric acid with potassium bicarbonate. This was after some promising work done on a theoretical level, and on initial screening tests. However the case was dropped after scale up tests could not reach the required level of performance	

		and issues with increased levels of smoke generation were noted. Phosphorus based flame retardants such as Ammonium Polyphosphate are widely used in Intumescent coatings for civil construction. These are manufactured by a number of German companies. These cannot be used as a direct replacement for boric acid in the case of the Oil Gas and Chemicals Fireproofing products. In fact, they are used as a synergist with boric acid in order to form Boron Phosphate. The use of boric acid in these products is important in a fire case in a number of key ways. • The low activation temperature of boric acid (c100°C) means that the coatings become active at that point. This is important in fire proofing life critical divisions (Bulkheads and Deckheads) between control rooms / accommodation modules and process equipment where the critical failure temperature is typically 140°C. • Boric acid can react with Phosphates and carbonaceous materials to form Boron phosphate esters, thus reducing the amount of soot and smoke generated. • Boron Phosphate is very thermally stable ensuring that the insulating material remains in place throughout a long hydrocarbon fuel fire, which can burn at temperatures of around 1100°C. • Borate glasses are formed on the outside of the insulating material. These help to keep the char together when presented with the erosive fire case of a jet fire. Other flame retardant technologies cannot provide all of the above benefits, in the way that boric acid can. The preferred route – especially for a jet fire and Division material is a blend of boric acid and Ammonium polyphosphate. Risk Industry or trade association Employees This can be split into two groups of workers. Group 1 – Factory production workers manufacturing batches of paint for sale to customers and Group 2 – Laboratory staff developing, spraying and testing of products. Additionally we have emissions from our processes via stacks to atmosphere and therefore have a third group who are our neighbours and the general public. Group1 Factory Personnel	

		The levels of exposure for employees making large batches of paint are currently well below the Workplace Exposure Limit of 10mg/m³. Exposure below 50% of a WEL would be regarded as a good level of control. The levels achieved on our site would be a factor of approximately 100 below the No Observed Adverse Effect Level (NO(A)EL). We therefore feel that the level of risk to our staff from the handling of boric acid via the control measures we employ are negligible from a reprotoxic perspective. European Borates Association have developed a series of models of both dermal and inhalation exposure scenarios as required under the REACH Regulation. The results from the inhalation model give a worse case exposure at 4.5mg/m³ and a typical case at 3.5mg/m³ for the small bag emptying into a mixer situation. These results show a good correlation with the practical figure achieved on our site and show that current good industrial practice is easily capable of controlling occupational exposure orders of magnitude below the NO(A)EL. (see Reference Documents 5-10) On these grounds there is no justification for a restriction of the use of boric acid or for a need for a tightening of the workplace exposure limit as this already provides a massive margin of safety against the NO(A)EL. Provided good industrial practice is followed then there is negligible risk from a reprotoxic perspective as the exposure generated is several orders of magnitude below the level where harm occurs. Group 2 Laboratory Personnel These staff manufacture small batches of product on miniature versions of the factory equipment with the same control measures in place. They apply these paints either by spray or by trowel. Neither of these routes provide any significant inhalation risk and the use of gloves, barrier creams and overalls minimises the dermal exposure risks. Operation of the furnace poses no risk to health. The only significant exposure is when a fire tested steel section has to be cleaned down. This task is short duration (15 minutes) and infrequent (less than once a day). The result obtained was from letting a stock pile build up over a week and then a person cleans down all the steel work in one go. Even with this worst case scenario, and without an extraction system in use, the level of exposure is comfortably below the WEL and therefore massively below the NO(A)EL.	

		On these grounds there is no justification for a restriction of the use of boric acid or for a need for a tightening of the workplace exposure limit as this already provides a massive margin of safety against the NO(A)EL. Group 3 Neighbours Exposed to extracted flue gases The concentration of particulate matter emitted from the stack is so low that once the dilution effect from the stack height is taken into account there is once again no perceptible risk to the general public or to neighbouring properties (Industrial units). Non Industry or trade association Risks 1) General Public The general public are not exposed to boric acid from its use in passive fire protection systems as they have virtually no potential for exposure to the cured coating as its use is within industrial sites predominantly on and off shore petrochemical installations. 2) Applicators This group of people have the potential for limited exposure to the boric acid but the level of exposure should be massively less than that for the employees of the manufacturer of the coating and therefore even further below the already minimal risk level of these staff. Other Societal Risks Asbestos This type of coating has been developed along with its sister coatings , the thin film cellulosic intumescents to provide a material which gives the fire protection qualities of asbestos without anything like the level of societal risks from its use. In use the coating is resistant to damage and does not break down. Any failure of the film does not release boric acid as the compound is fully encapsulated within the film, unlike asbestos. The intumescent coatings have been tested to show that they do not deform or detach in the event of an explosion so ensuring structural integrity of the building or article they protect. This is in contrast to asbestos as observed with the World Trade Centre.	

		Fire Risks Society needs both oil and its derivatives for it to live in a manner to which it has become accustomed. Therefore we need to have installations which process and store highly flammable liquids and gases. To minimise the risks from these installations and to reduce the risks for the various employees and contractors working on these sites, fire protection systems need to be in place. Epoxy passive fire protection systems incorporating boric acid as one of the key ingredients provide part of the fire risk management strategy for such installations. In some ways, these systems provide a better line of defence than active systems as these paints do not rely on any mechanical, electrical or air systems to operate. They are purely activated by a rise in temperature inducing a chemical reaction. They have been developed in response to a major incident, and it would be a significant step backwards if we were unable to continue to develop this technology. These coatings containing boric acid also pose a minimal risk to the environment. Boric acid is fully encapsulated within the epoxy resin matrix, and this prevents leaching to the environment. Furthermore, these coatings are predominantly specified with a sealer coat, which provides a decorative appearance, and also aids in providing a durable top layer. Studies have been carried out involving these coatings being exposed to a range of different accelerated weathering techniques and then tested for weight loss / fire performance. These tests are in accordance with ISO20340 and UL1709. The tests have been carried out both with and without the presence of a sealercoat. Results show and no significant weight loss and no loss in fire resistance performance when so tested. The materials have also been exposed to a number of real time exposure criteria including industrial atmospheric exposure and immersion for up to 10 years in fresh water. No leaching of boric acid and loss of fire resistance performance was observed. Commercial Risk There is a significant commercial risk to the EU if REACH prevents the use of boric acid in Intumescent fire resisting coatings. This is a €100million pa market, where the EU predominantly exports product and technology to the rest of the world. If the EU restricts the use of boric acid in this fashion, several EU based SME's will have their	

		market access curtailed. One key player already carries out R&D in the USA, and another has set up R&D facilities in the UAE, so that they can continue to operate outside any REACH restrictions. Many EU scientists will be forced to relocate to areas where restrictions are not enforced. In addition to the above – boric acid represents less than 10% of the raw cost of the total formulation for an Intumescent coating. There is typically €60 million of other spend within the wider EU chemicals industry in addition to the boric acid spend for this technology. If the use of boric acid in this market is restricted, the formulation / manufacture of these coatings will be moved outside the EU. As a direct result local sources of the other chemistries will also be considered. The EU will therefore lose epoxy resin / polyamide curative and other sales of materials totalling upto €60 million.	
20100420	The Association of Contact Lens Manufacturers Ltd, Industry or trade association, United Kingdom	Exposure / Risks: Manufactures of contact lenses have for over 20 years been using borate buffer as a part of these devices. The exposure to diluted borates is limited by the topical (ocular and skin) route of delivery upon contact lens insertion. However, according to published data discussed in Annex XV and RPA report (2008), a dermal absorption of 0.5% is used as worse case approach greatly limiting systemic delivery of borates. Thus, exposure to borates in contact lenses, which are well below thresholds discussed above, will be further greatly reduced due to topical route of administration. We therefore propose to consider the topical route while evaluating the overall human risk of exposure to boron-containing substances discussed in the comments on Classification and Labelling. Boron is known to be a critical element for the normal growth and productivity of aquatic and terrestrial plants. Per RPA report (2008), the available data support the interpretation that borates are not significantly bioaccumulated. In addition, data from animals and humans indicates that boron is quickly removed via feces and urine, so body concentrations do not continually increase. Thus, there is no chronic human or environmental concern from limited exposure to boron present in the contact lenses. The WHO review of Boron (1998) noted that highly water soluble materials are unlikely to bioaccumulate to any significant degree and that any borate species are all present essentially as undissociated and highly soluble boric acid at neutral pH. The available data indicate that both experimental data and field observations support the interpretation that borates are not significantly bioaccumulated. Both oral and inhalation exposures to boron-based substances are major human routes	Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its high production volume. So far, boric acid meets as well the criteria according to REACH article 57c as those of article 58. However, we are aware that boric acid will be registered by the end of this year and further information may become available. Risk assessment needs to take into account all routes and sources of exposure to boron compounds.

		of exposure. However since the borates are in solution the oral and inhalation routes are not relevant to contact lens products. In conclusion, contact lenses, contact lens care solutions and eye drops contain boric acid and disodium tetraborate well below the accepted threshold safety level. The systemic exposure is further limited by the topical delivery, and there is no concern of chronic bioaccumulation. Alternatives: Borate buffers exhibit microcidal properties thereby reducing the risk of contamination during the contact lens manufacturing process. Additionally borate buffers are fully compatible with the contact lens polymer matrix assuring the stability of the device over the entire shelf life.	
20100420	Chambre Syndicale Nationale de l'Industrie des Lubrifiants, Industry or trade association, France	EBA comments Annex XV 100104 final.pdf Exposure to boric acid in use as metalworking fluid. The official UK method for determining metalworking fluid mist is based on a tracer. This could be: sodium or boron. See the link below for details: http://www.hse.gov.uk/pubns/mdhs/pdfs/mdhs95-2.pdf The UK Guidance value metal working fluid end users for mist is 1 mg/m3; assuming a worse case scenario of a 10% MWF containing 10% boric acid, than the maximum exposure would give the extremely low 0,01 mg/m3 boric acid. Since March 2007 a health risk based exposure limit of 2,6 mg/m3 boric acid is in place in Germany (“gesundheitsbasierter AGW”, published in the TRGS 900), corresponding to 0,5 mg/m3 Boron (lead component). According to the definition of an AGW, acute or long term hazard can be excluded if the exposure limit is not exceeded. Furthermore, there is a remark (“Y”), that there is no expected risk for fertility/harm to the unborn child (R60/61) if the limit is not exceeded. Initial measurements of the Berufsgenossenschaft showed that the limit was never exceeded. Link to the TRGS 900: http://www.baua.de/cae/servlet/contentblob/666762/publicationFile/55576/TRGS-900.pdf Data generated by the BG Metall and the Verband Schmierstoffindustrie (VSI) in Germany showed, that the concentration of free boric acid in metalworking fluid concentrates is by far below 10%. Measurements performed by 11B NMR spectroscopy showed an average concentration of 2% in the metalworking fluid concentrate, leading to a maximum of 0,1% in the emulsion used by the end user	See response to EBA comments

		(metalworking fluids are a mixture of 4-5% concentrate in water). Apart from health and safety aspects, there are a number of other issues to look for Boric Acid Benefits: • stable buffer capacity, thus robust against microbial attacks. • good availability • good price performance ratio • used without problems for many decades in the metalworking fluid industry. Are there alternatives? • Although industry investigated alternatives for many years, no alternatives were found • All alternative formulations are, due to reduced buffer capacity, much less robust against bacterial attacks leading to increased usage of biocides, which from a health, safety and environment perspective is undesirable. • The lifetime of alternative formulations is significantly lower, resulting in a more frequent change and will have a higher consumption of resources and thus is poorer from a sustainability standpoint. • Lastly, the alternative formulations that use higher biocide levels are coupled with increased disposal rates and these higher waste levels will cause increased pressures on the environment. The European metalworking fluid manufacturers support the Product Stewardship principle to supply products that can be manufactured, transported and used safely. We work with suppliers, customers and regulatory authorities to reduce the health and environmental impact of metalworking fluids. We believe the use of boric acid / borates is safe within our industry. The below give links to documents that demonstrates our work. Safe handling of metalworking fluids: http://www.hse.gov.uk/metalworking/video/ Comment of the Berufsgenossenschaft (Accident Prevention & Insurance Association, Germany) on boric acid containing metalworking fluids: “The MWF product containing derivatives of boric acid shows a good stability to colonisation with mycobacteria already in the non-preserved state (formulation without biocides) and thus also the best effect of the biocides tested”, cited from: http://www.bg-metall.de/praevention/gesundheitsschutz/biologische-	

		gefaehrdungen/kuehlschmierstoffe/mykobakterien.html UKLA boric acid position paper: http://ueil.org/health_environment/documents/ukla-boric-oct09.pdf . BG boric acid information sheet http://www.vsi-schmierstoffe.de/fileadmin/template/VSI-Verwaltung/Texte/030_MFS_E2009-04_Boric_Acid.pdf Concluding, we feel that the use of boric acid is safe. Including Boric acid and disodium tetraborates on the list of SVHC will force end-users to move to boron free metalworking fluids. This will result in higher biocide usage (with their related health issues) and higher consumption of resources. Including boric acid and disodium tetraborates on the list of SVHC will have an opposite effect compared to REACH's targets.	
20100420	UNITI, Industry or trade association, Germany	EBA comments Annex XV 100104 final.pdf Boric acid exposure in metalworking fluid manufacturing applications: In Germany there is already a workplace threshold for boron established and the experience shows that this limit is never exceeded. Our members have already installed measurements to minimize boric acid exposure Boric acid exposure in metalworking fluids According to the German regulation TRGS 900 a health risk based threshold exposure limit of 2,6 mg/m3 boric acid is required. This is equivalent to 0,5 mg/m3 boron as the lead component. Referring to the definition of these thresholds acute or long term hazard can be excluded if the exposure limit is not exceeded. Furthermore, there is a remark ("Y"), that there is no expected risk for fertility/harm to the unborn child (R60/61) if the limit is not exceeded. Available date from the German " Berufsgenossenschaft" indicate that the limits are never exceeded. Measurements performed by 11B NMR spectroscopy clearly showed that due to chemical reactions the boric acid concentration in the metalworking fluid is far below 5 %. In the metalworking fluid concentrate an average boric acid content of 2 % is realistic. Therefore in the finally applied emulsion(4-5%) used for metalworking the maximum amount is 0.1 %. In order to get the full picture some benefits of boric acid need to be considered as well: - robustness regarding microbial degradation	See response to EBA comments

		- excellent price performance ratio - very good long-term experience in metalworking fluid applications Taking into account performance, sustainability and cost considerations equivalent replacements are not available. Potential alternatives have a shorter lifetime, are less prone to bacterial degradation and need a higher biocide level. So all in all they would be detrimental for health and environment. In summary, based on the available data we are convinced that the careful and safe use of boric acid is not dangerous to human health. Moreover we are convinced that applying boric acid is the better approach instead of forcing the industry to use low performance alternatives which would result in higher biocide usage. Therefore including boric acid on the SVHC list will not be beneficial and may even have a negative effect on human health and the environment	
20100420	Silvaprodukt, Company, Slovenia	Silvaprodukt d.o.o. Dolenjska cesta 42, 1000 Ljubljana European Chemicals Agency Urad Republike Slovenije za kemikalije Ajdovščina 4 1000 Ljubljana Response to the Proposals to identify Substances of Very High Concern: Annex XV reports for commenting by Interested Parties – BORIC ACID The decision of the European Chemicals Agency to identify Boric acid as Substance of very high concern surprised us. Our company Silvaprodukt has long tradition of producing wood preservatives. We are producing wood preservatives for more than 60 years. Products, based on (containing) boric acid are in our market for almost 50 years. They are extensively used in the industrial scale and “do it yourself” program. Despite of the fact that boric acid is used for decades, there was no report on the any kind of the CMR issues nor by the employees in our company, nor by the our consumers, nor by the users.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low

		Boron is present in small amounts in nature everywhere. It is located in the soil, water, plants and animals. The average concentration of boron in soil is between 3 mg/kg and 10 mg/kg of soil (Adams, 1964). Sea water on average contains 4,5 mg/kg of B (Jenkins, 1980) and drinking water between 0,05 mg/L and 0,3 mg/L. Concentrations can be higher, depending on the location, mostly (Yazbeck et al., 2005). For example, boron concentration in drinking water, in the sounding of boron mines in Turkey, is between 21 mg/L to 29 mg/L (Sayli et al., 1998). Boron is also used as an additive or in can preservative in food products. Estimates of daily intakes vary. They depend on local eating habits and the use of preservatives in food. The average daily intake of boron per person in the US is according to Murray (1995) at least 1,5 mg of B/day/person. Rainer (1993) estimated, that the average daily intake is even higher (up to 3 mg of B/day/person), and can reach up to 10 mg of B/day/person. While Roper (1992) indicates even higher quantities of boron compounds, each day we consume between 10 and 25 mg of B/day/person. The most famous dish which preserved with boric acid is caviar. Only the use of boric acid allows the transport of caviar Boron may enter the human body through the skin and respiratory tract. Inhalation of air, which contains 4,1 mg/m3 of boron, causes irritation of the nose, throat or eyes. Boron irritate the eyes, but only when workers are exposed to boron over longer period (Roper, 1992). Maximum working concentration of boron oxide and borax in the air is 10 mg/m3. On the other hand, studies of borates in practice showed, that the introduction of the borates to the inhalator tract does not reflected in any detectable chronic effect; additionally dermal contact did not cause any irritation or inflammation of the skin also (Culver and Shen, 1994). Boron toxicity studies on mammals (mice, rats and dogs) showed that it affects the male sex organs (reproductive toxicity). This was shown especially in tests where the animals have consumed large quantities of boric acid for shorter or longer period of time (Roper, 1992). Similar studies of influence of boric acid on the pregnant mice, rats and rabbits showed a lesser effect on the cub development (Fail, 1998). On the other hand, Weir and Fisher (1972) report that 8,8 mg boron/kg/ day, which was added to the dogs food for two years, did not affect their reproduction. Adverse effect of boron on reproductive was found in rats chronically exposed to significantly higher concentrations (58,5 mg boron/kg/day). So person of 75 kg, should consume daily 4 m3 of impregnated wood to achieve this intake. The survey data on influence of boron on reproductive toxicity of humans are too poor to be able to confirm or discard the boron reproductive toxicity toward humans. There are also no available data to confirm teratogenicity properties of boron compounds. In a survey based study carried out on 542 men employed in the manufacture of borax (boron mining and processing), which were more than five years daily exposed to the high concentrations of boron (at	dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided. Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its high production volume. So far boric acid meets as well the criteria according to REACH article 57c as those of article 58. Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification and therefore the toxic effects will not be questioned.

least 23,2 mg borax/m3, 0,48 boric acid mg/kg body weight/day), noted that there were no statistically significant effects on their reproductive properties. Fertility of the men was in the average reported for the US (Whorton, 1994). Similar conclusions were reported by Sayli and colleagues (1998), who conclude that high concentrations of boron in drinking water (21 mg/L to 29 mg/L) does not affect fertility and reproduction of population in this region in Turkey.
Boron compounds are not accumulated in the human body. Research mobility of boron in the human body have shown that 50 % of the consumed boron is excreted by the urine within 21 hours. The remaining amount is excreted in 95 hours after ingestion of the boron (Rainer, 1993).
However, it should be considered, that boric acid based wood preservatives used for treatment of wood are stable. They are used for impregnation of construction that is not in contact with people. This construction is covered by insulation, façade… Boric acid does not evaporate from wood. It is stabilized in wood. Furthermore, impregnation of wood is rather hard physical work. It is not suitable for pregnant women in general. Therefore, in our 60 year old history, we have never met pregnant women working on the impregnation plant.

However, it should be considered, that treatment of wood with wood preservatives based on boric acid is taking place in closed system in impregnation tank. The surface of impregnated wood is rather dry at the end of impregnation procedure. So users are not in direct contact with boric acid aqueous solution, but in with boric acid fixed in wood. So there are other type of interaction then described in this study. Furthermore, it should be considered, that boric acid treated wood is generally treated with surface coatings that limit contact of boric acid with wood. Furthermore it should be considered, that boric acid remained in wood and does not evaporate from wood during wood service life.

Therefore we believe, that the authorities will consider, that the boric acid in not chemical of high concern, at least in the applications related to wood preservation, and can be used for industrial applications.

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20100421	Rhenus Lub GmbH & Co KG, Company, Germany	EBA comments Annex XV 100104 final.pdf We and our customers have a long experience in using boric acid in metal working fluids. Until now we have no information or evidence that the use of boric acid leads to increased health problems of the workers or to negative effects to the environment in our plant and in the plants of our customers. We have workplace measurements regarding the exposure to boric acid during the manufacturing process. The result of this study shows that the exposure to boric acid for human and environment is extremely unlikely.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to

		In Germany a health risk based exposure limit of 2,6 mg/m^3 boric acid is in place (gesundheitsbasierter AGW) and is published in the TRGS 900. This TRGS points out, that an acute or long time hazard can be excluded if the exposure limit is not exceeded. Also there is no expected risk for fertility or harm to the unborn child if the limit is not exceeded. The German Berufsgenossenschaft found in initial measurements that the limit is not reached. http://www.baua.de/cae/servlet/contentblob/666762/publicationFile/55576/TRGS-900.pdf The BG Metall and the VSI in Germany have realized a project to measure the free boric acid in metalworking fluids containing boric acid. They used 11B-NMR spectroscopy to quantify this concentration. The results showed an average concentration of 2% boric acid in metalworking concentrates. The end user mixes the concentrate with water before using it. The concentration is normally 4-5%, so the concentration of free boric acid in the dilution is 0.1%. Apart from health and safety aspects, there are other important facts: Benefits of boric acid: - Stable buffer capacity, which leads to a very good long time stability - Good availability - Used without problems regarding human health and environment over a long time in the metalworking industry Alternatives to Boric acid: - We search for an alternative to boric acid for 20 years, but no alternative has been found yet. - Alternative formulations without boric acid have a reduced buffer capacity and are less long time stable. - Because of that an increased use of biocides is necessary, which can be critical regarding human health and environment. - The lifetime of the coolant is lower. This will lead to a higher consumption of resources and to more waste, which is poorer from the sustainability view. We as a part of the European metalworking fluid manufacturers support the principle to supply products, which can be used safely. We work together with suppliers, customers and regulatory authorities to make the use of metalworking fluids safe. We believe that the use of boric acid is safe in the metalworking industry. Below we give some links to demonstrate that work.	overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided. See response to EBA comments

		Safe handling to metalworking fluids: http://www.hse.gov.uk/metalworking/video/ UKLA boric acid position paper http://ueil.org/health_environment/documents/ukla-boric-oct09.pdf BG boric acid information sheet http://www.vsi-schmierstoffe.de/fileadmin/template/VSI-Verwaltung/Texte/030_MFS_E2009-04_Boric_Acid.pdf In our opinion the use of boric acid in the metalworking industry is safe. A change to boric acid free formulations, which has to be done if the boric acid will be part of the SVHC-list, will lead to higher consumption of resources, more waste and a higher usage of biocides. We think that this is not the target of REACH.	
20100421	Industry or trade association, Company, France	Boric acid is used to control nuclear reaction. Boric acid is added to water within primar network to ensure reactor activity management. In the initial tests, Boric acid is also used to optimize properties of the mixture (pH...). Boric acide is also used for : - reproduction of synthetic circuit for hydrogen boucle (0,20 kg/year). - bore monitoring within our product. We use a solution of bore (1g/L) or crystalline form. Calibration solution is made according to ASTM 2371, which mentioned boric acid. No bore is present on equipment produce. Very few people could manipulate this product and quantity as well as concentration are very low. Wastes are collected by a company specialised in waste treatment. Protection equipments are gloves, glasses and anti-acid coat. Substitution is not possible due to administrative and technic reasons.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low

			dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100421	Česká společnost pro povrchové úpravy, Industry or trade association, Czech Republic	BORIC ACID is necessary and important chemical for electroplating (nickel and zinc electroplating bath contain 30 -50 g/l). Boric acid occurs during electroplating process only, that is strongly controlled technology, and is not contained in the deposition on the article to be treated, so any hazard for the human health will be excluded. The restriction of boric acid will result in serious setback in proceeding of many industrial premises for surface treatment. For example there are above than 150 users – electroplating plant in the Czech Republic	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low

			dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100421	EDF, Company, France	English version : -Page 11: Information from the provisional file and the RPA report : The "Appendix XV" file on boric acid submitted by Germany and Slovenia is based on a report called "Assessment of the risk to consumers and the impact of potential restrictions on their marketing and use" published in 2008 by a British consulting company named Risk and Policy Analysts Limited (RPA); this report was sponsored by the European Commission. Section 3.2.17 "Nuclear reactors and parts thereof" of this report states that using boron in nuclear reactors cannot be considered a use that leads to consumer exposure. Therefore, the "Appendix XV" file does not refer to the use of boric acid in nuclear power plants. As a "Downstream User", EDF provided the REACH consortium (Development of exposure scenarios for the EU risk assessment and REACH dossiers) data related to the use of boric acid in its nuclear power plants and occupational exposure and discharge in the environment. -Page 17: Risk-related information EDF's use of boric acid in its facilities does not expose workers, consumers, or the environment to risk. Managing the risks of using boric acid in EDF's nuclear electric power plants: protecting workers	Your comment is highly appreciated. Alternatives or substitution will have to be discussed in case an application for authorization for production processes, uses or applications becomes necessary.

		To manage the risk of boric acid exposure among employees working at the plants and to protect them, EDF implements the actions prescribed by the French labour code: -Personal protective equipment recommended in the supplier's safety data sheet must be worn, particularly the FPP3 protective mask -Exposure tracking -Annual exposure measures for workers. Moreover, organizational provisions and methods are implemented at EDF nuclear sites to prevent dispersal of materials. Managing the risks of effluent discharge from nuclear electric power plants: Effluent discharges containing boric acid are strictly regulated and monitored by the nuclear safety Authority. Managing the source at the origin an Treating these effluents (recycling, evaporation, and demineralization) allow to limit the flows and concentrations of boric acid liquid discharge into the surrounding environment. One part of the boric acid is discharged as a liquid; the other part is concentrated . The biggest part of concentrates is incinerated with other burnable waste (Centraco facility of SOCODEI cie, an Group EDF'subsidiary specialized in conditioning and treatment of industrial radioactive waste and effluents) ; the remaining part is directly cemented in concrete blocks by the Nuclear Power Plants. All waste packages containing boron are disposed of in the ANDRA (the National Radiation Waste Management Agency) surface repository storage CSFMA (Low Level Waste/Intermediate Level Waste). Steps for improving the management of effluents and reducing them at the source have helped reduce boric acid in liquid discharge by a factor of more than 2 over the last few years . In 2009, 58 EDF nuclear electric power plants discharged 163 tons of boric acid liquid effluent; i.e. an average of 2.8 tons per reactor. Below, we will separate evaluations related to managing public health risks and those related to managing environmental risk. Managing the public health risk : An evaluation of the health risk of boric acid liquid discharge from water nuclear	

		plants was conducted by EDF based on the quantitative evaluation of health risks (Évaluation Quantitative des Risques Sanitaires - EQRS), in compliance with recommendations (INERIS 2003 guide) from the French national institute for industrial environment and risks (INERIS - Institut National de l'EnviRonnement Industriel et des rISques). The INERIS is a French public institution under administrative control of the Ministry of Ecology, Energy, Sustainable Development and the Ocean (MEEDDM). Its mission is to conduct studies and research that can help prevent risks that economic activities impose upon the safety of people and goods. Boric acid is a threshold substance: its effect only occurs beyond a dose threshold, and its severity increases with the dose. It is considered there to be no effect if the level of boric acid is below this threshold dose, called the Toxicity Reference Value (VTR). For threshold effects, the risk indicator is the HQ, hazard quotient (or risk index), which is the ratio between the daily exposure dose and the Toxicity Reference Value (VTR). When the HQ is lower than 1, the risk of a toxic effect is unlikely. When the HQ exceeds 1, the occurrence of a toxic effect cannot be ruled out, and a second, more in-depth evaluation must be conducted by re-examining all of the hypotheses, data and parameters used. The Toxicity Reference Values (VTR) used to characterize the potentially toxic effects of boric acid (dose-effect relationship) are based on the critical analysis of toxicology, epidemiology, and clinical information established by international bodies (WHO) or national institutions (US-EPA and US-ATSDR in the United States, the RIVM in the Netherlands, Health Canada, etc.) Evaluations of the health risk of boric acid liquid discharge from nuclear power plants show that the hazard quotient related to chronic exposure or acute exposure from ingestion is still lower than 1. Consequently, the health risk associated with boric acid liquid discharge, based on current knowledge and methods tested by reputable scientific organisations, is not considered to be a concern. Managing the environmental risk Impact studies have been carried out for nuclear sites located either by rivers or by the sea, according to a methodological approach for evaluating the environmental impact of the liquid chemical discharge specified at the end of this document. For nuclear sites by rivers: 1. In France, there is no regulatory limit for boric acid concentration in surface waters,	

		apart from that defined in the order of 11 January 2007 on the quality limits and references for raw waters and waters intended for human consumption (quality limit for "fresh surface waters used to produce water intended for human consumption"); 2. An ecotoxicological approach has been carried out for boric acid, supplemented by a risk index calculation. The cumulated chronic risk indices (taking account of concentrations upstream from power plants), calculated according to the methodology recognized and presented in regulatory and recognized files, are less than 1 (between 0.01 and 0.4 according to sites), which shows that chronic boric acid liquid discharge from nuclear power plants does not present a chronic risk for the environment. The calculated cumulated acute risk indices are also less than 1 (between 0.01 and 0.1 according to sites) which shows that boric acid liquid discharge from nuclear sites does not present an acute risk for the environment. For sites by the sea: 1. Boric acid is a substance belonging to the main constituents of marine waters; it is therefore naturally present in the aquatic environment. The maximum concentration in added boric acid after mixing accounts for a few percent of the natural background noise; it is of the same order of magnitude as the natural fluctuations of boric acid concentration in the environment. 2. Use of ecotoxicity data obtained in the laboratory, as part of an evaluation carried out by the ecotoxicological approach, does not seem relevant given the natural levels of boric acid concentrations found in marine waters, of about ten milligrams per litre of boron, with species acclimatized to these high concentrations. Hydroecological monitoring performed around each nuclear site moreover has never demonstrated a significant influence of boric acid liquid discharge from the site on the marine ecosystem. Consequently, the boric acid liquid discharge produced by nuclear sites by the sea has no impact on the marine ecosystem. In conclusion, impact studies carried out in particular as part of authorization requests for liquid discharge and water intake on the one hand, and data from the environmental monitoring of sites on the other hand, demonstrate the absence of impact on the environment of boric acid liquid discharge due to the operation of nuclear power plants. -Page 17: Information on alternatives A study has been carried out (see attachment) on the possible substitutes for boric acid in the primary circuit of water (PWR) nuclear power plants. Five criteria must be complied with to guarantee the substitution:	

		-neutron absorption role, for controlling the nuclear reaction, -solubility in water: high solubility is essential to guarantee homogeneity in the circuits, -compatibility with the radiation protection of workers, -compatibility with the integrity requirement of the primary circuit: absence of corrosion risk of the primary circuit materials in the presence of lithium hydroxide, -control of the chemical risk for workers. No product satisfies all these technical, health and safety criteria for boric acid substitution. There is therefore no boric acid substitute for water (PWR) nuclear power plants whereas its use is vital for the nuclear power sector. Remember that electricity from nuclear plants represents 25% of the electricity consumed in Europe (75% in France). ANNEX : Methodology for evaluating the environmental impact of the chemical substances applied by EDF as part of the authorization studies for water withdrawal and the liquid discharge of nuclear plants producing electricity A medium scenario ("chronic" approach) and a penalizing scenario ("acute" approach) are studied on the basis of envelope liquid discharge scenarios, taking into account the maximum authorized limits (and not the actual liquid discharge) and the concentrations upstream of the environment. These two approaches are completed with feedback and conclusions from the hydrobiological monitoring carried out annually in the environment of each nuclear plant. The evaluation approach for the environmental impact of a substance like boric acid is carried out according to the following steps: · Step one is based on a comparison with the guide values and/or thresholds given in the regulations or proposed by the Administration. · Step two: If there is no guide value or threshold, an ecotoxicological approach is implemented, based on a comparison of the concentration values from the studied scenarios with the available ecotoxicological data (values from laboratory tests produced by the scientific community and enabling threshold values to be defined for an observed population). · In addition to step two, and when valid data are available, the ecotoxicological approach is coupled with an environmental risk analysis. Environmental risk analysis is a method recommended by the European Union (approach proposed in the European guide "Technical Guidance Document on Risk Assessment") for	

		characterizing the risk of producing and marketing new or existing substances in Europe, and not for determining the local impact of substances in a particular environment, especially when it is naturally present in the sea, like for boric acid. It is based on the establishment of a Risk Index. The environmental risk analysis method as understood by this guide concludes the absence of risk when this risk index is less than 1; it provides no interpretable information as to the presence of risk (probability of occurrence, amplitude) for a risk index greater than 1. In this case, the risk is not demonstrated; it is necessary, in order to specify this risk, to refine the analysis undertaken by other means, in particular by taking into account the specific characteristics of the substance in the environment, and especially the results found on the biological indicators in situ. Comments also available in pdf format in attachment Version française : -Page 11 : information émanant du dossier provisoire et du rapport RPA : Le dossier « Annexe XV » sur l'acide borique, déposé par l'Allemagne et la Slovénie, s'appuie sur un rapport publié en 2008 par la société de consulting anglaise Risk and Policy Analysts Limited (RPA) « Assessment of the risk to consumers and the impact of potentiel restrictions on their marketing and use », rapport commandité par la Commission Européenne. Au § 3.2.17 "Nuclear reactors and parts therof" dudit rapport, il est fait mention que l'usage du bore dans les réacteurs nucléaires ne peut être considéré comme un usage conduisant à une exposition des consommateurs. A ce titre, le dossier « Annexe XV » ne fait pas référence à l'utilisation de l'acide borique dans les centrales nucléaires. En tant que « Downstream User », EDF a fourni au consortium REACH (Development of exposure scenarios for the EU risk assessment and REACH dossiers) les données relatives aux expositions professionnelles et aux rejets dans l'environnement concernant l'utilisation de l'acide borique dans ses centrales nucléaires. -Page 17 : Risk related information L'usage par EDF de l'acide borique dans ses installations n'expose pas les personnels, les consommateurs ou l'environnement à un risque. Maîtrise des risques liés à la mise en œuvre de l'acide borique dans les centres nucléaires de production d'électricité d'EDF : protection des travailleurs Afin de maîtriser le risque d'exposition à l'acide borique des travailleurs intervenant	

		sur les installations et assurer leur protection, EDF met en oeuvre les actions prescrites par le code du travail français : -port des équipements de protection individuels préconisés dans la Fiche de Données Sécurité du fournisseur, en particulier le masque de protection FPP3, -traçabilité des expositions, -mesures d'exposition des travailleurs à périodicité annuelle. Des dispositions organisationnelles et des moyens sont par ailleurs mis en œuvre sur les sites nucléaires EDF afin d'éviter la dispersion de produits. Maîtrise des risques liés aux rejets d'effluents des centres nucléaires de production d'électricité : Les rejets d'effluents contenant de l'acide borique sont strictement réglementés et soumis au contrôle de l'Autorité de sûreté nucléaire. La maîtrise à la source et le traitement de ces effluents (recyclage, traitement sur évaporateurs et déminéraliseurs) permettent de limiter les flux et les concentrations des rejets d'acide borique sous forme liquide, dans le milieu environnant. Une partie de l'acide borique est rejetée sous forme liquide, une autre partie est concentrée. La plus grande partie des concentrats est traitée par incinération avec d'autres déchets combustibles (usine Centraco de SOCODEI, filiale du Groupe EDF spécialisée dans le conditionnement et le traitement de déchets et effluents industriels radioactifs) ; le reste est directement cimenté en conteneurs béton, sur sites. Tous les colis de déchets contenant du bore sont stockés au centre de stockage en surface des déchets de faible et moyenne activité CSFMA géré par l'ANDRA (Agence Nationale de traitement des Déchets RAdioactifs). Les démarches de réduction à la source et d'optimisation de la gestion des effluents ont permis de réduire de plus d'un facteur 2 les rejets d'acide borique au cours des dernières années . En 2009, les 58 unités nucléaires de production d'électricité d'EDF ont rejeté 163 tonnes d'acide borique sous forme d'effluents liquides, soit une moyenne de 2.8 t par réacteur. On distinguera ci-après les évaluations liées à la maîtrise des risques vis-à-vis de la santé publique de celles liées à la maîtrise du risque environnemental	

		Maîtrise du risque vis-à-vis de la santé publique : L'évaluation du risque sanitaire des rejets d'acide borique des centrales nucléaires à eau est réalisée par EDF pour chaque site selon la méthode d'Évaluation Quantitative des Risques Sanitaires (EQRS), conformément aux recommandations (guide INERIS 2003) de l'Institut national de l'Environnement Industriel et des risqueS (INERIS). Cet Institut est un établissement public français, placé sous la tutelle du ministère de l'Ecologie, de l'Energie, du Développement Durable et de la Mer (MEEDDM), il a pour mission de réaliser des études et des recherches permettant de prévenir les risques que les activités économiques font peser sur la sécurité des personnes et des biens. L'acide borique est une substance à effets à seuil : l'effet ne survient qu'au-delà d'un seuil de dose et la gravité de l'effet croît avec la dose. En deçà de cette dose seuil, appelée Valeur Toxicologique de Référence (VTR), on considère que l'effet ne surviendra pas. Pour les effets à seuil, l'indicateur de risque est le Quotient de Danger QD (ou Indice de Risque) qui est le rapport entre la dose journalière d'exposition et la VTR. Lorsque le QD est inférieur à 1, le risque d'apparition d'un effet toxique est peu probable. Quand le QD dépasse 1, l'apparition d'un effet toxique ne peut être exclue et une seconde évaluation plus approfondie doit être entreprise en réexaminant l'ensemble des hypothèses, données et paramètres utilisés. Les Valeurs Toxicologiques de Référence (VTR) utilisées pour caractériser les effets toxiques potentiels de l'acide borique (relation dose-effet) sont fondées sur l'analyse critique des connaissances toxicologiques, épidémiologiques ou cliniques établies par les instances internationales (OMS) ou des structures nationales (US-EPA et US-ATSDR aux Etats-Unis, RIVM aux Pays-Bas, Health Canada, etc.). Les évaluations du risque sanitaire des rejets d'acide borique des centrales nucléaires montrent que le quotient de danger associé à une exposition chronique ou aiguë par ingestion, est toujours inférieur à 1. Par conséquent, le risque sanitaire associé aux rejets d'acide borique est considéré, sur la base des connaissances actuelles et de méthodes éprouvées par des organismes scientifiques reconnus, comme non préoccupant. Maîtrise du risque environnemental Des études d'impact ont été faites pour les sites nucléaires situés soit en bord de rivière soit en bord de mer, selon une démarche méthodologique d'évaluation de l'impact environnemental des rejets chimiques liquides précisée au bas de ce	

		document Pour les sites nucléaires en bord de rivière : 1. En France, il n'existe pas de limite réglementaire de la concentration en acide borique dans les eaux superficielles, hormis celle définie dans l'arrêté du 11 janvier 2007 relative aux limites et références de qualité des eaux brutes et des eaux destinées à la consommation humaine (limite de qualité des « eaux douces superficielles utilisées pour la production d'eau destinée à la consommation humaine ») ; 2. Une approche écotoxicologique a été menée pour l'acide borique, complétée par un calcul d'indice de risque. Les indices de risque chronique cumulés (donc tenant compte des concentrations en amont des centres de production d'électricité), calculés selon la méthodologie reconnue et présentée dans les dossiers réglementaires, sont inférieurs à 1 (compris entre 0.01 et 0.4 selon les sites), ce qui indique que les rejets chroniques en acide borique des centrales nucléaires de production d'électricité ne présentent pas de risque chronique pour l'environnement. Les indices de risque aigu cumulés calculés sont aussi inférieurs à 1 (compris entre 0.01 et 0.1 selon les sites) ce qui indique que les rejets en acide borique des sites nucléaires ne présentent pas de risque aigu pour l'environnement. Pour les sites en bord de mer : 1. L'acide borique est une substance appartenant aux constituants majeurs des eaux marines ; il est donc naturellement présent dans l'environnement aquatique. La concentration maximale en acide borique ajoutée après mélange représente quelques pour cent du bruit de fond naturel ; elle est du même ordre de grandeur que les fluctuations naturelles de la concentration en acide borique dans l'environnement. 2. L'utilisation de données d'écotoxicité obtenues en laboratoire, dans le cadre d'une évaluation menée par approche écotoxicologique, n'apparaît pas pertinente compte tenu des niveaux de concentrations naturelles en acide borique rencontrés dans les eaux marines, de l'ordre de la dizaine de milligrammes par litre de bore, avec des espèces acclimatées à ces concentrations élevées. Le suivi hydroécologique effectué autour de chaque site nucléaire n'a d'ailleurs jamais montré une influence notable des rejets en acide borique du site sur l'écosystème marin. En conséquence, les rejets en acide borique réalisés par les sites nucléaires bord de mer n'ont pas d'impact sur l'écosystème marin. En conclusion, les études d'impact réalisées dans le cadre notamment des demandes d'autorisation de rejets et de prise d'eau d'une part, et les données de la surveillance environnementales des sites d'autre part, montrent l'absence d'impact sur l'environnement des rejets d'acide borique dû au fonctionnement des centrales	

		nucléaires de production d'électricité. - Page 17 : Information on alternatives : Une étude a été menée (voir en pièce jointe) sur les substituts possibles à l'acide borique dans le circuit primaire des centrales nucléaires à eau. Cinq critères sont à respecter pour garantir la substitution : -rôle d'absorbant neutronique, pour le contrôle de la réaction nucléaire, -solubilité dans l'eau : une solubilité élevée est indispensable pour garantir l'homogénéité dans les circuits, -compatibilité avec la protection radiologique des travailleurs, -compatibilité avec l'exigence d'intégrité du circuit primaire : absence de risque de corrosion des matériaux du circuit primaire en présence de lithine, -maîtrise du risque chimique pour les travailleurs. Aucun produit ne satisfait à l'ensemble de ces critères techniques, d'hygiène et sécurité pour la substitution de l'acide borique. Il n'y a donc pas de substitut à l'acide borique pour les centrales nucléaires à eau or son usage est vital pour la filière nucléaire de production d'électricité. Pour mémoire, l'électricité d'origine nucléaire représente 25% de l'électricité consommée en Europe (75% en France). Annexe : Méthodologie d'évaluation de l'impact environnemental des substances chimiques appliquée par EDF dans le cadre des études d'autorisation de prélèvements d'eau et de rejets des centrales nucléaires de production d'électricité Un scénario moyen (approche dite chronique) et un scénario pénalisant (approche dite aiguë) sont étudiés sur la base de scénarii de rejets enveloppes, prenant en compte les limites maximales autorisées (et non les rejets réels) et les concentrations en amont du milieu. Ces deux approches sont complétées du retour d'expérience et des conclusions issues du suivi hydrobiologique réalisé annuellement dans l'environnement de chacune des centrales nucléaires. La démarche d'évaluation de l'impact environnemental d'une substance comme l'acide borique est réalisée selon les étapes suivantes : · La première étape s'appuie sur une comparaison aux seuils et/ou valeurs guides existant dans la réglementation ou proposés par l'Administration. · 2ème étape : S'il n'existe aucun seuil ou valeur guide, une démarche écotoxicologique est mise en oeuvre, basée sur une comparaison des valeurs de	

		concentrations issues des scénarii étudiés aux données écotoxicologiques disponibles (valeurs issues de tests en laboratoire produits par la communauté scientifique et permettant de définir des valeurs seuil sur une population observée). · En complément de la deuxième étape, et quand des données validées sont disponibles, la démarche écotoxicologique est assortie d'une analyse du risque environnemental. L'analyse du risque environnemental est une méthode recommandée par la communauté européenne (démarche proposée dans le guide européen « Technical Guidance Document on Risk Assessment ») pour la caractérisation du risque de production et de mise sur le marché européen de substances nouvelles ou existantes, et non pour déterminer l'impact local de substances dans un milieu particulier, surtout quand elle est présente naturellement en mer, comme pour l'acide borique. Elle se fonde sur l'établissement d'un Indice de Risque. La méthode d'analyse du risque environnemental au sens de ce guide permet de conclure à l'absence de risque lorsque cet indice de risque est inférieur à 1 ; elle n'apporte pas d'information interprétable quant à la présence de risque (probabilité d'occurrence, amplitude) pour un indice de risque supérieur à 1. Dans ce cas, le risque n'est pas démontré ; il est nécessaire, pour préciser ce risque, d'affiner par d'autres voies l'analyse engagée, en tenant compte notamment des caractéristiques spécifiques de la substance dans l'environnement, et surtout des résultats sur des indicateurs biologiques acquis in situ. Ces commentaires sont également disponibles au format pdf dans la pièce jointe	
2010421	Euromcontact, Industry or trade association, Belgium	Exposure / Risks: Manufactures of contact lenses have for over 20 years been using borate buffer as a part of these devices. The exposure to diluted borates is limited by the topical (ocular and skin) route of delivery upon contact lens insertion. However, according to published data discussed in Annex XV and RPA report (2008), a dermal absorption of 0.5% is used as worse case approach greatly limiting systemic delivery of borates. Thus, exposure to borates in contact lenses, which are well below thresholds discussed above, will be further greatly reduced due to topical route of administration. We therefore propose to consider the topical route while evaluating the overall human risk of exposure to boron-containing substances discussed in the comments on Classification and Labelling. Boron is known to be a critical element for the normal growth and productivity of aquatic and terrestrial plants. Per RPA report (2008), the available data support the interpretation that borates are not significantly bioaccumulated. In addition, data from animals and humans indicates that boron is quickly removed via feces and urine, so	Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its high production volume. So far, boric acid meets as well the criteria according to REACH article 57c as those of article 58. However, we are aware that boric acid will be registered by the end of this year and further information may become available. Risk assessment needs to take into account all routes and sources of exposure to boron compounds.

		body concentrations do not continually increase. Thus, there is no chronic human or environmental concern from limited exposure to boron present in the contact lenses. The WHO review of Boron (1998) noted that highly water soluble materials are unlikely to bioaccumulate to any significant degree and that any borate species are all present essentially as undissociated and highly soluble boric acid at neutral pH. The available data indicate that both experimental data and field observations support the interpretation that borates are not significantly bioaccumulated. Both oral and inhalation exposures to boron-based substances are major human routes of exposure. However since the borates are in solution the oral and inhalation routes are not relevant to contact lens products. In conclusion, contact lenses, contact lens care solutions and eye drops contain boric acid and disodium tetraborate well below the accepted threshold safety level. The systemic exposure is further limited by the topical delivery, and there is no concern of chronic bioaccumulation. Alternatives: Borate buffers exhibit microcidal properties thereby reducing the risk of contamination during the contact lens manufacturing process. Additionally borate buffers are fully compatible with the contact lens polymer matrix assuring the stability of the device over the entire shelf life.	
20100421	Industry or trade association, Company, United Kingdom	Borates Objection ECHA.pdf Please see attached confidential information	Boric acid was proposed as SVHC based on its classification as toxic to reproduction, its use in consumer products, and its high production volume. However, we are aware that boric acid will be registered by the end of this year and further information may become available.
20100421	MSCA, United Kingdom	Although information on the risks associated with exposures from workplace sources and consumer products is available in the transition report for boric acid, this has not been summarised here. Consequently it is not possible to get an accurate picture of the risks arising from current use from the SVHC dossier. In relation to occupational exposure, it is noted that exposure estimates are based on tier 1 modelled data. A more refined approach to exposure estimation may demonstrate lower exposure and hence lower risks. The transition dossier did not reach a view on the risks associated with consumer exposure because of insufficient information, but noted that the EU Commission were undertaking a study on the presence of borates in consumer products. No mention of this study has been made in the SVHC dossier. No	Risks associated with worker exposures have not been addressed in the annex XV dossier, but all quantitative information on risks associated with consumer exposure contained in the transitional dossier (cited as ECHA 2008a) and in the study undertaken by the EU Commission (cited as RPA 2008) have been evaluated for the annex XV dossier.

		information has been provided on the availability of alternatives. This information is not sufficient to judge whether or not additional regulatory action is required. The dossier does not provide any justification for prioritising boron compounds on Annex XIV. The major source of exposure to boron is via the diet. Exposures from use in the workplace and consumer products appear to make a relatively small contribution to total daily exposure. Better information on exposure is required before decisions can be taken on the need for additional regulatory action. If further action is warranted, for the sake of regulatory coherence it is important to consider whether the decisions being taken on this boron compounds should apply to other borates. Decisions about what is an acceptable level of exposure to boron compounds need to take into account the possible nutritional benefits of this element.	
20100421	VGB PowerTech e.V., Industry or trade association, Germany	In the primary loop of a pressurized water reactor the normal boron concentration varies from about 2600 ppm to about 5 ppm. In the fuel cooling installation the normal boron concentration is up to 2600 ppm. A higher concentration is located in the emergency tanks (about 7100ppm) and in the tank of the boric acid mixing station. By this system boric acid is dissolved in demineralised water. Boric acid is normally delivered in special 25 kilogram paper bags or in 40 kilogram drums. The mixing process is done by workers. They have to fill the solid boric acid into the mixing tank. This procedure normally does not happen more than 5 times a year. The highest risk is to have direct contact with boric acid during the dissolving process. For this process safety instructions (look at attachment) as well as special personal protection equipment have to be followed and used. Authorized personal check annually the boric acid exposition of the workers. (Attached one picture).	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden.

			Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100421	FUCHS Lubrificanti S.p.A., Company, Italy	p.14 - Boric acid is used in metalworking water soluble concentrates, which are sold to industries where workers are prepared to use this kind of products; these fluids are not sold to general Consumers. Besides these kind of emulsions are used in closed systems. As additional comment, to replace boric acid effect in contrast of bacterial growth a more concentration of other chemical toxic substances (biocides) are required in order to keep under reasonable control emulsion stability and the development of potential pathogenic bacteria. In service, the handling of these biocides substances exhibits more risks of exposure than the one related to boric acid.	Alternatives will also have to be discussed in case an application for authorisation becomes necessary.
20100421	UKLA Metalworking Fluid Product Stewardship Group, Industry or trade association, United Kingdom	EBA comments Annex XV 100104 final.pdf These comments refer to exposure to boric acid in use in metalworking fluids. Although there is no statutory limit at present in UK for exposure to the mist from water-mix metalworking fluids (WMMWFs), it is considered good practice to limit the mist concentration to 1 mg/cu.metre. On this basis and taking a worst case scenario of a metalworking fluid used at 10% concentration and containing 10% boric acid, the exposure would correspond to 0.01 mg/cu.metre which is exremely low. Boric acid has several important benefits for use in WMMWFs: - contributes to maintaining a stable pH and inhibits corrosion - readily available - cost effective - excellent track record of successful use in WMMWFs for decades Availability of alternative materials: No alternatives have been found which can be used as direct replacementsin the same	See response to EBA comments

		formulations.	
20100421	Industry or trade association, Company, Germany	Confidential document submitted	Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its high production volume. We are aware that boric acid will be registered by the end of this year and further information may become available.
20100421	Eye-Care Industries European Economic Interest Grouping, Industry or trade association, United Kingdom	Boric acid and borates - response from Eye-Care Industries - REACH.pdf Exposure / Risks Manufactures of ophthalmic pharmaceutical products have been using borate buffers as a part of these medicines for many years. The resulting exposure to diluted borates is limited by the topical (ocular and skin) route of delivery upon instillation of the medicine into the eye(s). However, according to published data discussed in Annex XV and RPA report (2008), a dermal absorption of 0.5% is used as a worse case approach, greatly limiting systemic delivery of borates. Thus the exposure to borates in ophthalmic pharmaceutical products, which are well below thresholds discussed above, will be further greatly reduced due to their topical route of administration. It is therefore proposed to consider the topical route while evaluating the overall human risk of exposure to boron-containing substances discussed in the comments on Classification and Labelling. Boron is known to be a critical element for the normal growth and productivity of aquatic and terrestrial plants. As indicated in the RPA report (2008), the available data support the interpretation that borates are not significantly bioaccumulated. In addition, data from animals and humans indicates that boron is quickly removed via faeces and urine so that body concentrations do not continually increase. Thus, there is no chronic human or environmental concern from limited exposure to boron present in ophthalmic pharmaceutical products. The WHO review of boron (1998) ‡ noted that highly water soluble materials are unlikely to bioaccumulate to any significant degree and that any borate species are all present essentially as undissociated and highly soluble boric acid at neutral pH.	Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its high production volume. So far, boric acid meets as well the criteria according to REACH article 57c as those of article 58. Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. Medicinal products are not subject to Title VII of the REACH regulation.

		Available data indicate that both experimental data and field observations support the interpretation that borates are not significantly bioaccumulated. ‡ IPCS (International Programme on Chemical Safety), 1998, Environmental Health Criteria 204: Boron. World Health Organization, Geneva, Switzerland Both oral and inhalation exposures to boron-based substances are major human routes of exposure. However since the borates are in solution the oral and inhalation routes are not relevant to ophthalmic pharmaceutical products. In summary, ophthalmic pharmaceutical products contain boric acid and disodium tetraborate well below the accepted threshold safety level. Systemic exposure arising from these products is further limited by their topical delivery, and there is no concern relating to chronic bio-accumulation. Alternatives Borate buffers used in ophthalmic pharmaceutical products can exhibit microbicidal properties and thereby reduce the risk of contamination during use of the products. This is in addition to the buffering properties of boric acid/borates. These properties are used to ensure that ophthalmic pharmaceutical products are stable and suitable for use throughout their shelf life and in-use period.	
20100421	Industry or trade association, Company, Luxembourg	EBA comments Annex XV 100104 final.pdf 1. The exposure estimations that are included in the dossier are incomplete and several of the RWC assumptions are not realistic. 2. Please see attached pdf file.	See response to EBA comments
20100421	MSCA, France	The use of boric acid as chemical for bathing water treatment (swimming pool) is excluded from title VII of Reach since it may be considered as a use in biocidal product within the scope of Directive 98/8/EC. This niche use seems to be very limited. According to the French public health code, swimming pool water treatments are subjected to preliminary authorisation in France and the use of boric acid is not allowed for this purpose. Because of a high cross-section for absorption of low energy (thermal) neutrons, boric acid is used in nuclear power plants to slow down the rate at which fission is occurring. By adding more boric acid to the reactor coolant which circulates through the reactor, the probability that a neutron can survive to cause fission is reduced.	Your comment and information is highly appreciated. Uses and exceptions from authorisation will also be discussed later in the process and when an authorisation will become necessary.

		Therefore, changes in boric acid concentration effectively regulate the rate of fission taking place in pressurized water reactors. For the same reason boric acid is also dissolved into the spent fuel pools containing used uranium rods in order to control neutron emissions and fuel reactivity. Boric acid may be also used - for the manufacturing of electronic capacitors (electrolyte components), - for the manufacturing of other borates compounds, - in the textile, leather and textile polymers sectors Pursuant to Commission decision of 30 January 2004 concerning "the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances", boric acid shall not be included in annex I to Directive 91/414/EEC (list of agreed active substances to enter the composition of plant protection products). The mentioned use of boric acid for insecticides and fungicides manufacturing, which is exempted from title VII, may be thus reviewed (cf. part 1.1.4.3. in the dossier).	
20100421	Cimcool Industrial Products B.V., Company, Netherlands	EBA comments Annex XV 100104 final.pdf Cimcool Industrial Products B.V. handles boric acid in fully enclosed and automatic production equipment. We have already workplace measures in place to reduce the exposure to boric acid to a minimum. All data show, that nowhere the threshold limit (as applicable in Germany, see further) is exceeded over an 8 hour working day. Exposure to boric acid in use as water miscible metalworking fluid. Metal working fluid concentrates are typically diluted (minimum recommended dilution for Cimcool products is 1 to 10) using local water before being filled into a metalworking machine. Germany Since March 2007 a health risk based exposure limit of 2,6 mg/m3 boric acid is in place in Germany ("gesundheitsbasierter AGW", published in the TRGS 900), corresponding to 0,5 mg/m3 Boron (lead component). According to the definition of an AGW, acute or long term hazard can be excluded if the exposure limit is not exceeded. Furthermore, there is a remark ("Y"), that there is no expected risk for fertility/harm to the unborn child (R60/61) if the limit is not exceeded. Initial measurements of the Berufsgenossenschaft showed that the limit was never exceeded. Link to the TRGS 900:	See response to EBA comments

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2010421	Cimcool Europe B.V.- Czech Branch, Company, Czech Republic	EBA comments Annex XV 100104 final.pdf Exposure to boric acid during metalworking fluid (MWF) manufacturing: Cimcool Europe B.V. metalworking fluids are produced by Cimcool Industrial Products B.V. Cimcool Industrial Products B.V. handles boric acid in fully enclosed and automatic production equipment. We have already workplace measures in place to reduce the exposure to boric acid to a minimum. All data show, that nowhere the threshold limit (as applicable in Germany, see further) is exceeded over an 8 hour working day. Exposure to boric acid in use as water miscible metalworking fluid. Metal working fluid concentrates are typically diluted (minimum recommended dilution for Cimcool products is 1 to 10) using local water before being filled into a metalworking machine. Germany Since March 2007 a health risk based exposure limit of 2,6 mg/m3 boric acid is in place in Germany ("gesundheitsbasierter AGW", published in the TRGS 900), corresponding to 0,5 mg/m3 Boron (lead component). According to the definition of	See response to EBA comments

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2010421	Cimcool Europe B.V.- Slovak Branch, Company, Slovakia	EBA comments Annex XV 100104 final.pdf Exposure to boric acid during metalworking fluid (MWF) manufacturing:	See response to EBA comments

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2010421	EURIMA, Industry or trade association, Belgium	Boron in Glass Wool Insulation GTS Final.pdf Article Risk assessment Boron in glass wool insulation Environ Sci Pollut Res 2009 A.A. Jensen.pdf • Boron in Glass Wool Insulation; Glass Technology Services; January 2007 - Attached • Risk assessment of Boron in Glass Wool Insulation – A.A. Jensen; January 2007 - Attached	The Article by Jensen has been cited in the annex XV dossier.
2010421	Cimcool Europe B.V.-UK branch, Company, United Kingdom	EBA comments Annex XV 100104 final.pdf Exposure to boric acid during metalworking fluid (MWF) manufacturing: Cimcool Europe B.V. metalworking fluids are produced by Cimcool Industrial Products B.V. Cimcool Industrial Products B.V. handles boric acid in fully enclosed and automatic production equipment. We have already workplace measures in place to reduce the exposure to boric acid to a minimum. All data show, that nowhere the threshold limit (as applicable in Germany, see further) is exceeded over an 8 hour working day. Exposure to boric acid in use as water miscible metalworking fluid. Metal working fluid concentrates are typically diluted (minimum recommended dilution for Cimcool products is 1 to 10) using local water before being filled into a metalworking machine.	See response to EBA comments

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2010421	Cimcool Europe B.V.- France branch, Company, France	EBA comments Annex XV 100104 final.pdf Exposure to boric acid during metalworking fluid (MWF) manufacturing: Cimcool Europe B.V. metalworking fluids are produced by Cimcool Industrial Products B.V. Cimcool Industrial Products B.V. handles boric acid in fully enclosed and automatic production equipment. We have already workplace measures in place to reduce the exposure to boric acid to a minimum. All data show, that nowhere the threshold limit (as applicable in Germany, see further) is exceeded over an 8 hour working day. Exposure to boric acid in use as water miscible metalworking fluid. Metal working fluid concentrates are typically diluted (minimum recommended dilution for Cimcool products is 1 to 10) using local water before being filled into a metalworking machine. Germany Since March 2007 a health risk based exposure limit of 2,6 mg/m3 boric acid is in place in Germany ("gesundheitsbasierter AGW", published in the TRGS 900), corresponding to 0,5 mg/m3 Boron (lead component). According to the definition of an AGW, acute or long term hazard can be excluded if the exposure limit is not exceeded. Furthermore, there is a remark ("Y"), that there is no expected risk for fertility/harm to the unborn child (R60/61) if the limit is not exceeded. Initial measurements of the Berufsgenossenschaft showed that the limit was never exceeded. Link to the TRGS 900: http://www.baua.de/cae/servlet/contentblob/666762/publicationFile/55576/TRGS-900.pdf Data generated by the BG Metall and the Verband Schmierstoffindustrie (VSI) in Germany showed, that the concentration of free boric acid in metalworking fluid concentrates is by far below 10%. Measurements performed by 11B NMR spectroscopy showed an average maximum concentration of 0,1% in the diluted metal working fluid as applied by the end user. UK The UK Guidance value metal working fluid end users for mist is 1 mg/m3; assuming a worst case scenario of a 10% MWF containing 10% boric acid, than the maximum exposure would give the extremely low 0,01 mg/m3 boric acid.	See response to EBA comments

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		gefaehrdungen/kuehlschmierstoffe/mykobakterien.html UKLA boric acid position paper: http://ueil.org/health_environment/documents/ukla-boric-oct09.pdf . BG boric acid information sheet http://www.vsi-schmierstoffe.de/fileadmin/template/VSI-Verwaltung/Texte/030_MFS_E2009-04_Boric_Acid.pdf Conclusion Concluding, we feel that the use of boric acid is safe. In our opinion Annex XV Dossiers should certainly not be filed before REACH Dossiers are reviewed in 2011. Including Boric acid and disodium tetraborates on the list of SVHC will force end-users to move to boron free metalworking fluids. This will result in higher biocide usage (with their related health issues) and higher consumption of resources. Including boric acid and disodium tetraborates on the list of SVHC will have an opposite effect compared to REACH's targets.	
2010421	Federchimica, Industry or trade association, Italy	The exposure estimations that are included in the boric acid dossier are incomplete and several of the realistic worst case (RWC) assumptions are not realistic. Examples of this are: • The maximum reported value of borates in mineral water is used as the exposure scenario even though the drinking water limit is 4 times lower. • The potential exposure from supplements was determined from a 16 year old personal communication from the United States reporting on body builder's use of supplements. The daily intake being proposed would be considered abusive. 1.1.4.2 Food contact material (p. 15) The substance boric acid is an intermediate to manufacture the substances glass and ceramic frits. Therefore it is no longer present in the final products. The boron present in ceramics and glass-ware is physically/chemically bound into the product, therefore in these cases, the potential for the consumers to be directly exposed to the borates present is minimal (RPA 2008). 1.1.4.4 Mineral water (p. 16) Maximum exposures are calculated using the maximum value reported in mineral water. This value of 4,35 mgB/L exceeds however the EU drinking water limit of 1	See response to EBA comments.

		mg B/L. A realistic worst case scenario should rather assume concentrations equivalent to the drinking water limit. This approach was also followed by ECHA (2008). 1.1.4.5 Food supplements (p. 16) It is stated that "Food supplements for bodybuilders may possibly lead to maximum boron intakes of up to 30 mg/day (0.5 mg/kg bw/day) for a 60 kg person, BfR 2006a". The original source of this statement (Loscutoff S. Personal Communication (Memorandum)) cannot be verified nor is it a peerreviewed or official publication. Therefore this value is not credible nor relevant. Further, consumption amounts of this nature as supplements would clearly be considered serious abuse by deliberate ingestion of extreme amounts and therefore is not relevant for this assessment. 2 INFORMATION ON ALTERNATIVES (p.17) The section indicates "no information on alternatives" It is important to underline that although industry investigated alternatives for many years, there are no alternatives found with sufficiently safety level. It is evident in in specific industrial sectors as: varnish, ceramics. All alternative formulations are much less robust against bacterial attacks leading to increased usage of biocides, which is from health and environment point of view not desired. The lifetime of alternative formulations are significantly lower, resulting in a more frequent change and thus higher consumption of resources, lastly, through increased disposal and higher waste there will be higher pressure on the environment	
20100421	Cimcool Europe B.V.-German branch, Company, Germany	EBA comments Annex XV 100104 final.pdf Exposure to boric acid during metalworking fluid (MWF) manufacturing: Cimcool Europe B.V. metalworking fluids are produced by Cimcool Industrial Products B.V. Cimcool Industrial Products B.V. handles boric acid in fully enclosed and automatic production equipment. We have already workplace measures in place to reduce the exposure to boric acid to a minimum. All data show, that nowhere the threshold limit (as applicable in Germany, see further) is exceeded over an 8 hour working day. Exposure to boric acid in use as water miscible metalworking fluid.	See response to EBA comments

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20100421	Bausch & Lomb, Inc, Medical Device and Pharmaceutical manufacturer, United States	Manufactures of contact lenses, contact lens solutions and other ophthalmic products intended for use in the eye have for over 20 years been using borate buffer as a part of these devices. The exposure to diluted borates is limited by the topical (ocular and skin) route of delivery upon contact lens insertion. However, according to published data discussed in Annex XV and RPA report (2008), a dermal absorption of 0.5% is used as worse case approach greatly limiting systemic delivery of borates. Thus, exposure to borates in contact lenses, which are well below thresholds discussed above, will be further greatly reduced due to topical route of administration. We therefore propose to consider the topical route while evaluating the overall human risk of exposure to boron-containing substances discussed in the comments on Classification and Labelling Boron is known to be a critical element for the normal growth and productivity of aquatic and terrestrial plants. Per RPA report (2008), the available data support the interpretation that borates are not significantly bioaccumulated. In addition, data from animals and humans indicates that boron is quickly removed via feces and urine, so body concentrations do not continually increase. Thus, there is no chronic human or environmental concern from limited exposure to boron present in the contact lenses. The WHO review of Boron (1998) noted that highly water soluble materials are unlikely to bioaccumulate to any significant degree and that any borate species are all present essentially as undissociated and highly soluble boric acid at neutral pH. The available data indicate that both experimental data and field observations support the interpretation that borates are not significantly bioaccumulated. Both oral and inhalation exposures to boron-based substances are major human routes of exposure. However since the borates are in solution the oral and inhalation routes are not relevant to contact lens products. In conclusion, contact lenses, contact lens care solutions and eye drops contain boric acid and disodium tetraborate well below the accepted threshold safety level. The systemic exposure is further limited by the topical delivery, and there is no concern of chronic bioaccumulation. Borate buffers can exhibit microcidal properties thereby reducing the risk of contamination during the contact lens manufacturing process. They also provide important buffering properties which are essential for the safe and effective use of ophthalmic products and finally, borate buffers are fully compatible with the contact	Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its high production volume. So far, boric acid meets as well the criteria according to REACH article 57c as those of article 58. However, we are aware that boric acid will be registered by the end of this year and further information may become available. Risk assessment needs to take into account all routes and sources of exposure to boron compounds.

		lens polymer matrix, are stable and suitable for use with ophthalmic products throughout the shelf life and use periods	
20100421	AFILUB, Industry or trade association, Spain	EBA comments Annex XV 100104 final.pdf Normally in our sector boric acid is used in metalworking fluids neutralized and esterified , and in 30 years using the product we never had any report from the manufacturers companies or customer of problems related to boric acid. Exposure to boric acid in use as metalworking fluid. The official UK method for determining metalworking fluid mist is based on a tracer. This could be: sodium or boron. See the link below for details: http://www.hse.gov.uk/pubns/mdhs/pdfs/mdhs95-2.pdf The UK Guidance value metal working fluid end users for mist is 1 mg/m3; assuming a worse case scenario of a 10% MWF containing 10% boric acid, than the maximum exposure would give the extremely low 0,01 mg/m3 boric acid. Since March 2007 a health risk based exposure limit of 2,6 mg/m3 boric acid is in place in Germany ("gesundheitsbasierter AGW", published in the TRGS 900), corresponding to 0,5 mg/m3 Boron (lead component). According to the definition of an AGW, acute or long term hazard can be excluded if the exposure limit is not exceeded. Furthermore, there is a remark ("Y"), that there is no expected risk for fertility/harm to the unborn child (R60/61) if the limit is not exceeded. Initial measurements of the Berufsgenossenschaft showed that the limit was never exceeded. Link to the TRGS 900: http://www.baua.de/cae/servlet/contentblob/666762/publicationFile/55576/TRGS-900.pdf Data generated by the BG Metall and the Verband Schmierstoffindustrie (VSI) in Germany showed, that the concentration of free boric acid in metalworking fluid concentrates is by far below 10%. Measurements performed by 11B NMR spectroscopy showed an average concentration of 2% in the metalworking fluid concentrate, leading to a maximum of 0,1% in the emulsion used by the end user (metalworking fluids are a mixture of 4-5% concentrate in water). Apart from health and safety aspects, there are a number of other issues to look for Boric Acid Benefits: • stable buffer capacity, thus robust against microbial attacks.	See response to EBA comments

		• good availability • good price performance ratio • used without problems for many decades in the metalworking fluid industry. Are there alternatives? • Although industry investigated alternatives for many years, no alternatives were found (Justifications: can we quantify this statement?) • All alternative formulations are, due to reduced buffer capacity, much less robust against bacterial attacks leading to increased usage of biocides, which from a health, safety and environment perspective is undesirable. • The lifetime of alternative formulations is significantly lower, resulting in a more frequent change and will have a higher consumption of resources and thus is poorer from a sustainability standpoint. • Lastly, the alternative formulations that use higher biocide levels are coupled with increased disposal rates and these higher waste levels will cause increased pressures on the environment. The European metalworking fluid manufacturers support the Product Stewardship principle to supply products that can be manufactured, transported and used safely. We work with suppliers, customers and regulatory authorities to reduce the health and environmental impact of metalworking fluids. We believe the use of boric acid / borates is safe within our industry. The below give links to documents that demonstrates our work. Safe handling of metalworking fluids: http://www.hse.gov.uk/metalworking/video/ Comment of the Berufsgenossenschaft (Accident Prevention & Insurance Association, Germany) on boric acid containing metalworking fluids: “The MWF product containing derivatives of boric acid shows a good stability to colonisation with mycobacteria already in the non-preserved state (formulation without biocides) and thus also the best effect of the biocides tested”, cited from: http://www.bg-metall.de/praevention/gesundheitsschutz/biologische-gefaehrdungen/kuehlschmierstoffe/mykobakterien.html UKLA boric acid position paper: http://ueil.org/health_environment/documents/ukla-boric-oct09.pdf . BG boric acid information sheet	

		http://www.vsi-schmierstoffe.de/fileadmin/template/VSI-Verwaltung/Texte/030_MFS_E2009-04_Boric_Acid.pdf Concluding, we feel that the use of boric acid is safe. Including Boric acid and disodium tetraborates on the list of SVHC will force end-users to move to boron free metalworking fluids. This will result in higher biocide usage (with their related health issues) and higher consumption of resources. Including boric acid and disodium tetraborates on the list of SVHC will have an opposite effect compared to REACH's targets	
20100421	MSCA, Ireland	General comments The Irish Competent Authority (IECA) has reviewed the Annex XV SVHC dossiers for boric acid. This particular review focused on the potential regulatory effectiveness of the authorisation process in addressing the risks associated with its classification as a category 1B reprotoxin. Following our review, we would like to put forward several observations as part of ECHA public consultation. Please note that some of these observations are the same for the three borate substances. 1) Consumers – The information on use and exposure contained in the Annex XV SVHC dossier is primarily focused on consumer products. This information was taken from the transitional Annex XV dossier and from the RPA report on the assessment of risks to consumers from borates. We believe that the majority of risks to consumers from borate substances and mixtures containing them, will be addressed by the Annex XVII general restriction on the placing on the market and use of substances or mixtures, classified as reprotoxic (category 1B) for supply to the general public. Therefore we feel that the need to place borates on Annex XIV, as a mechanism to address the risk becomes less of a priority. 2) Occupational exposure – The Annex XV SVHC dossier does not contain actual information on exposure in an occupational setting. Having referred to the transitional Annex XV dossier for boric acid, we see that the risk characterisation chapter concluded "there is a need for more information to adequately characterise the risks to workers and consumers for boron exposure via boric acid and sodium tetraborates". We believe that this conclusion is very relevant and reference to it should be included in the 'Use, Exposure, Alternatives and Risks' chapter of the Annex XV SVHC dossiers for the borates. We expect the registration dossiers to yield a lot of this type of missing occupational and consumer exposure information, which will help to	Your comment is highly appreciated. We are, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation, both of which appeared concurrent to the SVHC dossier preparation. For the SVHC dossier we reviewed and used the information available by the time of the dossier preparation. We are also aware, that boric acid will be registered by the end of this year and further information may become available. Risks associated with worker exposures have not been addressed in the annex XV dossier.

		identify whether or not any risk in occupational and consumer scenarios is not being adequately controlled. We feel that the apparent information gap for occupational exposure in particular, could further support the possible selection of the authorisation process as the appropriate RMO. In order for authorisation to be granted, operators will primarily have to demonstrate that any risk is adequately controlled. This could indirectly result in the collection of use-specific exposure information in occupational settings.	
20100421	Federchimica-Gail, Industry or trade association, Italy	EBA comments Annex XV 100104 final.pdf Exposure to boric acid in use as metalworking fluid. The official UK method for determining metalworking fluid mist is based on a tracer. This could be: sodium or boron. See the link below for details: http://www.hse.gov.uk/pubns/mdhs/pdfs/mdhs95-2.pdf The UK Guidance value metal working fluid end users for mist is 1 mg/m3; assuming a worse case scenario of a 10% MWF containing 10% boric acid, than the maximum exposure would give the extremely low 0,01 mg/m3 boric acid. Since March 2007 a health risk based exposure limit of 2,6 mg/m3 boric acid is in place in Germany ("gesundheitsbasierter AGW", published in the TRGS 900), corresponding to 0,5 mg/m3 Boron (lead component). According to the definition of an AGW, acute or long term hazard can be excluded if the exposure limit is not exceeded. Furthermore, there is a remark ("Y"), that there is no expected risk for fertility/harm to the unborn child (R60/61) if the limit is not exceeded. Initial measurements of the Berufsgenossenschaft showed that the limit was never exceeded. Link to the TRGS 900: http://www.baua.de/cae/servlet/contentblob/666762/publicationFile/55576/TRGS-900.pdf Data generated by the BG Metall and the Verband Schmierstoffindustrie (VSI) in Germany showed, that the concentration of free boric acid in metalworking fluid concentrates is by far below 10%. Measurements performed by 11B NMR spectroscopy showed an average concentration of 2% in the metalworking fluid concentrate, leading to a maximum of 0,1% in the emulsion used by the end user (metalworking fluids are a mixture of 4-5% concentrate in water). Apart from health and safety aspects, there are a number of other issues to look for	See response to EBA comments

		Boric Acid Benefits: • stable buffer capacity, thus robust against microbial attacks. • good availability • good price performance ratio • used without problems for many decades in the metalworking fluid industry. Are there alternatives? • Although industry investigated alternatives for many years, no alternatives were found • All alternative formulations are, due to reduced buffer capacity, much less robust against bacterial attacks leading to increased usage of biocides, which from a health, safety and environment perspective is undesirable. • The lifetime of alternative formulations is significantly lower, resulting in a more frequent change and will have a higher consumption of resources and thus is poorer from a sustainability standpoint. • Lastly, the alternative formulations that use higher biocide levels are coupled with increased disposal rates and these higher waste levels will cause increased pressures on the environment. The European metalworking fluid manufacturers support the Product Stewardship principle to supply products that can be manufactured, transported and used safely. We work with suppliers, customers and regulatory authorities to reduce the health and environmental impact of metalworking fluids. We believe the use of boric acid / borates is safe within our industry. The below give links to documents that demonstrates our work. Safe handling of metalworking fluids: http://www.hse.gov.uk/metalworking/video/ Comment of the Berufsgenossenschaft (Accident Prevention & Insurance Association, Germany) on boric acid containing metalworking fluids: “The MWF product containing derivatives of boric acid shows a good stability to colonisation with mycobacteria already in the non-preserved state (formulation without biocides) and thus also the best effect of the biocides tested”, cited from: http://www.bg-metall.de/praevention/gesundheitsschutz/biologische-gefaehrdungen/kuehlschmierstoffe/mykobakterien.html UKLA boric acid position paper: http://ueil.org/health_environment/documents/ukla-boric-oct09.pdf	

		. BG boric acid information sheet http://www.vsi-schmierstoffe.de/fileadmin/template/VSI-Verwaltung/Texte/030_MFS_E2009-04_Boric_Acid.pdf Concluding, we feel that the use of boric acid is safe. Including Boric acid and disodium tetraborates on the list of SVHC will force end-users to move to boron free metalworking fluids. This will result in higher biocide usage (with their related health issues) and higher consumption of resources. Including boric acid and disodium tetraborates on the list of SVHC will have an opposite effect compared to REACH's targets.	
20100421	Industry or trade association, Company, Albania	EBA comments Annex XV 100104 final.pdf 1. Use in Metalworking Fluids Formulation of Boric Acid containing products : Boric Acid is used in the formulation of water-miscible metalworking fluids concentrates. These concentrates are complex mixtures of several acids and alkaline compounds and a number of other substances. Currently nearly 80 Boric Acid containing formulations are blended in Europe and more than 50 of these are offered in Member States of the European community. This represents more than 40% of the total number of water-miscible metalworking fluid concentrates and - for 2009 – represents more than 60% of the total volume of concentrates sold in Europe. Seventy five percent are blended by use of pure boric acid and 25% based on additive packages containing boric acid, mainly in ionic form. Frequency and duration of handling Boric Acid is usually 1 to 2 times per day with 0.25 to 2 hours exposure and quantities used in this step range between 100 to 2000 kg. Due to occupational exposure limits for dust or Boric Acid 1) - exposure (main route : inhalation) is minimised by organisational/ technical measures : semi-automated filling to liquid in blending vessel directly, local exhaust ventilation, automatic equipment for folding the empty bags, dedicated well-ventilated areas and/or mandatory personal protective equipment including respiratory protection.	See response to EBA comments Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to

		The finished products are concentrates with alkaline pH-values due to surplus of alkaline compounds and contain less than 5.5% Boric Acid. Filling/packaging of finished Boric Acid containing concentrate depends on package size which varies from filling pails to bulk loading. End use of formulated Boric Acid containing products : The Metalworking fluid concentrates are used as aqueous dilutions, i.e. solutions or emulsions, in industrial/professional applications only. The solutions/emulsions are used for a variety of Metalworking applications, mainly in central machining systems of high technical standards, but also in small machines of lower technical standards. Concentrates usually are (semi-)automatically mixed with water at recommended concentrations of mainly 3-10 % concentrates. The dilutions are complex ionic mixtures of various salts and alkaline pH-values (value in solution/emulsion is mainly in the range 9.0 to 9.5). The concentration of Boric Acid in solution/emulsions is usually far below 1%. Only as an exception due to severe machining the concentration of the concentrate in dilution is higher or the pH-value exceeds the average range. Exposure to Boric Acid containing products at end customers might occur by skin contact to the concentrate and to solutions/emulsions in use, and by inhalation due to exposure to aerosols. The level of exposure is usually at very low level : - The UK Guidance value metal working fluid end users for mist is 1 mg/m3; assuming a worse case scenario of a 10% MWF containing 10% Boric Acid, than the maximum exposure would give the extremely low 0,01 mg/m3 Boric Acid. 2) - Data generated by the BG Metall and the Verband Schmierstoffindustrie (VSI) in Germany have shown that the concentration of free Boric Acid in metalworking fluid concentrates is far below the concentration of Boric Acid used for formulating the concentrate. 3) In addition routine measures are taken : the balance of organisational/ technical measures (e.g. automated dilution and technical standard of machines) and personal protective equipment will be applied by the end customers.	boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.

		Used solutions/emulsions are disposed as a hazardous waste and subject to specific provisions in accordance to Directive 91/689/EEC on hazardous waste. Apart from health and safety aspects, there are a number of other issues to consider : Benefit of Boric Acid containing Metalworking products : - Stable buffer capacity - Robust against microbial attacks (incl. Mycobacteria 4)) - Good availability - Good price performance ratio - Used without problems for many decades in the Metalworking industry Industry investigated alternative substances for many years but there are currently no suitable Boric Acid free alternative substances for Metalworking applications. Although there are some potential alternative Boric Acid products these are less robust against bacterial attacks which leads to an increased usage of biocides. In turn, this raises other health and environment issues and requires higher consumption of resources and therefore is poorer from a sustainability standpoint. As such, the increase of biocide consumption and decrease of lifetime of the products lead to increase of disposal, waste volumes and waste treatment for the boric acid free alternatives. This increases a potential to have negative effects to humans and the environment. Furthermore, this leads to higher costs due to disposal and maintenance of fluids in use which are in addition to the initial higher prices for the boric acid free Metalworking fluid concentrates. We fully support the Product Stewardship principle to supply products that can be manufactured, transported and used safely. In addition to our internal standards we work with suppliers, customers and regulatory authorities to reduce the health and environmental impact of metalworking fluids5) and believe the use of boric acid/borates is safe within our industry.6) End-users of Metalworking Fluid concentrates are dealing with the various aspects and challenges of REACH and it is likely that different approaches will be used	

		depending upon a range of factors including level of knowledge of product composition. Substances themselves or mixtures of substances used in industrial or professional sectors are already regulated to ensure these are handled safely e.g. by being in scope of specific requirements on protecting people exposed to these substances or protecting the environment. The prospect that substances like Boric acid containing metalworking fluids might become subject of authorisation leads to a status of uncertainty regarding future supplies for industrial and professional end users. This is a real concern within the metalworking industry where several end users of Metalworking products already consider substances on the Candidate List are subject to authorisation. Unfortunately, this is a failure to recognise that even if the identification of a substance as a Substance of Very High Concern (SVHC) is merely the first step toward the authorisation procedure and does not mean that formulators and end users of Metalworking fluids have to apply for authorisation for their use. Formulators and end users are under considerable pressure to remove SVHCs from the production of their products. Depending on the Metalworking application this might require some cost-intensive and time-consuming effort to demonstrate that the risk mitigation measures applied to a particular application are acceptable and the associated use should not be subject to authorisation For consumer products the situation and effect of substances being included in the candidate list is, at least for the time being, expected to be less significant. Therefore in general the identification of SVHC without differentiation of sectors of use is open to be interpreted as unjustified stigmatisation. In conclusion, we feel that the use of boric acid is safe. Inclusion of Boric Acid on the candidate list is expected to "force" end-users to move to boron free metalworking fluids at a very early stage of the authorisation process and probably without justification. This will result in higher biocide usage and higher consumption of resources. So inclusion of Boric Acid on the Candidate list will have an opposite effect compared to the targets of REACH and therefore, Annex XV Dossiers should not be filed until REACH registration dossiers (which are going to give a full view on Use & Exposure of Boric Acid) are reviewed in 2011.	

		1) Since March 2007 a health risk based exposure limit of 2,6 mg/m3 boric acid is in place in Germany (“gesundheitsbasierter AGW”, published in the TRGS 900), corresponding to 0,5 mg/m3 Boron (lead component). According to the definition of an AGW, acute or long-term hazard can be excluded if the exposure limit is not exceeded. Furthermore, there is a remark (“Y”), that there is no expected risk for fertility/harm to the unborn child (R60/61) if the limit is not exceeded. Initial measurements of the Berufsgenossenschaft showed that the limit was never exceeded. Link to the TRGS 900: http://www.baua.de/cae/servlet/contentblob/666762/publicationFile/55576/TRGS-900.pdf 2) The official UK method for determining metalworking fluid mist is based on a tracer. This could be: sodium or boron. See the link below for details: http://www.hse.gov.uk/pubns/mdhs/pdfs/mdhs95-2.pdf 3) Data generated by the BG Metall and the Verband Schmierstoffindustrie (VSI) in Germany showed, that the concentration of free boric acid in metalworking fluid concentrates is by far below 10%. Measurements performed by 11B NMR spectroscopy showed an average concentration of 2% in the metalworking fluid concentrate, leading to a maximum of 0,1% in the solution/emulsion used by the end user (metalworking fluids are a mixture of 4-5% concentrate in water). BG boric acid information sheet http://www.vsi-schmierstoffe.de/fileadmin/template/VSI-Verwaltung/Texte/030_MFS_E2009-04_Boric_Acid.pdf 4) Comment of the Berufsgenossenschaft (Accident Prevention & Insurance Association, Germany) on boric acid containing metalworking fluids: “The MWF product containing derivatives of boric acid shows a good stability to colonisation with mycobacteria already in the non-preserved state (formulation without biocides) and thus also the best effect of the biocides tested”, cited from: http://www.bg-metall.de/praevention/gesundheitsschutz/biologische-gefaehrdungen/kuehlschmierstoffe/mykobakterien.html 5) Safe handling of metalworking fluids: http://www.hse.gov.uk/metalworking/video/ Tätigkeiten mit Kühlschmierstoffen (BGR/GUV-R 143, Mai 2009)	

		6) UKLA boric acid position paper: UKLA boric acid position paper: http://ueil.org/health_environment/documents/ukla-boric-oct09.pdf 2. Use in the manufacture of grease thickeners Boric Acid is used as an intermediate in the manufacture of borate complex grease thickeners. Boric acid is used in the formulation of Li-complex greases. The boric acid complexing agent provides a superior thickener formulation over conventional lithium soap greases contributing to a better high temperature performance in many automotive and industrial applications. The H3BO3 and LiOH.H2O (+sebacic acid in some cases) is mixed with liquids (oil, water and in some cases also dispersant/detergents) to prepare a slurry that is then pumped into an autoclave where grease manufacture takes place. The boric acid is stored in the existing additive storage unit (cabinet with extraction cabinet) and is transferred to the slurry preparation vessel, by manual operator action. This vessel has also an air extraction system. The operator wears overalls, safety glasses, dust mask and gloves during the manual dosing. After adding the slurry components to the slurry preparation vessel, the vessel is closed and mixing takes place. When the mix is ready, it is transferred to the autoclave. The vessel is flushed with oil to be sure all the contents go into the autoclave. Final treat rate of boric acid in the grease formulations is below 3%. In the autoclave, the reaction takes place with formation of the Li-complex structure where the boric acid is fully reacted away. No boric acid remains in the finished greases During all next steps in the production process to produce the final grease the operator is wearing overalls, glasses and gloves. 3. Use in borated brake fluids Boric Acid is used as an intermediate to produce Borated Glycol Ethers. These esters are used as components in brake fluids.	

		Description of the process : At elevated temperature Boric Acid reacts with Glycol Ethers to produce the tri-ester of the Glycol Ether with orthoBorate. This esterfication is completed by the removal of water with the aim of distillation As the esterfication is driven to completion by removal of the water no residual Boric Acid is left in the solution. The main component of a Brake Fluid is the Glycol Ether and only a smaller percentage is the Borated Glycol Ether. Additives are added to the Brake Fluid to act as pH buffer or corrosion inhibitor. Exposure to Boric Acid is possible during handling of the big bags. However the handling of the bags is an automatic process with sufficient ventilation to remove dust. Exposure to Boric Acid : Exposure time: 7-11 minutes a day Measured : inhalable dust. No Boric acid was detected. This means the Boric Acid concentration was below 0.06 mg/m3. In 1998 and 2001, measurements were performed for exposure to boric acid of the operator during the dropping of the boric acid in the vessel. In 1998, three measurements were performed, all during the operation of a single big bag. All results were < 0,06 mg/m3 (measuring time was 8 to 10 minutes). In 2001, one measurement was performed during the operation of 4 big bags. The concentration boric acid was also < 0,06 mg/m3 (measuring time was 36 minutes).	
20100421	CPIV, Industry or trade association, Belgium	Statement on Exposure to Borates and REACH.pdf Please see attached document.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne

			concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided. A clarification has been added to the consumer exposure part of the annex XV dossier for boric acid.
20100421	Industry or trade association, Company, Germany	We use boric acid as a main part of our metal working fluid products since the end of the 1970ties. We need about 250to boric acid per year. The average percentage of boric acid incorporated in our products is about 6% The main part of this 6% boric	See response to EBA comments

		acid will be neutralized with several alkalines mainly amines. The amount of free boric acid in our products is much lower than 5%. This has been proven Data generated by the BG Metall and the Verband Schmierstoffindustrie (VSI) in Germany where 15 of our boric acid containing products have been analysed (see attached document "Handlungshilfe für KSS-Anwender.."). For Estimation of the exposure of metal workers with boric acid in cutting fluids you can use data about metal working fluid emission measurements generated by the german BGIA (see attachment "BIA-Report 4/2004"). The 2004 testing programm of the BGIA had shown that in most cases the emmission was lower than 10 mg/cbm at the workplace. Using a worst case scenario you can estimate an exposure of 5% boric acid in the MWF concentrate, 10% of the concentrate in water for the water mixed fluid in the machine tool and 20 ppm MWF emission. That means a boric acid concentration of about 0,1 ppm in the air at the workplace. We use solid boric acid in our production facility since more than 30 years. We did not get any information about health problems connected to the use in our production plant. Since March 2007 a health risk based exposure limit of 2,6 mg/m3 boric acid is in place in Germany ("gesundheitsbasierter AGW", published in the TRGS 900), corresponding to 0,5 mg/m3 Boron (lead component). According to the definition of an AGW, acute or long term hazard can be excluded if the exposure limit is not exceeded. Furthermore, there is a remark ("Y"), that there is no expected risk for fertility/harm to the unborn child (R60/61) if the limit is not exceeded. Initial measurements of the Berufsgenossenschaft showed that the limit was never exceeded. Link to the TRGS 900: http://www.baua.de/cae/servlet/contentblob/666762/publicationFile/55576/TRGS-900.pdf We are quite sure that the use of boric acid in our production plant is safe	
20100421	Bundesverband Glasindustrie e.V., Industry or trade association, Germany	EBA comments Annex XV 100104 final.pdf CPIV Statement on Exposure to Borates and REACH.pdf VBG Borauswertung_Glas.pdf	See response to EBA comments A clarification has been added to the consumer exposure part of the annex XV dossier for boric acid.
20100421	Eucomed, Industry or trade association, Belgium	Manufactures of contact lenses have for over 20 years been using borate buffer as a part of these devices. The exposure to diluted borates is limited by the topical (ocular and skin) route of delivery upon contact lens insertion. However, according to published data discussed in Annex XV and RPA report (2008), a dermal absorption of 0.5% is used as worse case approach greatly limiting systemic delivery of borates. Thus, exposure to borates in contact lenses, which are well below thresholds discussed	Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its high production volume. So far, boric acid meets as well the criteria

		above, will be further greatly reduced due to topical route of administration. We therefore propose to consider the topical route while evaluating the overall human risk of exposure to boron-containing substances discussed in the comments on Classification and Labelling. Boron is known to be a critical element for the normal growth and productivity of aquatic and terrestrial plants. Per RPA report (2008), the available data support the interpretation that borates are not significantly bioaccumulated. In addition, data from animals and humans indicates that boron is quickly removed via faeces and urine, so body concentrations do not continually increase. Thus, there is no chronic human or environmental concern from limited exposure to boron present in the contact lenses. The WHO review of Boron (1998) noted that highly water soluble materials are unlikely to bioaccumulate to any significant degree and that any borate species are all present essentially as undissociated and highly soluble boric acid at neutral pH. The available data indicate that both experimental data and field observations support the interpretation that borates are not significantly bioaccumulated. Both oral and inhalation exposures to boron-based substances are major human routes of exposure. However since the borates are in solution the oral and inhalation routes are not relevant to contact lens products. In conclusion, contact lenses, contact lens care solutions and eye drops contain boric acid and disodium tetraborate well below the accepted threshold safety level. The systemic exposure is further limited by the topical delivery, and there is no concern of chronic bioaccumulation. Alternatives: Borate buffers exhibit microcidal properties thereby reducing the risk of contamination during the contact lens manufacturing process. Additionally borate buffers are fully compatible with the contact lens polymer matrix assuring the stability of the device over the entire shelf life.	according to REACH article 57c as those of article 58. However, we are aware that boric acid will be registered by the end of this year and further information may become available. Risk assessment needs to take into account all routes and sources of exposure to boron compounds.
20100421	Industry or trade association, Belgium	In short: The compounds delivered by the starch industry (starch and borates) are mixed in typical applications at low levels, for industrial uses. Exposure to workers is, as a consequence, very low and to humans is very limited. To our best knowledge, to date, no alternative technology and products to borax exist for the use in starch based adhesives for the corrugated board industry.	Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its high production volume. So far, boric acid meets as well the criteria

		Borates already are regulated Borates are widely regulated and limits for its use exist. It is questioned whether, provided the existence of this sector legislation, which takes into account actual exposure and risk, any authorization regime under REACH would be appropriate/necessary for borates. As a way of example, the specific migration limit for boric acid and its salts in Directive 2002/72 (Relating to plastic materials and articles intended to come into contact with food) is of max. 6 ppm (in conjunction with boron assumed through drinking water). However, based on REACH – Art 56.6 (b) - borate used in food contact material does not need an authorization. The same rationale goes, for example, for uses of Borax in cosmetics – Art 56.6 (a) of REACH – and for regulated uses of Borax under sector specific legislation. In conclusion, and again, the same logic should lead to question the need for an authorisation for a substance whose use is regulated under sector-specific legislation. As said above, EU legislation/scientific work exist on Borates, among which – non-exhaustive list • Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances (this Directive does not deal with the uses of Borax but only on classification, packaging and labelling); • Directive 98/8/EC of the European Parliament and of the Council on the placing on the market of biocidal products; • Opinion of the Scientific Committee on Food on the 13th additional list of monomers and additives for food contact materials - Adopted by the SCF on 30 May 2001(This Opinion suggests a TDI of 0.1 mg/kg b.w. of Sodium tetraborate (This Opinion describes a TDI of 0.1 mg/kg b.w. of sodium tetraborate); • Opinion of the Scientific Panel on Contaminants in the Food Chain on a request of the Commission related to concentration limits for boron and fluoride in natural mineral waters Adopted on 22 June 2005 (This Opinion describes a TDI of 0.1 mg/kg b.w. of sodium tetraborate); As well as at the national level, that allows borates as an additive – Non-exhaustive list: • In paper and board for food packaging by Dutch laws - VGB (Warenwet) II.1.2.2.h (Adhesives and fibre binding agents for Paper & Board); • In papers, cardboard and corrugated boards by German laws - Recommendation 36/2 BfR – Papers, Cardboard and Corrugated Boards (baking purposes).	according to REACH article 57c as those of article 58. Alternatives and socioeconomic aspects will also have to be discussed in case an application for authorisation becomes necessary.

		Typical USE of Borax and EXPOSURE - One of the typical applications of Borax includes use in corrugated board and in adhesives – at least this is what the starch industry uses it for - Borax is normally used in mixes for industrial users (as opposed to use by the general public) so that they can operate on big scale (silos) and smaller scale (bags). In practice, the starch industry in most of the cases delivers one bag mix in solid form. All these circumstances suggest that exposure to workers or environment, if any, is expected to be very low. As specifically concerns the use in adhesives, they are included in the internal/ “in between parts” of corrugated board, and are therefore not present in the outside/external part (hence, exposure to humans and environment is limited). Properties of borax and why customers ask it is used -For some industrial applications, the properties of native starch are inadequate. To obtain new physical properties, borax is added in the presence of small amounts of sodium hydroxide. The addition of borax: o gives the required viscosity and structure to the glue; o increases tack during initial phase of the gluing and holds the fluting and liner in the required position until the starch is being gelatinized by water and heat; o improves film forming of the starch based glue onto the papers; o improves water holding of the glue so that less water is penetrating into the paper and enough water remains available for reaction with the starch; o adjusts or fine tunes the temperature sensitivity of the starch based glue recipe to the appropriate temperature on the corrugating production line. RISK– It is much lower for borates than for other dangerous preparations Much higher concentration limits are set for boron containing substances: a number of boron containing substances can be used in preparations in levels below 3.1 to 8.5 %. This is acceptable in dangerous preparations and no classification and labelling is required on the packaging in such cases since in preparations the classification will be communicated either on the basis of the substance or via the safety data sheets. The fact that borax is considered to be significantly less harmful is provided by the fact that the limit of harmless use for products which are toxic to reproduction is 0.3%. In addition, and as a complement of the above, it has to be<generally specified that for SVHC the limit is 0.1 % in articles (e.g. corrugated board glue, which contains boron clearly below 1000 ppm - at least following our calculations). Dilution makes this even lower.	

		Alternatives - To our best knowledge, to date, no alternatives exist to the use of borax exist for the use in starch based adhesives for the corrugating industry	
20100421	BP International Ltd, Company, United Kingdom	Exposure to boric acid during metalworking fluid manufacturing: For decades, BP has handled boric acid and borax as additives during metalworking fluid formulation at many sites in- and outside Europe. We supply such metalworking fluids to numerous customers globally. No known human health effects, potentially resulting from the boric acid or borax are known during formulation nor were reported to us from our customers, the industrial users. We interpret this absence of data to indicate that the use of boric acid and borax as additives in metalworking fluids is safe. The boric acid as a raw material is usually supplied to our sites in so called 'big bags' (500 – 1000 kg) and is then transferred from these bags directly into mixing vessels. BP has many safety precautions such as personal protection wear (e.g. dusk masks), ventilation systems, etc. in place to protect workers so that they can handle this material safely by minimizing exposure. BP quantified boric acid exposure from two typical working operations of a production site in Germany. These measurements show that the current German threshold limit for safe use is never exceeded. Operation 1: Direct transfer of boric acid into a mixing vessel by pouring from big bags using mechanical equipment: The measured boric acid exposure level for the worker was < 0.11 mg/m³. Operation 2: Transfer of boric acid from a big bag into a mixing vessel with a particle pump: The measured boric acid exposure level for the worker was 0.061 mg/m³. Exposure to boric acid in typical metalworking applications: In March 2007, a legally binding health risk based exposure limit of 2,6 mg/m3 boric acid was established for Germany (published in the TRGS 900), corresponding to 0,5 mg/m3 Boron (leading component). According to the definition of this exposure limit, an acute or long term hazard can be excluded if the exposure limit is not exceeded.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council

		Furthermore, there is a remark that there is no expected risk for fertility/harm to the unborn child if the limit is not exceeded. Initial measurements of the 'Berufsgenossenschaft' (Accident Prevention & Insurance Association, Germany) showed that the limit was never exceeded in typical metalworking applications. The metalworking fluid products supplied by BP are concentrates that are diluted by users (typically 10 to 25 fold) with water to form an emulsion. Data generated by the (Berufsgenossenschaft and VSI) in Germany showed that free boric acid concentration in undiluted metalworking fluid is far below 10 %. Measurements performed by 11B NMR spectroscopy showed an average concentration of 2 % in undiluted metalworking fluid leading to a 0.1 % maximum in the final diluted emulsion. The official UK method for determining metalworking fluid mist is based on a tracer. This could be sodium or boron. See the link below for details: http://www.hse.gov.uk/pubns/mdhs/pdfs/mdhs95-2.pdf For metalworking fluid end users, the UK Guidance value for mist is 1 mg/m³; assuming a worse case scenario of a 10 % MWF containing 10 % boric acid, then the maximum exposure would be the extremely low level of 0.01 mg/m³ boric acid. Besides the above mentioned health and safety aspects, there are other important facts to consider. The use of boric acid as a metalworking fluid additive has several clear benefits: • Boric acid forms a very stable buffer system with various base components to ensure constant pH-level and important anti-corrosion properties • The use of boric acid enhances the lifetime of the fluid, reduces maintenance costs and the consumption of service additives • Boric acid enhances the bio-resistance of metalworking fluids. This decreases the amount of biocide that must be incorporated into the undiluted fluid. It also reduces the quantity and frequency at which biocide must be added in order to maintain bio-stability of the diluted fluid. • Boric acid is a common raw-material with a good price-performance ratio • Boric acid has been used for decades in the metalworking fluid industry without any HSSE related problems What are the potential substitutes for boric acid and borax in metalworking fluid formulations?	Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.

		There are no equivalent pH adjusters and corrosion protection substances available on the market. All substitutes will reduce the buffer capacity of the system and hence result in a lower lifetime of metalworking fluids in industrial applications. Consequently the change intervals will go down (i.e. frequency of changes will increase); this will lead to higher consumption of various resources (higher energy consumption, increase of raw-material demand, increase of waste, more consumption of service additives, waste of time etc.). As a European metalworking fluid manufacturer BP stands for the Product Stewardship principle to supply products that can be manufactured, transported and used safely. We work with our suppliers, customers and regulatory authorities to reduce the health and environmental impact of metalworking fluids. We believe the use of boric acid / borates is safe within our industry. The links below will give some more information on the safe handling and use of metalworking fluids: http://www.hse.gov.uk/metalworking/video/ http://ueil.org/health_environment/documents/ukla-boric-oct09.pdf Conclusion: From our experience we believe that the use of boric acid and borax in metalworking fluids is safe. The inclusion of boric acid and borax on the candidate list of SVHC will drive end-users of metalworking fluids to move to boron-free products. This will negatively affect the lifetime of these products and will result in higher consumption of resources; this is in our opinion not in line with the overall aims of the REACH legislation.	
20100421	Industry or trade association Company, United Kingdom	p.7 Classification and labelling Animal studies do not appear to relate to human studies as in Chinese Borate mine worker study.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned.

20100421	Industry or trade association, Company, Ireland	Specific Comments on use, exposure, alternatives, and risks Exposure / Risks: Contact lenses have been manufactured for over 20 years using borate buffer as a part of these devices. The exposure to diluted borates is limited by the topical (ocular and skin) route of delivery upon contact lens insertion. However, according to published data discussed in Annex XV and RPA report (2008), a dermal absorption of 0.5% is used as worse case approach greatly limiting systemic delivery of borates. Thus, exposure to borates in contact lenses, which are well below thresholds discussed above, will be further greatly reduced due to topical route of administration. It is proposed that the topical route is considered while evaluating the overall human risk of exposure to boron-containing substances discussed in the comments on Classification and Labeling. 1. Boron is known to be a critical element for the normal growth and productivity of aquatic and terrestrial plants. Per RPA report (2008), the available data support the interpretation that borates are not significantly bioaccumulated. In addition, data from animals and humans indicates that boron is quickly removed via feces and urine, so body concentrations do not continually increase. Thus, there is no chronic human or environmental concern from limited exposure to boron present in the contact lenses. 2. Both oral and inhalation exposures to boron-based substances are major human routes of exposure. However since the borates are in solution in a contact lens product the oral and inhalation routes are not relevant. In conclusion, contact lenses contain boric acid and disodium tetraborate well below the accepted threshold safety level. The systemic exposure is further limited by the topical delivery, and there is no concern of chronic bioaccumulation. Alternatives: Borate buffers exhibit microcidal properties thereby reducing the risk of contamination during the contact lens manufacturing process. Additionally borate buffers are fully compatible with the contact lens polymer matrix assuring the stability of the device over the entire shelf life.	Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its high production volume. So far, boric acid meets as well the criteria according to REACH article 57c as those of article 58. However, we are aware that boric acid will be registered by the end of this year and further information may become available. Risk assessment needs to take into account all routes and sources of exposure to boron compounds.
20100420	Jones Fiber Products, Inc, Company, United States	Binder1.pdf Page 10 of Dr Jay Murray's report	Dr Murray´s report has been cited in the annex XV dossier for boric acid.
20100421	Rohm and Haas Company, Company, United States	The products we have made using boric acid have been produced without negative (known) medical history or incidents for over 50 years. SBH is used in bleaching applications (newsprint, textiles, kaolin) and as a reductant in synthesis and process applications. In the manufacture of SBH, boric acid is used under strictly controlled	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric

		conditions, and potential exposure to boric acid in SBH manufacture is below detectable limits. SBH applications provide a benefit over alternative technologies. SBH is safer than the direct sodium hydrosulfite process for bleaching and specialties synthesis. Use of SBH for bleaching enables the safe and cost effective production of paper from recycled paper and reduces the need to harvest trees to make paper. Also, SBH provides unique advantages for specialties synthesis in new molecules developed by the pharma, agro, fine chemicals and nutraceutical industries.	acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100421	Cerame-Unie, Industry or trade association, Belgium	Cerame-Unie position on boric acid and disodium tetraborates.pdf Boric acid and disodium tetraborates are essential substances for the ceramic industry.	Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its

		• Borates have been used in ceramic glazes in China since the 10th century. Glazes are the thin, glassy coatings fused onto ceramics in tiles, tableware and porcelain. Borates 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 in glazes also increase the refractive index, or luster, and enhance the durability of the glaze. Using borates significantly lowers the glaze firing temperature and provides manufacturers alternatives to substances that pose health risks (such as lead). • Borates are also used as a raw material for ceramic products 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. • Boric acid and disodium tetraborates are also very important as binders for refractory products. These substances increase the lifetime of the refractory product thereby reducing the frequency to replace the refractory product in the industrial kiln and reducing the use of raw materials, the waste produced and the CO2 emissions. Refractory products with boric acid and disodium tetraborates are used in the steel, glass, cement and aluminium industry. Placing these substances on the list for authorisation would therefore have severe consequences for these industries as well. • Boric acid is also used in the high volume manufacturing of boron carbide, boron nitride, titanium boride, zirconium boride and calcium boride. o Boron nitride is used as a raw material in the refractory industry . o Calcium boride, zirconium diboride and boron carbide are used as antioxidants in carbon bonded refractory materials. Calcium boride is also used as deoxidant in copper melts. o Titanium diboride is used in evaporation boats which are used in the aluminium coating of plastic films and used a refractory material is aluminium smelters. o Boron carbide is the most widely used material for protective body and vehicle armour systems and sand blasting nozzles. It is also readily used for the grinding and lapping of hard metals and ceramics, as shield and control component in nuclear reactors, as a boronizing agent, as antioxidant improving service life and it is used to improve service life of electrodes in the harsh environment during welding. For the uses described above, substitution is not possible and the use of boric acid and disodium tetraborates is essential.	high production volume.

		To our knowledge, no adverse health effects have been reported with workers exposed to inhalable boric acid dust, even in a company working with boric acid since 70 years (ESK Ceramics GmBH &Co. KG).	
20100422	National Cotton Batting Institute, Industry or trade association, United States	P. 1 the conclusion on p. 2 National Cotton Batting Institute (N.C.B.I.) Comments on Annex XV Dossier Filed with the European Chemicals Agency April 22, 2010 The National Cotton Batting Institute (N.C.B.I.) wishes to thank the European Chemicals Agency for allowing the N.C.B.I. to comment on the Annex XV dossier to identify boric acid as Substance of High Concern (SVHC). Our comments are directed toward potential consumer exposure to boric acid through its use as a fire retardant. This association has been in existence for 56 years and represents U.S. companies that manufacture flame-resistant cotton batting that is used in mattresses, futons, and upholstered furniture as well as suppliers of the boric acid that is used to make the cotton flame resistant. The association also represents fiber suppliers for this industry. The N.C.B.I. participated in the public hearing for a United States mattress flammability standard developed by the U.S. Consumer Products Safety Commission that became effective in 2007. Questions were posed on the safety of boric acid. Those questions addressed issues such as ingestion, air quality above and in the room of mattresses containing boric acid, and dermal absorption as the result of sleeping on mattresses constructed with cotton batting treated with boric acid. The N.C.B.I. commissioned an independent study to test for boric acid emissions in an effort to address the data gaps that existed in previous studies of boric acid as a safe fire retardant material. In order to support the continued use of boric acid as a flame retardant in cotton batting used in sleep products and other soft furnishings, we intend to submit our study through the REACH consortium in support registration dossier for boric acid. Boric acid has been used with cotton as a fire retardant since 1972 with no known health problems. The results of this extensive testing would seem to uphold the N.C.B.I. position that boric acid poses no health problems to mattress consumers. The test results directly correlate with testing that has been performed by two other national companies. All tests indicate that boric acid is as safe as common table salt. Among the findings of the testing were: • Based on normal consumer use patterns, the dermal and oral exposures to boric acid	Thank you for the information. The CPSC exposure assessment is cited in the annex XV dossier for boric acid.

		via contact with mattresses is more than 1400-fold less than the U.S. Environmental Protection Agency's threshold level. The anticipated boric acid exposure is also well below human health criteria established by the U.S. Agency for Toxic Substances and Disease Registry (A.T.S.D.R.) and the U.S. National Academy of Sciences (N.A.S.). • The evaluation of dermal exposure assumed direct contact between a mattress surface and unclothed skin. That is unlikely to occur in most situations given the typical use of sheets and mattress pads. • Air sampling tests found no detectable airborne boric acid. • Because no boric acid was detected in the air samples, inhalation is not considered as a pathway of exposure to boric acid. • There was no significant variance between the sampling locations – above the mattress and away from the mattress – in the measurement of respirable particles, nor was there any observed increase in respirable particles over the course of the impact testing. • Although surface wipe tests contained measurable amounts of boric acid, there was not a consistent increase in surface concentrations following testing. Analyses for only 4 of the 9 mattresses tested showed an appreciable increase in surface boric acid following the impact testing. Again, boric acid on the surface does not contribute to human intake that would be considered significant from a health standpoint. In their evaluation of potential consumer exposure to boric acid in the normal use of mattresses, the Geomatrix toxicologists determined that boric acid exposure in not expected to present any significant health risks to consumers. The model of exposure in these tests represents the high end of consumer exposure which is far below the EPA allowable thresholds. Based on these findings, which were accepted by the U.S. Consumer Product Safety Commission (CPSC) in the final rulemaking for the Standard for Flammability (Open Flame) of Mattress Sets, the N.C.B.I. suggests that cotton batting incorporating boric acid presents absolutely no health or safety risk to the consumer and is durable in the home setting. The inhalation and dermal exposures estimated for sleeping on a mattress containing boric acid-treated cotton as a flame retardant is but a small fraction of the boric acid intake derived from healthy diets including fruits, vegetables, and juices. We view both cotton and boric acid as "green" products based on their natural origins which allow for the production of mattresses which fire safe. Sincererly, Weston Arnall, President National Cotton Batting Institute 4322 Bloombury St. Southaven, MS 38672 662-449-0000	

		662-449-0046 (fax) info@natbat.com	
20100422	StonCor Europe, Company, Belgium	EBA comments Annex XV (00059414).PDF Memo to ECHA on behalf of StonCor re boric acid (00059408).PDF Please see appended documents.	See response to EBA comments
20100422	Alcon Laboratories, Inc, Company, United States	Exposure / Risks: Manufactures of contact lenses have for over 20 years been using borate buffer as a part of these devices. The exposure to diluted borates is limited by the topical (ocular and skin) route of delivery upon contact lens insertion. However, according to published data discussed in Annex XV and RPA report (2008), a dermal absorption of 0.5% is used as worse case approach greatly limiting systemic delivery of borates. Thus, exposure to borates in contact lenses, which are well below thresholds discussed above, will be further greatly reduced due to topical route of administration. We therefore propose to consider the topical route while evaluating the overall human risk of exposure to boron-containing substances discussed in the comments on Classification and Labelling. Boron is known to be a critical element for the normal growth and productivity of aquatic and terrestrial plants. Per RPA report (2008), the available data support the interpretation that borates are not significantly bioaccumulated. In addition, data from animals and humans indicates that boron is quickly removed via feces and urine, so body concentrations do not continually increase. Thus, there is no chronic human or environmental concern from limited exposure to boron present in the contact lenses. The WHO review of Boron (1998) noted that highly water soluble materials are unlikely to bioaccumulate to any significant degree and that any borate species are all present essentially as undissociated and highly soluble boric acid at neutral pH. The available data indicate that both experimental data and field observations support the interpretation that borates are not significantly bioaccumulated. Both oral and inhalation exposures to boron-based substances are major human routes of exposure. However since the borates are in solution the oral and inhalation routes are not relevant to contact lens products. In conclusion, contact lenses, contact lens care solutions and eye drops contain boric acid and disodium tetraborate well below the accepted threshold safety level. The systemic exposure is further limited by the topical delivery, and there is no concern of chronic bioaccumulation.	Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its high production volume. So far, boric acid meets as well the criteria according to REACH article 57c as those of article 58. However, we are aware that boric acid will be registered by the end of this year and further information may become available. Risk assessment needs to take into account all routes and sources of exposure to boron compounds.

		Alternatives: Borate buffers exhibit microcidal properties thereby reducing the risk of contamination during the contact lens manufacturing process. Additionally borate buffers are fully compatible with the contact lens polymer matrix assuring the stability of the device over the entire shelf life.	
20100422	Bausch & Lomb Inc, Company, United States	Manufactures of contact lenses have for over 20 years been using borate buffer as a part of these devices. The exposure to diluted borates is limited by the topical (ocular and skin) route of delivery upon contact lens insertion. However, according to published data discussed in Annex XV and RPA report (2008), a dermal absorption of 0.5% is used as worse case approach greatly limiting systemic delivery of borates. Thus, exposure to borates in contact lenses, which are well below thresholds discussed above, will be further greatly reduced due to topical route of administration. We therefore propose to consider the topical route while evaluating the overall human risk of exposure to boron-containing substances discussed in the comments on Classification and Labelling. Boron is known to be a critical element for the normal growth and productivity of aquatic and terrestrial plants. Per RPA report (2008), the available data support the interpretation that borates are not significantly bioaccumulated. In addition, data from animals and humans indicates that boron is quickly removed via feces and urine, so body concentrations do not continually increase. Thus, there is no chronic human or environmental concern from limited exposure to boron present in the contact lenses. The WHO review of Boron (1998) noted that highly water soluble materials are unlikely to bioaccumulate to any significant degree and that any borate species are all present essentially as undissociated and highly soluble boric acid at neutral pH. The available data indicate that both experimental data and field observations support the interpretation that borates are not significantly bioaccumulated. Both oral and inhalation exposures to boron-based substances are major human routes of exposure. However since the borates are in solution the oral and inhalation routes are not relevant to contact lens products. In conclusion, contact lenses, contact lens care solutions and eye drops contain boric acid and disodium tetraborate well below the accepted threshold safety level. The systemic exposure is further limited by the topical delivery, and there is no concern of chronic bioaccumulation. Borate buffers exhibit microcidal properties thereby reducing the risk of contamination during the contact lens manufacturing process. Additionally borate	Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its high production volume. So far, boric acid meets as well the criteria according to REACH article 57c as those of article 58. However, we are aware that boric acid will be registered by the end of this year and further information may become available. Risk assessment needs to take into account all routes and sources of exposure to boron compounds.

		buffers are fully compatible with the contact lens polymer matrix assuring the stability of the device over the entire shelf life.	
20100422	Individual, Germany	Letter_Bolt_ECHA.pdf Conclusions and Summary, p. 35/36: The point of possible quantities of human exposure, under any exposure conditions feasible for normal or reasonably foreseeable conditions of use, is not adequately covered in the Dossier. For details, I refer to the uploaded attachment.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are, however, aware of the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation.
20100422	CETS, Industry or trade association, Belgium	p. 12 Boric acid is essential in electroplating process as: Buffer of pH of nickel plating baths Boric acid is a week acid, it enables the buffering of pH of the nickel plating bath that during the process of electrolysis fluctuates and increases. As a rule the concentration of boric acid is in the range between 35 and 50 g/l. As far as alternatives are concerned, at present there is no substance that can replace it giving the same effectiveness and quality of production. Major implications are: Without boric acid it is impossible to assure good quality indexes. The use of strong acids to control the pH needs frequent additions. Sulphuric acid with concentration between 33 and 66% enhances as time goes by the instability of pH due to the electroplating process. As a matter of fact the process will be no longer under control with dramatic increase of low quality products and waste. The buffering effect of boric acid cannot actually be replaced even by careful additions of sulphuric or hydrochloric acid that give to the nickel coating the burn effect. It enables the substitution of hexavalent chromium bath	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the

			transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100422	Industry or trade association, Company, Germany	Biotest.xls Metalworking fluids without boric acid are more exposed to bacterial attacks than boric acidic metalworking fluids. That means there will be a higher consumption of biocides on one hand or a higher consumption of metal working fluids on the other hand. A higher consumption of biocides means a higher risk for machine operators who are subject to the biocide containing metalworking fluid due to occupational health and safety aspects. Because of higher metalworking fluid consumptions we will see more waste of metalworking fluids due to shorter durability. Attached is a biotest which shows that boric acid free metalworking formulations are more labile in bacterial or fungizide harmful medium in comparison to boric acid containing formulations.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the

			transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100422	ECOMETAL, Industry or trade association, Italy	Boric acid is essential in electroplating process as buffer of pH of nickel plating baths. Boric acid is a weak acid, it enables the buffering of pH of the nickel plating bath that during the process of electrolysis fluctuates and increases. As a rule the concentration of boric acid is in the range between 35 and 50 g/l. As far as alternatives are concerned, at present there is no substance that can replace it giving the same effectiveness and quality of production. Major implications are: - Without boric acid it is impossible to assure good quality indexes. - The use of strong acids to control the pH needs frequent additions. Sulphuric acid with concentration between 33 and 66% enhances as time goes by the instability of pH due to the electroplating process. As a matter of fact the process will be no longer under control with dramatic increase of low quality products and waste. - The buffering effect of boric acid can not actually be replaced even by careful additions of sulphuric or hydrochloric acid that give to the nickel coating the burn effect. Boric acid is essential in electroplating process because it enables the substitution of hexavalent chromium bath. Boric acid is an essential component of the saline matrix used in the most recent, low	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the

		concentration bath of trivalent chromium (< 7g/l) that increasingly substitutes the electroplating process based on hexavalent chromium both in chromium and in acid zinc plating.	transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100422	Fédération des industries mécaniques, Industry or trade association, France	Réponse.pdf p.17 Boric acid is used in substitutes of chromium VI. There are no alternative substances or techniques for boric acid. We ask an exemption for surface treatment.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the

			transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100422	UITS, Industry or trade association, France	USE OF BORIC ACID IN SURFACE FINISHING.pdf Borid acid is necessary in formulation developped for remplacing chromium compounds . There are no alternative techniques in our surface treatment activity that why we need an exemption for surface treatment.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the

			transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100422	Chemservice S.A. / REACH Zinc-Borate Consortium, Industry or trade association, Luxembourg	EFSA opinion on BA and STB as food add 80.pdf EFSA PUB Statement of AFC on BA and ST as nutrient sources of boron.pdf For the production of Zinc-Borate, Boric acid cannot be substituted. The use is safe and there is no epidemiological evidence, that boric acid is reprotoxic to humans. In contrary, a Chinese Study proofs the opposite.	Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its high production volume. So far, boric acid meets as well the criteria according to REACH article 57c as those of article 58.
2010422	Independent Lubricant Manufacturers Association, Industry or trade association, United States	EBA comments Annex XV 100104 final.pdf Exposure to boric acid in use as metalworking fluid. The Reproductive Toxicology Center (RTC) in Bethesda, Maryland has concluded that typical human exposure to boric acid is not expected to increase the risk of congenital anomalies. Two extensive reviews of the reproductive toxicity literature on boric acid and other borates have concluded that typical human exposures are below the minimum level considered to be adverse to reproduction (Moore et al., 1997, Fail et al., 1998). A recent study of borax miners in China who likely have the highest exposure of any occupation, did not find any clear evidence of male reproductive effects attributable to boron in studies of highly exposed workers. (Scialli et al.,	See response to EBA comments

		2010). The latter paper cites levels of total boron exposure to Chinese miners as 11-125 mg/day (equivalent to 70-850 mg borate/day) and total boron US miners as 0.5-10.5 mg/day (equivalent to 4-75 mg borate/day). These exposure levels are likely many fold higher than exposure to industrial and consumer products in the EU. With regard to exposure from metalworking fluid, there is potential for inhalation and dermal exposure to machinists. For inhalation exposure, an 8 hour exposure to a very high mist level of 5 mg/cu M to metalworking fluid with 0.5% borate, assuming inhalation of 10 cu M of air over that period, would give a maximum exposure of 0.25 mg borate /day. Dermal exposure is not of a concern because borate would not expected to be dermally absorbed. Apart from health and safety aspects, there are a number of other issues to look for Boric Acid Benefits: • stable buffer capacity, thus robust against microbial attacks. • good availability • good price performance ratio • used without problems for many decades in the metalworking fluid industry. Are there alternatives? • Although industry investigated alternatives for many years, no alternatives were found • All alternative formulations are, due to reduced buffer capacity, much less robust against bacterial attacks leading to increased usage of biocides, which from a health, safety and environment perspective is undesirable. • The lifetime of alternative formulations is significantly lower, resulting in a more frequent change and will have a higher consumption of resources and thus is poorer from a sustainability standpoint. • Lastly, the alternative formulations that use higher biocide levels are coupled with increased disposal rates and these higher waste levels will cause increased pressures on the environment. With this in mind, we conclude: Considering the low risk, it would be an unnecessary to burden the industry with justifying use of borates in the authorization process when it is clear from a cursory examination of the exposure data available and the lack of evidence of any real risk of human reproductive harm in humans. We conclude that the risk of any reproductive harm to consumers and workers in the EU is very low. Proper labelling and	

		compliance with safety data sheet compliance of borate containing products is sufficient to adequately manage occupational and consumer exposure. Including Boric acid and disodium tetraborates on the list of SVHC will force end-users to move to boron free metalworking fluids. This will result in higher biocide usage (with their related health issues) and higher consumption of resources. Including boric acid and disodium tetraborates on the list of SVHC will have an opposite effect compared to REACH's targets References Moore JA and Expert Scientific Committee: An assessment of boric acid and borax using the IEHR evaluative process for assessing human developmental and reproductive toxicity of agents. Reprod Toxicol 11:123-160, 1997. Fail PA, Chapin RE, Price CJ, Heindel JJ: General, reproductive, developmental, and endocrine toxicity of boronated compounds. Reprod Toxicol 1998;12:1-18. Reproductive Toxicology Center (RTC), Bethesda, MD Reprotox Record Number: 162 BORIC ACID Last. 48, No. 3, pp. 209–217, 2004 Anthony R. Scialli a,∗,1, Jens Peter Bondeb,1, Irene Brüske-Hohlfeldc,1, B. Dwight Culverd,1,Yanhong Li e,1, Frank M. Sullivanf,1 An overview of male reproductive studies of boron with an emphasis on studiesof highly exposed Chinese workers. Reproductive Toxicology 29 (2010) 10–24	
2010422	Industry or trade association, Company, Netherlands	Page 1 - 4, contains technical and economic confidential information	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates

			indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided. See also response to EBA comments.
20100422	Industry or trade association, Company, United Kingdom	EXPOSURE/RISKS: For IVD products, exposure by professional users is NOT an issue (even though these substances are below the threshold stated in the EU Dangerous Substance Directive) because: In Vitro Diagnostic products♣ are designed to be used in a professional clinical laboratory setting where trained users do not come in contact with the components of these products under standard conditions of the product use. They are used in a clinical♣ laboratory environment by professionally trained clinical laboratory professionals Laboratory practices, professional guidelines and standard♣ precautions are implemented that are designed to protect individuals from biohazards associated with the samples being measured by the IVD products	Boric acid was proposed as SVHC based on its classification as toxic to reproduction category 1B, its wide use in consumer products, and its high production volume. Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. Alternatives, socioeconomic aspects and exemptions will have to be

		♣ Commercial IVD products are designed in a way to ensure that laboratory personnel never come into contact with the products or the product waste during their normal usage and disposal. The Risk & Policy Analysts Limited (RPA) Study commissioned by DG Enterprises and Industry (November 2008) 1 provided input to the Commission on exceptions to the restriction for certain uses of borates as proposed under the 30th and 31st Adaptations to Technical Progress (ATP's) of Directive 67/548/EC. The study gave consideration to the likely exposure of consumers to borates present in the product and prioritized uses of borates on the basis of their potential degree of exposure. The process resulted in a shortlist of uses with a significant degree of exposure and which are not regulated by sector-specific legislation. These shortlisted uses were prioritized for further evaluation. After reviewing the uses and risks associated with borates for consumers not currently regulated by some sector-specific legislation, the RPA Study concluded that risks associated with these other uses are unlikely to be of serious concern. Products containing borates used by professionals and not placed on the market for the general public were considered to present no direct risk to the general public from the formulation stage. 1 "Assessment of the Risk to Consumers from Borates and the Impact of Potential Restrictions on their Marketing and Use – Final Report", prepared for European Commission – DG Enterprise and Industry, Risk & Policy Analysts Limited, November 2008. (http://ec.europa.eu/enterprise/sectors/chemicals/files/docs_studies/final_report_borates_en.pdf) ALTERNATIVES: 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 have been specifically chosen to 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). Additionally, borate compounds are very commonly used as ionic strength adjustment buffers in biological preparations. It is the combination of	discussed when an application for authorisaton becomes necessary.

		these properties which render borates ideal for use in IVD products. Our company is not aware of an alternative to boric acid and sodium borate which would deliver all these properties. The original formulation of our borate-containing products took many years to develop and no other viable options were available to achieve the parallel goals of stability and reagent function. THE CASE FOR AN EXEMPTION FOR BORATES USED IN IVD'S Should authorities confirm the inclusion of borates in the Candidate List of Substances of Very High Concern, and later on in Annex XIV, an exemption for uses of borates in IVDs would be appropriate because: - Risks associated with the use of borates in IVDs are adequately covered by the IVD industry. - Reformulation efforts for assays containing borates would be extremely costly. - As the level of risk associated with the use of borates in IVDs is low, benefits to customers would not outweigh the costs of potential restrictions. - Borates are proposed for inclusion in the Candidate List on the basis of their potential hazards to human health. The REACH Regulation prevents the Commission from considering the human health risks associated with this substance use in in vitro diagnostic medical devices. Article 60.2 states explicitly: "The Commission shall not consider the risks to human health arising from the use of a substance in a medical device regulated by (…) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices." Because only a potential human health risk is assigned to borates, and because this risk may not be considered in respect of the use of borates in in vitro diagnostic medical devices, there would be nothing to consider in an authorization procedure concerning the use of borates in these products. IVDs should therefore be exempted.	
20100422	Industry or trade association, Company, Belgium	P 10 Consumer Exposure. A limited ammount of uses have been identified in the Annex XV Dossier. One of them, that could be critical for the Nuclear Power sector, is missing. In a nuclear reactor, the Boric Acid is used to keep the nuclear reaction under control, by absorption of the neutrons. After dilution of the solid chips of this substance into a water tank, the mixture is	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne

		injected into to primary water circuit, at about 2000ppm concentration. This whole circuit is under constant supervision as main element of the nuclear equipment. Specific individual protection equipments (gloves, glasses, ..) are used during the handling. The purges are also carefully handeld, the concentrated slurry is sent to accredited organisms, the liquid part is subject to strict emission limit values before release to the river. There is no viable alternative to Boric Acid in nuclear reactors, so this use is absolutely indispensable and should not be restricted by the Authorisation procedure. The energy supply of many countries, like France, Belgium ... is depending on nuclear energy thus, among others, boric acid.	concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100422	Federchimica, Industry or trade association, Italy	SPECIFIC COMMENTS ON USE, EXPOSURE, ALTERNATIVES AND RISK: The exposure estimations that are included in the boric acid dossier are incomplete and several of the realistic worst case (RWC) assumptions are not realistic. Examples of this are: • The maximum reported value of borates in mineral water is used as the exposure scenario even though the drinking water limit is 4 times lower. • The potential exposure from supplements was determined from a 16 year old personal communication from the United States reporting on body builder's use of	See response to EBA comments.

		supplements. The daily intake being proposed would be considered abusive. 1.1.4.2 Food contact material (p. 15) The substance boric acid is an intermediate to manufacture the substances glass and ceramic frits. Therefore it is no longer present in the final products. The boron present in ceramics and glass-ware is physically/chemically bound into the product, therefore in these cases, the potential for the consumers to be directly exposed to the borates present is minimal (RPA 2008). 1.1.4.4 Mineral water (p. 16) Maximum exposures are calculated using the maximum value reported in mineral water. This value of 4,35 mgB/L exceeds however the EU drinking water limit of 1 mg B/L. A realistic worst case scenario should rather assume concentrations equivalent to the drinking water limit. This approach was also followed by ECHA (2008). 1.1.4.5 Food supplements (p. 16) It is stated that "Food supplements for bodybuilders may possibly lead to maximum boron intakes of up to 30 mg/day (0.5 mg/kg bw/day) for a 60 kg person, BfR 2006a". The original source of this statement (Loscutoff S. Personal Communication (Memorandum)) cannot be verified nor is it a peerreviewed or official publication. Therefore this value is not credible nor relevant. Further, consumption amounts of this nature as supplements would clearly be considered serious abuse by deliberate ingestion of extreme amounts and therefore is not relevant for this assessment. 2 INFORMATION ON ALTERNATIVES (p.17) The section indicates "no information on alternatives" It is important to underline that although industry investigated alternatives for many years, there are no alternatives found with sufficiently safety level. It is evident in in specific industrial sectors as: varnish, ceramics. All alternative formulations are much less robust against bacterial attacks leading to increased usage of biocides, which is from health and environment point of view not desired. The lifetime of alternative formulations are significantly lower, resulting in a more frequent change and thus higher consumption of resources, lastly, through increased disposal and higher waste there will be higher pressure on the environment.	

20100422	Industry or trade association, Company, United Kingdom	Exposure to boric acid in use in metalworking fluids: Although there is no statutory limit at present for exposure to the mist from water mix metalworking fluids, it is considered good practice to limit any mist concentration, generated during metalworking processes to 1 mg/cu. metre of air. On this basis and taking the worst case scenario of a metalworking fluid mixed at 10% concentration in water and containing 10% boric acid, the exposure would correspond to 0.01 mg/cu metre which is extremely low. Boric acid has several important benefits for use in metalworking fluids: It provides anti-corrosion properties to protect both the metal part and machine tool processing the part from rusting and the subsequent financial penalty of such. It contributes to the buffering system which promotes a stable alkalinity(pH). It is both readily available, cost effective and has a successful record of use in metalworking fluids for at least 25 years.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.

20100422	Industry or trade association, Company, France	In our company, the employees exposed to these grease are protected by security glasses and gloves. Their exposure is followed by a work doctor of the company.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.

20100422	Industry or trade association, Company, France	Page 1- Specific comments on the justification Exposure/risks: Boric acid contains boron, which is a natural element. Boric acid has been used for many years with very weak buffer properties which are very similar to amino acids. Boric acid perturbs the biological elements very little which makes them harmless. The main advantage of boron and its derivates are their tendency of hybridization which allows them to create weak links with numerous constituents. So, when used in preparations, they should not be assessed on their own but in association with other chemical compound(s).The use in the form of neutral salts allows antiseptic effects and biological properties to be obtained, in particular concerning healing, therefore contributing to the success of certain therapies. Boric acid has been used safely by our company for a long time. It can be used for the manufacturing of some of our washing solutions on the eye and the skin. That is the reason why we feel concerned by the proposal of classification as a substance with very high concern (SVHC) under REACH regulation. We do not believe that adding boric acid or some borates to the candidate list is appropriate. Our products are used in an acute manner for the management of highly dangerous situations for workers: they are washing solutions to decrease or avoid the lesions due to chemical splashes on skin and eye received by workers in industries. It is a unique and isolated application, used in a specific emergency case, in order to avoid or limit extensive burn injuries. The time of washing is short, only a few minutes (3 minutes on the eye and 5 minutes on the skin). Our products are medical devices, class IIa, under the directive 93/42 EEC and the innocuousness of our products has been evaluated following the international standard of biological evaluation of medical devices ISO 10993. Page 3- Specific comments on the justification Alternatives: Appropriate substitute products for boric acids and borates having the same properties are not known. Chemically speaking, phosphates can be substitutes but they appreciably modify the local free calcium equilibrium and can induce, during eye uses, important calcifications, even after a single use. In Europe during the 1980s, borates in ocular solutions were replaced by phosphates,	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1^{st} adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are, however, aware of the ongoing activities regarding worker studies, the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation. We recognize the discrepancy between the specific concentration limit and the limit of 0.1% mentioned in REACH Art. 33.

		under the pressure of German recommendations based on some scientific papers. Phosphates could have a lower profile in terms of harmfulness but there are other aspects that should be added: the producers of eye lens solutions added phosphates until they noticed that these solutions containing phosphates could induce calcification (7). This subsequently led to the withdrawal from the market of these solutions with phosphates. Bibliography: 7. Kompa S, Redbrake C, Dunkel B, Weber A, Schrage N; Corneal calcification after chemical eye burns caused by eye drops containing phosphate buffer; Burns 2006 (32) 744-747	
20100422	Industry or trade association, Company, United Kingdom	1. With regard to use, borates have been used safely by the metallurgical industry for many years. 2. We have used borates since the 1980s. We changed from the previously used substances on the basis of a reduction of risk to the environment and a reduction in costs, with borates being the best of the alternatives investigated. We herewith submit research reports from this time in support of this.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned. We are, however, aware of the ongoing activities regarding worker studies, the pending decision of the European General Court regarding boric acid and the Commission proposal to include boric acid in Annex XVII of the REACH regulation.
20100422	European Oilfield Speciality Chemicals Association, Industry or trade association, United Kingdom	Submission re borates to ECHA final.pdf We would request that exposure to seawater eg by fishermen and other marine users including recreational users, and to soil eg by farmers and land workers including gardeners be given due cognisance in any assessment which may lead to authorization. We question whether it is practicable to subject to authorisation substances so widely distributed in the natural environment.	Boric acid has been classified as toxic to reproduction category 1B with directive (EC) No. 790/2009 (1st adaptation of regulation 1272/2008 to the technical progress) with a specific concentration limit for boric acid in preparations of 5.5 %. As this is applicable law at present, the current classification will not be questioned.

20100422	Frit Manufacturers and Importers, A.E.I.E., Industry or trade association, Spain	Frit Consortium- Comments of borates Annex XV.pdf p.3-4	Thank you. A clarification has been added to the consumer exposure part of the annex XV dossier.
20100422	ANFFECC, Industry or trade association, Spain	We support all the comments sent by the Frits Manufacturers and Importers A.E.I.E.	See response to Frits Manufacturers and Importers A.E.I.E.
20100422	AIMPR, Industry or trade association, Spain	We support all the comments sent by the Frits Manufacturers and Importers A.E.I.E.	See response to Frits Manufacturers and Importers A.E.I.E.
20100422	Individual, Sweden	The Boric Acid is only used in closed batch process where the predominant handling is in a contained manner, and exposure is thus limited.	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total

			dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.
20100422	Zentralverband Oberflächentechnik e.V., Industry or trade association, Germany	Boric acid and their application in the surface metal finishing industry In the surface metal finishing industry the boric acid has different, but many applications. For instance boric acid is applied in electro and electroless plating processes. Namely in metal plating solutions like nickel electrolytes, low acid zinc electrolytes, trivalent chrome electrolytes, electroless Nickel etc. The surface finishing companies are strictly controlled by the German authorities as to the prescribed limit values. The law primarily commits the employer to provide security and health protection and takes measurements for compliance with prescribed work station limit values (AGW formerly MAK). For these applications to this day analyses concerning boron were not especially done. The measurements mostly concerned the evaluation of the heavy metals concentration of air at the work station. In the nickel electrolytes the boric acid will be kept constant within a range of 30 – 55 g/L. The concentration of nickel as a divalent cation amounts to ≥ 50 g/L. The AGW for nickel was fixed to c¬Ni = 0,05 mg/m³. The AGW for boron amounts to cH3BO3 = 0,5 mg/m³ (Gestis-data bank). Assumpted a homogenous solution of all salts in the solution the max. concentration of boric acid amounts to less than 50% of the nickel value and the 10-fold higher AGW and is significantly below the limit value for Boron of 0,5 mg/m³. When using the low acid zinc electrolytes 20 - 30 g/L divalent zinc will be constantly kept in solution. These electrolytes will be operated at room temperature or max. 35 °C. The electrochemical efficiency amounts to 100%, so that aerosols, which can arise during a electrolysis can not be assumed. The AGW for zinc amounts to cZn = 0,1 mg/m³; recommended. For equal concentration of boric acid in this solution, approximately ≥ 30g/L, the AGW is five times as high as the zinc value. If the zinc value in the air at work station will be respected, a significant lower limit of the AGW	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations. Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total

		for boron can be assumed. In case of trivalent chromic electrolytes, which also include boric acid for stabilisation, they are characterized by a significant higher electrochemical degree of efficiency as hexavalent chrome electrolytes, this means a higher dragout into the rinse water compared with the above mentioned processes. The trivalent chrome electrolytes have been developed to obtain at least for the decorative chromium plating a future alternative for plating in hexavalent chromium solutions. The maximum allowable value of emission at work station for trivalent chromium is relative high with 2 mg Cr/m³. The concentration of boric acid can be amount to 90 g/L at < 10 g/L Cr3+. Nevertheless we see the possibility after determining the chromium value of the air at the work station to draw conclusions to the boric acid-concentration. During surface treatment mostly "open" systems are used. This means that the applied solutions for the metallic coating are held available in open tanks. These plants are almost all connected with exhauster plants. Emergent fumes or aerosols are removed by suction at the place of production. The plants are mostly designed for an eight times room air exchange rate during production. The dosing (measuring) of application and regeneration of the electrolytes occurs by adding salts, which are dissolved in (warm) water. The contact times are limited and smaller than 30 min/d. For this work the employees are provided with absolutely mandatory to carry personal protect equipment. In the field of surface treatment or electroplating there is only an industrial application of boric acid. In these production lines suitably trained staff is working. Due to the current application of the use of chemicals, the workforce according to current legislation will be informed about the risk of these substances, at least annually, or respectively before starting to work and will be enabled to a safe handling. Automatically operated plants will probably show a lower contamination for the workforce than 30 min/d. In case of manually operated plants it is conceivable that the workforce will be present at the working area for more than 8 hours a day. An adequate dimensioned exhauster plant guarantees a high degree of responsibility with these substances. Results of studies of the German Accident Prevention & Insurance Association have shown the possibility to disclaim the gloves specially for using boric acid. Quotation	dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.

		of Gestis Data Bank: “If AGW and BRW at the working station are below the limit, there is no risk for the Repro toxin. In order to deposit metals in low acid electrolytes solutions frequently mixtures containing boric acid are used. The concentrations in these solutions are between 30 – 50 g/L. This means that considering the density of the ready-made solution 5 % will not be exceeded. In producing mixtures almost exclusively closed systems are used which guarantee a safe handling. On the part of the Zentralverband Oberflächentechnik e.V. this expert statement was presented on the occasion of an internet consultation. It confirms that we do not agree with the critical assessment of the Danish government concerning the applications of the surface metal finishing industry. Due to the experiences for decades with the handling of those substances no diseases have been published. These substances must be preserved in the future and not even be more restricted. A safe handling of the surface technology by respecting the chemicals regulations is ensured. Zentralverband Oberflächentechnik e.V. D-40724 Hilden, Max-Volmer-Straße 1, 12. April 2010	
20100422	Messer Castolin Eutectic, Company, France	Messer Castolin Eutectic is a manufacturer of products of brazing and welding since 1906. We are present all over the world and our products are well-known for their efficiency and their quality. We will be and the users will be in big difficulties if the products of type "BORAX" must be stopped. In our profession by the brazing and by the similar joining it is a major component in the formulation of fluxes and brazing pastes. These fluxes and these brazing pastes are used in very numerous cases of joining. Metals and alloys to be assembled are very different, copper-brass-steel-stainless steel... The use of these products can be manual or mostly in automatic. The automation allows for avoiding the contact with the product and the fumes during brazing time. The users are in very different industrial areas. Car industry Renault-PSA-WW-BMW-AUDI Heat exchanger CIAT-CARRIER Aircraft industry SAFRAM-BOMBARDIER-GE Aerospace industry EADS Railway SNCF-RATP Army industry DCAN-GIAT	Prior to the preparation of the Annex XV dossier, the BAuA made a brief investigation concerning the exposure of workers towards boric acid. Neither the transitional dossier nor the literature publicly available gave measurements on boric acid in the air. Therefore, the airborne concentration of boric acid at workplaces was estimated using the EASE-Model which tends to overestimate exposure. Solely in the case of load up of ships (EASE: typically 4.81 mg B/m^3) as well as cleaning procedures (EASE: typically 1.75 mg B/m^3, especially when swept up) the EASE estimates indicated higher concentrations.

		Plumbing Jewellery-making Medical industry And the list is long for the different activities. A very big number of the users above have rigorous specifications for the supply of fluxes, a simple change in the formulation or the process of production has to be indicated and often long and expensive tests must be realized. To date we have no products of replacement giving the same performances of result. We have no possibility of proposing a perfect equivalent without product of type "BORAX" in a formulation. In the case of a complete stop of the use of this one, we will put many industries in trouble of a quality production. We have to find new solution for improving the live quality and we are working on new products. We need more time to finalise a right product without "BORAX" (This product is really the base concerning a lot of formulation). Our duty for the moment is to advise our customers of the use of automatic equipments for the brazing, what they make mostly. Gérard Auclair European Welding Engineer (EWE)	Based on the NOEL published in the transitional dossier, an OEL of approximately 0.8 mg B/m^3 was derived; in Germany an OEL of 0.5 mg B/m^3 is established. Due to low dermal resorptions, dermal contact to boric acid was regarded to be irrelevant regarding systemic burden. Therefore, only load up of ships and cleaning procedures were regarded to be activities related to risk. The total dust exposure in both cases has been estimated to be approximately 5.0 – 50.0 mg/m^3 (inhalable fraction) which is not regarded acceptable and would trigger an immediate reduction of exposure according to Council Directive 98/24/EC. Especially the sweeping of dry dusts has to be avoided.

Attachments

Comments from Affiliated with an organisation, DALIC, Company, France:

http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/nid+axle_euro_gb.pdf

http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/slat_nickel_d+gb.pdf

http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/spoornet07fr.pdf

http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/sncf.ax.fr.pdf http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/tr1_011.pdf

Comments from On behalf of an organisation, Industry or trade association, Belgium:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/080707_borates_final.pdf

Comments from European Borates Association, Industry or trade association, Belgium:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/eba_comments_hazard_assess_annex_ XV.pdf

Comments from CARL BECHEM GMBH, Company, Germany:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/carl_bechem_statement_public_consultation.pdf

Comments from AffiliatedWithOrganisation, Industry or trade association, International NGO, Belgium:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/svhcreaction_de.pdf

Comments from UEIL, Industry or trade association, Belgium:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/eba_comments_annex_xv_100104_final.pdf

Comments from BMS Micro-Nutrients NV, Company, Belgium:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/comments_regarding_different_lists.pdf

Comment from Redco NV, Company, Belgium:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/boric_acid.pdf
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/fail_1998.pdf
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/ntp_1987.pdf
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/turkez_2008.pdf

Comments from Industry or trade association Company, United Kingdom:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/echa_reference_document_1.pdf
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/echa_reference_document_2.pdf
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/echa_reference_document_3.pdf
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/echa_reference_document_4.pdf
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/echa_reference_document_5.pdf
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/echa_reference_document_6.pdf
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/echa_reference_document_7.pdf
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/echa_reference_document_8.pdf
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/echa_reference_document_9.pdf
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/echa_reference_document_10.pdf

Comments from Proviron Industries, Company, Belgium:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/boric_acid_comments_20100419.pdf

Comments from Verband der Deutschen Feuerfest-Industrie e. V., Industry or trade association, Germany:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/boric_acid_comments.pdf

Comments from EURIMA, Industry or trade association, Belgium:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/boron_in_glass_wool_insulation_gts_final.pdf
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/article_risk_assessment_boron_in_glass_wool_insulation.pdf

Comments from UNIFA, Industry or trade association, France:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/unifa_comments_on_bore_proposed_for_authorisation.pdf

Comments from Industry or trade association, Company, Germany:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/acs_boric_acid.pdf
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/reag_ph_eur_borsaure.pdf

Comments from CPIV, Industry or trade association, Belgium:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/statement_on_exposure_to_borates.pdf

Comments from EDMA, Industry or trade association, Belgium:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/edma_comments_borates_final.pdf

Comments from Bundesverband Glasindustrie e.V., Industry or trade association, Germany:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/cpiv_statement_on_exposure_to_borates.pdf
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/vbg_borauswertung_glas.pdf

Comments from Jones Fiber Products, Inc, Company, United States:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/binder1.pdf

Comments from Cerame-Unie, Industry or trade association, Belgium:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/cerame_unie_position_on_boric_acid_and_disodiumtetraborates.pdf

Comments from StonCor Europe, Company, Belgium:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/eba_comments_annex_xv_(00059414).pdf
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/memo_to_echa_on_behalf_of_stoncor.pdf

Comments from Individual, Germany:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/letter_bolt_echa.pdf

Comments from Wirtschaftskammer Österreich, Chamber, Austria:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/su_133_offentliche_konsultation_echa_boric_acid.pdf

Comments from Industry or trade association, Company, Germany:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/biotest.pdf

Comments from Fédération des industries mécaniques, Industry or trade association, France:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/reponse.pdf

Comments from UITS, Industry or trade association, France:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/use_of_boric_acid_in_surface_finishing.pdf

Comments from Chemservice S.A. / REACH Zinc-Borate Consortium, Industry or trade association, Luxembourg:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/efsa_opinion_on_ba_and_stb_as_food_add.pdf
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/efsa_pub_statement_of_afc_on_ba_and_stb.pdf

Comments from Eurocolour, Industry or trade association, Belgium:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/frits_borates_final_version.pdf

Comments from Verband Deutscher Schleifmittelwerke e.V., Industry or trade association, Germany:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/vds_statement_20100422.pdf

Comments from GIFAS, Industry or trade association, France:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/20012_100419_echa.pdf

Comments from Ceramicolor - National Association of Ceramic Glaze, Inorganic Pigments and Metal Oxides, Industry or trade association, Italy:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/frits_borate_ceramicolor.pdf

Comments from European Oilfield Speciality Chemicals Association, Industry or trade association, United Kingdom:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/submission_re_borates_to_echa_final.pdf

Comments from Frit Manufacturers and Importers, A.E.I.E., Industry or trade association, Spain:
http://echa.europa.eu/doc/about/organisation/msc/msc_rcoms2010/rcom_boric_acid/frit_consortium_comments_of_borates.pdf